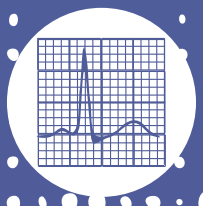
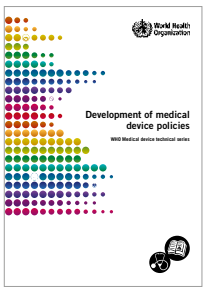
World Health Organization

Inventory and maintenance management information system for medical devices

WHO Medical device technical series





2011

2022

2017

Regulation

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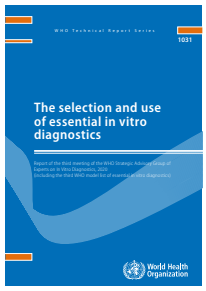
Medical devices



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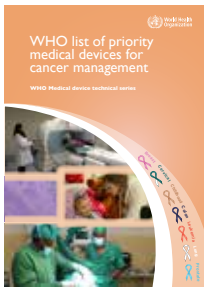

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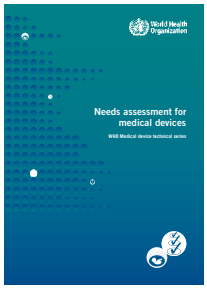

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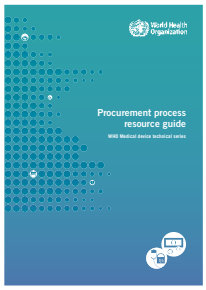

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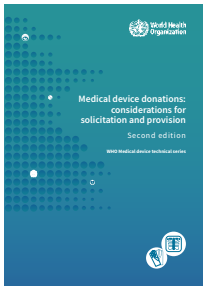

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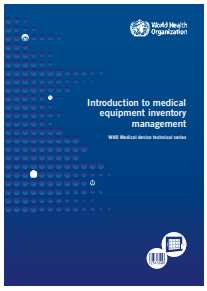

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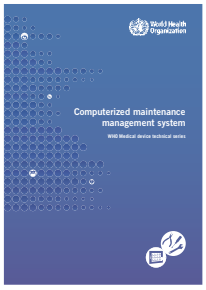

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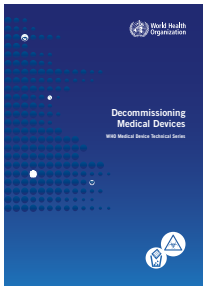

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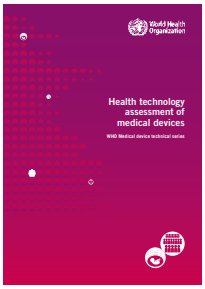


2011*

* To be updated in 2024

World Health Organization

Inventory and maintenance management information system for medical devices

WHO Medical device technical series

Inventory and maintenance management information system for medical devices
(WHO medical device technical series)

This document is an updated version that draws upon two earlier WHO publications: *Introduction to medical equipment inventory management* and *Computerized maintenance management system*, both published in 2011.

ISBN 978-92-4-011125-7 (electronic version)
ISBN 978-92-4-011126-4 (print version)

Suggested citation. Inventory and maintenance management information system for medical devices. Geneva: World Health Organization; 2025 (WHO medical device technical series). Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at https://iris.who.int/.

Design and layout by Genève Design

Contents

Preface

The Sixtieth World Health Assembly in May 2007 adopted resolution WHA60.29, which mandates the World Health Organization (WHO) to increase access to health technologies, in particular to medical devices, and to support Member States in this regard *(1)*. As noted in report 148/13 by the Executive Board *(2)*, medical devices are necessary for the prevention, diagnosis and treatment of illness and disease and for patient rehabilitation.

Medical devices include in vitro diagnostic tests, imaging equipment, medical equipment, single-use devices and digital health products for diagnostics and treatment. The WHO Medical Devices Team has developed tools and guidance to improve access to medical devices as a basis for national lists of devices and of priority medical devices.

This document is part of a series of reference documents developed for countries, the WHO Medical device technical series. The series covers the following topics:

- development of medical device policies (2011) *(3)*;
- global model regulatory framework for medical devices, including in vitro diagnostics (2017, 2023) *(4,5)*;
- health technology assessment *(6)*;
- health technology management (HTM):
  - needs assessment for medical devices *(7)*;
  - medical device donations *(8)*;
  - medical device procurement *(9)*;
  - medical equipment inventory management *(10)*;
  - medical equipment maintenance *(11)*; and
  - computerized maintenance management systems *(12)*;
- decommissioning medical devices *(13)*;
- lists of priority medical devices and the associated Medical Devices Information System (MeDevIS) *(14)*:
  - for reproductive, maternal, newborn and child health *(15)*;
  - for management of cancer diseases *(16)*;
  - for management of cardiovascular diseases and diabetes *(17)*;
  - for the COVID-19 response *(18)*;
  - package for eye care interventions *(19)*; and
- human resources for medical devices, the role of biomedical engineers *(20)*.

This publication replaces two previous documents, published in 2011, on medical equipment inventory management *(10)* and computerized maintenance management systems (CMMS) *(12)* in the Medical Devices Technical Series.

The above-mentioned documents are intended for use by any organization, expert or practitioner involved in the design, assessment, donation, procurement, management, maintenance or disposal of medical devices and related technologies, including health workers, biomedical engineers, health managers, policymakers, donors, nongovernmental organizations and district, national, regional and global institutions involved in health technology, aiming to increase access to medical devices for universal health coverage and emergency preparedness and response.

The best practices and considerations proposed in this document are intended to improve the quality of inventories and CMMS for medical equipment to ensure the maximum benefit to all stakeholders. The considerations provided can be used for better management of institutional medical equipment and may also be useful, especially for health systems in low- and middle-income countries, which often depend on donations.

Recent World Health Assembly resolutions and WHO governing body documents call for WHO to work with and support countries in HTM and maintenance, in particular:

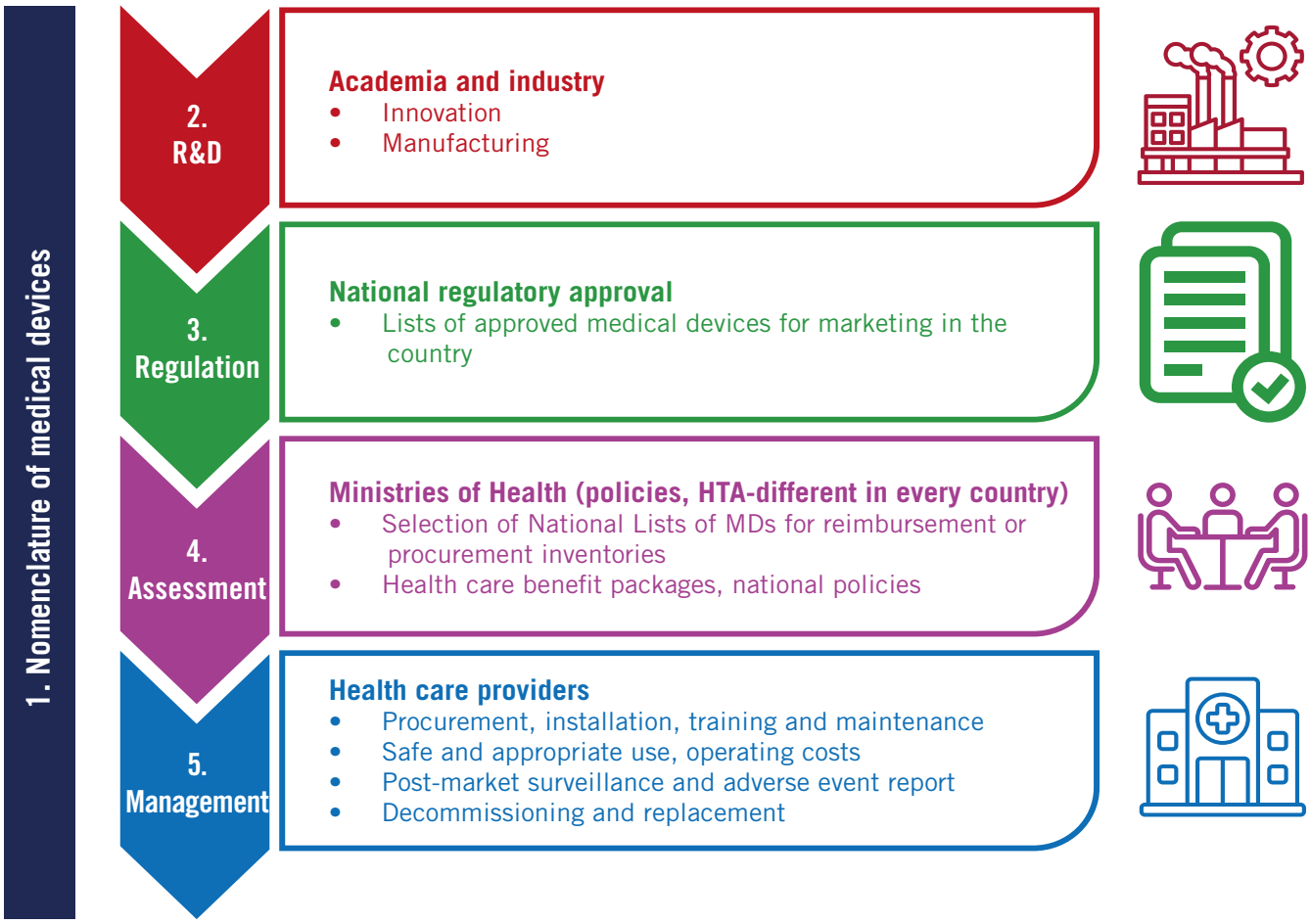
- WHA76.5 (2023) Strengthening diagnostics capacity. In this resolution, the term "diagnostics" includes medical devices used for the diagnosis, screening, monitoring, prediction, staging or surveillance of diseases or health conditions, both in vitro and non-in vitro types.
    a. "(5) to support Member States upon their request to develop policies for health technology management of diagnostics, including national maintenance systems and disposal;" *(21)*
- WHA76.3 (2023) Increasing access to medical oxygen *(22)*:
    b. "(1.10) to provide for adequate numbers of qualified staff, including engineers and other staff as required, to establish demand, select, set up, operate and maintain the equipment and all the infrastructure related to medical oxygen production, storage and uninterrupted distribution to patients;
    c. "(2.4) to support Member States' efforts to provide adequate, predictable and sustainable financing for affordable medical oxygen and for the trained workforce required to install, operate and maintain medical oxygen systems safely;".
- EB156(17) (2025) Strengthening medical imaging capacity *(23)*:
    d. "(1.8)to promote the use of health technology management practices, with the support of biomedical engineers, medical physicists and trained related professionals in all the phases of the life cycle of technologies, including procurement, installation, maintenance, calibration and safe use towards the optimization of the medical imaging capacity."

The publications in the WHO Medical Devices Technical Series correspond to the different stages of HTM. They cover: procurement and incorporation, installation, inventory, maintenance, training for safe, appropriate use and operating costs until decommissioning and replacement.

This document describes the importance of inventories and maintenance management systems, their elements, trends and guidance on their use. It does not include maintenance routines, which are described in other publications.

Fig. 1 presents the elements of value chain of medical devices as referred in the WHO medical devices technical series.

Fig. 1. *Elements of the value chain of medical devices*



Source: Health Technology assessment for medical devices. Second edition. In press.

Acknowledgements

Due to their expertise, and after assessment of candidate institutions, this publication was commissioned by WHO to the Verlab Research Institute for Biomedical Engineering, Medical Devices and Artificial Intelligence (Bosnia and Herzegovina). Lejla Gurbeta Pokvićr was the main writer, Almir Badnjević and Adna Softić were co-editors. The team compiled and integrated the texts of the international experts listed below with the guidance and coordination of Adriana Velazquez Berumen, team lead, Medical Devices and In Vitro Diagnostics at WHO, Geneva.

WHO is grateful to the international group of experts who drafted the document, who were proposed and selected by WHO to ensure global and regional perspectives as well as having a gender balance. The collaborators were Wisal Alahdab, International Committee of the Red Cross, Jordan; Almir Badnjević, Faculty of Pharmacy, University of Sarajevo, Bosnia and Herzegovina; Tazeen Saeed Bukhari, International Federation of Medical and Biological Engineering (IFMBE), Pakistan; Luis E. Fernández, Tecnología en Ingeniería Clínica, Mexico; Keiko Fukuta, University of Osaka, Japan; Bill Gentles, BT Medical Technology Consulting, Canada; Stephen Himley, WHO Regional Office for South-East Asia, India; Ernesto Iadanza, University of Siena, Italy; Michael Lane, University of Vermont, United States of America; Fabiola Martinez, Clinical Engineering Division, IFMBE, Mexico; Marc Nyssen, Free University Brussels, Belgium; Leandro Pecchia, University Campus Bio-Medico of Rome, Italy, Lejla Gurbeta Pokvić, Verlab Institute, Bosnia and Herzegovina; Adna Softić, Verlab Institute, Bosnia and Herzegovina; Martha Sebi Tusabe, WHO Regional Office for Africa, Uganda; Prashiksha Ulak, Nepal Mediciti, Nepal; Adriana Velazquez Berumen, Team Lead Medical Devices, WHO, Geneva, Switzerland; and Mohamad Wehbi, WHO Regional Office for the Eastern Mediterranean Region, Egypt.

WHO expresses particular appreciation for the insightful feedback of the reviewers in the Strategic and Technical Advisory Group on Medical Devices (WHO STAG MEDEV), which enriched the quality and comprehensiveness of the guidance. The document was presented to members of the STAG MEDEV between June 2023 and December 2024. Those who commented during drafting of the document were: Millicent Alooh, NEST360 and Association of Medical Engineering of Kenya, Kenya; Mulugeta Mideksa Amene, biomedical engineering consultant to the United Nations Children's Fund in the Middle East and North Africa, Ethiopia; Bukola Esan, EBME Engineering Ltd, Nigeria; Pedro Galvan, Health Science Research Institute, German Paraguayan University, Paraguay; Tom Judd, Global Clinical Engineering Alliance, United States of America; Bousso Niang, Ministry of Health and Social Action, Senegal; Ledina Picari, Medical Devices and Cosmetic Products Unit, Ministry of Health and Social Protection, Albania; Sandy Rihana, Biomedical Engineering Department, Holy Spirit University of Kaslik, Lebanon; Bukhari Tazeen Saeed, biomedical engineer, Pakistan; Sanjita Sharma, Ministry of Health and Population, Nepal; and Kun Zheng, Governance Risk and Compliance, Children's Hospital, Zhejiang University School of Medicine, China.

In March 2025, the following WHO STAG MEDEV members reviewed the document: Millicent Alooh, NEST360 and Association of Medical Engineering of Kenya, Kenya; Sue Horton, University of Waterloo, Canada; Placide Muhayimana, Rwanda Food and Drugs Authority, Rwanda; and Bousso Niang, Ministry of Health and Social Action, Senegal.

Additional review and insight were provided by members of the Verlab team: Velid Dlakić, Samira Ficić and Lemana Spahić. WHO expresses appreciation to Dena Duraković for her exceptional technical support in preparation of this publications.

Other WHO staff that provided input to the document during 2024 and 2025 from regional offices: Edith Annan, Sheick Oumar Coulibaly, Theonille Mukabagorora, Aissatou Sougou, Martha Tusabe, Regional Office for Africa; Alexandre Lemgruber and Alfonso Rosales, Regional Office for the Americas; Mohamed Wehbi, Regional Office for the Eastern Mediterranean; Rasmus Gjesing, and Tifenn Humbert, Regional Office for Europe; Mohammad Ameel, Regional Office for South-East Asia and Jinho Shin, Regional Office for the Western Pacific. Noting that the document was being reviewed in the monthly meetings of the STAG MEDEV where the regional advisors, listed above, also participate.

The professionalism and commitment of all the authors and reviewers are deeply appreciated, as their contributions significantly enhanced the quality and credibility of this publication.

Declarations of interests

Statements of conflicts of interest were collected from all those involved in development of this publication. No conflicts of interest were found.

Abbreviations

AI	artificial Intelligence
CMMS	computerized maintenance management system
COVID-19	coronavirus disease 2019
CT	computed tomography
EHR	electronic health record
EMDN	European Medical Device Nomenclature
FDA	Food and Drug Administration
GMDN	Global Medical Device Nomenclature
HTM	health technology management
IFMBE	International Federation of Medical and Biological Engineering
IMMIS	inventory and maintenance management information system
IoT	Internet of Things
IT	information technology
KPI	key performance indicator
MRI	magnetic resonance imaging
PdM	predictive maintenance
PET	positron emission tomography
PM	preventive maintenance
PMS	post-marketing surveillance
QA	quality assurance
QMS	quality management system
SOP	standard operating procedure
STAG MEDEV	Strategic and Technical Advisory Group of Experts on Medical Devices
UDI	unique device identifier
WHO	World Health Organization

Executive summary

The objective of Health technology management (HTM), is to ensure patient safety and appropriate use of medical devices, towards ensuring quality of health care. The HTM process includes the needs assessment, then procurement and supply, and, after reception of the medical device in the facility, continues with incoming inspections, inventory, training for safe use, and maintenance, until decommissioning.

This publication, Inventory and maintenance management information systems for medical devices, builds on the two earlier WHO publications, published in 2011: Introduction to medical equipment inventory management *(10)* and Computerized maintenance management systems *(12)*, which are part of the WHO Medical Device Technical Series. While the previous publications provide important information on best practices for managing medical equipment in health-care settings, this edition combines updated guidance with emerging trends in health-care technology management. With the inclusion of modern digital systems, data-driven maintenance strategies and improved inventory frameworks, this book provides practical solutions for health-care institutions to improve the reliability of equipment, extend the life of devices, confirm asset management, towards the most efficient use of technological resources, while ensuring regulatory compliance.

The publication presents a holistic approach to HTM throughout the life cycle of medical devices. It outlines the elements of an effective system, including regular maintenance, inventory tracking and compliance with international standards. As inventory management is a crucial part of HTM, the importance is stressed of standardizing inventory practices with international nomenclature systems, recognized by WHO, such as the European Medical Device Nomenclature (EMDN) and the Global Medical Device Nomenclature (GMDN), with use of unique device identification (UDI) to ensure structured tracking of medical devices in health-care facilities. Addition of automated registration and real-time tracking systems further increases the efficiency and accuracy of management of medical equipment. A well-organized inventory system must also include standard maintenance and management procedures. Therefore, the publication includes quality assurance (QA), such as incoming inspection, calibration and adherence to international standards, to ensure that medical devices remain reliable and safe for patient care. It also differentiates between preventive maintenance (PM), corrective maintenance and predictive maintenance (PdM) strategies, recommending proactive maintenance to minimize downtime (the period during which a device is unavailable for use), extend device lifespan and optimize operational efficiency. The book also discusses emerging trends, such as artificial intelligence (AI)-based PdM and automation, showing how these technologies can revolutionize HTM. The Inventory and Maintenance Management Information System (IMMIS) is described, which is a structured framework for efficient tracking and maintenance of medical devices, and the publication provides practical guidance on selecting and implementing modern IMMIS solutions, outlining key requirements and implementation strategies tailored to different health-care settings. By integrating advanced technologies and standard practices, IMMIS enhances operational efficiency and ensures regulatory compliance and data-based decision-making in HTM.

The annexes to this publications are designed to provide practical support for implementing the concepts discussed, serving as essential resources for health-care administrators, biomedical engineers and policymakers. By using the templates, tools and checklists provided, health-care institutions can implement standardized processes, reduce equipment downtime and improve patient outcomes. The annexes ensure that the guidance can be translated into real-world improvements in HTM.

1. Introduction and purpose

Health-care technology has played a fundamental role in medicine for centuries, evolving with scientific advances to improve patient diagnosis, treatment and monitoring. Medical devices are a crucial subset of health technology. As essential components of health-care delivery, medical devices support diagnosis, treatment, monitoring and rehabilitation. Their availability and proper management are therefore vital to patient outcomes.

WHO, aligned with the International Medical Devices Regulatory Forum, (IMDRF), describes a medical device as 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 specific medical purposes of diagnosis, monitoring treatment or alleviation of disease, which does not achieve its primary intended action by pharmacological, immunological or metabolic means. (*24*).

The post-market life cycles of medical devices differ significantly around the world according to infrastructure, resource allocation and organization of health-care systems. Despite these differences, all health-care systems must manage and maintain their medical devices to ensure that they remain accurate, reliable and safe for use *(25–27)*.

A story of two health-care systems: preparedness versus crisis

The significance of medical devices was underlined by the coronavirus disease 2019 (COVID-19) pandemic *(28)*, when they became a lifeline for patients and medical professionals, irrespective of resources and capabilities in different regions. During this time, differences were found in how medical devices are maintained and managed in health-care systems worldwide, revealing both strengths and weaknesses.

During the COVID-19 pandemic, health-care institutions became battlegrounds where preparedness – or the lack of it – determined life and death. In some health-care institutions, inventory systems were robust and maintained with meticulous tracking and real-time updates. In countries in which medical device management was centralized, a national database provided information on critical medical devices. When shortages arose in one region, devices could be swiftly relocated from areas with a surplus, ensuring equitable distribution. In decentralized systems, in which health-care institutions operate in silos, one health-care institution might have had an excess of critical medical devices while another just a few kilometres away struggled to keep patients alive. This lack of coordination led to unbalanced distribution, in which some institutions with many resources while others searched for solutions. In health-care facilities with organized maintenance management systems equipped with Internet of Things (IoT) sensors and AI algorithms, maintenance was conducted as scheduled without disrupting patient care. Medical devices remained functional, limiting unexpected breakdowns at critical moments. In other systems, maintenance was an afterthought. Devices were repaired only when they failed, often in a crisis. Engineers worked frantically to bring failing devices back to life, although the damage had often been done, as delays meant disruptions in patient care.

As the pandemic came under control, the contrast between preparedness and crisis became clear. The difference was not just in the number of critical medical devices that a health-care institution had but in how well they were tracked, maintained and managed. COVID-19 demonstrated the importance of robust inventory systems, efficient maintenance and management protocols and regulatory compliance. Effective inventory management is essential in sustaining the performance, safety and reliability of health-care technologies, which directly impact patient outcomes and the efficiency of medical operations.

In practice, it became clear that the performance of health-care technologies directly influences the efficiency of medical procedures, the accuracy of diagnoses and the overall efficacy of treatment. Clinical engineers and biomedical engineers are vital for maintaining the functionality and safety of these technologies.

Foundation of maintenance management systems for medical devices: inventory and maintenance management systems

As health-care systems continue to advance, a fundamental truth remains unchanged: no medical device can serve its intended purpose if it is misplaced, unaccounted for or inoperable due to poor maintenance. A well-functioning health-care system depends on the ability to track, manage and maintain medical devices efficiently.

This publication is a guide for health-care professionals, biomedical and clinical engineers, policymakers and health-care institution administrators for developing a structured framework for effective inventory and maintenance management of medical devices in health-care systems, ensuring their availability, functionality, safety and compliance with regulatory requirements. It introduces a synergistic model that bridges three critical pillars of medical device oversight: HTM, QA and computerized maintenance management systems (CMMS). The synergy also explains the significant role of the biomedical and clinical engineering department in health-care infrastructure.

2. Methods

The medical devices team of WHO noted and discussed updating of the publications *Computerized maintenance management system (12)* and *Introduction to medical equipment inventory management (10)*, which were published in 2011, with the Strategic and Advisory Group of Experts on Medical Devices (STAG MEDEV), an advisory body to WHO, which shapes global policies and strategies on medical devices and health technologies and provides guidance to WHO on priorities and emerging issues. The updates were considered necessary to account for recent technological developments as well as recent World Health Assembly resolutions that calls for health technology management as well as the implication of the use of specific nomenclature systems of medical devices for inventory and maintenance management.

The current edition was developed using a multi-step approach combining a structured literature review, grey literature analysis, synthesis of national experiences, and expert consultation through the WHO Strategic and Technical Advisory Group on Medical Devices (STAG-MEDEV), international experts and WHO regional and HQ technical officers.

a) Methodological Objectives

This document is a narrative review describing the current landscape of inventories and maintenance of medical devices, current practice and providing the characteristics and challenges of management of medical devices. As such it is *not* intended to provide a methodology or framework for the inventory and maintenance

of specific medical devices. This narrative review of the general concepts of inventories and maintenance for medical devices was conducted by searching the literature in PubMed published since 2000. Relevant papers were reviewed for inclusion, and identified other relevant references in addition to searching the grey literature. The main objective was to identify and synthesize current best practices, policies, and methodological recommendations related to the health technology management of medical devices, with a specific focus on the needs and realities of inventories and maintenance systems in low- and middle-income countries (LMICs). The aim was to support evidence-informed and context-appropriate adoption of medical technologies aligned with universal health coverage (UHC) priorities.

b) Literature Search Framework

A targeted literature review was conducted from October 2023 to March 2025. The scope of the search was framed by key questions related to:

- Inventory systems
- Maintenance management systems.
- Automation of data management
- Data challenges and governance structures in resource-limited settings

The following databases and sources were used:

- Scientific and indexed sources: PubMed, Embase.
- WHO publications, Global Clinical Engineering Alliance (GCEA) journal, Advanced association for medical instrumentation publications (AAMI) , International Standards Organization (ISO), International Medical Devices Regulatory Forum (IMDRF), FDA and other regulatory agencies, and normative frameworks: WHO guidelines and tools, OECD reports, PAHO publications,
- Search terms included: *"health technology management»*, «computerized maintenance management systems", *"medical devices"*, *"low-income countries"*, *"inventory systems"*, *"nomenclature of medical devices"*, and were adapted for each database's syntax.

c) Inclusion Criteria and Evidence Appraisal

Documents were selected based on:

- Publication date: 2010 to 2023
- Geographic relevance: Focus on LMICs, or applicable to LMIC health systems
- Methodological rigor: Peer-reviewed systematic reviews, official guidelines, evaluated institutional experiences, case studies, and WHO normative documents.

All sources were independently screened by at least two reviewers. The evidence was synthesized narratively, and grouped according to thematic areas aligned with the structure of the report.

d) Validation Process

The first draft of this report was prepared by a technical writer in collaboration with WHO and reviewed by the STAG-MEDEV HTM subgroup.

The final version of the document underwent technical editing, WHO internal clearance, and layout review prior to publication.

e) The development process

At the beginning of 2023, Verlab Research Institute for Biomedical Engineering, Medical Devices and Artificial Intelligence (Verlab Institute), Bosnia and Herzegovina, proposed to use its technical expertise to support WHO, pro bono, in compiling this publication, also envisaging becoming a WHO Collaborating Centre. The medical devices team in WHO, with Verlab and STAG MEDEV members, proposed experts to provide technical input to the draft table of contents proposed by STAG MEDEV and WHO. Experts in various disciplines of inventory and maintenance, with no conflict of interest, were selected from several regions, who would serve as the working group for preparation of the publication. It was agreed that a team at Verlab Institute would compile the texts by the international experts, towards an updated version of the two WHO publications *(10,12)*. A draft was prepared, which was reviewed by members of the STAG MEDEV.

All meetings of the working group were held online. At the first meeting, in May 2023, the contributors introduced themselves, presented the project's conceptual framework and discussed the table of contents. A Google Drive folder was organized to ensure feedback during preparation of the document. The publication was formally presented to the STAG MEDEV in June 2023, and the coordinators provided regular updates at monthly meetings. Experts and advisers continued to collaborate online to exchange information and develop individual chapters.

The full document was reviewed three times by the WHO secretariat, the Verlab Institute, STAG MEDEV members with expertise on the topics and by the writers of the chapters to harmonize the document.

In November 2024, a WHO editor edited the document and ensured alignment with the WHO Style guide.

The draft text was reviewed in February 2025 by all the writers and by WHO staff responsible for medical devices, at both headquarters and in the regions, who indicated some duplication of material and proposed merging of some chapters into a revised version. The text was then reviewed by Dr Lejla Gurbeta Pokvić, Verlab Institute, and further input was provided by three STAG MEDEV members and Adriana Velazquez at WHO headquarters for a new version to be submitted for WHO publication.

The STAG MEDEV members, along with the WHO staff both from HQ and regional offices reviewed the revised version and agreed that the technical information and flow of information is correct, that duplications were removed, and that references have been updated.

A new revision by an approved WHO editor took place to ensure alignment to WHO Style guide, and to adhere to the publications check list. The document underwent review and acceptance of editorial proposals by Dr Gurbeta and by Ms Velazquez, responsible for this publication at WHO HQ, and submitted for publication approval, layout and design.

The document is to be presented at the 5th WHO Global Forum on medical devices, in June 2025, and will be then disseminated widely, with the support of NGOs and academic institutions, towards better management of medical devices in health facilities, for patients benefit.

