



# NATIONAL POLICY ON MANAGEMENT AND MAINTENANCE OF MEDICAL EQUIPMENT AND DEVICES

MINISTRY OF HEALTH AND SANITATION, SIERRA LEONE



# POLICIES AND STRATEGIES FOR THE MANAGEMENT AND MAINTENANCE OF MEDICAL EQUIPMENT AND DEVICES

# MINISTRY OF HEALTH AND SANITATION SIERRA LEONE

FEBRUARY 2021

# **FOREWORD**



I wish to congratulate the management and staff of the MOHS Directorates and staff who have the courage and foresight behind the development of this policies and strategies on management and maintenance of medical equipment and devices.

MOHS is aware of these issues surrounding medical equipment and its effect on quality health care service delivery. However, the issues on these assets are usually not addressed head-on and set aside in favor of the more current and significant health concerns of the health system.

This Policies and Strategies for medical equipment and devices therefore is envisaged to be the framework for a more efficient, effective and coordinated decision-making process in the future. As the intervention of medical technology in the health care system has grown leaps and bounds in unbelievable pace, and its applications are considered a necessity and unparallel in the recent medical history, it becomes clear that policies and strategies for its management and maintenance is the way forward.

However, this Policies and Strategies should not be taken as the 'cure all medicine' for the challenges in this important frontier, but rather, it is our individual and collective actions to look at these challenges with fresh sets of eyes, having in mind this Policies and Strategies - that is expected to make a difference.

It is therefore my expectation that better cooperation, collaboration and coordination among the key players involved in this arena will also be the key outcomes of this Policies and Strategies.

I wish to thank and express my gratitude and sincere appreciation to UNICEF; FCDO, our longtime partner and benefactor, together with other health partners, for spearheading a relentless drive to pursue the development of this Policies and Strategies.

Likewise, to my fellow colleagues in the Government, particularly the MOHS Directorates that are instrumental in the formulation of this document. To name some, DPPI led by Dr. Smart and Dr. Cham and its staff, Dr. Kenneh of RCH and DCMO; the HRH, HSS, the QIP, HAS, the Heads of the Hospital Maintenance Units, the Medical Superintendent, the DHMOs and many other key

Special thanks to other MOHS staff and personnel who have contributed in one way or the other in the finalization of this document.

Rev. Canon ThomasT. Samba Chief, Medical Officer

Ministry of Health

Sierra Leone

# **Table of Contents**

ΑI	3BREV	/IATIONS AND ACRONYMS	3
1.	II	NTRODUCTION	4
	1.1.	Purpose	5
	1.2.	Definitions	5
	1.3.	Scope and limitations	6
2.	S	ITUATIONAL ANALYSIS	6
3.		OLICY AND STRATEGY FRAMEWORK	
4.		GUIDING PRINCIPLES	
٦.	4.1.	Goal	
	4.2.	Objectives	
	4.3.	Implementation	9
5.	Р	OLICIES AND STRATEGIES	. 10
	5.1.	Policy and strategy statements	.10
6.	II	MPLEMENTATION PLAN	
Αſ	NNEXE	ES	. 16
	Anne	x I. Health Facility Maintenance Unit (HFMU) Mandates, Duties, Responsibilities and Tasks	17
	Anne	x II. Ideal Health Facility Maintenance Workshop	19
	Anne	x III. Components of Medical Equipment Acquisition, Management and Maintenance	20
	Anne	x IV. Guidelines on Acquisition and Disposal of Medical Equipment	22
	Anne	x V. Monitoring and Evaluation of the Strategic Plan for the Maintenance and Management of	f
	Medi	cal Equipment and Devices: Key Benchmarks. Next Steps and Way Forward	25

# ABBREVIATIONS AND ACRONYMS

CM Corrective maintenance

CMMS Computerized maintenance management system

DHMT District Health Management Team

DPPI Directorate of Policy, Planning and Information

GoSL Government of Sierra Leone

HFMU Health facility maintenance unit

HRH Human Resources for Health

HSS Health Systems Strengthening

IPC Infection prevention and control

IPM Inspection and preventive maintenance

ISO Independent service organization

IT Information technology

LCC Lifecycle costing

MET Medical Equipment Technician

MOHS Ministry of Health and Sanitation

NGO Nongovernmental organization

NHSSP National Health Sector Strategic Plan

PHC Primary health care

PHU Peripheral health unit

PPP Public-private partnership

QIP Quality Improvement Programme

RCH Reproductive and Child Health

RMU Referral Maintenance Unit

SCBU Special Care Baby Unit

Sort, set in order, shine, standardize, sustain

TQM Total quality management

UHC Universal Health Coverage

# 1. INTRODUCTION

Health is one of the fundamental rights of every human being.<sup>1</sup> The Government of Sierra Leone (GoSL), through its Ministry of Health and Sanitation (MOHS), endeavours to provide equitable access to quality, affordable and timely health service delivery to achieve this goal.<sup>2</sup>

To this end, the MOHS has developed strategic policies, programmes and projects guided by its aspirational Vision and Mission.

The MOHS's Vision is "to ensure a functional national health system delivering efficient, acceptable, quality health care services that are accessible, equitable and affordable for everybody in Sierra Leone, and the overall goal is to maintain and improve the health of its citizens". Its Mission is "to contribute to socio-economic development by promoting and ensuring quality health for the Sierra Leone population".

Infrastructure, medical equipment and other devices are critical to meeting and sustaining these goals, over and above the availability of human resources and pharmaceuticals. However, managing and maintaining these elements has proven to be rather difficult in the Sierra Leonean health system.