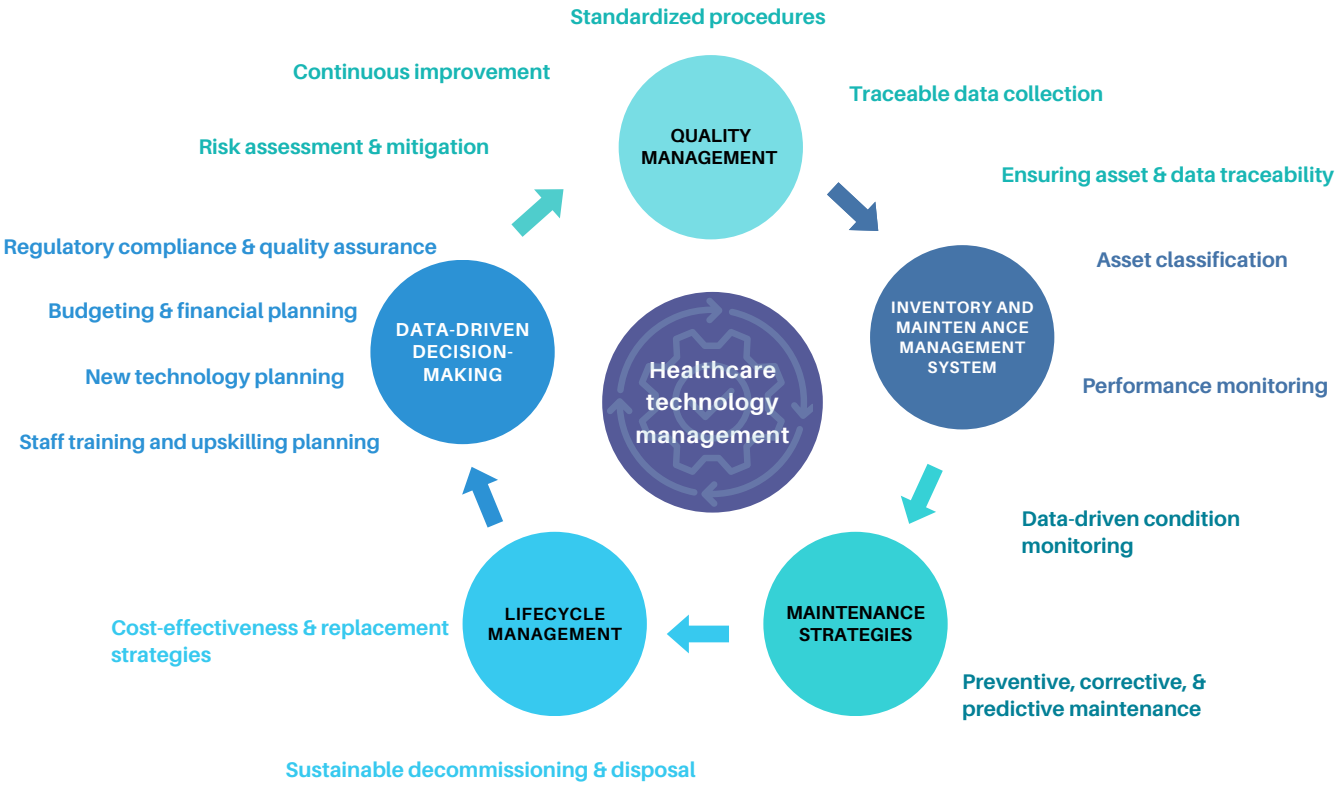
3. Health technology management: holistic perspective

3.1 Scope of HTM

Health Technology Management (HTM) is a set of activities aimed at ensuring that medical equipment is available and operates effectively and safely, in order to support healthcare services in an efficient, cost-effective and sustainable manner (6, 24).

In modern health-care systems, ensuring the availability, functionality and safety of medical equipment is not merely a technical requirement but a fundamental component of effective health-care service delivery. In many health-care systems, procurement, maintenance, compliance, decommissioning and financial planning of medical devices are handled independently. Simple management of these aspects is not, however, enough (Fig. 2), as times have changed, and many factors now influence the efficiency and safety of medical devices. They must be interconnected in health-care institutions to ensure seamless operation and optimal outcomes, thus requiring a holistic approach that goes beyond managing individual processes to enable their interconnection with new technologies. The holistic approach to HTM addresses not only individual processes but also ensures that people, processes and technology work together efficiently. As the health-care landscape evolves, new aspects, such as digital transformation, sustainability, regulatory compliance and patient care, interact and influence it.

Fig. 2. *Holistic approach to HTM*



Source: Own illustration.

To ensure that medical devices are available and operate effectively and safely, HTM also includes inventory management, maintenance management, QA, financial planning, regulatory compliance and sustainability initiatives, all of which should be supported by **information technology (IT) for integration, automation and data-based decision-making** *(29)*.

The transition to data-based, automated, environmentally responsible practices in medical device inventory and maintenance management is no longer optional but is essential for ensuring high-quality, sustainable, future-ready health-care systems. These lessons were learnt during the COVID-19 pandemic, when the health-care sector accelerated introduction of innovative technologies such as AI and the IoT.

The scope of HTM thus extends beyond simple asset management to a comprehensive strategy that integrates technology, policy and sustainability to improve health-care efficiency, patient safety and long-term system resilience.

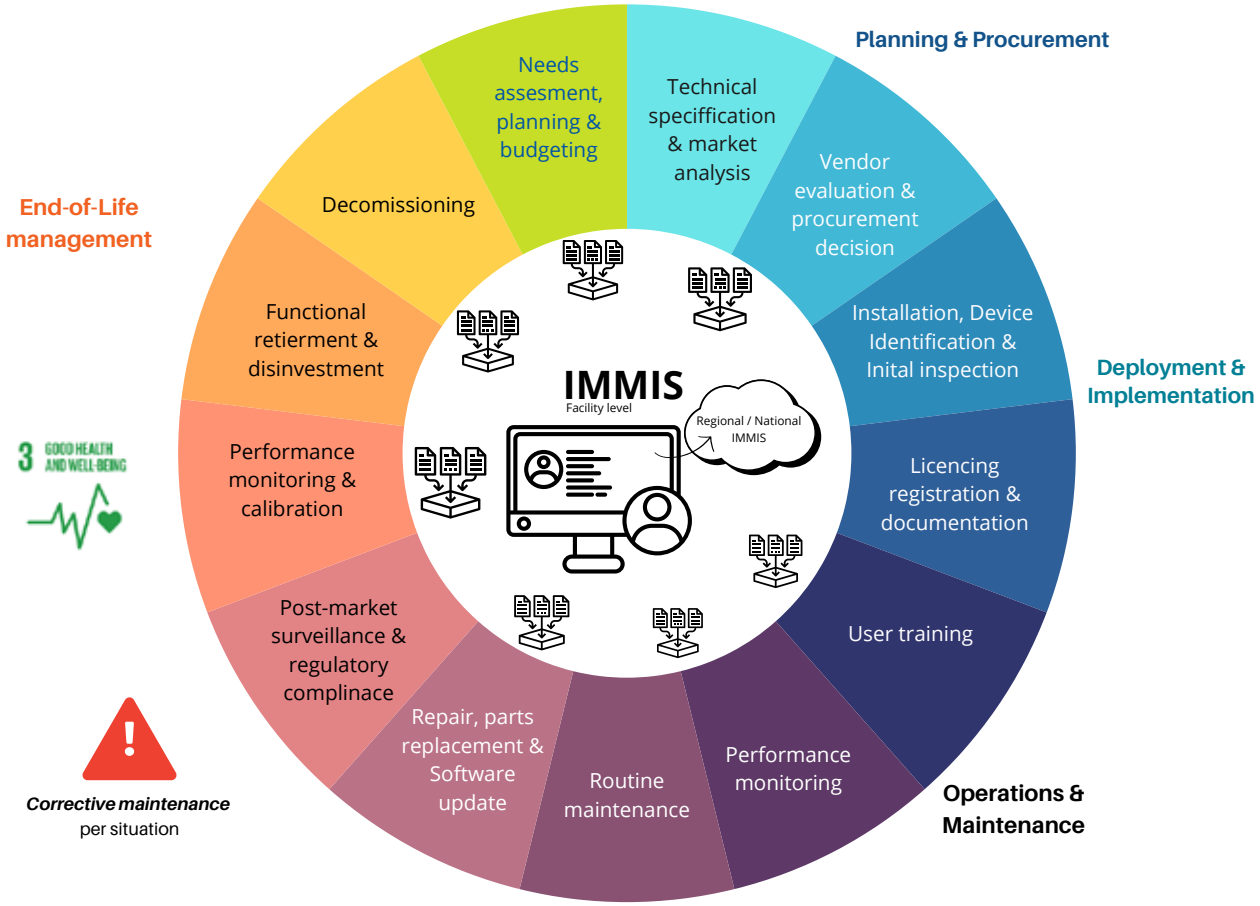
To fully understand this approach, it is essential first to recognize all stages of the medical device life cycle, from procurement to decommissioning. A medical device follows a structured pathway that ensures its optimal functionality, safety and regulatory compliance throughout its use in health-care institutions. Understanding the medical device life cycle is fundamental to HTM, as it demonstrates the importance of an interconnected system in which procurement, maintenance, regulatory compliance, financial planning and sustainability are integrated rather than managed independently.

Health-care technology is only as effective as its management. Without structured inventory and proactive maintenance, even the most advanced medical devices become liabilities instead of assets. A ventilator in an intensive care unit can save lives if it is available, functioning and properly maintained at the time it is needed.

3.2 Life cycle of medical devices: from procurement to decommissioning

The life cycle of medical devices is a structured, multi-phase process that requires careful planning, technical oversight and regulatory adherence (Fig. 3). Effective life-cycle management of medical devices comprises initial selection of a device to its decommissioning. Each phase – procurement, installation, maintenance, post-market surveillance and disposal – is crucial to ensuring that medical equipment remains safe, effective and compliant.

Fig. 3. *Life cycle of medical devices in a health-care facility: from procurement to decommissioning*



Source: Own illustration.
IMMIS, inventory and maintenance management system

3.2.1 Procurement and selection

This stage involves identifying health requirements and the equipment that best meets them. A formal needs assessment is often conducted to determine clinical requirements and context. WHO advises that decision-makers use evidence-based criteria in selecting medical devices, taking into account technical specifications and the priorities for the population. In practice, this means evaluating whether a device's functions are aligned with the intended medical procedures and the local disease burden *(7)*.

> By prioritizing devices to be used for high-burden health conditions in the local context, health-care providers ensure that the equipment will be used effectively in that setting.

For instance, WHO has issued lists of priority medical devices for various health conditions (including an emergency list for COVID-19), other for cancer management and for cardiovascular and diabetes, to guide countries in choosing essential equipment appropriate to their epidemiological context *(28).*

Once the requirements are clearly identified, procurement teams should check the performance parameters (such as accuracy, capacity and software features) and verify that the device under consideration has been approved by relevant regulatory authorities and that it adheres to recognized quality standards. Compliance with a quality management system (QMS) standard such as ISO 13485 is a clear indicator that the manufacturer follows rigorous processes to ensure device safety and efficacy *(30)*. Adherence to such international standards and ensures that only devices that are "of good quality, safe and perform as intended" are acquired *(4)*. WHO supports Member States by providing policy guidance, norms and standards for medical devices, including guidance on procurement and technical specifications, to ensure selection of high-quality, appropriate devices *(14)*.

Another critical aspect of selection is assessment of the supplier's credibility and of the support it will provide. Procurement consists essentially of forming a long-term partnership with the device's supplier or manufacturer. The reliability, after-sales support and service capability of suppliers should be evaluated, such as evidence of use of a robust quality system (such as ISO 13485 manufacturer certification or equivalent) and assured provision of spare parts, warranties and technical support. Due diligence of suppliers might include their track record, financial stability and capacity to provide training and maintenance services. Selection of a reputable supplier with a strong support network ensures that a device can be maintained and repaired promptly.

Budgeting and cost are major considerations in procurement decisions. With the purchase price, decision-makers should calculate the total cost of ownership of a device. This includes installation costs, training costs, maintenance agreements, the price of consumables or reagents and energy or infrastructure requirements. A device that is very low cost to buy but requires very expensive consumable parts (or has long downtime) might not be cost-effective in the long run. Thus, procurement committees often compare not only the clinical merits of devices but also their long-term operational costs and compatibility with other systems. Compatibility with other equipment and IT systems (for digital devices) ensures that a new device can be integrated easily. Ensuring compatibility can reduce hidden costs and technical problems.

During selection, regulatory compliance and alignment with best-practice guidelines are considered non-negotiable. Many countries require that public-sector procurements conform to their health technology policies or to their lists of essential devices according to WHO recommendations.

Procurement of the right device is the foundation of all subsequent life cycle stages. A well-chosen device that fulfils its clinical purpose in the context is more likely to be used correctly, maintained well and be useful throughout its lifecycle.

3.2.2 Installation

Proper installation goes beyond simply plugging in a machine; it requires preparing the site, verifying the device's performance and training users, to make sure that devices are correctly installed and ready to operate safely.

The first step is often ensuring that the location at which the device will be used meets all the requirements for power supply, ventilation, water or other utilities that might be required. The absence of these environmental and infrastructure conditions could lead to suboptimal performance or even hazards. Thus, before a device arrives, health-care facilities usually renovate or equip the site according to the manufacturer's specifications (often detailed in the device's technical documents), which may include reinforcing floors for heavy equipment, setting up network connections for digital systems or arranging special electrical outlets and backup power for critical devices.

Once the environment is ready, the device is delivered and physically installed by technicians or engineers (often with the supplier's assistance). Installation includes assembling the equipment if it comes in parts, making all the necessary connections (electrical, network, gas and configuring the device's settings for operation.

3.2.3 Initial inspection

After assembly, tests or initial or incoming inspection are performed. Commissioning or initial inspection consists of formal testing and validation that the device works as intended before it is put into routine clinical use. Its purpose is to confirm that the device complies with the approved design and meets all specified requirements.

Usually, biomedical engineers or qualified technicians conduct performance and safety checks according to international standards or the manufacturer's guidelines. This step ensures verification, responding to the question, "Does the device, as installed here, perform correctly and safely?".

Inspection according to the ISO/IEC 17020 standard *(31)* comprises systematic visual checks, functional testing and measurement accuracy, which are explained in more detail in section 8.2. Before the technical checks, the device is carefully identified and recorded by documenting details such as the manufacturer, model, serial number, year of manufacture and device category. This step ensures traceability and proper documentation, which are critical for maintaining inspection records in information systems and meeting regulatory requirements.

3.2.4 User training

Equally important is user training. Even a perfectly installed device can pose risks if the medical and technical staff who use it are not familiar with its operation. Therefore, part of commissioning includes training the end users such as doctors, nurses and technicians – on proper, safe use of a new device. The manufacturer or vendor usually provides initial training, covering the device's operating procedures, basic troubleshooting and maintenance tips. Proper user training ensure that staff are confident and competent in using technology, which reduces misuse and enhances patient safety. Safe use and performance of most medical devices therefore often relies on users being given clear instructions and training in operation and maintenance *(32)*. Training during commissioning ensures effective use.

> For instance, if a healthcare facility installs a new dialysis machine, the renal unit's nurses and clinicians need to be trained on the machine's interface, how to set up a dialysis session on it, what the alarms mean and how to respond if something goes wrong.

Finally, once a device has passed all tests and staff are trained, it is formally added to the facility's inventory or asset management system. Registering a device in an inventory database (with details such as serial number, location, installation date, warranty period and maintenance schedule) is a best practice for health-care facilities. It creates a record that a particular piece of equipment is now in service. This is important for tracking maintenance, recalls or eventual replacement. The inventory tools for biomedical equipment as part of health system assessments are needed, to provide information on exactly what devices are available and their status *(11).*

3.2.5 Performance monitoring

Medical devices, like any complex equipment, degrade or require re-calibration over time. Without proper upkeep, they may fail unexpectedly or give inaccurate results, which could directly impact patient outcomes. Performance monitoring by periodic inspection of medical devices provides important data on device performance and safety and enables a shift from reactive maintenance to predictive strategies *(33)*.

Periodic inspection, like initial incoming inspection, can be structured according to the ISO 17020 international standard *(31)*. Inspection needs to be conducted at regular intervals to ensure that a device maintains its accuracy and adherence to regulatory requirements throughout its operational life. The frequency of inspections should be based on the risk classification of the devices *(34)*.

The steps in inspection of medical devices are:

- visual check: physical damage, contamination or missing parts, ensuring that all accessories such as cables, sensors and electrodes are intact;
- functional inspection: testing of the device's operational features, including displays, alarms and indicator lights, and confirming that it powers on, initializes and responds correctly to user inputs; and
- verification of accuracy: comparison of the device's readings with known reference values from calibrated equipment *(35)*.

This method (see Annex 5 for an example of a standard operating procedure [SOP]) consists of evaluating the metrological characteristics of devices and assessing their essential safety and performance parameters. Adoption of a standardized performance monitoring method not only ensures that devices meet regulatory standards throughout their operational life but allows for PdM strategies *(36)*.

Performance monitoring does not replace preventive maintenance (PM) but significantly reduces the need for corrective maintenance and is a step towards PdM, as it provides valid, device-specific data for predictions. Maintenance strategies are described in more detail in section 6.

3.2.6 Routine maintenance

Ensuring optimal performance and safety of medical devices is crucial in health care settings. Health-care facilities implement programmes that include preventive, corrective and PdM strategies. These approaches, supported by modern tools such as IoT sensors and AI, help to minimize downtime and extend the effective life of a device *(37)*.

3.2.7 Post-market surveillance and QA

Post-market surveillance (PMS) is conducted after a medical device is on the market and in use, to monitor its performance, detect any safety issues and ensure continued compliance with regulatory standards. Unlike maintenance (which consists of keeping a device working), PMS is often part of a broader regulatory and quality control system, providing feedback to manufacturers, regulators and health-care providers about how devices are performing in the real world. WHO and international regulators consider PMS to be a critical component of the medical device life cycle, as it provides data to prevent accidents and improve devices over time *(25)*.

Effective PMS requires coordination among health-care providers, device manufacturers, regulatory agencies and international organizations. WHO provides guidance and encourages Member States to strengthen PMS as part of overall health technology management. It was reported in 2022, however, that, despite regulatory requirements, PMS worldwide is often fragmented and not fully aligned with international standards *(25)*.

Some countries might lack a national reporting database, or healthcare facilities might not be fully aware of reporting mechanisms. This can result in missed opportunities to detect problems early. Therefore, improving training on incident reporting and creating robust, standardized surveillance systems are ongoing goals in global health tech policy.

3.2.8. Decommissioning and disposal

All medical devices eventually reach the end of their lives, due to ageing, wear and tear or technological obsolescence. Decommissioning and disposal constitute the final phase of the device life cycle, in which a device is safely removed from service and is appropriately disposed of, by recycling, donation or reuse. This stage must be managed properly to ensure health and environmental safety and legal compliance (see section 8).

WHO guidance *(13)* states that medical equipment should be decommissioned in a structured way, with clear reasons and methods. In practice, health-care facilities should assess when a device should be taken out of use, how to do so safely and how to dispose of the device.

During each stage, a vast amount of data is generated, which, if properly managed and analyzed, can enhance informed decision-making in health-care technology management. The key is in how each step is structured, how data are collected and how effectively they are used in decision-making.

3.3 Regulatory frameworks for medical device management

HTM s should align to national and international regulations designed to standardize practices and ensure the safety and efficacy of medical devices in health-care systems.

Medical device regulations differ by region, and each country uses the frameworks to ensure the safety, efficacy and quality of medical devices. In its Global model regulatory framework for medical devices *(5)*, WHO provides guiding principles, harmonized definitions and the attributes of effective, efficient regulation to be embodied in binding, enforceable law. The model includes reference to guidance to the International Medical Device Regulators Forum. The general overview of medical device regulation includes several common practices, such as device classification, quality management, premarket review and approval, and post-market surveillance.

- Device classification. Medical devices are categorized according to their intended use and any potential risk they pose to patients. This classification determines the level of regulatory scrutiny required.
- QMS. Manufacturers are obliged to establish and maintain robust QMS to ensure consistent product quality and compliance with regulatory standards. The systems cover all aspects of production, from design and development to manufacture and post-market surveillance.
- Premarket review and approval. Before a medical device can enter the market, it must undergo a premarket review to demonstrate its safety and effectiveness. Depending on the type of device, this may require submission of clinical data, technical specifications and performance evaluations to the relevant regulatory authority.
- PMS. Continuous monitoring of medical devices after their release onto the market is essential for prompt identification and action on any issue that arises during real-world use. Activities include reporting of adverse events, periodic safety updates and, when necessary, product recalls (see also section 3).

More details about the above mentioned is in the WHO book: WHO Global Model Regulatory Framework for Medical Devices including *in vitro* diagnostic medical devices *(38).*

While HTM is not explicitly mentioned in regulatory practices, it inherently arises from them to ensure the effective management and use of medical devices in health-care settings. WHO provides guidelines and recommendations for HTM, emphasizing the importance of integrating HTM into national health policies and strategies *(32)*.

Regulatory bodies and accreditation agencies require comprehensive audits to ensure that medical devices comply with safety and performance standards. The audits involve reviewing documentation, inspecting device conditions and verifying adherence to maintenance schedules. Compliance reports are official records that confirm that an institution has followed the relevant guidelines.

3.4 Challenges in managing medical devices in various health-care settings

In all health-care settings, medical devices play a vital role in health-care delivery, ensuring accurate diagnostics, effective treatment and patient safety. Although medical devices that enter the market should comply with standards, how they are managed, maintained and integrated into health-care systems differs significantly by region; however, the fundamental requirement remains the same: to keep medical devices safe, functional and reliable. The conditions under which this objective is pursued differ.

- Low-resource settings usually have shortages of trained personnel, financing and structured maintenance protocols.
- Middle-resource settings often find difficulty in improving their medical technology infrastructure while ensuring compliance with evolving regulatory and quality standards.
- High-resource settings manage complex networks of advanced medical equipment, with sophisticated inventory systems, PdM and interoperability.

Regardless of the setting, maintaining the common goal – to keep medical devices safe, functional and reliable – is determined by factors such as workforce availability, financial constraints, regulatory frameworks and technological capability.

3.4.1 Workforce availability and training

One of the most significant challenges in managing medical equipment is a shortage of trained personnel responsible for its inventory and maintenance. Many health-care settings, particularly in low-resource environments, find difficulty in recruiting and retaining biomedical engineers, technicians and/or clinical engineers *(39)*, both in the health care facility or by local representatives to support maintenance, WHO has reported a stark disparity between different regions in the availability of skilled biomedical engineers and technicians *(40)*.

Even when technical staff are available, lack of continuous operational training or support in the use and also on the maintenance of medical devices is a problem. When staff are not properly trained, medical devices are likely to be used incorrectly or handled incorrectly, resulting in malfunction, damage or even safety incidents.

Most high-technology equipment imported to developing countries becomes unusable because of inadequate support in infrastructure or capability *(41)*. In many cases, donated medical equipment remains nonfunctional or is not used effectively in health-care facilities due to factors such as inadequate user training and lack of technical support. Even a minor missing component or accessory can render a machine unusable if local staff are unable to make the necessary repairs *(42)*. Nevertheless, the recent WHO guidance on donations

of medical devices consider indispensable to proceed with a regulations clearance before the device are accepted *(4)* which is aligned with the Global Model regulatory framework published in 2023 *(5)*.

Poorly trained users may operate equipment outside its intended parameters or neglect necessary precautions, leading to avoidable failures *(39)*.

In many resource-limited health-care facilities, technical staff are often limited to a single, often untrained individual, so that a substantial proportion of medical equipment remains nonfunctional, which limits effective health-care delivery *(43)*.

Every device comes with an obligation: without knowledgeable operators and caretakers, even the best technology can become ineffective or dangerous. Shortage of qualified health technology personnel is therefore a major barrier to keeping medical devices operational in developing health systems. As a result:

- medical equipment can remain unused or underused due to a lack of operational knowledge;
- maintenance can be delayed increasing equipment downtime, reducing availability; and
- poorly trained staff may misuse medical devices, leading to premature failure and increased repair costs.

Training challenges include:

- introduction of new medical technologies without adequate hands-on training;
- few refresher courses, resulting in lack of skill in troubleshooting and maintenance; and
- lack of standardized training programmes, resulting in inconsistent knowledge transfer.

3.4.2 Technological capability

Challenges to technological capability include the following.

- In high-income countries, the inventory includes advanced, AI-driven, automated, high-tech medical devices, which require frequent upgrades.
- In middle-income countries, the inventory includes both advanced and basic technologies, and use of older devices is often prolonged due to cost constraints.
- In low-income countries, the inventory includes basic, essential medical devices, with significant gaps in advanced diagnostics, life-support and highly specialized surgical devices due to financial and infrastructural limitations.

Although medical equipment inventory and maintenance have until recently relied on manual record-keeping, decentralized databases and reactive maintenance strategies – which are still used in many settings, this publication addresses modern, systematic, proactive automated management methods.

Health-care systems differ widely in their approach to medical device inventory and maintenance management, some adopting centralized systems and others decentralized, fragmented settings. All approaches are, however, supported by IT. Common issues in HTM include:

- outdated or missing records, which leads to mismanagement of resources;
- ineffective tracking of the location of equipment, delaying access and use;
- lack of real-time monitoring, so that health-care facilities do not identify underused or malfunctioning devices;
- difficulty in regulatory compliance, resulting in safety risks;
- lack of standardized protocols for medical device procurement, use and maintenance; and
- lack of structured emergency response plans for medical device failures in critical care units, shortages of essential equipment and supply chain disruptions.

3.4.3 Financial constraints

Health facilities that have no in-house biomedical maintenance expertise often rely on costly emergency repairs or external contractors, further straining limited budgets. Nevertheless, it is noted that multiple complex medical equipment requires the calibration and repair from the original manufacturer and it is very important to keep the financial track of those contracts. . Financial constraints lead to:

- deferred maintenance, increasing the risk of unexpected equipment failure;
- reliance on donations, which may not meet the specific needs of the facility; and
- limited access to spare parts, delaying repairs and reducing equipment lifespans.

3.4.4 Regulatory frameworks

PMS is critical for tracking medical device performance and identifying safety concerns. Independent third-party inspection and PMS of medical devices and health-care technology during their use in health-care institutions depend on the system. Many health-care institutions face:

- lack of structured systems for reporting adverse events and device failures;
- limited regulatory enforcement, leading to inconsistent monitoring of equipment safety; and
- delays in implementing corrective actions, increasing the risks to patient safety.

3.5 Recommendations for improving HTM practices

A holistic approach to HTM integrates technical processes, workforce training, digital transformation, regulatory compliance and financial planning to optimize health-care services. The following recommendations represent good practices that should be adopted by health-care institutions to improve the management of medical devices.

3.5.1 A well-trained workforce

Without regular education and skills development, health-care professionals may have difficulty in operating and maintaining complex medical equipment effectively. The WHO Global strategy on human resources for health: workforce 2030 *(41)* calls for recognition of biomedical engineers and technicians as part of the health workforce, recommending their integration into national health-care plans. To address workforce shortages and enhance expertise, health-care systems should invest in training more biomedical engineers and providing continuous professional development for technicians and clinical engineers.

The WHO publication "Human resources for medical devices, the role of biomedical engineers" *(20)* describes the role of biomedical engineers in the management of medical devices in national organizations and health-care facilities (see section 11).

Training of users – nurses, doctors and other health-care professionals – is equally important. Ensuring that they are proficient in operating medical equipment and performing routine checks can significantly reduce misuse, accidental damage and operational downtime. Capacity-building workshops and online training programmes for health-care staff can further improve their competence in medical device management, reduce user errors, promote safety and extend the working life of medical equipment.

The IFMBE Clinical Engineering Division offers educational materials, training programmes and collaboration opportunities to strengthen the capacity of health-care technology professionals. By using these resources, health-care facilities can enhance workforce competence, improve medical equipment management and ensure sustainable health-care technology systems *(43)*.

Alignment of medical device inventory and maintenance management with appropriate international standards provides evidence-based management and better traceability, leading to better quality, safety and performance of medical devices. Standards ISO 9001, ISO 55000 or ISO/CD TS 5137 provide a good basis for process standardization.

Minimal standardized practices and guidelines that are applicable in diverse environments are essential for maintaining consistency in HTM when addressed holistically. WHO also advocates for appropriate technology selection, favouring robust equipment that can be operated safely with minimal training and in local conditions, to avoid overwhelming under-resourced facilities.

WHO guidelines reinforce these principles by offering best practices for medical equipment management, ensuring that devices meet safety, performance and operational benchmarks. By integrating HTM into a health-care facility's QMS, facilities can achieve greater efficiency, better risk mitigation and alignment with regulations. Alignment of HTM policies with international standards ensures that health-care institutions maintain the availability of equipment, cost-effective maintenance and adherence to safety regulations, enhancing the quality of patient care and operational sustainability *(6)*.

3.5.2 A comprehensive inventory system

An inventory is not merely a list of assets but the basis for planning, procuring and maintaining medical equipment. Establishment of a well-maintained inventory system requires:

- data collection, digitization and organization, ensuring that medical equipment records are up to date;
- advanced analytics and algorithms to assess use of equipment, requirements for maintenance and long-term investment planning; and
- automated tracking and real-time updates to prevent duplication, misplacement or underutilization of devices.

3.5.3 Integration of digital technologies into HTM to improve equipment traceability, streamline maintenance planning and ensure regulatory compliance

One of the most effective tools for managing medical equipment is a CMMS, which provides:

- a centralized digital inventory of all medical devices;
- service history records for tracking preventive and corrective maintenance;
- automated alerts and scheduling for calibration, inspection and compliance checks; and
- performance monitoring and analytics for optimizing asset use and maintenance efficiency.

These digital information systems reduce manual errors, improve maintenance response times and ensure better compliance with safety standards.

3.5.4 Mitigating financial challenges

Allocation of sufficient resources for medical equipment maintenance and replacement is vital for continuous delivery of high-quality health-care services. Furthermore, where feasible, in-house maintenance capability and cost-effective service contracts can improve response times and equipment reliability *(44)*.

3.5.5 Ensuring uninterrupted health-care services

A common objective of HTM is proactive risk management to minimize operational disruption and improve health-care system preparedness for challenges. To ensure uninterrupted health-care services, health-care institutions must have risk mitigation strategies to prepare for equipment shortages, supply chain disruptions and emergencies. The recommendations include:

- maintaining reserves of essential medical devices to ensure their availability in a crisis;
- diversifying procurement strategies to avoid reliance on a single supplier; and
- making the supply chain more resilient by improving coordination among manufacturers, distributors and health-care providers.

Effective HTM practices are based on accurate inventory management, robust QMS procedures, well-implemented digital systems and clearly defined key performance indicators (KPIs). When these elements are properly integrated, they ensure data-based decisions, efficient resource allocation and optimal medical device performance.

4. Inventory and nomenclature

4.1 Objectives of inventory management

In health-care settings, an inventory consists of systematic tracking and management of medical assets, including medical devices, equipment and consumables, . A medical device inventory is an essential part of an effective HTM system, as it provides a comprehensive record of real-time data on the availability, operational status, maintenance history and location of medical devices in a healthcare facility. Inventories are held at several organizational levels: in individual health-care facilities, in regional health-care networks and at national level, for centralized oversight and policy planning.

An inventory of medical equipment is a comprehensive, organized list or record of all the medical devices and equipment available in a health-care facility *(10)*. It includes information on the maintenance schedule and calibration requirements for each item. An equipment inventory can also include financial information for budgeting and planning procurement of new equipment, for assessing which equipment should be replaced or upgraded and for estimating the costs *(45)*.

Inventory management in HTM consists not only of maintaining a list of assets. With clear nomenclature (naming and classification system), it ensures that health-care institutions have the right medical devices in the right place at the right time, minimizing the risks associated with shortages, inefficiency and safety.

4.1.1 Objective 1: Ensuring device availability

Health-care facilities often have thousands of devices, from simple thermometers to multiple surgical instruments, monitors, infusion pumps, all the way to complex magnetic resonance imaging (MRI) equipment. As patients' lives may depend on the immediate availability of functional equipment, poor inventory practices can lead to a situation in which critical devices are missing, expired or out of service without anyone's knowledge. It has been noted that health-care institutions frequently find that they have malfunctioning or unavailable medical equipment, which disrupts patient services, and this is often due to deficient management and maintenance of devices. Proper inventory management ensures that the location and status of each device is known, so that staff can quickly find it and administrators can identify shortages before they affect care.

4.1.2 Objective 2: Reducing losses of equipment

In the chaos of a busy health-care environment, devices can be misplaced, accidentally thrown away or even stolen. A detailed inventory with unique identifiers for each item creates accountability, as it inidicates which department or person last had the device, and missing items are quickly noted. Such accountability ensures that valuable medical devices are not simply lost in the system. Furthermore, inventory records prevent unnecessary purchases.

4.1.3 Objective 3: Improving patient safety

Medical devices must be functional and safe to use; any failure can directly affect patient health. An inventory contributes to safety by providing a record of maintenance and calibration for each device, ensuring that no equipment is overlooked in regular safety checks. It also allows health-care facilities to respond promptly to safety notices or recalls. If a manufacturer recalls a certain model of defibrillator, for instance, an accurate inventory allows the health-care facility to identify exactly how many such units it has and where they are, so that they can be removed or repaired at once. Inventory management therefore supports a culture of safety: every device is documented, its performance is monitored, and any problems are addressed in a timely manner. An inventory allows identification of potential risks (such as outdated or unreliable equipment) and planning actions to reduce them. By keeping equipment in safe working order and ensuring that back-up devices are available, inventory management reduces the risk of device-related errors or downtime that could harm patients.

4.1.4 Objective 4: Enhancing regulatory compliance

Many countries have regulations to mandate scheduled safety inspections or performance verification (legal inspections) for specific devices. An inventory system should be configured to log each inspection and alert managers about the next check, thereby ensuring that the facility complies with safety laws. Moreover, introduction of the UDI system (discussed below) allows health-care providers to keep track of devices. Lack of an inventory could result in violations if a facility cannot account for devices and their UDI during a regulatory audit. Thus, inventory management is a technical, legal and ethical task. It provides the documentation and oversight necessary to satisfy regulatory standards and to ensure that every device in use meets current safety and performance requirements.

While the goals of inventory management differ at each level, they have a common objective: to enhance patient safety. A well-structured inventory ultimately safeguards the quality, reliability and accessibility of medical technology in health-care systems by ensuring the immediate availability of a device in a health-care facility, optimizing regional equipment allocation or enforcing national safety regulations.

4.2 Types of medical device inventories

4.2.1 Facility-level inventory system

A facility inventory is one maintained by individual health-care institutions, such as hospitals, clinics, diagnostic centres and specialized medical facilities. The clinical engineering departments in institutions are primarily responsible for managing medical devices, which are considered capital equipment and are a subset of the organization's inventory of assets. This usually excludes non-medical items such as office furniture, although such items may be included in the organization's overall capital assets inventory. Before collecting data for a medical equipment inventory, an organization should establish a policy on which devices are to be included and the data to be collected on each device. This basic step ensures a systematic, comprehensive approach to inventory management *(45)*.

WHO has noted that inventory management can be classified into three stages, initial data collection being the first, most critical step. This includes establishing a policy on the devices to be included and the data to be collected on each device *(10)*. After data collection, standardized procedures should be used for maintaining and updating the inventory, including defining roles and responsibilities, setting schedules for regular audits and devising protocols for adding or removing equipment from the inventory. The final stage is effective use of the collected data for decision-making, including planning maintenance schedules, forecasting equipment requirements, budgeting for replacements or upgrades and ensuring compliance with regulatory requirements.

In a medical equipment inventory, each piece of equipment is assigned a unique number, so that it can be identified. All the information on each piece of equipment, such as service history, maintenance procedures and schedules, repair history and spare parts used, is then linked to the identification number for tracing. Facilities often use a CMMS or information system (see section 7) to streamline inventory management. A CMMS is a digital platform designed to streamline the tracking, maintenance and performance monitoring of medical equipment. It includes various data, including UDI, nomenclature codes and operational status to ensure equipment reliability and compliance *(2)*.

4.2.2 Regional-level inventory system

A regional inventory consolidates data from multiple health-care facilities in a geographical area, such as a province, state or district. An inventory at this level ensures good coordination of medical equipment distribution and allows health-care authorities to address disparities in resource availability. A major function of regional inventories is to support disaster and emergency response. During public health crises, such as pandemics or natural disasters, regional inventory systems indicate the available medical assets, allowing rapid mobilization of ventilators or mobile medical units where they are most needed. Inventories of single-use medical devices such as syringes and personal protective equipment are usually kept in stock at health-care facilities. Regional health agencies often use standardized inventory protocols to ensure uniform data collection and reporting from all facilities in their jurisdiction. Standardization facilitates compliance with national health-care regulations and allows for aggregation of data for use in policy development and broader health-care planning.

For example, the inventory system operated by the medical device inspection laboratory in Bosnia and Herzegovina is a web-based system providing performance tracking of medical devices, generating insights on device reliability and failure trends. Currently used in more than 220 healthcare institutions with over 40,800 inspection reports, it provides an overview of types and models of medical devices used in healthcare institutions in the regions of this country *(47-49)*.

4.2.3. National-level inventory system

A national inventory provides an overarching view of medical equipment availability across an entire country. It is used for strategic planning, policy development and large-scale public health initiatives. National inventories provide the highest level of medical device tracking and management in a country. They are usually managed by government agencies, the ministry of health or national regulatory bodies. The registry is used by the government to monitor the availability and distribution of essential medical technologies in order to plan national procurement strategies. By analyzing data from a national medical equipment inventory, policymakers can determine which regions require additional investment in medical technology. The data thus support evidence-based decision-making, ensuring that health-care budgets are allocated efficiently. Additionally, the inventory allows policymakers to ensure compliance with regulatory standards and safety guidelines from post-market surveillance data on medical devices. In the event of a recall, a centralized inventory allows rapid identification and removal of affected products from health-care facilities, minimizing patient risk.

Many countries use national medical device registries to enhance patient safety and streamline regulatory oversight.

For example, the European Union's EUDAMED system and the U.S. FDA's Global Unique Device Identification Database (GUDID) provide structured frameworks for national-level medical device tracking. By implementing such databases, governments can track medical devices from manufacturing to end-of-life, ensuring accountability and preventing the circulation of counterfeit or non-compliant equipment.

National inventories: Some countries have national inventory only of high cost medical equipment.

In Mexico, the information system of equipment, health work force and infrastructure named "Subsistema de Información de Equipamiento, Recursos Humanos e Infraestructura para la Atención de la Salud (SINERHIAS)".

Effective medical equipment inventory management follows a bottom-up approach, beginning at the facility level and extending to regional and national systems. At each level, clear policies dictate what devices are recorded, how the inventory is maintained and how decisions are made. While health-care facilities seek operational efficiency, maintenance and real-time tracking, regional systems ensure resource coordination and emergency preparedness, and national inventories enable strategic planning, policy development and regulatory oversight.

Synergy among all three levels is essential for a truly effective inventory system. Institutional inventories must be aligned with regional and national frameworks to ensure seamless data exchange and standardization. An interconnected structure ensures better resource distribution, faster response to public health emergencies and better compliance with safety regulations.

4.3 Data elements in an effective inventory system

Key data elements in an effective inventory system include standardized nomenclature for device classification, UDI and manufacturer data for traceability and location, and information on status and operational condition for real-time asset management. UDI and medical device nomenclature have distinct yet complementary roles in the management and regulation of medical devices.

Nomenclature is a standardized system of naming medical devices and related health products into generic groups, ensuring clear communication despite linguistic and other barriers, and supporting the management and regulation of medical devices. The UDI is a unique numeric or alphanumerical code assigned to medical devices for their identification from the production which can be tracked during supply and use.

4.3.1 Standardized nomenclature

One of the basic elements of an effective inventory system is standardized classification of medical devices. Medical device nomenclature systems provide a structured, uniform way of categorizing medical equipment, ensuring consistency in record-keeping, procurement, regulatory reporting and risk management. Without a unified system, the same device might be recorded under several names, leading to inefficient tracking, reporting and decision-making. WHO has stated that a harmonized nomenclature system enhances medical device traceability and facilitates effective inventory management *(50)*.

Medical device nomenclature systems are intricate frameworks of rules, codes and definitions used in health-care systems and organizations to identify medical devices and related health products. According to WHO, the systems cover more than 7,000 different types of medical device, ranging from very simple to highly complex instruments. Furthermore, the number and variety of these devices are increasing exponentially *(50)*.

In 2018 the WHO defined the principles of the , coding and nomenclature of medical devices:

- "ensure that stakeholders in different regions can provide feedback;
- provide a transparent method for classification, coding and nomenclature and processes for updates; and
- provide a source of information that:
  - can be referenced and used by regulators, procurers, managers and all users;
  - is freely available and considered a global public good;
  - supports the UDI system;
  - is accessible in a simple, intuitive search; and
  - is available for use in all health-related database systems."

The guiding principles for a standardized nomenclature system are inclusivity, transparency and accessibility, with potential harmonization of the selection, regulation, assessment and management of medical devices to improve the quality of health-care delivery *(50)*.

A WHO survey conducted in 2021–2022 *(51)* and the 2022 Global Atlas of Medical Devices *(52)* indicate that 75 of 180 countries did not use formal nomenclature, while 15 used more than one system. Although several medical device nomenclature systems are used globally, the two most widely adopted are the GMND and the EMND. In the WHO survey, 16 countries were using UMDNS, 15 were using GMDN, and the 27 countries in the European Union were using EMDN. National nomenclature systems were used in 32 countries .

The United Nations Development Programme has its own standard codes, which are used in the United Nations Global Market Place and are known as the United Nations Standard Product and Service Code, in which medical equipment is categorized under "E, Medical, Laboratory & Test Equipment & Supplies & Pharmaceuticals" *(53)*.

Global Medical Device Nomenclature (GMDN)

The GMDN was developed by the European Committee for Standardization and global experts in medical devices, including manufacturers, health-care authorities and regulators. It is managed and maintained by a not-for-profit company, the GMDN Agency, which reports to a board of trustees on which medical device regulators and industry are represented. To ensure the permanency of the GMDN, revenues are generated through licensing and sale of GMDN Agency products, such as the GMDN codes. GMDN can be used internally by registering on the GMDN system but cannot be used for public documents because of copyright *(54)*.

Product identifiers consist of unique five-digit numbers that are associated with a term (medical device name), a definition that includes the intended use(s) and the device category (according to application, technology or other common characteristics). The GMDN five-digit code thus contains the following information: the term name, the code number and the definition. Medical devices with substantially similar generic features can be identified by cross-referencing *(54,55)*.

European Medical Device Nomenclature (EMDN)

The European Commission Medical Device Coordination Group decided to use national classifications of medical devices in the European database, EUDAMED, which is used by manufacturers to register medical devices, because of its structure, purpose, usability and updating method. The EMDN became the official nomenclature system in the European Union, with the EUDAMED database *(55)*.

The main purpose of the EMDN is to meet the requirements of regulations on medical and in-vitro diagnostic devices. It is therefore used in all technical documentation, audits conducted by notified bodies, post-market surveillance, monitoring, vigilance and data analysis. The EMDN is accessible to manufacturers, patients, research organizations, practitioners, health-care facilities and pharmacies free of charge. It is based on the "*Classificazione Nazionale Dispositivi medici"*, the national Italian nomenclature. In the EMDN, medical devices are divided into categories (first level), groups (second level) and types (third level), each level with an assigned alphanumerical code. The code attributed to every device consists of a letter referring to the category and two numbers, referring to the group, and a series of other numbers referring to the type *(56,57)*.

Each of the 22 categories is identified by a letter, and each may be further categorized as anatomical (eight), functional (nine) or special (five) (Table 1).

Table 1. *Categorization of medical devices in the EMDN*

Category by anatomical area of use	Functional category, by intended use or clinical method	Special categories by other criteria
B – haematology and haemotransfusion devices C – cardiocirculatory devices F – dialysis devices G – gastrointestinal devices N – devices for nervous and medullary systems R – respiratory and anaesthesia devices U – urogenital apparatus devices	A – devices for administration, collecting and picking D – disinfectants, antiseptics and proteolytics for medical devices H – suture devices K – endotherapy and electrosurgical devices L – reusable surgical instruments M – devices for generic and specialist medication S – sterilization devices T – protection devices and incontinence aids V – medical devices, various	J – active-implantable medical devices P – implantable prosthetic and osteosynthesis devices and non-active implantable medical devices Y – supports or technical aids for disabled people W – in-vitro diagnostic devices Z – medical equipment and related accessories and materials

WHO has advocated for creation of a standardized international classification *(2)*, coding and nomenclature for medical devices that would be available to all Member States and would be used to ensure patient safety, access to medical devices for universal health coverage, emergency preparedness and response, improving the quality of health-care, and achievement of Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages).

Using a standardized medical device nomenclature is essential for information systems and for maintaining an inventory or CMMS. Ideally, devices are classified in an inventory by standard nomenclature according to basic information on their intended use, equipment category, risk class (if applicable), location, location of the manufacturer and the model. Use of standard nomenclature ensures consistency and accuracy and avoids duplication in equipment records. It not only ensures efficient inventory management but also facilitates:

- management of maintenance and decommissioning;
- procurement, such as for making technical and financial comparisons;
- accounting and inventory control;
- conforming to regulatory matters, such as market authorization and post-marketing surveillance;
- monitoring, evaluation and reporting of adverse events;
- tracking of donated and refurbished equipment;
- assigning customs codes and taxes; and
- ensuring compliance with the UDI.

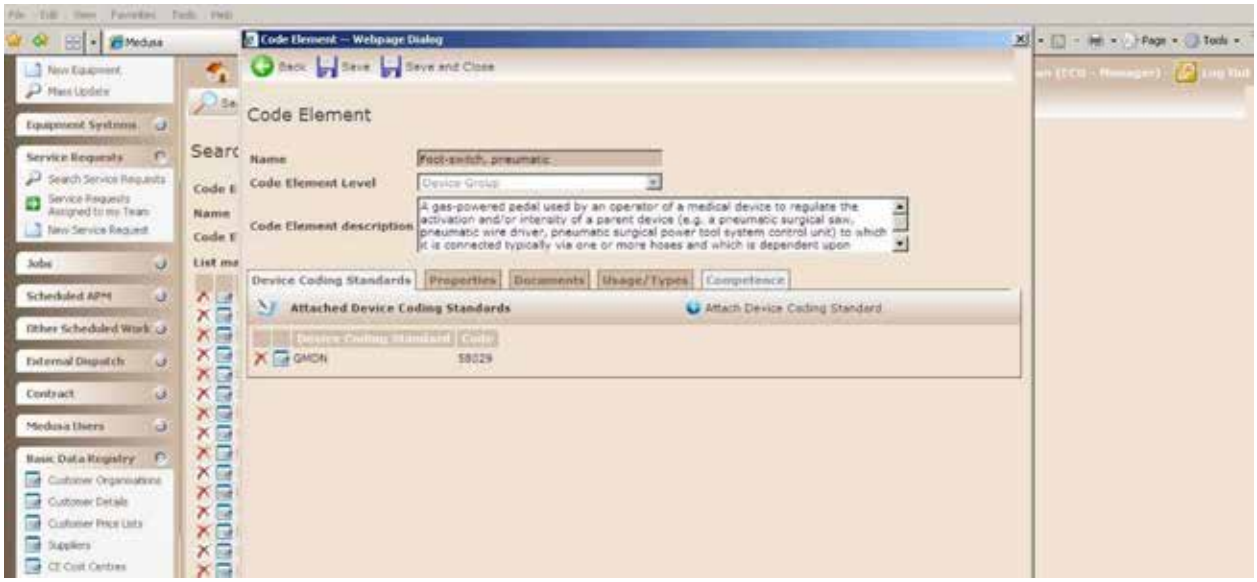
WHO recommends use of EMDN and GMDN, as they are now available in the MEDEVIS database and clearinghouse, with references to the EMDN and GMDN webpages in alignment to the WHA75.25 decision from WHO World Health Assembly. Table 2 presents a comparison of the two nomenclatures.

Table 2. *Comparison of GMDN and EMDN nomenclatures*

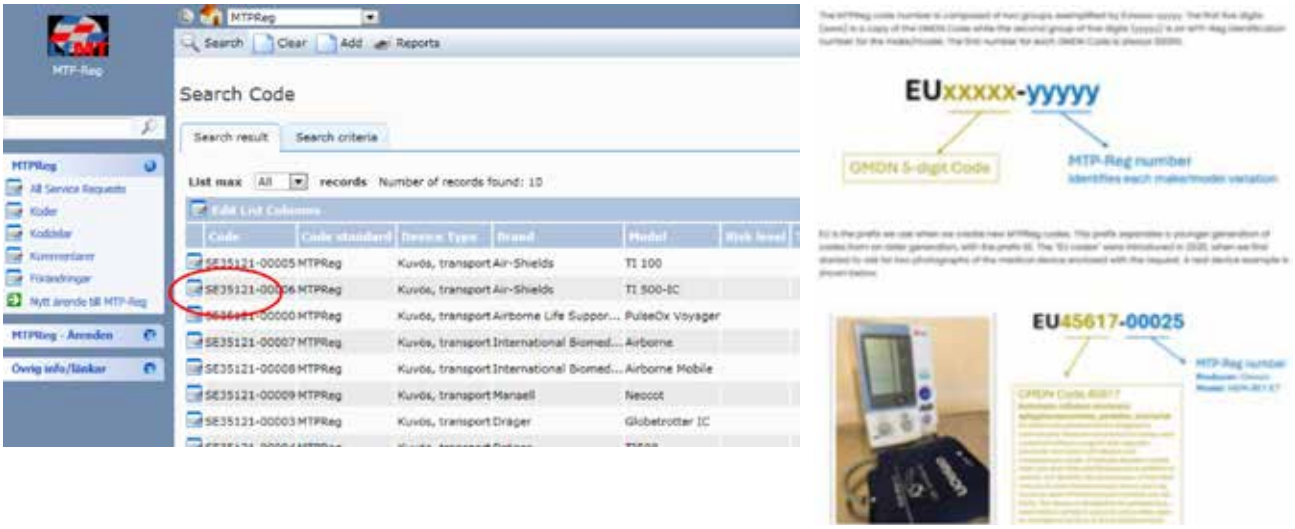
	GMDN	EMDN
Purpose	Standardizes names of medical devices worldwide	Used for medical device registration and regulatory purposes in the European Union under the Medical Device Regulation
Governance	Managed by the GMDN Agency	Managed by the European Commission
Scope	Global: used in many countries, including outside the European Union	Tied to the European Union regulatory framework
Structure	Polyhierarchical structure, so that terms can belong to several categories	Single-hierarchical structure, with terms organized into a single category
Access	Requires a subscription for full access; some terms available for free	Free access through the European Commission's EUDAMED database
Example	"Syringe, hypodermic" (Code: 47017)	"Hypodermic syringe" (Code: CA.02.04.01)

Fig. 4. *Inventory screens showing medical equipment labelled according to the Global Medical Device Nomenclature (GMDN)*

Nottingham University Hospital Database



Swedish public health-care providers *(46)*



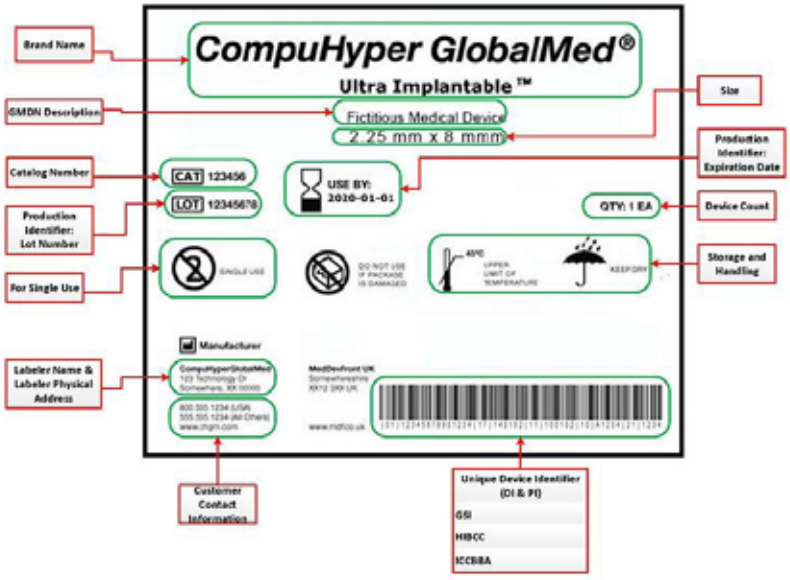
4.3.2 Unique Device Identification (UDI) and manufacturer data

The UDI system is a global initiative for standardizing the identification of medical devices to enhance patient safety, streamline supply chain management and facilitate device tracking and maintenance. The International Medical Device Regulatory Forum developed initial guidelines for the UDI system *(58)* and established principles that could be adopted voluntarily by jurisdictions to develop UDI systems in a globally harmonized manner. The US Food and Drug Administration and the European Union were among the first jurisdictions to establish UDI regulations, in 2013 and 2017, respectively. Other jurisdictions that have or are establishing UDI regulations are Australia, Brazil, China, Republic of Korea, Saudi Arabia, and Singapore.

The system requires assignment of an alphanumerical code to each medical device according to globally accepted standards. The UDI is a series of numerical or alphanumerical characters for unambiguous identification of a medical device throughout its distribution and use. It is composed of the device identifier and the production identifier (Fig. 5):

- device identifier: a mandatory, fixed portion of a UDI that identifies the labeler and the version or model of a device; and
- production identifier: a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
  - lot of batch number when a device was manufactured;
  - serial number of the device;
  - expiration date of the device or date of manufacture;
  - version for software as a medical device (in certain jurisdictions); and
  - the distinct identification code, used for medical products of human origin that are regulated as medical devices.

Fig. 5. *UDI label*



Source: US Food & Drug Administration *(59)*

Benefits of integrating UDI data into an HTM information system

Use of UDI can improve the ability of manufacturers, distributors and health-care facilities to manage recalls more effectively and to reduce medical errors by allowing health-care teams to identify a device more rapidly and precisely and to obtain information about the device characteristics. This provides the basis for a secure global distribution chain and more accurate reporting, review and analysis of adverse events.

UDI allows health-care organizations to track detailed maintenance and servicing histories. Thus, a CMMS that stores UDI data can more easily group all identical models (via the device identifier) and ensure that maintenance checks are performed according to the manufacturer's guidelines for that model. This reduces human error in record-keeping (no mistyping of model or serial numbers) and creates a traceable history for the unique device. Logging of the UDI with each service event during the equipment's life cycle builds a comprehensive profile that can be analyzed for trends in reliability or failure for all devices of that type.

Requiring a UDI field in electronic work orders facilitates compliance by standardizing the process and reducing audit risk. During audits or investigations (such as a patient incident involving a device), a health-care facility can readily retrieve records of all maintenance performed on that UDI-identified unit.

4.4 Connection of UDI, nomenclature and inventory management

Integration of UDI and nomenclature into information systems for management of inventory ensures effective health-care technology management. Thus, each device is uniquely identifiable, reducing errors in asset tracking and minimizing discrepancies in inventory records. Every medical device in a health-care facility can be precisely accounted for by linking its UDI with real-time data on its location and maintenance status. Data on the current condition or operating status of equipment are essential for managing maintenance status and should always be collected. Even equipment that is not in current use should be included in the inventory. The operating status of equipment should be assigned a standard "condition" code, such as:

1. in active service
2. broken but reparable
3. inactive; in storage
4. retired; available for parts
5. retired, disposed of.

Such condition codes could be used to calculate a "functional capacity ratio", which is the percentage of assets that are functional and available for use. This parameter is useful for demonstrating the impact of implementation of a CMMS.

Looking at the big picture, recent policy trends emphasize not just having UDI, but using it effectively. Regulators have largely done the work of requiring UDIs on devices. As health care moves towards more integrated technology (such as "smart" operating rooms, radio frequency identification cabinets, IoT devices for reporting status), the UDI will probably be used for communication with a common identifier. Policymakers are also considering use of UDIs in complying with emerging regulations such as on device cybersecurity and supply chain resilience. The UDI has thus become an essential component of medical device governance.

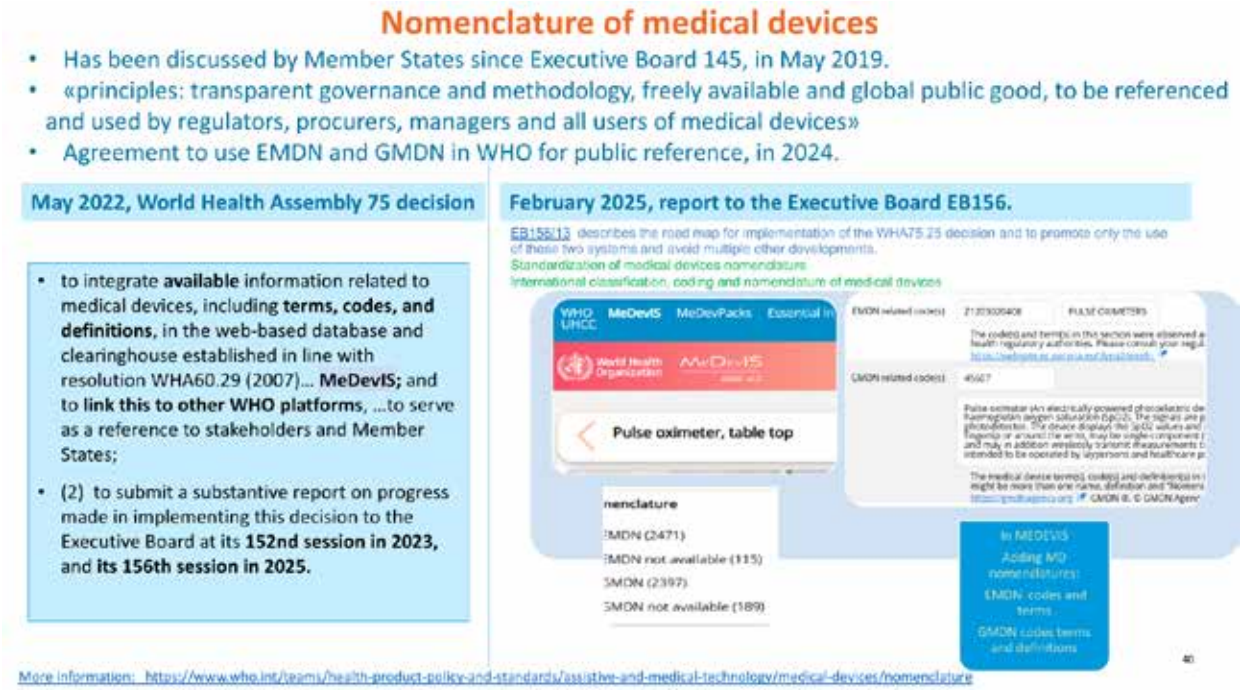
4.5 Priority Medical Devices Information System (MeDevIS)

The Priority Medical Devices Information System (MeDevIS) *(14)* was developed by WHO as the first global, open-access clearinghouse for information on medical devices, including terms, codes and definitions of medical devcies as mandated by the WHA75.25 Resolution *(50)*Launched in July 2024, its primary purpose is for use by governments, regulators and health-care providers in making informed decisions on the selection, procurement and use of medical devices for various health conditions.

The second version, released in February 2025 (Fig. 6), includes 2596 types of medical device for a wide range of health issues, including reproductive, maternal, newborn and child health, noncommunicable diseases such as cancer, cardiovascular diseases and diabetes, and infectious diseases such as COVID-19. It replaces paper-based literature searches for non-standard device names. By providing a single platform, the System make naming of medical devices more straightforward.

The platform refers to the two international naming systems for medical devices, the EMDN and the GMDN, and was established to streamline access to standard information on medical devices.*(50)*

Fig. 6. *Nomenclature of medical devices*



Source: WHO *(50)*

5. Quality assurance in management of medical devices

By embedding QA into each stage of the medical device life cycle, HTM is not only a reactive asset management process but a proactive, risk-mitigating system for ensuring the long-term sustainability of health care.

5.1 Scope

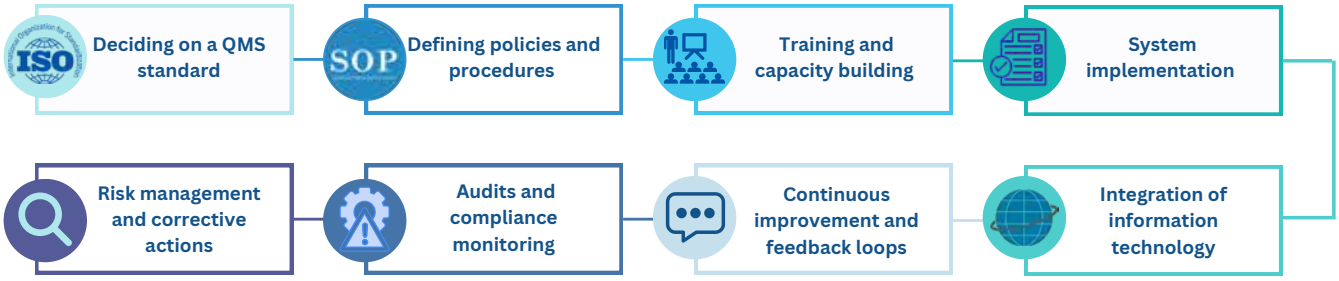
QA is designed to ensure that products or services meet defined standards of quality, safety and performance. It is widely used in industry, including in manufacture of pharmaceuticals and medical devices, IT and health care. Table 3 lists international standards for QA in health care and medical device management, which distinguish between QA of products and of processes. Product QA ensures that medical devices are designed, manufactured and delivered to meet established standards of safety and performance, while process QA ensures consistently high-quality outcomes.

Table 3. *International standards for product and process QA in management of health care and medical devices*

Aspect	Standard	Focus	Responsible party
Product QA	ISO 13485: Medical devices – Quality management systems – Requirements for regulatory purposes *(31)*	Ensuring the quality of medical devices throughout their life cycle through design, production and delivery	Manufacturer
Asset management: process QA	ISO 55000: Asset management – Overview, principles, and terminology *(61)*	Management of physical assets to optimize performance and minimize risk	Asset owner – organization or facility
Asset management: process QA	ISO 9001: Quality management systems – Requirements *(62)*	Ensures the quality of processes in an organization to enhance customer satisfaction and meet regulatory requirements	Asset owner – organization or facility
Asset management: process QA	ISO/CD TS 5137 (in preparation)	Provides guidance on managing maintenance activities for medical devices in health-care delivery organizations	Asset owner – organization or facility

At institutional level, process QA is implemented through structured policies, standardized procedures and continuous monitoring to ensure compliance with regulatory requirements and industry standards (Fig. 7).

Fig. 7. *Components of a comprehensive process QA framework*



In a health-care institution, QA is comprehensive, covering clinical, operational, administrative and technological aspects to ensure high-quality, safe, efficient health-care services. A well-structured QA system improves not only patient care but also institutional reputation, regulatory compliance and overall operational efficiency. HTM is a subset of QA, specifically addressing management of medical equipment and devices. It is crucial in the QA framework, as it ensures that medical technologies meet regulatory, operational and safety standards throughout their life cycle of use in health-care facilities.

5.2 Objectives

The established objectives of QA are derived from recognized, standardized guidelines in the global healthcare sector. Their implementation is essential for ensuring patient safety, regulatory compliance and the overall efficiency of health-care service delivery.

To ensure the safety of clinical procedures, QA:

- prevents risks associated with faulty medical equipment and clinical errors;
- reduces the likelihood of adverse events and patient harm; and
- ensures PM and quality control for medical devices.

For risk management and incident prevention, QA is used to:

- identify potential risks due to failure of medical technology and lapses in quality;
- apply corrective and preventive actions to address the identified risks; and
- monitor and report incidents related to medical devices, recalls and malfunctions.

For compliance with regulations and standards, QA is used to:

- meet national and international standards of quality and safety;
- ensure that medical devices are regularly calibrated and their performance checked; and
- conduct internal audits, quality checks and documentation reviews to maintain compliance.

Training and capacity-building of the workforce includes:

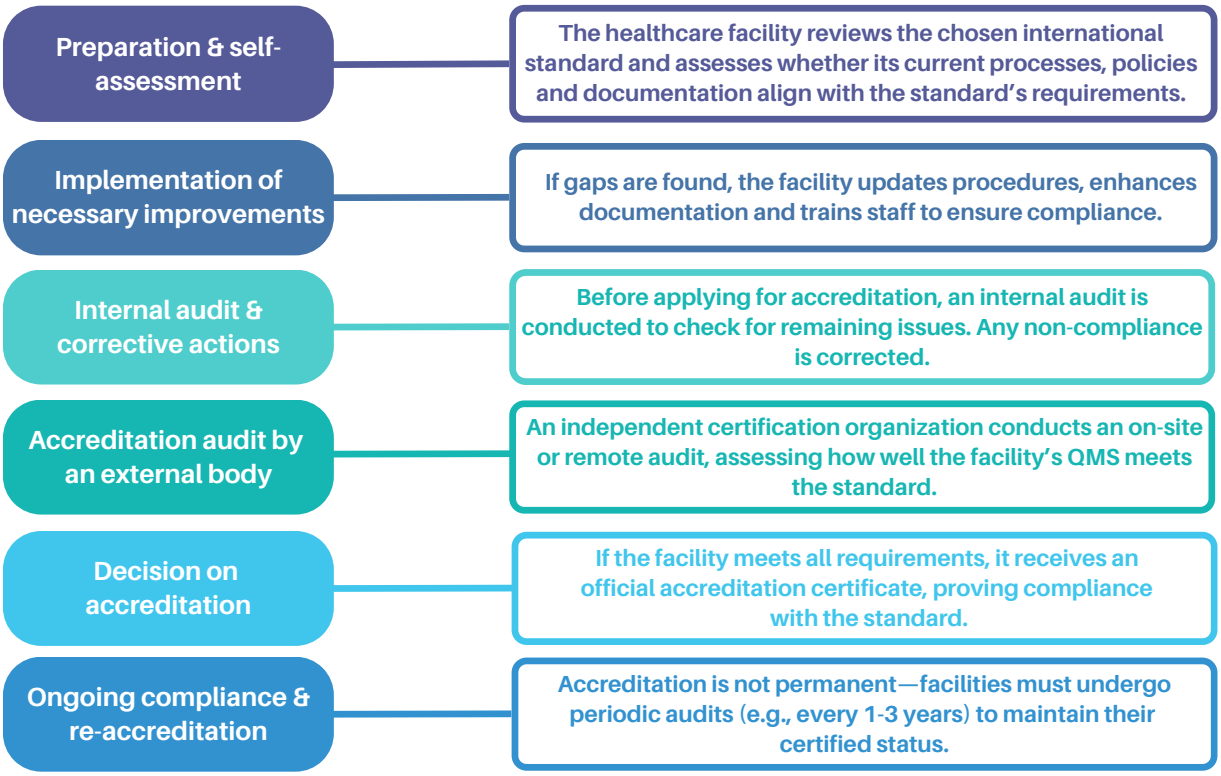
- educating health-care professionals and technicians in best practices in equipment use, maintenance and quality control;
- providing technical training in use of new medical devices and emerging health-care technologies; and
- fostering a culture of quality and accountability in healthcare institutions.
- Performance monitoring for continuous enhancement and improved cost–effectiveness requires:
- use of KPIs to evaluate the performance of health-care and medical equipment;
- regular assessments and optimization of processes to improve efficiency;
- reducing equipment downtime and optimizing resource use;
- improving procurement processes for cost-effective, high-quality medical devices; and
- ensuring the longevity and optimal performance of health-care infrastructure.

5.3 Accreditation and why a health-care facility should accredit its QMS

Health-care institutions have begun to use accreditation, according to national legislation, to ensure the quality of the treatment provided to their patients and also because of increasing national and international competitivity, especially with the current shift from public to private health care.

Accreditation consists of formal recognition that a facility meets established international standards for quality, safety and efficiency (Fig. 8). It is conducted by an independent body, which evaluates whether the facility's QMS complies with a specific standard *(60)*.

Fig. 8. *Steps in accreditation*



The terms "accreditation" and "certification" are often used interchangeably, but they are not the same. Both require meeting specific standards and evaluation by an external body, but they serve different purposes and apply to different entities. Accreditation represents validation that an institution or programme has confirmed that high-quality standards have been met, while certification refers to confirmation that a product, process or system complies with a requirement.

Accreditation is an investment, not a cost. It is not a bureaucratic requirement but improves the reputation of an institution, generates commitment among employees, improves credibility and ensures standardized processes at all levels.

Commitment of employees

- When a facility is formally accredited, employees understand that compliance is no longer optional but is a strategic priority.
- Accreditation sets clear expectations, making it easier to ensure staff accountability and engagement.

- Because the process is structured and monitored, employees are more likely to follow best practices and maintain high performance levels.

Long-term cost efficiency and compliance

- While accreditation requires investment, it prevents financial losses due to inefficiency, poor management and legal non-compliance.
- Facilities that adhere to standardized accreditation are less likely to face penalties, lawsuits or operational shutdowns due to regulatory violations.
- Proactive quality management reduces unexpected maintenance costs, emergency repairs and medical errors, ultimately improving financial sustainability.

Improving credibility

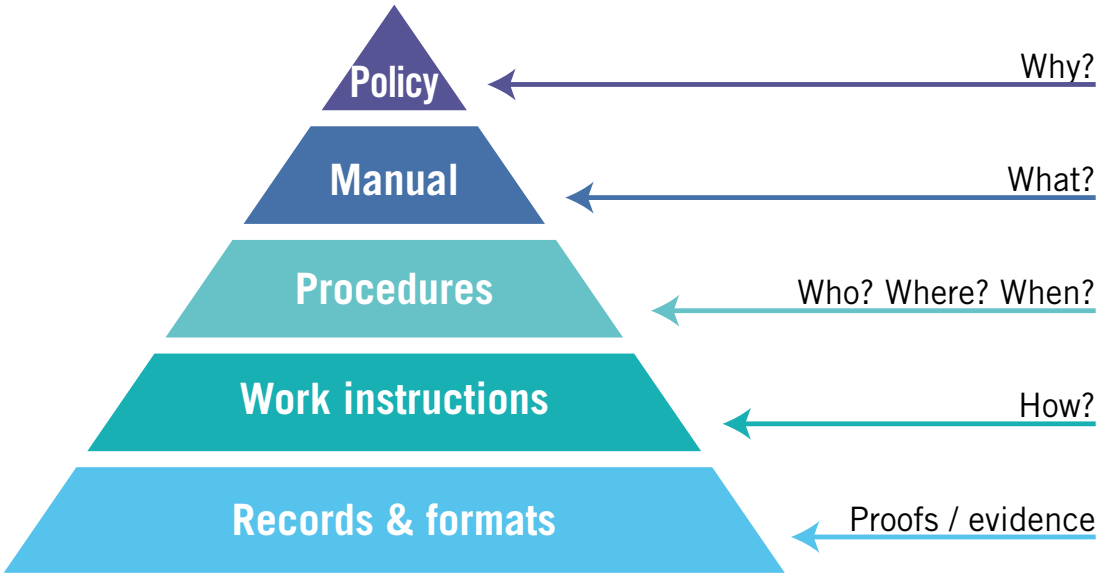
- Accreditation is recognized nationally, internationally or regionally, making the facility more credible for patients, regulatory bodies, investors and partners.
- A facility with accredited QMS is seen as more trustworthy, reliable and committed to patient safety.
- For private health-care institutions, accreditation can be a competitive advantage, attracting more patients, funding opportunities and partnerships.

5.4 Implementation in facilities

Implementation of QA in a health-care facility is a complex, multi-phase process that requires strategic planning, adherence to regulatory requirements and continuous monitoring. Implementation of QA is based on a strategic decision by the health-care facility's leadership (e.g. hospital administration, board of directors, quality committee) to establish a formal quality management structure. First, a QA implementation team should be formed, comprising representatives from clinical, technical, administrative and regulatory departments, which is responsible for overseeing integration of QA into all health-care functions.

A QMS provides a structured framework for quality control, compliance and continuous improvement. The components of QMS in health care are listed in Fig. 9.

Fig. 9. *Structure of quality management documentation*



- Quality policy: At the apex of the pyramid, the policy defines the organization's commitment to quality and continuous improvement and serves as a guiding principle for all quality-related activities.
- Quality manual: This document outlines the overall structure of the QMS, including the scope, processes and interactions within the system. It provides a high-level overview of how the organization intends to meet its objectives for quality.
- Standard operating procedures: SOPs describe the methods and responsibilities for various processes. They ensure that activities are performed consistently and in compliance with relevant standards.
- Work instructions: These provide detailed, step-by-step guidance for the performance of individual tasks. They are essential for maintaining uniformity and quality in daily operations.
- Records and formats: At the base of the pyramid, these provide evidence that procedures and work instructions have been followed. They document the outcomes of processes and are used for audits and continuous improvement.

Internal QMS may adhere to ISO 55000 *(61)*, a framework for effective asset management, which is particularly relevant for maintaining high-value medical devices. It includes medical devices as critical assets, providing a framework for establishing, implementing, maintaining and improving an asset management system, including aspects such as risk management, cost-effective operational performance, independent performance inspections and strategic asset management planning.

5.4.1 Standard Operating Procedures

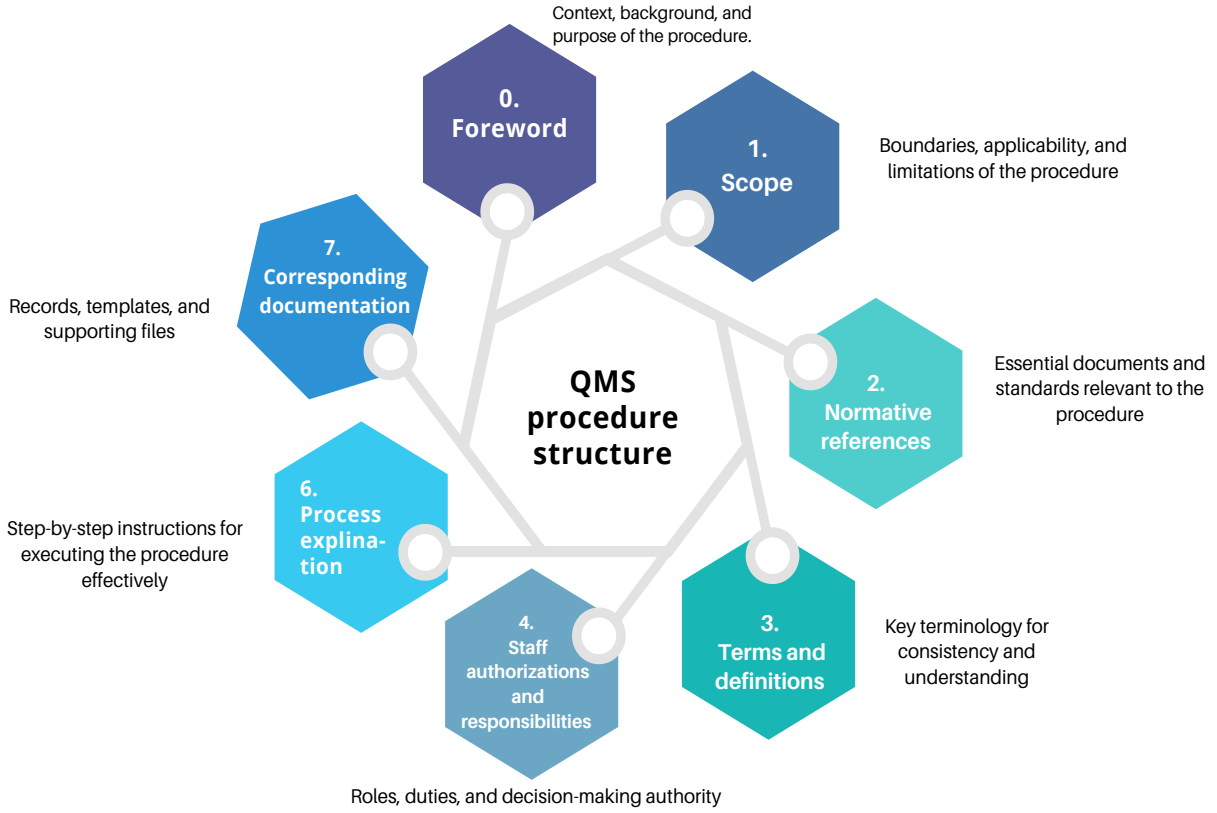
At the core of effective medical device management are standardized procedures. Institutions should carefully define how devices are handled, maintained, inspected and monitored to ensure their long-term safety and effectiveness. These procedures are not arbitrary but are based on internationally recognized standards specific to medical devices. In addition, each category of medical device is subject to specific technical regulations that further refine the procedures for safe, effective use. These include electrical safety standards, radiation protection guidelines and biocompatibility assessments. Further, manufacturers provide recommendations for the maintenance schedules, calibration requirements and operating conditions of each device. These recommendations must be included in health-care facility protocols to maximize the longevity and performance of devices. (See also Annex 5.)

In the management of medical devices, SOPs are comprehensive guides for both preventive and corrective maintenance, ensuring uniformity, reliability and compliance with regulatory standards. These detailed written instructions provide standardized procedures for the management and maintenance of medical devices. The procedures are designed to be simple, reliable and reproducible, replacing the complex traditional service manuals, and their use maintains consistent preventive and corrective maintenance *(62,63)*. They should be written according to a checklist of essential details, such as date, place, requester implementer and equipment identification number. The technical requirements and processes described in SOPs are referenced and based on relevant international standard or verified methods *(3)*.

To ensure that they are clear, Standard Operating Procedures (SOPs) should provide step-by-step guides with concise, comprehensible explanatory text. Use of visual aids, such as images, videos, illustrations, flowcharts and lists, is essential. A standard approach should be used in developing an SOP, as indicated in ISO 9001:2015 *(64)*, for example. The minimum content of an SOP is: foreword; scope; references to norms; terms, including definitions; authorizations and responsibilities; relevant regulatory requirements; and procedure, including documentation (Fig. 10).

Supporting documentation for staff who use the SOP should be provided as a work order, checklist, a sample report, a template report or other. (See also Annex 3.)

Fig. 10. *Structure of a QMS SOP*



SOPs ensure consistent, replicable processes. They enable an organization to maintain high standards of quality by ensuring that each task is performed correctly and consistently, with predictable, reliable outcomes. They are important for identifying and maintaining the quality of each process and provide a reference for audits. In the case of deviations or non-conformity, SOPs are a standard against which practices can be assessed and corrected for continuous quality improvement.

5.4.2 Towards timely, transparent, evidence-based decision-making

In a QMS and in regulations, work that is not documented is work that was never performed. If a technician conducts a scheduled PM procedure on a life-sustaining device but does not document the work, the QMS cannot register the device as ready for clinical use. A CMMS can record work performed and provide the evidence. A robust CMMS can manage not just equipment but also the data and workflows associated with different types of maintenance.

Medical device QA requires data-based decision-making; therefore, detailed reports are a crucial component of any QMS. Such reports not only document compliance but are also valuable resources for performance evaluation and risk assessment. Adoption of a digitalized QMS allows centralized control of and real-time access to all documentation on quality, including policies, procedures and records of the design, manufacture and distribution of a device. Digitization of these documents makes them readily accessible to authorized personnel, improving traceability and accountability. It also simplifies updating of documents and maintenance of version control, which are critical for compliance and audits. It interconnects QA and HTM, as data are digitalized and become accessible for further analysis.

The data that are usually managed in a CMMS are those on:

- compliance with PM;
- corrective maintenance and work orders;
- device inspections and calibration;
- asset inventory and status updates;
- regulatory compliance and safety notifications.

Additional QMS data that enhance CMMS when integrated are those on:

- adverse event and incidents (linking maintenance and risk management);
- user error and documentation of training (improving operational safety);
- supplier and service provider performance (vendor accountability and compliance);
- quality control of spare parts and materials (ensuring device integrity); and
- audit readiness and compliance documentation (bridging CMMS with ISO and regulatory standards).

The availability of these data provides a holistic approach to device management by bridging gaps between QA and operational maintenance. While a QMS is used to manage documentation, compliance, audits and corrective and preventive actions, a CMMS manages the logistical aspects of medical device management, such as scheduling maintenance, monitoring repairs, managing the inventory and analyzing equipment performance.

Standardization of procedures in a QMS and integration into a CMMS ensure the collection of uniform data, which is essential for reliable PdM of medical devices.

5.5 Regional and national perspectives

ISO 9001 certification has been shown to be positively associated with better quality and safety structures in health-care facilities, including better health-care facility management, clinical practice and patient-centredness *(64)*.

Themes that have emerged in the context of QA within HTM are as follows.

- Regular, standardized data collection and consistent use of SOPs are essential for ensuring reliable data, which serve as the foundation for effective maintenance strategies.
- Evidence-based approach: Use of empirical data and risk assessments to decide on the frequency and scope of inspections ensures that maintenance is both efficient and effective.
- Multi-level coordination: Device safety requires collaboration at various organizational levels, from health-care facility departments to national regulatory bodies.

Use of quality standards at institutional level is essential for achieving objectives such as ensuring patient safety, regulatory compliance and the overall efficiency of health-care service delivery. Locally, this consists of operational patient safety; nationally, it is a public health mandate.

Regional and national policies should be adapted to support and recognize such objectives. A standardized approach to HTM that includes standardized SOPs contributes to timely, transparent, evidence-based decision-making in HTM. This approach aligns medical device management with harmonized standards, similar to those in pre-market processes.

6. Maintenance management system for medical devices

6.1 Objectives and importance of a maintenance system

Maintenance management systems have been developed to safeguard working tools, assets and facilities by ensuring that they remain in good condition for as long as possible. The management and maintenance of medical devices must be based on solid data and empirical evidence. Maintenance and management of health-care technology, including medical devices, ensure that devices are safe, effective and reliable for patient care.

6.2 Current practices and limitations

It is recognized that manual maintenance management systems, including paper-based records, logbooks and manual scheduling, are still used in some settings. While these methods have ensured equipment reliability and compliance to the present through structured workflows and meticulous documentation, their inefficiency, administrative burden and limitations for data analysis have led to a shift towards the modern, technology-driven approaches described in this publication.

6.3 Elements of a comprehensive maintenance system

A robust medical device maintenance system consists of several elements for enhancing efficiency, minimizing downtime and ensuring regulatory compliance. Table 5 summarizes the main components of such a system and their functions.

Table 5. *Components of a comprehensive medical device maintenance system*

Component	Description	Benefits
Asset tracking and inventory management	UDI and naming terms and codes in GMDN or EMDN are assigned to medical devices, assets are categorized, and real-time location tracking is ensured.	Prevents asset misplacement, improves procurement planning, enhances accountability.
PM	Ensures scheduled inspections, calibrations and servicing to prevent unexpected failures.	Extends equipment lifespan, reduces downtime, minimizes emergency repairs.
PdM	IoT sensors, machine learning and real-time analytics are used to identify risks of failure before they occur.	Enhances device reliability, optimizes maintenance schedules, reduces overall costs.
Corrective maintenance	Provides a mechanism for immediate response to equipment failures and malfunctions.	Ensures rapid problem resolution, maintains patient care continuity.
Regulatory compliance and audit readiness	Aligns maintenance activities with ISO 13485, FDA 21 CFR Part 11 and WHO guidelines.	Ensures accreditation, improves reporting on safety measures, prevents legal penalties.
Work order management and automation	Automates the creation, assignment and tracking of maintenance work orders.	Reduces administrative workload, enhances workflow efficiency.
Integration with IT systems (electronic health records [EHR], enterprise resource planning, IoT)	Ensures seamless connectivity with hospital systems for data exchange and automation.	Eliminates manual data entry, synchronizes maintenance tasks with clinical workflows.
Spare parts and inventory control	Tracks use, procurement and availability of spare parts for maintenance.	Reduces procurement costs, prevents delays in maintenance, optimizes stock levels.
Mobile and Cloud-based access	Enable remote access to CMMS platforms via mobile apps and Cloud services.	Facilitates real-time updates, improves field technician response times.
Data analysis and reporting	Generates compliance reports, performance analytics and failure trend analysis.	Improves decision-making, enables proactive maintenance planning, enhances accountability.

6.4 Maintenance strategies for medical devices

6.4.1 Preventive maintenance

WHO's guidance on medical equipment management stresses that periodic inspection and prevention are essential for keeping devices safe *(10)*. By conducting scheduled check-ups, health-care facilities keep traceable records of device performance, which contribute to greater reliability of devices in actual operation *(35)*.

PM comprises scheduled servicing, calibrations and replacement of components to prevent failures before they occur. It is based on manufacturers' guidelines and is often managed in a CMMS. Key characteristics are that it:

- consists of intervention rather than assessment;
- is conducted on a fixed schedule (e.g. every 6 months);
- includes lubrication, calibration and replacement of worn-out parts to prevent unexpected failures; and
- reduces downtime and extends device lifespan by addressing wear and tear proactively.

PM is a proactive strategy for reducing the risk of device failure through scheduled servicing, recalibration and part replacement. Reports on PM document completed maintenance activities, ensuring that all the necessary checks are performed on time. By following a structured maintenance plan, health-care institutions can extend the lifespan of medical devices and avoid costly emergency repairs.

6.4.2 Performance inspection of medical devices

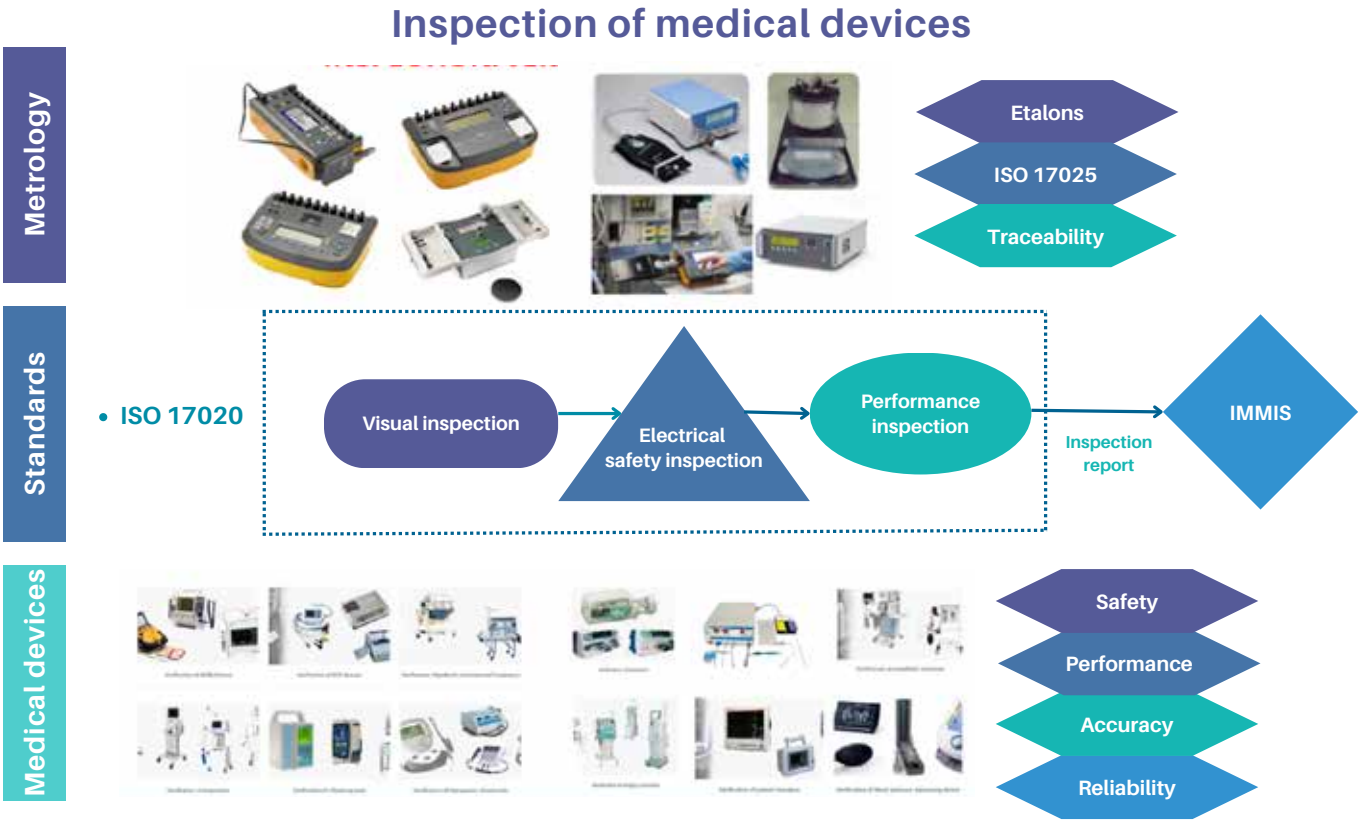
Inspection of medical devices comprises periodic and ad-hoc evaluation of equipment performance and safety, guided by regulatory standards and best practices (Fig. 11). Performance inspection consists of systematic evaluation of medical devices to detect early signs of malfunction, verify operational integrity and ensure compliance with safety standards. The main characteristics of performance inspection are that it:

- comprises assessment rather than intervention;
- is performed periodically or before use to confirm the proper functioning of a device; and
- ensures regulatory compliance by meeting the requirements for safety and performance.

Periodic inspections are a valuable QA method in health-care facilities. Furthermore, regulatory bodies worldwide recognize the importance of medical device inspections post-marketing to ensure ongoing compliance for patient safety.

A comprehensive maintenance strategy "includes procedures for inspection, as well as preventive and corrective maintenance". Performance inspections ensure that equipment functions correctly, while safety inspections confirm that a device is safe for patients and operators. These guidelines ensure that regular inspection is an integral part of health-care technology management for extending equipment life and reducing failure rates *(61)*.

Fig. 11. *Three components of medical device inspection*



Medical device inspections can be classified into:

- routine inspections: regularly scheduled checks according to the manufacturer's recommendations;
- pre-use inspections: conducted before a device is operated to ensure that it is in proper working condition;
- post-repair inspections: conducted after maintenance or repairs to verify restored functionality; and
- regulatory inspections, which are compliance checks mandated by regulatory bodies.

An effective performance inspection should include:

- visual examination for physical damage, loose connections or corrosion;
- functional testing to determine whether a device operates according to specifications;
- safety testing by measuring electrical safety, leakage of currents and compliance with radiation or sterilization standards; and
- software and firmware validation to ensure that the latest software updates and cybersecurity protocols have been applied.

Patient safety is the foremost reason for medical device inspection. Even a subtle degradation in device performance can pose a significant risk if undetected. Regular inspections act as a safety net to catch such issues early, ensuring the reliability of a device by verifying that outputs (such as dosage, energy and readings) remain accurate and within safe tolerances. They include checks of safety features (such as alarms, electrical safety, leakage currents and mechanical integrity) to prevent accidents. By enforcing compliance with technical standards, inspections reduce the likelihood of preventable adverse events. More broadly, a culture of regular inspection and maintenance ensures a safer health-care environment, as devices are less likely to fail suddenly.

Inspections protect patients by preemptively identifying potential failures and prompting repairs before harm can occur. They also protect health-care providers and institutions from liability and reputational damage, as a robust inspection record demonstrates due diligence in maintaining a safe environment of care. Safety considerations extend to ensuring accuracy in diagnosis and treatment. A medical device (such as a patient monitor or a laboratory analyzer) that is out of calibration could lead to misdiagnosis or an incorrect treatment decision. Regular performance verification maintains the accuracy of measurements on which clinicians rely. An evidence-based, metrology-backed inspection programme can "contribute to higher reliability of medical device performance and consequently to higher reliability of diagnosis and treatments" *(65)*.

6.4.3 Calibration

Calibration of medical devices is essential to ensure the accuracy, reliability and safety of clinical measurements, which directly influence patient outcomes and the overall quality of health care. Integration of systematic testing and calibration into health-care facility protocols demonstrates a facility's commitment to maintaining high-quality standards and continuous improvement.

Growing reliance on sophisticated medical devices in modern medicine necessitates stringent calibration protocols to uphold the integrity of clinical data. Despite widespread acknowledgment of the importance of calibration, medical errors resulting from poorly maintained equipment remain a significant issue, and strict, independent testing to verify device performance against established international standards is essential. Calibration establishes the conformity of the readings on a medical device and a known reference value under controlled conditions, ensuring that the displayed measurements align with those expected. A robust calibration strategy confirms that a medical device meets regulatory and manufacturer specifications and ensures compliance with international health-care standards *(66)*.

Calibration is conducted in a structured method involving baseline measurement, adjustment, verification of results and maintenance of thorough documentation for regulatory compliance (Fig. 12). Effective coordination of calibration is essential to minimize equipment downtime while maintaining compliance with evolving industry standards.

Fig. 12. *Calibration process*

Baseline measurement	Adjustment	Verification	Documentation
Documenting current device output against a reference standard	Modifying the device settings if discrepancies are detected	Retesting the device post-adjustment to confirm compliance	Logging calibration results, test conditions and corrective actions taken

6.4.4 Corrective maintenance

Despite the best preventive maintenance, devices may still malfunction unexpectedly. When this happens, clinical engineering or technical teams perform corrective maintenance: resolving the problem, replacing or mending faulty parts and testing the device to return it to service.

In WHO guidelines, corrective maintenance is categorized with inspection and PM. While inspection and PM comprise scheduled activities to ensure the functionality of equipment and prevent breakdowns, such as performance and safety inspections, calibrations, part replacements, lubrication and cleaning, corrective maintenance consists of repairing and restoring equipment after a failure, malfunction or performance degradation has been identified *(11)*. It is thus unscheduled maintenance to address device failure, problems reported by users or issues identified in diagnostic tests. Corrective maintenance:

- is performed after a failure occurs;
- may be planned or unplanned;
- restores the functionality of a medical device;
- includes diagnostics, repair and replacement; and
- requires an efficient response.

The goal is to minimize the downtime. HTM systems can be used track metrics such as "mean time to repair", which is the average time it takes to mend a device after a failure, a measure of the effectiveness of the corrective maintenance. With a shorter mean time to repair, use of medical devices can be restored faster, reducing disruptions to patient care. Heavy reliance on corrective maintenance (i.e. waiting for things to break) is not, however, recommended, as a device failure at a critical moment can risk patient safety. The emphasis is therefore increasingly on PM and PdM, to detect problems early.

The priority of different types of repairs is summarized in Table 6.

Table 6. *Examples of priority and response times for device maintenance*

Priority	Definition	No. of calendar days for completion
Emergent	Defined by the customer as a device the failure of which could result in a serious deficiency in patient care or a device the design or manufacture of which is critical	2
Urgent	Defined by the customer as a device the failure of which could result in a serious deficiency in patient care	7
Routine	Defined as a device or system that does not perform as intended but with no effect on patient care	30
Long-term	For work that has been deferred at the request of the customer and for work orders that will require a long time. Time off and support time work orders are long-term.	90

7. Computerized maintenance management systems (CMMS)

7.1 Definition and scope

Generally, a CMMS consists of software for centralizing information on maintenance, which facilitates maintenance operations by managing assets, scheduling maintenance and tracking work orders, thereby optimizing the use and availability of physical equipment such as vehicles, machinery and plant infrastructure.

A CMMS for use in health care is a digital platform designed to streamline the tracking, maintenance and performance monitoring of medical devices, including planning equipment, managing the inventory, corrective and PM, control of spare parts, service contracts and recalls and alerts for medical devices. The system integrates various data, including UDI, nomenclature terms and codes and operational status, to increase the reliability of equipment and compliance with regulations. In the context of HTM, a CMMS is used to automate documentation of all activities related to medical devices.

This section provides a practical framework for implementing CMMS in a health-care facility. It explains how CMMS can be customized to meet the needs of a specific health-care facility, with commercial, open-source or custom-built solutions. For a broader theoretical foundation for the selection of a CMMS, global regulatory compliance and methods for evaluating systems, see Computerized maintenance management system *(12)* in the WHO Medical Device Technical Series, which provides a detailed conceptual framework for CMMS adoption, technical specifications and strategies for assessing vendors.

7.2 Historical development

Development of CMMS for use in health care was the first step in facilitating health-care facility operations and supply chain performance. CMMS began in 1965 with a punch-card system, which required technicians to enter tasks to produce a paper checklist. These systems were expensive and were thus available only to large organizations *(67,68)*. With the development of minicomputer systems in the 1970s, maintenance was monitored on paper, and clerks entered the data into a main computer system. With the arrival of sophisticated medical appliances, including imaging systems and continuous monitoring appliances, the traditional maintenance system was considered no longer adequately efficient. The first CMMS were used to manage work orders and track assets for purchasing and for inventories. The systems resulted in a more efficient workflow, minimized downtime and increased use of assets.

As the technology progressed, CMMS evolved, with the addition of features such as PdM, data analysis and compatibility with electronic case reporting systems. This allowed health-care facilities to monitor the maintenance of equipment, evaluate failures and report incidents *(69)*. Advances in the early twenty-first century resulted in a Cloud-based CMMS system that allows remote access, can be scaled up and improves collaboration among health-care facilities. IoT, Cloud and mobile solutions have since been integrated to increase the possibility of real-time monitoring and proactive maintenance programmes *(70,71)*.

Access to real-time data and automation is effective for managing and tracking assets. Use of computerized systems in the management of the assets of health-care facilities enables organizations to monitor their assets and find optimal strategies. Reporting was also improved by adoption of CMMS, as it resulted in clear records that are easy to access and comply with requirements.

7.3 Types of information systems available

7.3.1 Commercial inventory and maintenance systems

Open-source CMMS software for collaboration and customization

Open-source CMMS software consists of programs that are freely available with their source code and can be viewed, modified and distributed. Open-source CMMS software thus benefits from collaboration among a community of developers and users, who contribute to its improvement and use each installation to enhance the tool by regular updates, repairs and new features, ensuring that the system remains current and effective. As formal support is limited, however, in-house expertise is sometimes required to solve problems and adapt the tool to a facility's operation and system. Perhaps the greatest potential advantage of an open-source tool for a health facility in low- and middle-income countries is elimination of licensing fees and annual maintenance and support fees, making it cost-effective for use in health-care facilities that require a CMMS for their medical equipment but have constrained budgets. A possible drawback is that the initial setup and configuration might require technical expertise, which could offset any cost savings.

A health-care facility can tailor open-source software to their needs, although customization requires skilled developers and extensive modifications. The security of all open-source solutions with a transparent source code relies on the user community.

Non-open-source CMMS software: stability and support

Non-open-source CMMS software often has advanced features, technical support and integration capabilities; however, factors such as cost, ease of use, possibility for integration and the customer support provided must be considered. This software is usually designed for easy use, with user-friendly interfaces that require minimal training, which can be an advantage in health-care facilities in which staff have various levels of technical expertise. Such proprietary software often provides dedicated, comprehensive customer support, ensuring prompt assistance and resolution of issues. Although this may be crucial for health-care facilities in resource-constrained environments, there is still the cost of annual licensing fees, which might be a concern for health-care facilities in low- and middle-income countries.

Established software vendors often provide stable, well-tested solutions, reducing the risk of unexpected issues. Adoption of solutions with limited customization might require adaptation of internal processes to the software. Many proprietary systems ensure that their software complies with health-care industry regulations and meets international standards and regulatory requirements, simplifying compliance for health-care institutions while helping them to maintain the highest levels of patient safety. Updates and adaptations to regulations might be slower than updating of open-source solutions by active user communities.

Non-open-source-solutions are often designed to be integrated seamlessly into proprietary health-care systems such as EHR and health-care facility management software, ensuring interoperability and a unified, efficient workflow *(72)*. Such integration might require additional modules or services, potentially adding to the overall cost.

7.3.2 Custom-built systems

A customized CMMS is optimal for efficient, compliant, cost-effective management of medical devices in health-care facilities. Unlike commercial CMMS, which often have generic features, a customized CMMS is tailored to the requirements of each health-care facility, diagnostic laboratory and regulatory agency, ensuring that maintenance is aligned with ISO standards, national health-care regulations and the guidelines of medical device manufacturers. A customized CMMS ensures that health-care institutions can streamline equipment tracking, maintenance scheduling and regulatory compliance according to their unique operational workflow and infrastructure.

While standard CMMS platforms offer initial support, they often cannot address the demands of complex health-care environments. A custom-built CMMS provides health-care professionals with a flexible, scalable, integrated solution that meets the specific demands of medical device life-cycle management, preventive and corrective maintenance and PMS. A customized CMMS includes:

- asset and inventory management;
- preventive and corrective maintenance programs;
- compliance with ISO standards and regulatory requirements;
- PMS and incident reporting;
- integration with digital health systems;
- customizable reporting and documentation management; and
- scalability and security.

A customized CMMS ensures that health-care facilities maintain a centralized, real-time inventory of medical devices, reducing the risk of misplaced or underused equipment. Each device is assigned a unique identifier (barcode, radio frequency identification or QR code), so that maintenance teams can identify its location, use

history, performance metrics and servicing schedule. Real-time asset tracking ensures that health-care facilities optimize equipment allocation, prevent shortages and ensure that critical devices are available when required.

A customized CMMS automates PM scheduling, reducing the risk of unexpected equipment failures that could disrupt clinical operations. The system generates automated work orders according to the manufacturer's recommendations, past performance and regulatory requirements, ensuring that devices are routinely serviced before problems arise. For corrective maintenance, a customized CMMS ensures a rapid response when a device malfunctions, allowing biomedical engineers to diagnose issues, request spare parts and document repairs efficiently. Integration with PdM models can further improve performance, with AI and IoT sensors to detect early signs of wear and failure.

Health-care facilities must comply with stringent regulations for quality and safety, including:

- ISO 13485 (Medical device quality management systems),
- ISO 15189 (Medical laboratories requirements),
- ISO 17020 (Inspection bodies – applicable for inspections in health care),
- ISO 55001 (Asset management) and
- ISO/CD TS 5137 (Medical device maintenance management for health-care delivery organizations) (being developed).

A customized CMMS provides automated regulatory compliance by tracking calibration records, inspection logs and maintenance reports, thus ensuring that the health-care facility is always prepared for an audit. The system generates customizable compliance reports, helping organizations to meet the requirements of national health-care agencies and accreditation bodies.

Effective PMS is essential for tracking the long-term safety and performance of medical devices. A customized CMMS allows health-care institutions to record, analyse and report incidents related to devices, ensuring that faulty or recalled equipment is immediately flagged for investigation. The system can also be integrated with manufacturers' databases and regulatory reporting platforms, enabling submission of incident reports and compliance documentation. This improves patient safety by ensuring that medical devices meet expectations for long-term performance.

A customized CMMS can be integrated with other health-care facility information systems, EHR and procurement platforms. This allows real-time synchronization of maintenance data with clinical operations, allowing health-care professionals to make informed decisions about device use, downtime and replacements. For example, if a ventilator is flagged for urgent maintenance, the system can automatically notify clinical teams, preventing its use on patients until it is repaired and certified for operation.

One of the greatest advantages of a customized CMMS is that it can generate tailored reports and documentation aligned with the QA protocols of an organization. These include:

- maintenance logs and service histories,
- calibration certificates and regulatory compliance reports,
- failure analysis and root cause investigations and
- analyses of the costs of device repairs and replacements.

Customized reports provide data that help health-care facilities to optimize their maintenance budgets, reduce equipment downtime and improve long-term asset planning.

A customized CMMS ensures that health-care facilities can increase the number of medical devices without compromising system performance. Such a scalable CMMS provides a centralized solution for medical device maintenance for either a single health-care facility or a multi-facility health-care network. Security is also a priority, with features such as access control according to role, encrypted data storage and compliance with health-care data protection standards (such as the General Data Protection Regulation in the European Union and the Health Insurance Portability and Accountability Act in the USA). This ensures that sensitive maintenance records and compliance data are protected.

A customized CMMS provides health-care organizations with a more efficient, compliant, cost-effective approach to medical device management. Some of its benefits are:

- less equipment downtime, as proactive scheduling of maintenance ensures that devices remain operational, minimizing disruption to patient care;
- better regulatory compliance, as automated compliance tracking simplifies audit preparation and regulatory reporting;
- cost optimization, as data allow health-care facilities to budget for maintenance, avoid unnecessary repairs and plan for timely equipment replacement;
- greater patient safety, as reliable medical devices contribute to higher standards of care and better clinical outcomes; and
- seamless integration with digital systems, as a customized CMMS is connected with other information systems of a health-care facility, ensuring real-time data exchange and an automated workflow.

7.4 Deployment

CMMS can be deployed in two main ways: online (Cloud-based) and offline (on-site). Each has its strengths and weaknesses, depending on the health-care facility's infrastructure, regulatory requirements and operational requirements (Table 7).

- Online CMMS solutions are hosted on the Cloud and accessed on the Internet. This model is the "software-as-a-service" approach, in which a third-party vendor manages the infrastructure, software updates and security.
- Offline CMMS solutions are installed and run on the health-care facility's local servers. This model provides full control over data and system customization.

Table 7. *Comparison of modes of deployment of CMMS*

Deployment model	Commercial inventory and maintenance management systems Non open-source		Commercial inventory and maintenance management systems Open-source		Inventory and maintenance management systems Custom-built	
	Cloud-based	On-site	Cloud-based	On-site	Cloud-based	On-site
External context						
AI feature possibilities	High (PdM, automated workflows)	Moderate (some automation, but AI analysis may be limited)	Moderate (community AI features possible)	Low (limited automation, no built-in AI capability)	High (can include cutting-edge AI and automation)	Moderate to high (depending on in-house development)
Education and training support	Vendor-provided training and certification	Vendor-provided but may require in-house support	Limited community or self-learning resources	Community or self training	Fully customizable training and educational modules	Fully customizable training and onboarding programmes
User support and maintenance	Vendor support 24 h per day 7 days/week	Regular vendor support but may depend on service agreement	Community support, no dedicated vendor assistance	Limited, requires in-house expertise	Dedicated in-house or outsourced support	Internal IT team required for support
Degree of customization	Limited to vendor options	Some customization possible but depends on vendor	Highly customizable	Fully customizable	Designed specifically for organizational requirements	Designed for exact institutional workflows
Regulatory compliance features	Built-in	Built-in	Depends on customization	Depends on configuration and updates	Fully tailored to regulatory requirements	Fully customizable
Adaptability to regulatory changes	Regular updates ensure compliance with evolving regulations.	Manual updates required for compliance tracking	Compliance must be tracked manually	Requires manual adaptation for regulatory updates	Easier adaptation to regulatory changes through internal control	Requires dedicated resources for tracking regulatory changes
Interoperability	High (EHR, procurement, finance)	High (can be integrated with internal IT)	Moderate (may require additional development for full interoperability)	Low (requires significant development for integration)	Fully customizable integration	Integration in full control of organization
Security and data protection	Vendor-managed security, strong encryption	Security managed by institution, requires IT oversight	Depends on implementation, requires security expertise	Security must be institutionally managed	Highly secure if well implemented	Institutional responsibility to ensure cybersecurity
Scalability	Highly scalable	Scalable but depends on hardware	Highly scalable	Limited scalability, depends on internal IT capacity	Highly scalable	Limited scalability unless planned for future growth

Deployment model	Commercial inventory and maintenance management systems Non open-source		Commercial inventory and maintenance management systems Open-source		Inventory and maintenance management systems Custom-built	
	Cloud-based	On-site	Cloud-based	On-site	Cloud-based	On-site
Integration with other systems (networking)	Strong integration capability	Possible but requires in-house IT expertise	Possible but requires technical modifications	Integration is complex, requires extensive development	Full integration control	Complex but possible with strong IT investment
User friendliness	User-friendly, optimized user interface	Generally user-friendly	May require optimization	May require time to learn	User-friendliness depends on design	Can be optimized but requires thoughtful design of user interface and user experience
Performance monitoring and reporting	Comprehensive analysis and reporting	Basic to advanced reporting, depending on vendor	Basic to advanced reporting, depending on customization	Basic reporting, requires customization for advanced analyses	Advanced reporting and real-time monitoring possible	Fully customizable reporting and analysis
Internal context						
Technical expertise required	Minimal technical expertise needed	Moderate technical expertise required	Moderate to high expertise required	High technical expertise required	High technical expertise required	High technical expertise required
Hardware requirements	Low (on Cloud, no need for powerful on-site hardware)	High (requires local servers and infrastructure)	Low (on Cloud infrastructure)	High (requires local infrastructure and IT support)	Low (Cloud hosting eliminates requirement for extensive hardware)	Very high (requires infrastructure, server management)
Data ownership and control	Limited (owned by vendor, restrictions apply)	Full (owned by institution)	Full (institution controls data)	Full (owned by institution)	Full (institution controls data)	Full (owned by institution)
Cost considerations	High licensing and subscription fees	High initial costs, licensing fees	No licensing fees, but maintenance costs	No licensing fees, but higher IT maintenance costs	Very high initial development cost, but long-term savings possible	Very high development and maintenance costs
Long-term sustainability	Strong vendor support for sustainability	Depends on internal IT support and funding	Depends on community updates and institutional IT support	Difficult to sustain without strong IT team	Strong if properly maintained	Sustainability depends on ongoing funding and technical support

7.4.1 Networking and integration of a CMMS

Networking consists of integration of a CMMS into a connected, multi-user environment that allows real-time data-sharing, remote access and system interoperability in a health-care facility or in several locations. A networked CMMS does not function as a stand-alone system but enables instant communication among departments, automated maintenance tracking and seamless interaction with other health-care facility IT systems (Table 8).

Table 8. *Examples of systems for CMMS networking*

Health-care system	Purpose of networking	Data required for CMMS
EHR	Link equipment usage to patient records	Device usage logs, operational hours, linked patient records
Hospital information systems	Integrate maintenance with health-care facility operations	Maintenance schedules linked to health-care facility operations
Enterprise resource planning	Track procurement and financial planning for medical devices	Device purchase details, budget allocation, depreciation tracking
Medical device management and IoT platforms	Monitor real-time device performance and PdM	Sensor data, error reports, predictive failure analysis
Building management systems	Manage environmental conditions that affect medical equipment	Temperature, humidity, other environmental conditions that affect devices
Supply chain and procurement systems	Ensure automatic procurement and spare parts tracking	Inventory stock levels, parts ordering and vendor tracking
QMS	Document regulatory compliance for maintenance records	Maintenance history, audit logs, compliance checklists
Regulatory and compliance databases	Ensure legal compliance and real-time tracking of medical devices	UDIs, regulatory documentation, recall data

CMMS networking began in the 1980s with the introduction of personal computers and local area networks and have since evolved significantly with advances in Internet and Cloud technologies. Integration of CMMS into network environments represents a fundamental shift in health-care technology management, as networking through a CMMS allows seamless communication, data-sharing and real-time monitoring of medical equipment. Table 9 presents a comparison of stand-alone and network CMMS.

Table 9. *Comparison of stand-alone and network CMMS*

Feature	Stand-alone CMMS	Network CMMS
Accessibility	Single location	Many locations
Data storage	On local servers	Cloud or centralized database
Integration capacity	Limited integration with other systems	Seamless integration with EHR, enterprise resource planning, IoT and others
Real-time monitoring	None	Real-time equipment tracking and alerts
Scalability	Difficult to scale up	Readily scalable to other facilities
Cost	Higher initial investment, lower long-term costs	Subscription model, lower upfront cost
Maintenance and updates	Manual updates required	Automatic updates managed by provider
Security	Greater control but risk of data loss if not backed up	Stronger cybersecurity measures and encryption
Collaboration	Internal teams only	Among many departments and locations
PdM	Rarely supported	Supports AI-based PdM
Complexity	Simpler	More complex

Networking within a CMMS with respect to medical equipment improves efficiency, capability and data use. Despite persistent challenges, the benefits, including greater efficiency, cost savings and better patient care, make CMMS worthwhile. Networking of CMMS is an important step towards the development of advanced IMMIS, in which AI-driven PdM, real-time analysis, blockchain for traceability and compliance tracking are integrated, providing more advanced capability, such as proactive decision-making, enforcement of regulatory compliance and seamless interoperability with other digital health-care and industrial ecosystems.

7.5 Implementing a CMMS: steps and considerations

Successful implementation of a CMMS requires a structured approach that ensures alignment with organizational requirements, efficient system integration and user adoption. This can be complex, as it involves many stakeholders, data migration, system configuration and comprehensive training. Use of a well-defined implementation strategy can, however, significantly increase the effectiveness of the system and provide long-term benefits.

Important considerations when implementing a CMMS include formation of a dedicated implementation team, defining clear objectives and scope, conducting a thorough needs assessment, selecting the appropriate vendor and developing a structured implementation plan. These initial steps lay the foundation for a smooth transition and successful adoption of the system.

When deciding on implementation of a CMMS or making improvements to an existing CMMS, a health-care organization should consider both the internal and the external context. The internal context for an organization consists of technological resources, staff resources and its QMS *(73)*.

7.5.1 Technological resources: available software, hardware and training

Limited infrastructure is a key factor, particularly where health-care systems are weak. Many clinical facilities may be unable to make sufficient investment in IT and communication networks, whereas resources such as a dependable Internet connection and up-to-date computers are important for system interconnectivity. Health-care facilities often have various interconnected systems, and integration with existing systems is complex and time-consuming, although integration of CMMS with EHR systems for health-care management is of considerable value *(69)*, as it streamlines workflows, improves the quality of care, increases productivity and reduces risks. When maintenance data are linked with health information and CMMS and EHR are integrated, patient information is inclusive.

For example, a CMMS can design work orders to correspond to timetables and thus avoid interrupting a patient's agenda and decrease the risk of equipment failures. Maintenance of both CMMS and EHR software with updated information on the status and availability of tools is highly beneficial during emergencies, although optimization of such data-sharing may still pose problems.

7.5.2 Staff resources: workforce skills and motivation

Shifting workflows may be met with reluctance, and staff should receive training and support. Healthcare staff must be trained to make proper use of the system so that all its possibilities, in terms of maintenance and patient assistance, can be used.

7.5.3 Existing QMS

Consistent data entry is essential for maintenance schedules and compliance. Ensuring that all relevant data are consistently entered and up to date requires vigilance and adherence to established procedures. Avoidance of duplication is crucial.

The external context consists of the regulations to which health-care institutions must adhere, which complicates use. Furthermore, round-the-clock health-care operations require robust support and contingency plans.

Once the system is selected, the next steps are installation and configuration, data migration and validation, and user training.

8. Reporting and performance monitoring in inventory and maintenance management

A sustainable HTM system is built on the synergistic interaction of three key resources – people, processes and technology – each of which plays a critical role in ensuring the availability, functionality and safety of medical devices.

- People: A well-trained workforce, including biomedical engineers, clinical staff, supply chain managers and IT specialists, ensures that medical devices are properly managed, maintained and optimized.
- Processes: Standardized workflows govern procurement, maintenance, compliance, decommissioning and financial planning, ensuring that each stage of the medical device life cycle is structured, transparent and efficient.
- Technology: Digital platforms such as IMMIS, QMS and asset tracking enhance automation, data accuracy and operational efficiency.

To transition from reactive management to proactive, evidence-based decision-making, institutions must use a structured reporting and performance monitoring system in which HTM is integrated with hospital-wide governance.

Management & Finance teams Require cost-benefit analyses, lifecycle tracking, and capital investment reports to optimize financial planning.	***Clinical staff*** Depend on equipment availability reports, incident tracking, and recall alerts to ensure uninterrupted patient care.
Biomedical & Clinical Engineering teams Utilize preventive maintenance schedules, failure trend analysis, and compliance monitoring to sustain equipment reliability.	***Regulatory & Compliance officers*** Monitor audit logs, adherence to regulatory requirements and standards, and incident response tracking for governance and accreditation.

Key Performance Indicators (KPIs of the management of medical devices and maintenance are the:

- mean time between failures of a medical device, indicating its reliability;
- mean time to repair a failed device, reflecting maintenance efficiency;
- how long medical equipment remains non-functional due to maintenance or repairs;
- rate of compliance with PM, as the percentage of scheduled PM activities completed on time;
- the number of unscheduled repairs required due to equipment failures according to corrective maintenance work orders;
- how frequently medical devices are used in clinical settings;
- availability of spare parts, i.e. stocks of critical spare parts, to avoid maintenance delays;
- the time taken by technicians to respond to and address maintenance requests;
- total maintenance cost for maintaining each medical device during its life cycle; and
- regulatory compliance rate, to ensure that all medical devices meet the required legal and accreditation standards.

Common types of such reports include:

- work order reports, to provide details of the status, priority and completion rates of maintenance tasks for use in workload management and scheduling;
- asset performance reports, to present metrics such as equipment downtime and mean time between failures, to facilitate assessment of asset reliability and efficiency;
- maintenance cost reports, to summarize expenses for labour, materials and services, for budget management and cost control;
- inventory reports, to monitor stocks of spare parts and consumables, ensuring optimal inventory management and readiness for maintenance activities;
- PM reports, to evaluate the effectiveness of scheduled maintenance programmes by comparing planned with completed tasks, to optimize maintenance strategies;
- compliance and safety reports, to document adherence to regulatory standards and safety protocols, which are essential for audits and ensuring a safe working environment; and
- labour use reports, to evaluate technician productivity and time allocation, which aids in workforce planning and identifying training requirements.

8.1 Budgeting for medical device maintenance

Effective budgeting for medical device maintenance is crucial for ensuring the continuous operation, reliability and regulatory compliance of health-care equipment. A well-structured budget accounts for both routine and unexpected expenses, balancing cost efficiency with the maintenance of high standards of patient care. Health-care institutions must consider various factors, such as PM and corrective maintenance costs, staff training, spare parts, digital management systems and long-term asset replacement. Without a proper financial plan, health-care facilities may face equipment failures, costly emergency repairs and potential regulatory non-compliance, all of which can compromise patient outcomes *(74)*.

Preparation of a budget for medical device maintenance includes a comprehensive breakdown of the costs associated with different maintenance strategies. PM, which includes scheduled servicing, software updates, calibration and inspections, constitutes a significant portion of the budget. In contrast, the costs of corrective maintenance, which are the costs incurred when medical equipment requires repairs due to malfunctions or wear and tear, can be unpredictable and can significantly impact the budget if not planned for properly. Health-care institutions should therefore allocate contingency funds for emergency repairs. Procurement of spare parts and consumables should also be included in the budget. Ensuring the availability of essential components reduces downtime, prevents prolonged equipment interoperability and enables quick resolution of technical failures *(48)*.

In a well-balanced budget, PM is prioritized as a cost-saving strategy. Numerous studies have demonstrated that institutions that invest in scheduled servicing and monitoring have lower long-term repair costs and longer equipment lifespans. PM reduces the likelihood of sudden equipment failures, which often lead to expensive emergency repairs, disruption of patient care and potential legal liability due to non-compliance with safety standards *(75,76)*.

Another essential item in budgeting for medical device maintenance is investment in staff training. The effectiveness of a maintenance programme depends not only on the availability of equipment but also on the skills and knowledge of the professionals responsible for its upkeep. Well-trained biomedical engineers, technicians and maintenance personnel ensure that medical equipment is serviced correctly and remains in compliance with international standards. The cost of continuous training programmes should be included in the budget to ensure that personnel are aware of the latest maintenance protocols, regulatory requirements and emerging technologies.

Many health-care institutions rely on maintenance contracts with third-party service providers or the original equipment manufacturers. Such contracts usually cover routine inspections, repairs, software updates and emergency service calls. Budgeting for service agreements should be preceded by a thorough cost–benefit analysis to determine whether in-house maintenance or outsourcing is more advantageous financially and operationally. Some health-care facilities find it more cost-effective to establish long-term service contracts with equipment manufacturers, while others use a hybrid model that combines in-house expertise with external support for specialized maintenance tasks. Long-term servicing and maintenance of medical devices is critical for ensuring patient safety, device reliability and adherence to regulatory standards. Over the years, medical technologies have evolved significantly, so that rigorous maintenance protocols are required for each type of device *(30)*.

General recommendations for medical device maintenance are as follows.

- Schedule regular inspections and performance monitoring tests to ensure that devices meet technical and safety specifications.
- Periodically calibrate devices that provide measurements or require precise readings (e.g. infusion pumps, diagnostic equipment).
- Update software or firmware regularly to avoid security vulnerability and improve functionality.
- Conduct continuous assessment to ensure that devices comply with changing safety standards and regulations.
- Keep detailed records of maintenance activities, including repairs, replacements, calibration and inspections.
- Find systems to address trends in malfunctioning or failure of equipment.

Periodic inspection, calibration and maintenance of all types of medical devices are essential.

In the case of diagnostic medical devices, this ensures accurate test results, reducing the risk of misdiagnosis and improving patient outcomes. For diagnostic devices such as electrocardiograms, ultrasound machines, laboratory equipment and MRI scanners, accuracy is paramount *(34)*, as the usefulness of these devices depends on precision, and even a small deviation in performance can lead to an inaccurate diagnosis. Routine inspection and calibration are essential to ensure that imaging sensors and diagnostic electrodes remain intact and continue to meet operational specifications. Software and firmware updates are also important in maintaining diagnostic devices, as new security vulnerability or improvements to efficiency may emerge over time.

Periodic inspection of patient monitoring systems such as pulse oximeters and blood pressure monitors ensures reliable provision of real-time, accurate data for decisions about patient care *(77)*. Such devices are used in both acute and chronic care, often for long-term patient management, and regular checks of sensors and electronic components are essential to ensure that the readings remain accurate. As these devices also require reliable battery life, periodic replacement of batteries or charging system maintenance is necessary to ensure continued functionality. Furthermore, many monitoring systems are integrated with EHR and other software platforms, which require periodic updates to ensure security and compliance with evolving health-care regulations *(78)*.

Therapeutic medical devices, such as infusion pumps and ventilators, must deliver precisely to ensure the safety and effectiveness of treatment. Infusion pumps, for instance, must be calibrated routinely to ensure precise fluid delivery to patients. Over time, seals, tubing and filters may degrade, potentially leading to malfunction or a risk of contamination. Similarly, ventilators, which provide respiratory support, must be checked regularly to confirm that the airflow and pressure settings are within prescribed ranges. Parts subject to wear, such as motors and mechanical components, should be inspected and replaced as necessary to avoid breakdowns in critical care *(79-81)*.

Maintenance of surgical instruments ensures optimal functionality and precision during procedures, reducing the risk of surgical complications. Surgical tools, particularly those with complex mechanics such as robotic surgery systems, undergo significant wear and tear with every use. Thorough cleaning and sterilization after each procedure is critical to prevent infections, and regular inspection is necessary to detect any damage, especially in moving parts such as joints and blades. A sharp blade or functional robotic arm can make a substantial difference in surgical outcomes, and timely maintenance or replacement is vital *(35,82)*.

For implantable devices such as pacemakers and joint replacements, regular monitoring, firmware updates (for electronic implants) and assessment of potential wear or biological response ensure long-term functionality, patient safety and device performance. Implantable devices present a unique challenge, as, although these devices often have longer life cycles and are designed for durability, they still require long-term monitoring. For example, pacemakers may require periodic follow-up to assess battery life and device performance, often with non-invasive diagnostic tools. As technology advances, software updates to these devices may be necessary, sometimes requiring a minor procedure to re-programme or adjust settings *(83)*.

Regardless of the device type, long-term maintenance of medical devices includes robust risk management. Prediction of potential failures with methods such as "failure mode and effects analysis" helps to mitigate risks before they occur. The goal is not just to react to failures but to predict and prevent them by regular inspection, updates and replacement of worn components.

Compliance with regulatory frameworks ensures that all devices meet the required safety standards. Regulations enforce quality control to which manufacturers, service providers and health-care institutions must adhere, ensuring that all devices continue to operate as intended and remain safe for patient use.

For example, In the USA, the Code of Federal Regulations *(84)* outlines the necessary steps for device servicing, including documentation, testing and training. In Europe, the Medical Device Regulation *(85)* sets forth similar obligations.

Budgeting for medical device maintenance should include long-term capital investments. Over time, even well-maintained medical devices reach the end of their operational life cycle and require replacement. Institutions should establish a depreciation schedule for medical equipment, setting aside funds for future acquisitions according to their expected service life and use patterns. A structured capital expenditure plan ensures that health-care facilities can replace outdated or inefficient devices without straining their financial resources.

Strategic asset management, in alignment with ISO 55001 *(86)*, ensures that institutions make data-based decisions on equipment upgrades, replacements and decommissioning. By analyzing performance data, maintenance history and cost-effectiveness, health-care administrators can determine when to repair, upgrade or replace a medical device. This systematic approach minimizes unnecessary spending and ensures that investments in new technologies are made at the right time, maximizing financial efficiency while maintaining optimal patient care.

Another aspect of safety inspections is risk management and mitigation during the device's lifespan. Medical devices are subject to wear and tear, calibration drift, software bugs and misuse; inspections serve as periodic risk assessments to identify such issues. They are an important part of the risk control measures of a device's life cycle (as also described in ISO 14971, risk management standards *(87)*, which are, however, mainly for manufacturers). A risk-based quality control approach prioritizes equipment according to the likelihood and impact of failure. This approach optimizes resource allocation by focusing on high-risk devices, reduces unnecessary downtime for low-risk equipment and enhances patient safety by ensuring that critical devices receive proactive attention.

Devices should be classified according to:

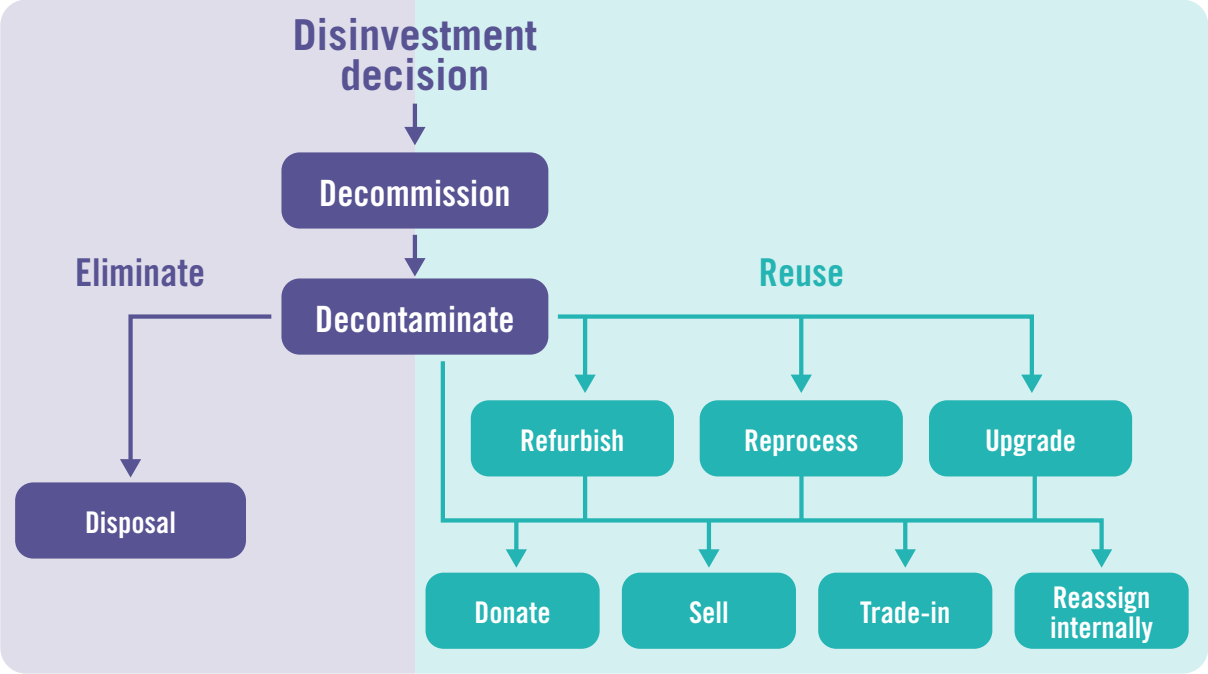
- their clinical importance: how critical the device is to patient care;
- the likelihood of failure: past failure rates and performance trends; and
- the potential consequences of failure, such as the severity of patient harm.

For hospitals and clinics, risks can be mitigated by performing a safety inspection before putting a new device into service (acceptance testing), conducting routine preventive checks and inspecting a device after any major repair or adverse event. Many national guidelines reflect these practices *(88).*

8.2 Decommissioning medical devices

Decommissioning is explained in detail in Decommissioning of medical devices in the WHO Medical Devices technical series *(13).* This often begins with an assessment of the device's condition and risks. Common reasons for decommissioning are that the device has become unsafe or unreliable (it fails calibration repeatedly, or critical components are no longer functional), the manufacturer has stopped providing support and spare parts (making maintenance impossible), or newer technology has made it obsolete or non-compliant with current standards. Sometimes, even if a device still works, it may be retired if it no longer meets updated regulations or clinical guidelines. For example, if a new safety standard is introduced for dialysis machines and an older machine cannot be upgraded to meet it, a health-care facility may phase out that equipment *(36,88-90).* Fig. 13 illustrates how a decision is made to decommission a medical device.

Fig. 13. *Making a decision to decommission a medical device*



A formal risk–benefit analysis can be conducted with the inclusion of factors such as repair costs, device performance and patient safety. Once it is decided that a device is at the end of its useful life, a plan is made for taking it out of active service.

The factors that determine whether a piece of medical equipment should be removed from service include the following.

Functional and clinical performance:

- The device no longer meets clinical requirements due to technological obsolescence or changes in medical practice.
- Persistent issues in performance occur, which impact diagnostic accuracy, therapeutic outcomes or patient safety.
- The rate of use has decreased due to the availability of more effective alternatives.

Age and life cycle:

- The device has exceeded the expected service life specified by the manufacturer or industry benchmarks.
- Increased failure rates or downtime make continued use inefficient and unreliable.
- Manufacturer support has been discontinued, including spare parts and software updates.

Safety:

- The device poses a hazard to patients or operators due to recurring malfunction.
- Documented adverse event reports or recalls have been received.
- Current compliance and regulatory standards cannot be met.

Maintenance and cost considerations:

- Rising maintenance costs exceed the cost of replacement.
- Frequent breakdowns lead to significant service disruption.
- Costly spare parts and specialized labour are required for repairs.

Environmental and regulatory compliance:

- The device contains hazardous material that requires proper disposal.
- Regulatory bodies mandate its decommissioning due to updated safety and performance requirements.
- The device no longer complies with evolving infection control protocols, particularly in sterilization-sensitive environments.

A systematic approach ensures that decommissioning is both effective and complies with institutional policies. The following tools can be used for organized, efficient decommissioning:

- risk-based decommissioning canvas: a framework for assessing whether a device should be removed according to safety, cost and performance metrics;
- decision matrix canvas: a visual tool for scoring equipment on criteria for decommissioning;
- disposal route selection chart: a structured method for determining whether to recycle, dispose of or donate medical devices; and
- regulatory compliance checklist: to ensure that all steps in decommissioning meet industry standards and legal requirements.

Not all decommissioned equipment is discarded.. Some devices are donated to other health-care providers, particularly in resource-limited settings, if the device is still usable. WHO has published and updated guidance on medical device donations, outlining best practices and cautioning against inappropriate donations that do more harm than good *(8).* According to WHO, donors and recipients have clear responsibilities before, during and after a donation to ensure that the donated device is safe, compatible with the recipient's needs and accompanied by the necessary accessories and documentation.

Many manufacturers and third-party companies offer trade-in programmes, in which older devices (such as an ultrasound or anaesthesia machine) is upgraded or reconditioned and then either sold to secondary markets or redeployed internally. This extends the equipment's life cycle and reduces waste. From an ethical standpoint, refurbishment is encouraged, as long as the device can be made reliable and safe. Regulatory bodies often hold refurbished devices to the same safety standards as new ones. For instance, in the European Union, refurbished devices that are put back into service must still conform to applicable requirements of the Medical Device Regulation. Servicing and refurbishment are acceptable but should not alter the device's intended use or introduce safety risks *(91)*.

Donation of decommissioned medical equipment to resource-limited settings is a common ethical initiativeWHO states that donations should respond to an expressed need and acceptance by the recipient *(92)*. Donors and recipients should communicate before a donation to make plans for installation, user training and long-term maintenance. to avoid a burden rather than a benefit *(93*

Safe disposal practices and environmental considerations

A device will have to be disposed of at some point, whether after reuse or directly by decommissioning. Medical devices often contain hazardous materials, such as batteries with heavy metals, electronic circuit boards, plastics and radioactive components (in devices such as some older radiotherapy machines). Regulatory compliance is crucial in disposal. Many countries have strict regulations on disposal of e-waste and biohazards by health-care facilities. Health-care facilities must dispose of devices by environmentally sound methods *(94)*.

WHO, the United Nations Children's Fund and other partners are strengthening safe, sustainable health-care waste practices in building climate-resilient health systems *(95)* by encouraging health-care facilities to adopt policies such as "green procurement" (buying devices that last longer or have an eco-friendly design) and responsible disposal (ensuring maximal recycling and minimal waste). Some medical device companies now accept old equipment for proper disposal or refurbishing.

Even simple steps such as removing and separately disposing of batteries or ensuring that an old device is fully drained of any hazardous fluids before transport are best practices.

Regulatory compliance and documentation

Another consideration in decommissioning is data security and privacy., It is important to ensure that any confidential patient information is cleared from the device's memory.

Inventory of retired or decommissioned devices

Ensure that all devices removed from the inventory are inactivated and removed from all schedules. Data on retired devices should not be removed from the CMMS but should be retained for as long as required in the organization's data retention policy.

The records of devices in the CMMS that are no longer in service, are to be disposed of or are ready for decommissioning should include the:

- retirement date, when the device was removed from service, due either to failure to locate it or at the request of the person in charge of the inventory; and
- a work order that states that the device was retired from the inventory on a specific date, with the reason for retirement and its final disposition, such as destroyed, traded in, recycled or sold.

Before a device can be removed from the inventory, all labels and control numbers must be removed. If the device model is the only one in the inventory, all disposable accessories used exclusively for the device should also be retired. Operator and service manuals should be included in the retirement, if there are no other devices of the same model in the inventory. Before a device is removed from the facility, a technician should remove all sensitive data, including network configurations, patient information and user identities. These actions should be documented in the retirement work order.

8.3 Generating reports for decision-making and compliance

Reporting of KPIs to evaluate the output of the CMMS is important, as it reflects the data entered daily and the summation of the data for effective decision-making. Reports should be prepared, although many CMMS have prepackaged dashboards and fixed reports for many common KPIs. Reports should be produced at a scheduled frequency. Many systems allow reports to be sent to a shared location by email or some other method.

The reporting matrix should include the audience, the KPI and the business goal(s) to be reviewed or improved by viewing the data. Trending can be included in most reports to determine whether the KPI is being achieved. Sample KPI prospective measures and definitions are presented in Table 10.

Table 10. *Model spreadsheet of future maintenance and reliability metrics*

Performance metric	Performance target	Calculation	Data 1 source	Data 2 source	Data 3 source	Data 4 source
Work orders returned to planning (%)	0%	No. of work orders returned to planning / total work orders planned x 100	No. of work orders returned to planning in CMMS	Total work orders planned in CMMS		
Maintenance labour costs	NA, trend	Maintenance labour costs in US$ / MGD	Maintenance labour costs in CMMS			
Material costs	NA, trend	Maintenance costs in US$ / MGD	Maintenance costs in US$ / MGD			
Work orders by priority (%)	NA, trend	No. of work orders by priority / total work orders x 100	No. of work orders by priority in CMMS	Total work orders by priority		
Estimated hours vs actual hours for work order (%)	< 10% deviation	Total estimated hours / total actual hours x 100	Total estimated hours on work orders in CMMS	Total actual hours in CMMS		
Scheduled hours vs actual hours (%)	100%	Scheduled labour hours / total available labour hours x 100	Scheduled labour hours in work orders in CMMS	Total available labour hours in CMMS		
Break-in labour hours vs total scheduled hours (%)	Downward trend if total is < 5%	Total scheduled break-in labour hours / total scheduled hours x 100	Total no. of scheduled break-in labour hours	Total scheduled labour hours		
After-hours calls (premium pay)	NA, decreasing trend	Total no. of after-hours calls	Total no. of after-hours calls in CMMS			
Labour hours by work category (proactive vs reactive vs support) (%)	80% proactive	Total emergency labour hours (order type "X") / total labour hours x 100	Total actual hours on type X work orders in CMMS	Total actual hours on work orders in CMMS		

Performance metric	Performance target	Calculation	Data 1 source	Data 2 source	Data 3 source	Data 4 source
Failure code trends	NA, decreasing trend	Sum of failures by failure code	No. of failures by failure code in CMMS			
Closed work orders with labour hours recorded (%)	100%	No. of closed work orders with labour hours recorded / total work orders x 100	No. of closed work orders with labour hours recorded in CMMS	Total no. of work orders in CMMS		
Closed non-PM work orders with failure codes recorded (%)	100%	No. of non-PM work orders with failure codes/ total work orders x 100	No. of non-PM work orders with failure codes in CMMS	Total no. of work orders in CMMS		
Average time for work orders in backlog awaiting materials (h)	NA, trend	Average: date and time of work orders in backlog awaiting materials – total no. of work orders in backlog x 100	Date and time of work orders in backlog awaiting materials	Date and time of work orders in backlog awaiting materials		
Total work orders in backlog awaiting materials (%)	NA, trend	Work orders in backlog awaiting materials / total no. of work orders in backlog x 100	Total work orders in backlog awaiting materials in CMMS	Total work orders in backlog in CMMS		
Inventory accuracy (%)	98%	No. of pieces in stock / expected no. of pieces in stock x 100	No. of pieces in stock in CMMS	Expected no. of pieces held in stock in CMMS		
Turnover ratio of spare parts/year	> 2 to 3	Value of stock issued in 1 year / value of stock held at tile of measurement	Value of stock issued in 1 year in CMMS	Value of stock held in inventory in CMMS		

NA, not applicable

9. Trends in management of medical devices

9.1 Evolution of CMMS: IMMIS

IMMIS represents the next generation of CMMS, with capabilities beyond traditional asset tracking and maintenance scheduling. Unlike conventional CMMS, which addresses mainly work order management and PM, IMMIS includes inventory tracking, predictive analysis, enforcement of regulatory compliance and data-based decision-making in a single digital ecosystem. IMMIS transforms the life cycle management of medical equipment by alignment with global regulatory frameworks), standardizing nomenclature systems (GMDN, EMDN) and using advanced technologies such as AI-driven PdM, IoT connectivity and Cloud-based interoperability.

IMMIS is a digital system designed to track, manage and optimize the life cycle of medical devices. It includes inventory management, PdM scheduling, regulatory compliance tracking and smart performance monitoring on a centralized platform, facilitating efficient oversight of medical equipment in health-care facilities.

The terms IMMIS and CMMS, used throughout this publication, both refer to systems designed to track, manage and optimize medical device maintenance and inventory; however, their scope is not the same. IMMIS represents the next generation of CMMS, including advanced technologies such as PdM powered by AI, real-time analytics, IoT-enabled device monitoring and blockchain-based traceability. Unlike CMMS, which mainly addresses scheduled and corrective maintenance, IMMIS extends the framework to include

proactive, intelligent decision-making tools, which increase efficiency, security and life cycle optimization for medical devices (Table 11).

In this publication, the term IMMIS is used to refer to next-generation capabilities, although it builds on the fundamental principles of CMMS.

Table 11. *General overview of CMMS and IMMIS*

Feature	Basic CMMS	IMMIS
Inventory management	Limited to asset tracking	Full integration with UDI-based real-time tracking, automated stock control
Remote monitoring and control	Limited to asset tracking	Remote diagnosis and resolution of issues with medical devices and alignment with telehealth and remote monitoring
Maintenance planning	PM and corrective maintenance	Predictive, AI-driven maintenance with IoT-based real-time monitoring
Regulatory compliance	Manually logged compliance reports	Automated alerts for recalls, inspections and compliance audits (e.g. European Union Medical Device Regulation, FDA)
Data analysis and decision support	Basic reports	Advanced analysis (failure prediction, life cycle cost analysis, procurement optimization); enhanced interfaces offer interactive dashboards for rapid analysis of equipment performance and predictive analysis
Integration with digital health systems	Limited connectivity	Interoperability with EHR, enterprise resource planning, procurement platforms and regulatory databases
Nomenclature and standardization	Device categorization by facility	Standardized device classification (GMDN, EMDN)
User access	Localized software access	Cloud-based, multi-location access for regional and national coordination
Cybersecurity and data integrity	Local back-ups, minimal encryption	Blockchain-based security, Cloud redundancy, real-time threat monitoring
Augmented reality maintenance support	Not available	Augmented reality glasses will guide technicians through maintenance and repair of devices, improving efficiency and reducing errors.

As IMMIS technology continues to progress, several emerging trends are poised to further transform inventory and maintenance management in health care. Innovations in AI, the IoT, blockchain and predictive analytics are driving next-generation features in these systems.

Use of an IMMIS fosters a culture of continuous improvement in health-care organizations. It promotes a proactive approach to equipment maintenance and management and a safer, more efficient health-care environment, which benefits patients, medical professionals and the broader health-care system. Use of such information systems for health technology management in a health-care institution allows use of AI for PdM, representing a shift to the next generation of the technology *(96,97)*.

9.1.1 PdM powered by AI

AI is increasingly being integrated into maintenance management to make systems smarter and more autonomous. PdM is an advanced strategy in which data and technology are used to predict when a device will fail, so that maintenance can be done just before an actual breakdown. IoT-enabled medical devices have

sensors and connectivity for reporting on use, error logs or performance parameters in real time to a central system. Data from continuous monitoring of these data are fed into algorithms that detect early warning signs of wear or impending failure. The standardization and traceability of data in the information system thus contribute to explainable, trustworthy AI predictors.

Research has been conducted on the use of standard methods for assessing the performance of infant incubators from data in a CMMS system managed by an independent inspection body *(98,99)*. The data were collected during routine inspections conducted in accordance with national legal requirements. In one study, five machine learning algorithms – naïve Bayes, decision tree, random forest, k-nearest neighbour and support vector machine – were used. The decision tree algorithm showed the highest overall accuracy, at 98.5%, suggesting that it could be used in monitoring and managing infant incubators. In another study *(100)*, an expert system was developed that included an artificial neural network and fuzzy logic classifiers to predict infant incubator failures. Validation of the system's performance showed an accuracy of 95.65%, a sensitivity of 97.23% and a specificity of 88.89%. Research was also conducted on management of a defibrillator in a CMMS enhanced with AI *(101)*. Machine learning algorithms were developed with the dataset, which achieved an accuracy of 97.98–99%, suggesting their potential clinical application in optimizing defibrillator maintenance and performance monitoring.

Many equipment failures still occur, however, despite regular maintenance. AI helps to close the gap by conducting interventions according to the condition of the equipment. Beyond PdM, AI can optimize maintenance workflows in other ways. Intelligent scheduling algorithms can be used to prioritize work orders according to their urgency and the availability of a technician or automatically assign the most qualified technician to a specific task. IMMIS can be used to create a digital twin of a medical device maintenance task, providing a virtual model of real-time data, operational conditions and maintenance activities.

AI chatbots or digital assistants are also being used to aid technicians, for instance by providing instant problem-solving guides or repair instructions. Some systems already include an AI assistant that can guide a technician through a repair step-by-step on a mobile device. Over time, AI could mean that IMMIS evolves from a reactive record-keeper to a proactive adviser. The trend towards smarter maintenance management is expected to continue as algorithms become more sophisticated with larger datasets. For medical device users as well, intelligent systems can offer clear, interactive instructions, ensuring proper device operation, enhancing safety and minimizing misuse.

9.1.2 Cloud-based IMMIS and remote monitoring

In the same way that smartphones are now used to collect medical data, use of IoT sensors for real-time data collection and remote equipment monitoring is making it possible for data on virtually every piece of equipment in a health-care facility to be reported to an information system. IMMIS platforms are increasingly being integrated with IoT networks for continuous monitoring of device conditions and use *(100)*. Many modern medical devices and facility systems (such as heating, ventilation, air-conditioning and power generators) are IoT-enabled by manufacturers or can be retrofitted with sensors that feed data such as hours of use, performance metrics, error alerts or environmental conditions directly into the maintenance system. The result is real-time equipment monitoring for deviations from the norm.

IoT data also enable more granular maintenance strategies, such as condition-based maintenance, in which a device is serviced according to its actual wear and tear rather than on a fixed schedule. Furthermore, as mentioned above, real-time location system technology (a facet of IoT) is being widely adopted in health-care facilities for asset tracking. When IMMIS is linked to real-time location systems, it indicates not only what maintenance is due but where the asset is currently located, which is invaluable for portable equipment. This

will probably evolve into smarter maintenance according to location. Use of IoT in health-care maintenance is increasing. As more devices become connected, IMMIS will contain far richer data streams, enabling highly proactive, optimized maintenance operations.

9.1.3 Blockchain for secure traceability of medical devices

Although blockchain technology is at an early stage in maintenance management, it is promising for the future of IMMIS, especially with respect to data security and auditability. Blockchain, a distributed ledger technology, can be used to record maintenance transactions (such as completed work orders, inspections or part replacements) in a way that is immutable and tamper-proof. In the context of health care, this would mean that, once a maintenance record for a medical device is logged (for instance, that a ventilator passed a safety test on a certain date), that record is cryptographically sealed. Such immutability is valuable for regulatory compliance and internal audits, as it provides confidence that maintenance data have not been altered to cover up lapses. Blockchain could also facilitate sharing of maintenance and asset histories between organizations. Thus, when one health-care facility buys a used MRI machine from another, the complete maintenance history would be available as a blockchain-verified record, providing confidence in the asset's condition.

Another potential application is in supply chain and inventory management for maintenance. Blockchain can be used to track the provenance of spare parts and ensure their authenticity (to avoid counterfeit parts in critical devices). It could record each transfer of a surgical instrument or implantable device through maintenance, sterilization and other interventions in a secure chain. While widespread adoption of blockchain in IMMIS will depend on industry standards and collaboration, pilot projects indicate that it can greatly improve data security, transparency and trust in maintenance records *(102)*. Cybersecurity and data integrity are paramount in health care, and blockchain-backed IMMIS modules may become more common to guard against data tampering and to simplify compliance reporting.

Real-time data, predictive analysis and intelligent insights can ensure that health-care systems optimize resources, ensure patient safety and maintain operational excellence. When AI, IoT and QMS are integrated into CMMS, additional KPIs can be generated:

- predictive failure alerts: AI-generated warning of potential equipment failures;
- real-time use: use of IoT sensors to track device use to signal availability;
- automated calibration adherence: ensures that all devices meet calibration standards in real time;
- energy efficiency: monitoring the energy consumption of each device to optimize sustainability;
- AI-based work order optimization: indicates whether AI maintenance recommendations improve efficiency;
- risk-based maintenance prioritization: maintenance schedules prioritized according to a risk assessment;
- device lifecycle cost analysis: use of AI to determine whether continuing repairs or replacement is the better financial decision;
- patient safety incident correlation: analysis of links between equipment failures and adverse patient outcomes;
- QMS compliance rate: monitoring of adherence to quality management policies in CMMS; and
- carbon footprint of medical devices: use of IoT and AI to determine the environmental impact of medical equipment.

As technology continues to advance, decision-makers and IMMS will undoubtedly shape a future in which health care is not just reactive but proactive, ensuring the best possible outcomes for patients and the institutions that serve them *(103)*. Examples of questions for generating reports from advanced analytics in IMMIS are listed below.

- Which medical devices are showing early signs of failure, such as performance anomalies detected during periodic inspections?
- Which medical devices are underused in all hospital departments, and could they be redistributed?
- Which assets require safety testing this month to comply with regulations?
- Which medical devices have the highest repair costs and should be considered for replacement?
- Where are all currently available ventilators located?
- Can a pattern in medical device failures that risk patient safety be derived from incident reports?
- Which biomedical engineering staff members require refresher training in use of specific equipment?
- Which medical devices consume the most energy, and could their use be optimized?
- Can a compliance readiness report be prepared for an upcoming regulatory audit, highlighting high-risk areas?
- Can the budget for next year's medical device maintenance be generated from past trends?

9.2 Continuous transformation

Health-care systems rely on many technologies, each of which has a critical role in ensuring efficiency, accuracy and patient safety. The true power of these systems is not, however, in their static capability but in their ability to adapt, evolve and integrate. A health-care information system that maintains a rigid design will inevitably become obsolete, unable to keep pace with new regulatory requirements, emerging technologies and the shifting demands of medical practice. Systems that are designed for modularity, scalability and interoperability allow seamless integration of new functions without disrupting workflows. Such adaptability ensures that organizations can respond to new challenges, such as evolving compliance standards, advances in medical device technology or shifts in patient care models. The new technologies in health-care systems will also affect the professional roles of clinical engineers and technicians, who ensure the operation of medical equipment. As technology evolves, their expertise must be adapted *(104)*. They must be trained and have experience in use of IoT, AI and data analysis to interpret data from connected devices, how AI algorithms work and the use of complex, integrated medical devices. This will reduce downtime and improve the quality of health care *(103)*.

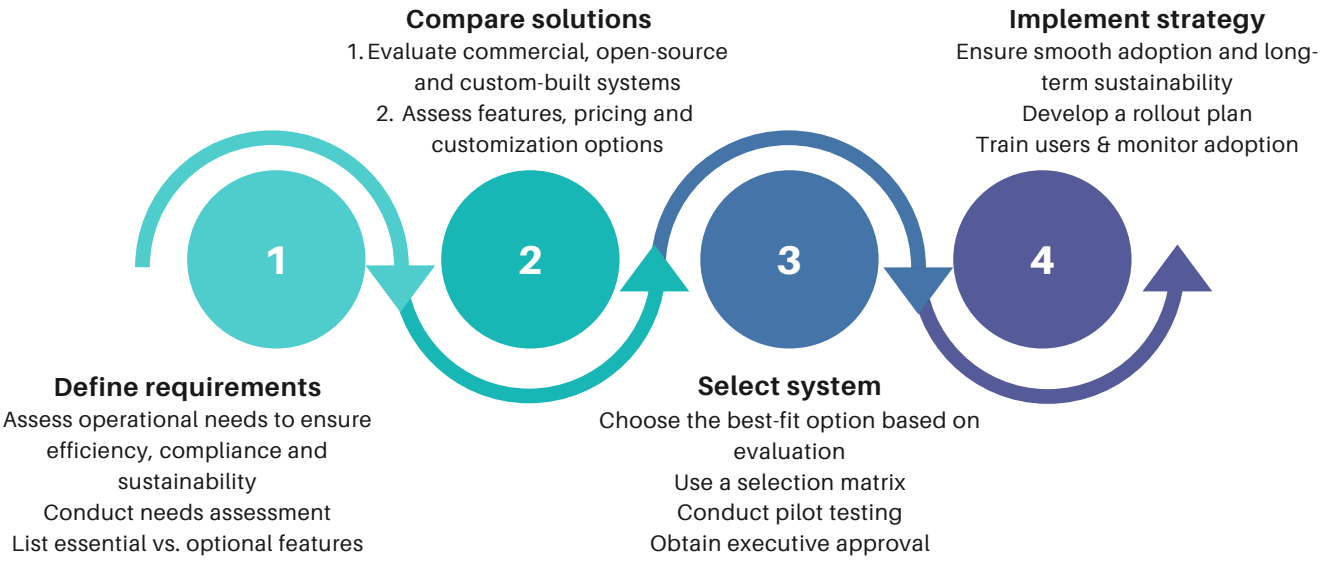
Standardized data on the performance and maintenance of medical devices and use of AI and novel technology provide valuable information on the quality and efficiency of devices. The approach also represents a step towards harmonizing medical device management practices globally. Pre-marketing of medical devices is already regulated by various standards. By introducing standardized procedures for medical device management and standard data collection methods, the post-market phase would become aligned with the pre-market approach.

It might be asked why introduction of international standards in medical laboratories could not also be standard practice for medical device maintenance. The goal is to use the collected data to build trustworthy AI systems capable of demonstrating the compliance of a medical device, which would alleviate the financial burden of the costly process in which manufacturers and distributors are required to confirm compliance to regulators. Additionally, health-care facilities would become actively involved, by improving data reliability and accelerating innovation by providing actionable insights*(102)*.

10. Selection of appropriate IMMIS for medical devices

Selection of an appropriate IMMIS for medical devices will ensure efficiency, regulatory compliance and patient safety in health-care facilities. This requires careful evaluation of criteria, comparison of possible solutions and ensuring compatibility with regulatory and IT infrastructure. This section provides a structured, stepwise approach to selecting an IMMIS (Fig. 14), based on best practices in inventory management, CMMS and recommendations.

Fig. 14. Steps in selecting an IMMIS



10.1 Needs assessment and problem definition

A needs assessment involves evaluating current practices, identifying weak points and areas for improvement and determining the requirements and functionalities of an HTM and information system. The assessment should include the types of users, critical modules and functions, hardware requirements and integration with other software *(105)*.

The first step is clear identification of the requirements and of any problems. A well-conducted needs assessment includes defining and prioritizing the requirements and considering the potential impact on users, with the overall aim of improving health outcomes or service delivery. This groundwork creates shared understanding of what is to be addressed and why, providing a clear objective for subsequent phases. To determine the functional requirements and user expectations of a new system and alignment with actual needs, techniques such as surveys, interviews and focus groups with users can be used.

IMMS for medical devices affect many departments (stakeholders), including biomedical and clinical engineering, procurement, clinical staff, IT and health-care facility administration. An inclusive approach is critical for identifying requirements, setting clear expectations and securing institutional buy-in. Mapping of all stakeholders and ensuring their early involvement will ensure that their perspectives and influence are understood. Early engagement of a multi-disciplinary group can bridge gaps between technical design and clinical reality. Stakeholder buy-in at this stage, such as in regular meetings or workshops, will smooth the path for adoption.

Practical tools and frameworks for use in this phase include the following.

- Analysis of the internal strengths and weaknesses of an organization and the opportunities and threats associated with a proposed technology indicates the context in which a technology will be used and any organizational resources or constraints. For example, it might reveal strong IT support (a strength) but a limited budget or regulatory hurdles (threats), which must be addressed early on.
- Root cause analysis can be conducted for a complex or poorly understood health-care problem. Tools such as the "5 Whys" and "Fishbone diagram" *(106)* can be used to identify the underlying causes. Understanding of root causes ensures that the team addresses the real problem rather than symptoms in order to align the solution and avoid misdirected work.

The outcome of this phase is a well-defined problem statement, a clear set of objectives and informed stakeholder support, which will guide effective solutions.

10.2 Choosing an appropriate system

Once the problem is clearly defined, creative solutions can be generated that are appropriate for users. Different options, such as commercial packages, open-source or local systems, should be compared to find that which best fits the context of the facility. "Design thinking" approaches can be used to ensure both innovation and user requirements. For example, the "Double Diamond" design comprises four stages, discover, define, develop and deliver *(107)*, that guide understanding a problem to developing and testing solutions. It is important to think broadly and not choose a single solution too quickly. Various discussion techniques can be used, from open sessions to more structured methods. This phase will allow the team to agree on a well-defined solution that meets user needs.

Before investing in custom-built development, the team should conduct a market analysis to find solutions that might meet the organization's requirements. This consists of evaluating commercial inventory and maintenance systems and open-source alternatives in a structured procurement approach, similar to that for acquiring medical devices, including defining technical and functional requirements, assessing vendor solutions, considering integration capability and evaluating the total cost of ownership.. As described in detail in section 7.3, each approach has its merits, requiring careful evaluation of the requirements of the health-care institution. As both offer distinct advantages and challenges, many health-care facilities may find a hybrid approach to be the most effective solution. This could involve use of open-source platforms for cost-effective customization and non-open-source platforms for integration into infrastructure and compliance with international standards.

Table 12 shows a comparison of commercial and custom-built solutions.

Table 12. *Comparison of commercial and custom-built maintenance management systems*

Commercial (non-open-source systems)	Commercial (open-source systems)	Custom-built
Positive aspects		
• well-tested and industry-approved • vendor support for resolving problems • regulatory compliance features included • usually user-friendly interfaces	• to some extent industry-approved • no licensing costs, best for low-resource settings • customizable and adaptable • community support	• designed for local workflows and regulations • full control over features and customization • greater flexibility in data management • can be designed for future scaling up
Challenges		
• high upfront costs and licensing fees • may require additional customization to fit specific workflows • potential vendor lock-in	• limited vendor support, requiring in-house expertise • may lack regulatory compliance features • potential security vulnerability	• expensive and time-consuming to develop • requires ongoing technical support to maintain • longer implementation timeline • risk of technical obsolescence

The choice depends on the requirements and resources of the health-care institution, such as budget, in-house technical expertise, customization required and the availability of timely support.

Criteria for choosing an appropriate system include the following.

Budget and total cost of ownership:

- What is the initial cost (licensing, setup and implementation fees)?
- What are the recurring costs (subscription fees, upgrades, maintenance)?
- Are there hidden costs, such as per-user fees or integration expenses?
- Is the cost similar to that of commercial and open-source solutions?
- Does the vendor offer financing or flexible payment models?
- Is the investment sustainable in the long run?

The overall cost of the IMMIS should be evaluated, including licensing fees, implementation costs, maintenance and support fees and any additional charges for customization, integration or upgrades. The more capable IMMIS is of integration with the organization's software and systems, the more valuable the system is. This will ensure smooth data exchange, eliminate manual data entry and improve efficiency and accuracy.

In-house technical expertise and IT support:

- Does the facility have an in-house IT team for implementation and maintenance of a CMMS?
- If necessary, could the system be used and managed by non-technical users?
- How complex is the training for biomedical engineers, facility managers and IT staff?
- Can the facility manage updates and security repairs internally, or will it rely on vendor support?

Customization and flexibility:

- Does the system allow customized maintenance workflows?
- Can new device categories, service levels and reporting templates be configured?
- Does it support role-based access control and permission customization?
- Can the system generate customized reports and dashboards tailored to health-care regulatory requirements?
- Can it accommodate multilingual or region-specific regulatory settings?

Support and vendor reliability:

- Does the vendor provide support 24 h per day, 7 days/week, especially for critical hospital environments?
- What are the response and resolution times for resolving issues?
- Are there service-level agreements that define support commitments?
- Does the vendor offer on-site training, online documentation or dedicated account managers?
- Are software updates and patches provided regularly?

Functional requirements:

- medical equipment inventory management for tracking devices, locations and use;
- planning for PM and corrective maintenance, scheduling service tasks and tracking repairs;
- management of spare parts and consumables by monitoring stock levels and reordering;
- regulatory compliance and generation of reports required for inspections and audits; and
- user access and security, with access only for clinical engineers, procurement teams and IT staff.

Scalability and customization:

- Can the system handle all the devices in the facility?
- Can it support future expansion, such as integration with health-care facility IT systems?
- Is it compatible with hospital information systems and enterprise resource planning systems?
- Can it support Cloud-based access for multi-location health-care facilities?

User-friendliness and training:

- Is the system intuitive and easy to use for biomedical engineers and health-care facility administrators?
- Does it offer training modules and support materials for new users?

Regulatory compliance:

- aligned with quality management standards for medical devices;
- supports UDI compliance for device tracking and nomenclature systems; and
- enables reporting for post-market surveillance and audits.

Security requirements:

- Does the system include encryption and access controls to protect sensitive equipment data?
- Does it comply with General Data Protection Regulation in the European Union, the Health Insurance Portability and Accountability Act in the USA or local health data protection laws?

Table 7 in section 7.4 provides a comparison of Cloud-based and on-site systems. To foresee future trends, consideration should be given to Cloud solutions rather than on site, as the Cloud vendor provides greater back-up and security. An on-site system requires hardware provided by the institution but may give greater control over overall deployment.

Once the needs are assessed and the technical specifications are established, the functionality and flexibility of the systems offered by each vendor should be assessed to ensure that which is chosen meets the requirements and workflow. Demonstrations can be used to evaluate the user interface, features and overall usability of the system. The organization should also evaluate the vendor's reputation and experience, such as from customer reviews, testimonials and case studies of their performance, reliability and customer satisfaction. Service agreements should be examined to determine whether they include training and after-sales support, any delays in technical support and resolution of issues.

Ensuring compatibility with regulatory requirements and healthcare IT Infrastructure

Selection of an IMMS also involves planning for integration into health-care facility processes and sustaining its use over time as part of best practices in HTM. In this phase, the purchaser considers how the solution will be realized and sustained. The concept is translated into a robust implementation plan, and its operational, technical, financial and regulatory feasibility is examined. The goal is to ensure that the solution is viable and is aligned with the strategic objectives of the health-care organization. Questions such as the following may be posed.

- Can the solution be integrated into existing systems and workflows?
- Are there any regulatory approval or compliance issues to be managed?
- What resources (human, technological, financial) are required?
- What are the timelines and milestones?

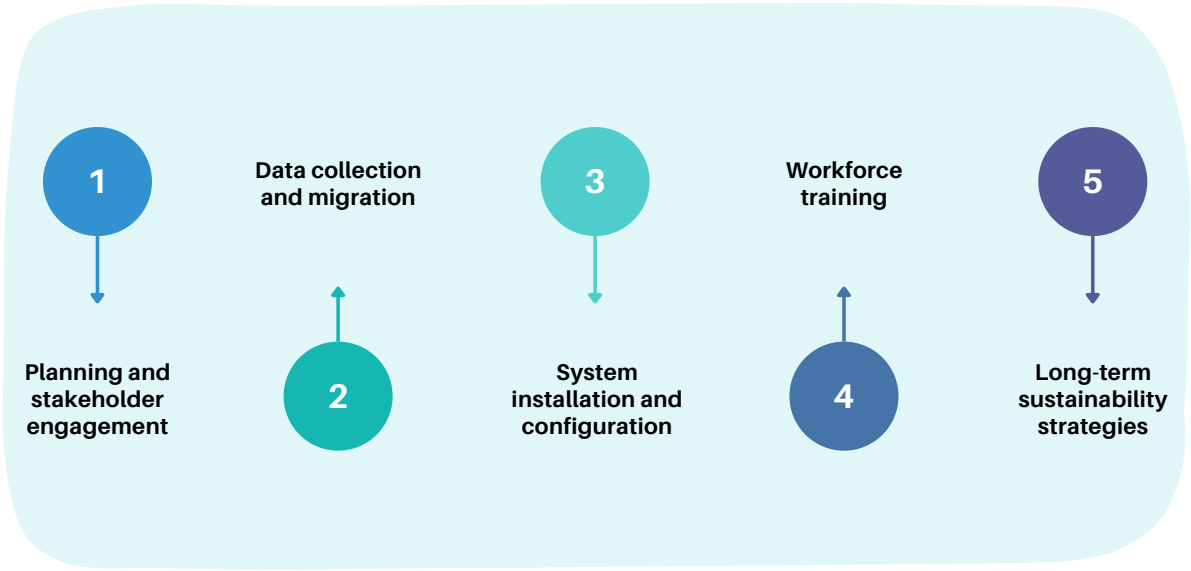
As for selection, the success of the system depends on factors including financial resources, technical expertise, regulatory requirements and the specific requirements of the health-care facility. Once a system has been chosen, a strategy for implementation is essential to ensure effective institutional HTM.

11. Strategies for effective implementation of an IMMS

Use of an IMMS for medical devices in health-care settings is not merely a technological upgrade but a comprehensive transformation to optimize processes, with cultural change and continuous education. Implementation of new technology is most effective when guided by a structured approach. Without a clear process, organizations risk failed pilot tests, user dissatisfaction or even patient harm. To avoid such outcomes, health-care and health technology managers should follow defined phases to ensure thorough planning, stakeholder alignment and continuous improvement.

Implementation of an IMMS for medical devices requires alignment of technology, people and work procedures. This section presents an implementation strategy for facilities, comprising planning and stakeholder engagement, data collection and migration, system installation and configuration, workforce training and long-term sustainability strategies (Fig. 15). Additionally, “canvases” can be used for teamwork, with collaborative tools to facilitate smooth transitions and encourage ownership, accountability and engagement of health-care professionals.

Fig. 15. *Strategies for implementation of an IMMS for medical devices*



11.1 Planning the implementation

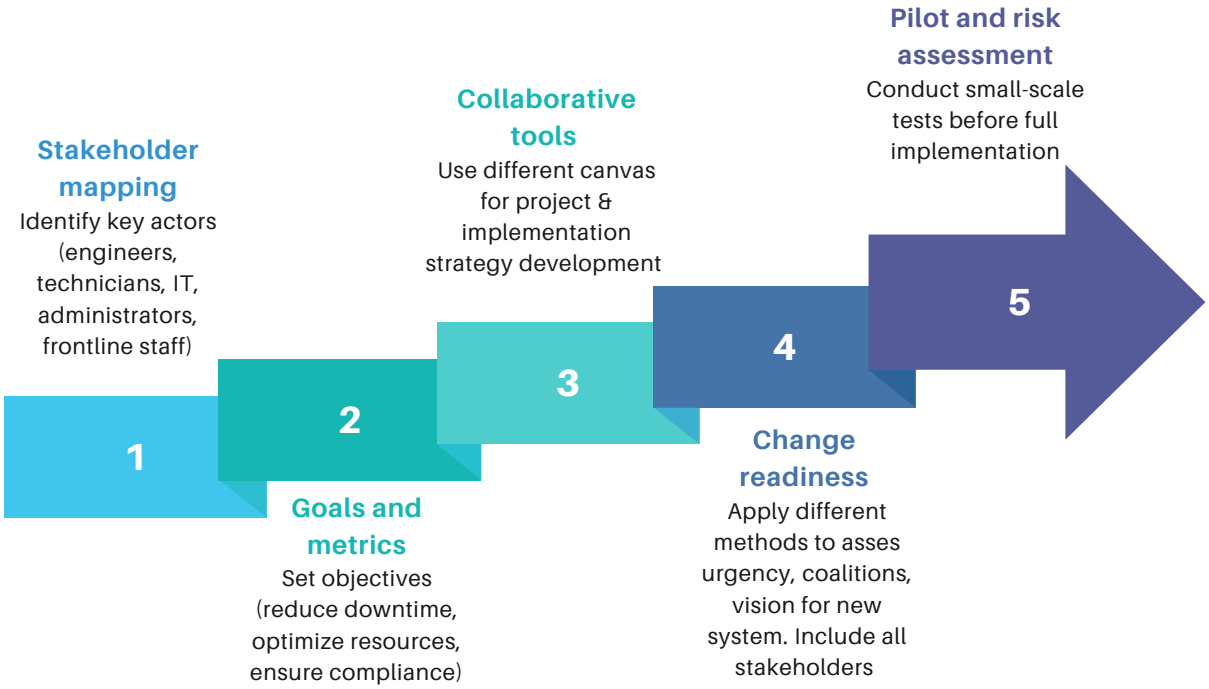
Just as in the procurement planning phase, a well-executed implementation starts with careful planning and active involvement of all relevant stakeholders. As stated before, healthcare inventory and maintenance management systems for medical devices impact multiple departments, including biomedical/clinical engineering, procurement, clinical staff, IT, and healthcare institution administration, therefore, an inclusive approach is critical to identify key needs, set clear expectations, and secure institutional buy-in.

Commitment of the leadership of the health-care facility and clear biomedical and clinical engineering policies are essential. When health-care facility executives and clinical leaders endorse a system, allocate budget for it and expect regular reports, its use is non-negotiable. When the IMMS is an integral part of the organization's operations (e.g. by requiring that all device requests and maintenance be logged in it), it will be adopted. Some health-care systems establish governance committees to oversee HTM and monitor the IMMS for medical devices. A supportive policy might include an institutional mandate that no new medical device goes into service until it is entered into the inventory system and inspected by biomedical staff.

Implementation requires a team of those who will use the system, such as people who make requests and use medical equipment, and those who will use the data; people who use the IMMIS daily to document work completed and equipment being worked on; managers who review data from the system in making decisions; and information technologists, who support the platform. The team should have a project manager to guide them in the phases of implementation *(108)*, such as data migration, system configuration, user training, pilot testing and deployment, with defined deliverables and timelines according to organizational priorities.

The team should define the objectives and scope of the implementation strategy to ensure alignment with the goals of the organization. This will also clarify the goals, expectations and challenges of the project and help organizations to allocate resources appropriately to ensure that the necessary investments are made to achieve the desired outcomes. In defining the objectives and scope, a list of KPIs could be established to ensure that the system that is selected addresses the measures considered important by the organization *(109)*. The KPIs could include mean time between failures, completion of PM, productivity and the cost of the device life cycle. Fig. 16 presents the steps involved in planning.

Fig. 16. *Steps in planning implementation of an IMMS*



A detailed timeline is then set, with flexibility for unforeseen challenges. It should include dates, milestones and individual assignments. A business case or project plan will ensure that the team considers the expected benefits versus the costs and risks. Pilot studies or literature reviews of similar projects might be used in a feasibility analysis to anticipate challenges. This phase consists of designing the model that will ensure that the innovation is successful in practice. Frameworks such as business or programme planning canvases may be useful to ensure that all critical components have been considered. These include *(110-113)*:

- stakeholder map canvas: visual tool for categorizing stakeholders according to their influence, interests and responsibilities in the project;
- goals and success metrics canvas: a structured board for aligning team members on outcomes, milestones and risk mitigation strategies;
- change readiness canvas: a framework for assessing organizational readiness for adoption, challenges and interventions;
- risk management canvas: used to identify, prioritize and mitigate risks associated with a technology, training and adaptation;
- business model canvas: a strategic planning tool that provides a one-page overview of how the solution will create, deliver and capture value, with nine building blocks: key partners, key activities, key resources, value propositions, groups of customers (or patients), customer relations, channels, cost structure and revenue streams;
- value proposition canvas: a framework for the value proposition and the customer segment of the business model canvas to ensure a strong product–market (or product–patient) match;
- feasibility study and risk assessment: evaluations of technological feasibility (with current technology and infrastructure), operational feasibility (with current staff and systems) and economic feasibility (cost–benefit projections); and
- project planning and management tools: Gantt charts or project management software (such as MS Project, Trello or Asana) for practical project management, to map tasks, timelines and responsibilities.

Clear milestones must be set for instance for prototype completion, pilot testing and deliverables, with a communication plan and governance structure (who will oversee the project, how often the team meets, how progress is reported). These ensure that the project is on schedule and within its scope.

By the end of this phase, the team should have a comprehensive implementation plan and a verified business model for implementation. All major questions about how to proceed should have been asked and answered: the resources are secured, stakeholder roles are defined, and the value proposition is solid. Essentially, this phase translates the innovative idea into an actionable blueprint, increasing confidence that the project is feasible and worth pursuing before implementation begins.

11.2 Data collection and migration

The effectiveness of an IMMIS for medical devices requires high-quality, standardized data that are accurate and consistent for tracking equipment status, planning maintenance schedules and ensuring regulatory compliance.

Organizations that are implementing an IMMS for the first time often have fragmented, inconsistent data, incomplete or outdated information on assets, no unique identifiers, no interoperability among systems and resistance of the workforce to change. For such organizations, the first step is a comprehensive asset audit to ensure that all medical equipment is properly documented and recorded, with standard conventions (e.g. location codes, equipment names, manufacturer names) to avoid duplication and confusion in the database. A standardized coding scheme for assets and ensuring that everyone follows it will improve data quality markedly. Important aspect in this process is data cleaning. This includes standardizing records by using consistent naming conventions, eliminating duplicate entries and filling in missing information. If the organization has no structured inventory, assets should be categorized according to their age, frequency of use and maintenance requirements to provide a clear strategy for planning future maintenance and equipment replacement.

As the second step, the detailed data structure of the system should be ascertained, and members of the project team or an additional ad-hoc team should be assigned to collect data on systematic forms *(105,107)*. The forms may include the departments in which assets are located or in which work is performed, the employees who perform the work and risk evaluations. A physical inventory check should be conducted to ensure that every asset is accounted for in the system. Once the asset list is completed, standardized data fields should be used to maintain consistency among records. Well-structured data entry and validation must be ensured to maintain data integrity.

For organizations that are changing from an existing CMMS, one benefit of using a dedicated system is the possibility for standardizing the recording of data on equipment and maintenance. Any errors in the data, such as mis-formatting, misspelling or incomplete records, should be corrected. Migration of a system also requires detailed mapping from the current CMMS to the fields in the new system. Data cleaning, during migration or data collection, ensures the overall quality of the system. (See also Annex 1.) For example, a control number used in the current system may be referred to as an "asset tag" in the new system. Mapping ensures that the fields in the new system are used properly. Maintenance and quality control should also be standardized. For instance, use of the system's libraries to define PM protocols for each device type ensures consistency in how work is performed and logged. Standardization not only facilitates day-to-day management but also enables meaningful analysis of data, such as comparing the performance of different departments or tracking failure rates by device model.

A plan for data migration and system configuration should be developed with the vendor or producer (for custom-built systems) to ensure smooth transfer and alignment with maintenance. The tools that could be used include *(114-117)*:

- data collection blueprint canvas: a structured sheet that defines the data to be collected, by whom and steps for validation;
- medical device categorization canvas: a structured board used to group devices according to function, regulatory classification and maintenance requirements;
- data cleaning checklist canvas: a visual checklist for validating data accuracy, completeness and integrity before migration; and
- data migration planning canvas: sheet for step-by-step data transfer, testing and troubleshooting.

11.3 System installation and configuration

Implementation of an IMMIS in a health-care setting should be strategic and phased to minimize risk and ensure a seamless transition. Gradual deployment, such as beginning with a pilot phase in a single department or for a specific category of medical devices, allows identification and resolution of technical issues, inefficient workflow and gaps in user training before adoption. A pilot phase may demonstrate successes, which can be used to demonstrate the value of the system to stakeholders and encourage broader organizational buy-in. Step-by-step implementation prevents overloading maintenance teams, so that they can manage data entry, verification and workflow adjustments in controlled stages. A good practice is to establish continuous feedback during the pilot phase, collecting real-time user feedback, monitoring system performance and making the necessary adjustments to ensure that the system is more intuitive and user-friendly before full deployment.

To ensure smooth, effective implementation, the system must be properly configured after installation. This comprises four key aspects: establishing access controls, automating maintenance schedules, integration with existing systems and optimizing user interfaces to improve usability and efficiency.

1. User roles and access control
   - Define user roles and permissions to regulate system access according to responsibilities.
   - Ensure role-based security measures to prevent unauthorized modifications or data breaches.
2. Automating PM
   - Configure automated alerts and maintenance schedules according to the manufacturer's recommendations.
   - Use real-time monitoring tools to track the condition of assets and predict maintenance requirements.
3. Standard Operating Procedures (SOPs) development
   - Establish clear protocols for asset registration, maintenance logging and performance reporting to ensure data consistency and regulatory compliance.
   - Adapt SOPs to institutional policies and best practices for inventory and maintenance management.
4. System integration with other platforms
   - Ensure that the new IMMIS is integrated seamlessly with procurement, finance and compliance management systems.
   - Test automated work order generation and real-time asset tracking to increase efficiency.

The choice of data entry tools significantly impacts the system usability and operational efficiency. Different hardware platforms offer different advantages, and careful consideration must be given to selecting the most suitable devices. These include:

- desktop computers: best for bulk data entry and advanced reporting but limited portability;
- laptop computers: offer flexibility and screen space; ideal for mobile maintenance teams;
- tablets: provide a balance between portability and usability, making them effective for on-site inspections; and
- cellular phones: useful for real-time updates, scanning QR codes and photographic records, although they may require additional scrolling because of their smaller screens.

Organizations should evaluate the hardware capabilities and compatibility of their infrastructure before finalizing system configuration *(118)*. In selecting a system, it should be evaluated on current hardware to understand its performance and limitations. Configuration of the system should be completed directly after its installation and testing. Any custom field names should be defined and values assigned. User configuration and security should be installed and tested to ensure that they work as designed. Testing of user acceptability ensures that the system meets their requirements and is ready for use.

11.4 Workforce training

Technology is only as effective as the people who use it. A major challenge in using new systems is overcoming resistance to change, fear of complexity and lack of familiarity with digital workflows. The implementation plan should therefore include comprehensive training for various users, with classroom sessions and practical training. Training programmes should be customized to different users, with hands-on practice, user-friendly interfaces and problem-solving scenarios. Proper training of users is one of the most important aspects of implementation of IMMIS. Users must not only understand how to use the system but must also be aware of the established SOPs for its use, including the importance of high-quality data. A detailed training plan will contribute to effective, efficient use of the system. If profiles of customers, users and managers have been established, detailed training plans should be made for each.

It is advisable to plan a pilot test of the system with representative users and facilities to gain feedback on usability and performance and to revise the system and training materials accordingly. A training site and materials will be required. Users should be trained in using the tools that will be used at the desk or in the field, such as a desktop or mobile application, to ensure retention of the training. The training should include realistic scenarios and assessments. The material should be divided into modules that could address unscheduled and scheduled work orders, equipment inventory management and reporting. Consideration should be given to recording the training sessions for new staff and to providing refresher training on use of the system *(119,120)*. The tools that could be used include *(121,124):*

- training needs analysis canvas: a structured framework for identifying who needs training, in what and the best method to be used;
- learning journey canvas: a system for measuring progress, skill acquisition and certification milestones;
- peer learning canvas: a board for organizing mentorship programmes and internal knowledge transfer; and
- user adoption and engagement canvas: a structured framework for ensuring psychological readiness and engagement.

11.5 Sustaining the system for long-term impact

Good implementation involves not only deployment but ensuring long-term sustainability through strategic transformation to ensure continuous optimization and user engagement. Without ongoing support, evaluation and optimization, even the most advanced systems risk becoming obsolete or underused. Many systems fail not because of technological limitations but due to organizational inertia, lack of accountability and insufficient long-term planning.

To ensure that an IMMIS has a lasting impact, health-care institutions must include policy-driven governance, adaptive technology, financial sustainability and a culture of continuous improvement. Governance provides the structure within which IMMIS operates. Policies ensure consistency, set expectations and create accountability. Without clear governance, data entry becomes inconsistent, maintenance schedules lose their reliability, and compliance with regulatory standards becomes a matter of chance rather than design. Establishing SOPs, defining user roles and integrating compliance requirements into the system ensure that medical device management is both structured and enforceable. Governance must be embedded in daily workflows with health-care facility leadership and reinforced by a culture in which adherence is non-negotiable. IMMIS must also be adaptive, capable of evolving with advances in health-care technology, changes in regulatory frameworks and the shifting needs of the organization. A system that cannot integrate EHRs, procurement software or financial systems will soon be an administrative burden rather than a solution. Interoperability is a necessity. Cloud-based solutions offer scalability, while AI-driven PdM reduces downtime and optimizes resource allocation. The ability to customize fields, automate work orders and conduct real-time analysis transforms IMMIS from a passive database into a dynamic decision-making tool.

Financial sustainability is the anchor that keeps IMMIS operational long after initial implementation. The true cost of IMMIS is not in its licensing fees but in the resources required to maintain its integrity. Without proper budget allocation for system updates, cybersecurity and user training, a once-promising platform can quickly become outdated, vulnerable and ineffective. The institutions that derive the most value from IMMIS are those that view it not as an expense but as a means for cost savings, efficiency and risk mitigation. A well-maintained system reduces equipment downtime, prevents unnecessary purchases and ensures compliance with financial and regulatory reporting requirements, thus ultimately paying for itself over time.

Perhaps the most critical element of a successful IMMIS is a culture of continuous improvement. Technology alone cannot drive change; it is the people who use it, refine it and challenge it to perform better who do so. Regular performance reviews, staff feedback and iterative system updates ensure that IMMIS remains relevant, user-friendly and aligned with the organization's evolving needs. The most effective medical device management systems are living frameworks that can be adapted to new regulatory demands, integrate emerging technologies and respond to real-world usage patterns.

The tools that could be used include:

- policy integration canvas: a structured plan for aligning inventory and maintenance processes with institutional frameworks;
- continuous system optimization canvas: a feedback-based board to track issues reported by users, enhancements and periodic evaluations;
- KPI dashboard canvas: structured visualization of ongoing performance tracking and improvements; and
- continuous improvement board: a collaborative tool for documenting process optimization, lessons learnt and suggested innovations.

11.6 Regional and national perspectives

An IMMIS is implemented regionally and nationally according to the same steps as for facilities. The objectives, scope and implementation teams are, however, different because of the broader policy, regulatory and coordination requirements. The project extends beyond individual health-care facilities to ensuring system-wide interoperability, compliance with national health policies and accreditation of QMS. Table 12 presents examples of national inventories for which management software is used for efficient data organization and tracking.

Table 12. *Examples of national inventories in which management software is used*

Country	Types of inventory used	Software *(125)*
Austria	National inventory only for high-cost technologies (such as MRI, computed tomography and positron emission tomography [PET] scanners)	Various: e.g. MTECS, Visual FM, SAP
Belarus	National inventory for medical equipment	None
Benin	National inventory only for high-cost technologies (such as MRI, CT and PET scanners)	G-MAINT software, developed in Benin and being tested in some hospitals
Bosnia and Herzegovina	National inventory for medical equipment	eLab
Burkina Faso	National functional inventory for medical equipment	PLAMAHS (heart consultancy)
Cambodia	National functional inventory for medical equipment	MEDEMIS
Costa Rica	National inventory for medical equipment	Visual Basic 6.0, Base de datos SQL Server 2005 and Access
Cuba	National functional inventory for medical equipment	Sistema de Gestión para la Ingeniería Clínica y Electromedicina
Denmark	National inventory for medical equipment	Several: e.g. MEDUSA, MERIDA, QAMAP, REMEDY
Ethiopia	National inventory for medical equipment	Medical Equipment Management Information System
Fiji	National functional inventory for medical equipment	EMS, EPICOR
Gambia	National inventory for medical equipment	AIMS program from Phoenix Data Systems Inc.
Greece	National inventory only for high-cost technologies (such as MRI, CT and PET scanners)	Praxis, developed by the Institute of Biomedical Technology
Grenada	National inventory for medical equipment	Medical device management system software
Haiti		GMAO
Honduras	National inventory for medical equipment	SIAFI

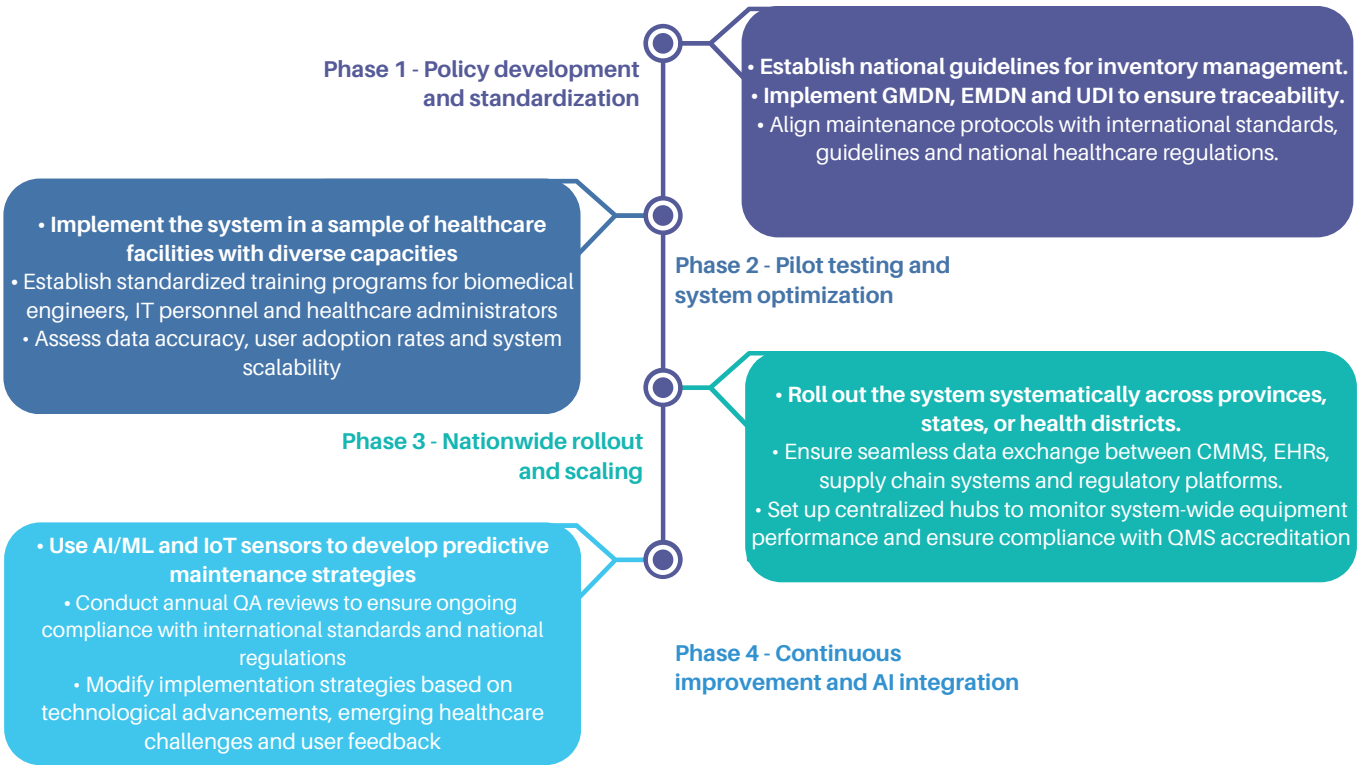
Country	Types of inventory used	Software *(125)*
Hungary	National inventory only for high-cost technologies (such as MRI, CT and PET scanners)	CT-EcoSTAT
Kyrgyzstan	National inventory for medical equipment	National database for public health medical facilities
Luxembourg	National inventory only for high-cost technologies (such as MRI, CT and PET scanners)	
Malaysia	National inventory for medical equipment	Central Management Information System
Malta	National inventory for medical equipment	Clingo
Morocco	National inventory for medical equipment	Up Manager Praxis
Mozambique	National inventory only for high-cost technologies (such as MRI, CT and PET scanners)	Simorganizer
Namibia	National inventory for medical equipment	Medical Equipment Management System Software
Oman	National inventory for medical equipment	Al Shifa
Qatar	National functional inventory for medical equipment	AssetPlus (GE)
Senegal	National inventory for medical equipment	Système de gestion de la maintenance assistée par ordinateur
Sri Lanka	National inventory only for high-cost technologies (such as MRI, CT and PET scanners)	VH Temp
Thailand	National inventory for medical equipment	RMC2005
Trinidad and Tobago	National inventory only for high-cost technologies (diagnostic Imaging)	WebTMA
Uganda	National functional inventory for medical equipment	New order for managing anything data

While the primary goals of inventory and maintenance management remain the same at all levels, regional and national implementation has additional objectives, to:

- ensure consistent medical device classification, maintenance protocols and reporting in many facilities;
- facilitate equipment redistribution among regions to prevent shortages and maximize use; and
- establish a real-time national monitoring system for crisis response and disaster preparedness.

National and regional implementation teams include health policymakers, regulatory authorities, IT experts, biomedical engineers and health-care administrators. Implementation is conducted in several stages and phases, as shown in Fig. 17.

Fig. 17. *Implementation of regional and national IMMS*



11.7 Practical insights into medical device inventory management

The first step is compilation of an inventory of all medical equipment. Sufficient resources must be allocated for collection of data and for the appropriate computer hardware and software. A team including a user with knowledge of the equipment and a clinical engineer responsible for inventory management visits each department in the facility and records details of every piece of equipment to be included in the inventory. Finding all equipment may include opening drawers, cupboards and storerooms. In many facilities, this may identify equipment that is obsolete or irreparable, which can be disposed of. For a new health-care facility, data should be collected before the facility is put into operation. This will ensure that good records are kept from the beginning. The collected data are compiled and entered into a computer-based inventory management system.

Although it may take only a few minutes to enter data, locating all the devices to be included can take much longer. If a device is in clinical use, it may be necessary to negotiate with clinical staff to gain access between uses.

A pilot inventory of 25 devices could be drawn up and the time required be used to calculate the staffing necessary to collect data for the entire inventory. The number of devices for which data must be collected will change as the inventory progresses. UDI scanners improve inventory management by automating data entry, reducing errors and saving time. Locating and documenting medical devices manually is time-consuming, especially when they are in clinical use. Scanners allow rapid, accurate data capture, minimizing disruptions and ensuring up-to-date records.

Consideration should be given to the experience of the personnel assigned to take the inventory. Use of students or unskilled staff will produce poor results, as the person taking the inventory must understand the function of the device that is being documented to ensure a correct description. Good relations with clinical staff and explanation of the importance of recording data on each device will minimize obstacles.

An inventory is effective only when it is comprehensive and accurate. It must therefore be updated for every change or addition and during annual audits and reviews. When a new piece of equipment is purchased or donated, the relevant information should be entered into the inventory before it is used. Equipment that is leased or borrowed for a long time should also be entered. Records of equipment already listed in the inventory should be updated if there are any changes.

The clinical engineering department should review the medical equipment inventory every year to check that all the information is accurate and to make any changes. As it might be onerous to verify every device each year, a sample of the inventory could be chosen for verification each year.

Once most of the data for an inventory have been collected, collection of maintenance data can begin. Maintenance data are linked by the unique ID number of each device. The data that could be recorded in the system for both scheduled and unscheduled maintenance are:

- the date the problem was reported or the scheduled maintenance date;
- the reported problem or requested work;
- problem(s) found, with use errors, as applicable;
- a succinct description of the maintenance performed, including "followed approved scheduled maintenance procedure", if applicable;
- functional check results;
- electrical safety check results;
- entry of parts and labour associated with work performed;
- date of completion of work order;
- failure code;
- cost of replaced parts; and
- date returned to service.

Data from the inventory and on maintenance in IMMIS are the basis for many decisions. The initial data are highly valuable and would be very costly to replace if they were lost due to hardware failure or a malware attack, and back-ups onto the Cloud are recommended. Another solution to avoid data loss might be a "store and forward" system on a local server or device. As a last resort, if Cloud back-up is not possible, is weekly back-ups onto removable media such as a USB memory stick.

12. Conclusion

The future of healthcare is not just smart, but wise, not just efficient, but strategic, not just automated, but human-centered.

At the intersection of health-care technology and digital transformation, the way in which medical devices are tracked, maintained and managed will define the future of patient care. Reactive maintenance, siloed inventory systems and fragmented data are outdated. The future is driven by intelligent automation, predictive analysis and seamless interoperability, in which health-care systems are proactive and are only as strong as the intelligence behind them. The future of inventory and maintenance management comprises not only automation, efficiency or even predictive analysis but also critical thinking, strategic collaboration and data-based decision-making. In an era of unprecedented technological advances, success will not be due only to simple collection of data but to questioning it, analysing it and acting on it with precision and purpose.

This publication lays the foundation for understanding IMMS as a strategic pillar of health-care efficiency. From structured inventory management to advanced AI-based maintenance strategies, evolution of medical equipment management is an imperative. Without a proactive, intelligent approach, even the most advanced equipment can fail when needed most and risk becoming a liability rather than an asset.

What must change?

Health-care institutions, policymakers and technology leaders must no longer view inventory and maintenance management as administrative burdens but as leading to better patient care. They must move beyond reactive maintenance and fragmented inventory systems and:

- champion critical thinking, encouraging professionals to ask questions and integrate real-time data analysis into their operations and use IoT sensors and AI to predict failures before they occur;
- foster collaboration among biomedical engineers, IT specialists, clinicians and policymakers to design inventory and maintenance ecosystems;
- integrate real-time analysis, AI and IoT to make maintenance predictive rather than reactive;
- standardize inventory protocols, adopting globally recognized nomenclature (GMDN, EMDN) to ensure transparency; and
- invest in human capital and continuous learning to ensure that the workforce is equipped with both technical knowledge and analytical skills to interpret data and make strategic decisions.

A fully integrated IMMIS is more than just a software platform—it is a living system that evolves with the needs of health-care professionals and patients. But even the most sophisticated technologies are meaningless without the people who drive them. The institutions that thrive in the next decade will be those that foster intellectual curiosity, encourage collaboration and demand evidence-based action.

At the heart of this transformation is a simple but powerful reality: trust is earned through data, and progress is made through collective wisdom. Health-care decisions have life-and-death consequences, and we must challenge assumptions, demand transparency and build systems that "think" as critically as the people who run them.

The strategies described in this book are a blueprint for a more efficient, reliable, intelligent health-care ecosystem. The challenge ahead is to revolutionize the foundation of health-care delivery through digital transformation, investment in sustainability and ensuring that medical devices are a catalyst for innovation.

What matters most is the patient

Every decision made and every technology used must serve the patient's needs first. IMMIS ensures not only management of inventory and maintenance, but assurance that that every patient receives safe, high-quality care.

IMMIS is more than a system: it is a commitment to ensure that technology, whether simple or complex, is available, reliable and ready.

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Annex 1. Migration of data

Asset information (inventory):

- Asset name, description category, and status
  - » Nomenclature
  - » UDI, which includes type of device and production identification
- Serial numbers, model and barcodes (if applicable)
- Asset nomenclature and classification information
- Purchase date, warranty information and expected life cycle
- Purchase cost
- Installation date
- Contract information
- Vendor name
- Location and "parent–child" relations (for hierarchical assets)
- Attachments such as manuals, schemes and images

Work orders:

- Work order number and status (open, closed, in progress)
- Description of the work and detailed task lists
- Priority levels and deadlines
- Assigned technicians and labour hours
- Costs associated with labour, parts and other expenses

Maintenance schedules:

- PM plans
- Inspection checklists
- Safety and performance inspection report
- Frequency for scheduled tasks

Spare parts:

- Part names and descriptions
- Stock levels, reorder points and reorder quantities
- Supplier information and purchasing details
- Storage locations
- Link to equipment model
- Price and date purchased

Maintenance history:

- Maintenance activities performed
- Dates, times and results of the activities
- Downtime records and reasons for downtime
- Safety and performance inspection report history

Vendor and supplier information:

- Contact details
- Contract terms, expiration dates and associated documents

Personnel data:

- Technician profiles, certifications and specialties
- Training records
- User profiles, roles and access rights

Financial

- Maintenance budgets and forecasts
- Actual expenses

Reports and dashboards:

- Saved report templates
- Historical reports and analysis
- KPIs and metrics

Maintenance requests:

- Requester details, date and urgency
- Description of problem or need
- Resolution status and completion notes

Safety and compliance data:

- Safety checklists and protocols
- Compliance certificates and expiration dates
- Records of safety incidents or violations

User customizations and settings:

- Custom fields or attributes
- Alerts, notifications and communication templates

Documentation and media:

- Images, videos or audio clips related to assets or maintenance activities
- Technical manuals, guidelines or procedural documents

Annex 2. Reporting

Asset management reports

- Asset life cycle analysis
- Total cost of ownership of each asset
- Percentages of asset downtime and uptime
- List of equipment by health facility, department or manufacturer
- Medical devices recalls

Work order reports

- Open or closed work orders
- Average time to complete work orders

PM reports

- PM compliance rate (completed vs planned PM tasks)
- Overdue PM tasks
- Planned PM schedule

Safety and PM reports

- Compliance rate (checked parameters and their compliance to requirements)
- Planned inspections

Spare parts reports

- Stock level and reorder reports
- Inventory turnover rate

Labour and technician reports

- Labour hours by technician
- Technician efficiency
- Overtime reports
- Training and certification status of technicians

Cost analysis reports

- Maintenance cost by asset or department
- Labour cost vs parts cost
- Budget vs actual maintenance expenditure
- Cost of service ratio (maintenance cost vs equipment value)

Downtime analysis

- Average downtime per asset or department
- Root cause analysis of frequent downtimes

Vendor and supplier reports

- Supplier performance ratings
- Cost analysis per vendor

Warranty claims reports

- Maintenance request reports
- Open vs closed maintenance requests
- Average response time to requests
- Source or department generating the most requests

KPI dashboards:

- Mean time between failures
- Equipment reliability metrics
- Maintenance frequency

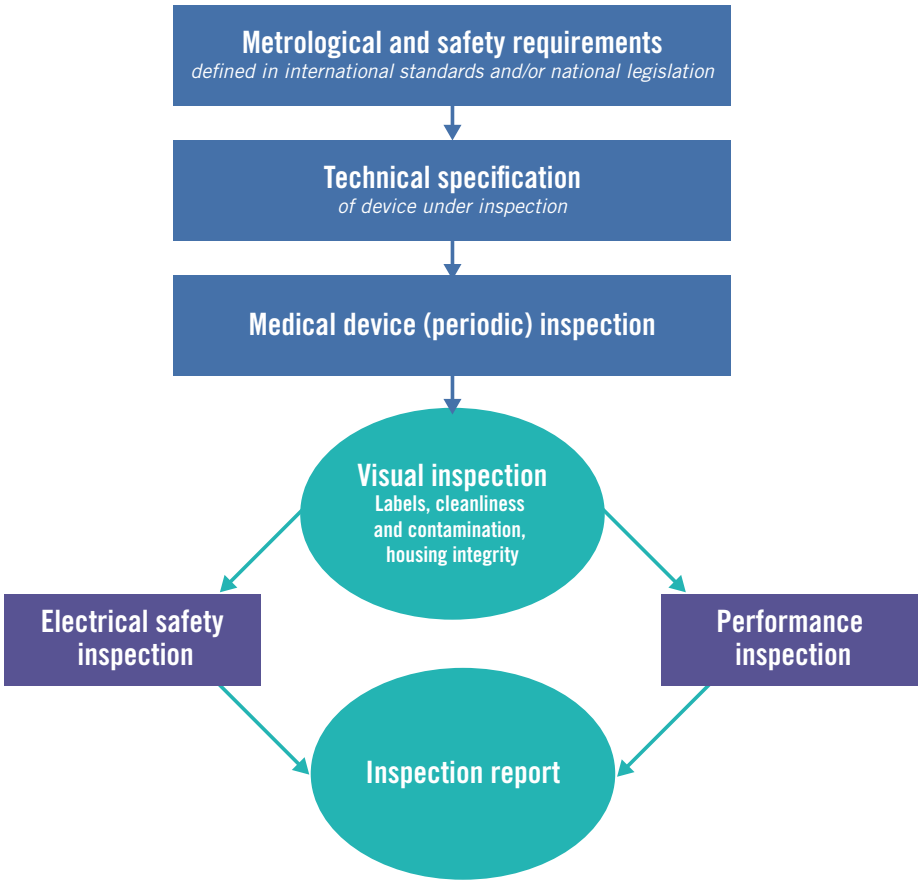
Failure analysis reports:

- Failure codes and their frequency
- Assets with the most frequent failures

Annex 3. Example of an SOP for inspection of medical device performance

The inspection procedure described in ISO 17020 presents the steps for inspecting the electrical safety and performance of infant incubators. The procedure consists of visual inspection, safety inspection and performance inspection (Fig. A3.1).

Fig. A3.1. *Procedure for inspection of a medical device*



Source: Medical Device Inspection Laboratory Verlab Ltd.

The SOP is structured as follows:

0. Foreword
1. Scope
2. Normative references
3. Terms and definitions
  3.1. Terms
  3.2. Definitions
4. Authorizations and responsibilities
5. Metrological and technical requirements for infant incubators
6. Inspection procedure
  6.1. Assessment of fitness for inspection
  6.2. Visual inspection

6.2.1. Inspection of cleanliness
6.2.2. Inspection of integrity
6.2.3. Inspection of markings
6.3. Inspection of electrical safety
6.3.1. Connecting and disconnecting the etalon from the infant incubator
6.4. Performance Inspection
6.4.1. Connecting and disconnecting the etalon from the infant incubator
6.5. Inspection report and certificate

Visual inspection

A visual inspection is conducted before inspection of electrical safety and performance. Although this step is not clearly defined in IEC 60601 *(1)*, it is an essential aspect of general safety inspection, as 70% of failures are detected during visual inspection of devices. During visual inspection, the inspector checks whether the device still conforms to the manufacturer's specification and has no external damage and/or contamination of the power supply, buttons, knobs, display or other visible parts. The integrity of the casing is checked, as well as device labels and the functionality or obstruction of moving parts. The device is checked for all appropriate connectors, such as temperature probes, relative humidity modules and skin sensors in the case of infant incubators.

Electrical safety inspection

The infant incubator is connected to an electrical safety analyser (etalon) through a power cord, and an automated test is conducted according to IEC 60601. Testing is conducted of mains voltage (live to neutral, neutral to earth, live to earth), protective earth resistance, insulation resistance (normal condition, mains to protective earth), earth leakage current (applied parts and normal condition, open neutral, normal condition – reversed mains, open neutral – reversed mains), enclosure leakage current (applied parts, normal condition, open neutral, normal condition – reversed mains, normal condition – reversed mains, open earth – reversed mains), and leakage of current from parts applied to the patient.

Performance inspection

Performance inspection is conducted with a multi-parameter analyser (etalon). Temperature, relative humidity and sound performance are evaluated by measurements at five points, with calculation of absolute or relative error. The values are then compared with standard values that represent the technical and metrological requirements for infant incubators defined by the manufacturer, international standards and regulations for medical devices. A decision is made and a conformity assessment statement generated. If the calculated error at all measuring points was inside the permitted error ranges, the device is considered to be accurate. If the measurement error at one or more points is outside of the permitted range, the device is faulty.

As not all infant incubators have controlled relative humidity, for such devices only temperature and noise are measured. All results are recorded and stored in a database to document each step of the inspection, a crucial requirement for ensuring traceability. The inspection thus consists of the following steps.

1. Visually inspect the incubator. Record the device manufacturer, model and serial number.
2. Test electrical safety.
3. Set up the etalon for measurement according to the device procedure. Connect the etalon to the power supply if necessary.
4. Place the etalon in the incubator, and close the incubator door.

5. Adjust the air temperature in the incubator to the initial measurement temperature (30 °C).
6. If relative humidity can be measured, the percentage should be set, with use of distilled water.
7. When the incubator reaches a set temperature, wait 5 min before recording of measured values from all sensors.
8. Set the incubator temperature to the next measurement point and wait a minimum of 10 min and a maximum of 15 min until the incubator reaches the required temperature. The increment is 1 °C.
9. Repeat the procedure until the air temperature has been recorded at all six measuring points.
10. If the incubator has skin temperature probes, change to servo control mode, which is regulated by skin temperature.
11. Set the skin temperature.
12. Wait a minimum of 10 min and a maximum of 15 min until the incubator reaches a set temperature.
13. Make recordings after 5 min.
14. Repeat the procedure for all measuring points. Note: The last measuring point should be at 37 °C to test any overshoot of the device. The temperature should not exceed the permissible error.
15. Verify the alarm systems by exposing the device sensors to unusually high and low temperatures and air circulation.
16. When the alarm is activated, check for noise in the incubator chamber.
17. When the inspection is finished, ensure that everything is in its original place. Remove the etalon from the incubator.
18. Analyse the results, and deliver the conclusion of the inspection.
19. If the result is “Pass”, mark the incubator with an inspection label. If the inspection result is “Fail”, place a red sticker on the incubator, stating “NOT FOR USE”.
20. Provide the results of the inspection to medical and technical professionals.

Reference

1. IEC 60601. Medical electrical equipment. Geneva: International Electrotechnical Commission; 2015 (https://www.iso.org/standard/65529.html).

Annex 4. Survey for developers and users of CMMS

During preparation of this publication, the Verlab Institute team sent a comprehensive survey to developers and users of CMMSs. The questions are listed below. The results are updated regularly and published on the official website of the Verlab Institute to ensure that the data remain relevant.

1. Name of CMMS
2. Vendor
3. How would you rate the user-friendliness of the CMMS interface when used by clinical engineering and health technology assessment professionals?
   a. Very difficult to use
   b. Somewhat difficult to use
   c. Neutral
   d. Somewhat easy to use
   e. Very easy to use
4. How would you rate the user-friendliness of the CMMS interface for health-care professionals?
   a. Very difficult to use
   b. Somewhat difficult to use
   c. Neutral
   d. Somewhat easy to use
   e. Very easy to use
5. How effective is the integration of the inventory management and nomenclature systems in the CMMS?
   a. Not at all effective
   b. Slightly effective
   c. Moderately effective
   d. Very effective
   e. Extremely effective
6. Which nomenclature system is used in the CMMS for inventory management and item categorization?
   a. None
   b. EMDN
   c. GMDN
   d. UMDNS
   e. National classification of medical devices
   f. Internally developed
7. Where are data primarily stored in the CMMS?
   a. Locally on premises
   b. Cloud-based
   c. Hybrid (both locally and on Cloud)

8. Which of the following services does the CMMS offer? (Select all that apply)
    a. Asset management
    b. Preventive maintenance scheduling
    c. Work order management
    d. Inventory control
    e. Other (please specify)
9. Does the CMMS offer online and offline functionality?
    a. Online only
    b. Offline only
    c. Both online and offline
10. What type of pricing model does your CMMS follow?
    a. Free
    b. One-time purchase
    c. Subscription-based (monthly, annually)
11. In which language(s) is the CMMS available?
    a. English
    b. French
    c. Spanish
    d. Chinese
    e. Arabic
    f. Russian
    g. Other or local (please specify)
12. Does the CMMS have multi-language ability?
    a. Yes
    b. No
13. How would you rate the cybersecurity measures in the CMMS?
    a. Inadequate: The CMMS has minimal or no obvious cybersecurity measures, leaving data highly vulnerable.
    b. Basic: The CMMS has basic cybersecurity measures, but they do not cover all potential vulnerability.
    c. Moderate: The CMMS has a reasonable level of cybersecurity in place, which protects against common threats.
    d. Advanced: The CMMS includes advanced cybersecurity measures, providing comprehensive protection against a wide range of threats.
    e. State-of-the-art: The CMMS has state-of-the-art cybersecurity measures, providing the highest level of protection and continuous adaptation to new threats.
14. Who retains ownership of the data entered into the CMMS?
    a. The user or company
    b. The CMMS provider
    c. Shared ownership

15. Are there any fees or restrictions if you decide to export your data from the CMMS to another system?
    a. No fees or restrictions
    b. Fees apply
    c. Restrictions apply
    d. Both fees and restrictions apply
16. Is the CMMS specific to a hospital, or can it be used on a wider scale?
    a. Specific for a hospital
    b. Can be used in several institutions
17. How are data imported into the system?
    a. Manually
    b. Automatically with import tools
    c. Integrated with EHR or electronic medical record systems
    d. Other (Please specify: _____)
18. What is the system's capability for integration with data systems at health-care facilities?
    a. Full support
    b. Partial support
    c. Limited support
    d. No support
19. Are there any compliance requirements for using this CMMS?
    a. Health Insurance Portability and Accountability Act
    b. General Data Protection Regulation
    c. No specific compliance requirements
    d. Other (Please specify: _____)
20. How does the CMMS contribute to the sustainability of public health and private health payers?
    a. Cost-effective maintenance solutions
    b. Improved operational efficiency
    c. Enhanced patient care and safety
    d. Customizable reporting for financial Optimization
    e. No direct impact on payer sustainability
    f. Other (Please specify: _____)

Please list the countries in which the CMMS is used.

If you are interested in contributing to the survey, find a link on https://cmms.verlabinstitute.com or directly by email to info@verlabinstitute.com.

Annex 5. Procedures that could be integrated into the asset management system of a health-care institution

1. Maintenance strategy

Develop a maintenance strategy that includes PM, corrective maintenance and PdM. Define procedures for each type of maintenance, including schedules, responsibilities and resources required.

2. Policy for the medical device management within health-care facility

- Establish the overall intentions and direction of medical device management aligned with the objectives of the organization.
- Develop a policy that clearly states the principles and mandates of medical device management, including compliance with all applicable regulations, risk management and performance objectives.

3. Procedure for planning medical device management

- Ensure that medical devices continue to fulfill the necessary functions and performance efficiently and cost-effectively.
- Create and maintain medical devices management plans that outline the activities and resources required for managing medical devices throughout their life cycle, including acquisition, use, maintenance and disposal.

4. Procedure for risk management in HTM

- Identify, assess and manage risks associated with medical devices to ensure their safety, reliability and regulatory compliance.
- Ensure risk management that includes risk assessment, mitigation strategies and monitoring plans specific to different types of medical device.
- Continually improve the effectiveness of the asset management system by analysing performance and encouraging feedback.
- Establish a continuous improvement programme that involves regular audits, performance reviews and inclusion of lessons learnt into asset management practices.

5. Procedure for monitoring of performance and condition of medical devices

- Monitor and analyse the performance and condition of medical devices to optimize their use and maintenance.
- Use ISO 17020 medical device inspection protocols to collect real-time data on device performance and condition. Establish thresholds for performance indicators, and schedule reviews and updates according to the data collected.

6. Procedure for analysis of medical device life-cycle costing

- Optimize the total cost of ownership of medical devices by analysing all the costs incurred throughout their life cycle.
- Use life-cycle costing methods to evaluate purchasing decisions, maintenance schedules and timing of replacement or disposal. Analyse data on expenditures and predict future costs for budgeting and investment.

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