To cite an example, in the Sierra Leone National Health Sector Strategic Plan (NHSSP) 2017–2021, specifically under its core health systems strengthening (HSS) pillars, the challenges in the management and maintenance of medical devices were not given prominence, even under the service delivery pillar. Even more so, the readiness index across 1,283 facilities was only 58% in 2017, indicating that the health sector was just over 50% ready to provide basic health services.<sup>3</sup> Results from a related survey of heads (in-charges) of health facilities showed that the main barrier to delivering quality health services was the availability of drugs and medical supplies and appropriate health infrastructure.<sup>4</sup>

However, the costs related to this equipment and maintenance expenditures have escalated sharply over the past several years, placing an additional burden on the health care delivery system. Since maintenance of this expensive equipment is critical to the operation of health care facilities, the only reasonable approach is to manage its maintenance, improve efficiency and effectiveness, and attempt to convert it from a loss item to a profit-making asset. Ignoring and neglecting the management of medical equipment and other devices may result in negative patient incidents (death and injury), poor clinical outcomes and/or a greater economic burden.

Additionally, human resources are inadequate and ill-prepared for managing and maintaining medical equipment and devices. Immediate attention must be given to address this enduring deficiency.

Between 2017 and 2020, the MOHS Directorate for Reproductive and Child Health (RCH), with the support of UNICEF, established Special Care Baby Units (SCBUs) in 10 government hospitals across the country as part of the Saving Lives in Sierra Leone Programme. The aim was to improve the quality of medical services and chances of survival of critical and pre-term babies/infants.

(https://extranet.who.int/countryplanningcycles/sites/default/files/planning cycle repository/sierra leone/sierra leone/si

<sup>&</sup>lt;sup>1</sup> Article 25 of the United Nations' 1948 Universal Declaration of **Human Rights** states that "Everyone has the **right** to a standard of living adequate for the **health** and well-being of himself/herself and of his/her family, including food, clothing, housing and medical care and necessary social services" (<a href="https://www.un.org/en/about-us/universal-declaration-of-human-rights">https://www.un.org/en/about-us/universal-declaration-of-human-rights</a>).

<sup>&</sup>lt;sup>2</sup> The Constitution of Sierra Leone, 1991. Chapter II: Fundamental Principles of State Policy; 8. (3) (d) "there are adequate medical and health facilities for all persons, having due regard to the resources of the State" (<a href="http://www.commonlii.org/sl/legis/const/1991/2.html">http://www.commonlii.org/sl/legis/const/1991/2.html</a>).

<sup>&</sup>lt;sup>3</sup> "The average service readiness index across 1,283 facilities – which measures the presence of basic amenities, basic equipment, standard precautions, diagnostic capacity and essential medicines – is only 58%" (p. 32). In: National Health Sector Strategic Plan 2017–2021. Freetown: Sierra Leone Ministry of Health and Sanitation; 2017 (<a href="https://extranet.who.int/countryplanningcycles/sites/default/files/planning\_cycle\_repository/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra\_leone/sierra

<sup>&</sup>lt;sup>4</sup> SARA 2017 results – general service availability (p. 32). In: National Health Sector Strategic Plan 2017–2021. Freetown: Sierra Leone Ministry of Health and Sanitation; 2017

To facilitate the Programme's goals, the units were equipped with high-end, sophisticated medical equipment and other devices, along with spare parts and consumables. It has become evident that in order to maximize the longevity of these assets, standards must be set for their management and maintenance. To this end, the MOHS, with the support of UNICEF, has created this document entitled, *Policies and Strategies for the Management and Maintenance of Medical Equipment and Devices*. While the SCBUs will be used as a template, the new policies and strategies will apply to all health care delivery units in public and private facilities across Sierra Leone.

# 1.1.Purpose

These policies and strategies shall serve:

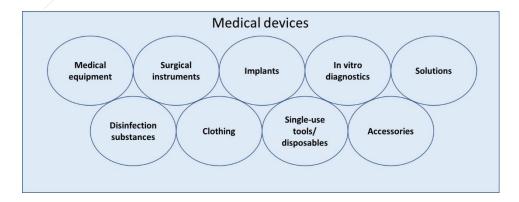
- as a framework for the sustainable management and maintenance of medical equipment and devices in the government health sector to support the achievement of quality health service delivery, Universal Health Coverage (UHC), and other government health care goals;
- as the bases for future policies and guidelines concerning medical equipment and devices used in Sierra Leone's public health system, specifically pertaining to their acquisition and procurement, acceptance testing, installation and commissioning, training, use, preventive and corrective maintenance, decommissioning, replacement and disposal;
- to strengthen, promote and propagate effective management and maintenance practices and experiences in medical technology at the health facility level as well as at the national level.

# 1.2. Definitions

A medical device is an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means. Medical devices include medical equipment, surgical instruments, implantable medical devices, in vitro diagnostics, solutions and disinfection substances, clothing, accessories and single-use devices.<sup>5,6</sup>

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

However, in the context of this Policy and to be more accessible to a broader audience, these two terms are used interchangeably.



<sup>&</sup>lt;sup>5</sup> Definitions. In: Medical devices. Geneva: World Health Organization (https://www.who.int/medical\_devices/definitions/en/).

<sup>&</sup>lt;sup>6</sup> Global Harmonization Task Force. Medical device regulations: global overview and guiding principles. Geneva: World Health Organization; 2003 (<a href="https://apps.who.int/iris/bitstream/handle/10665/42744/9241546182-eng.pdf">https://apps.who.int/iris/bitstream/handle/10665/42744/9241546182-eng.pdf</a>).

# 1.3. Scope and limitations

This document covers the management and maintenance of electronic, mechanical and electro-mechanical medical equipment and other devices used for diagnosis, monitoring, life support, therapy, surgery, sterilization and rehabilitation. The document covers cold chain and other refrigeration-based equipment, laboratory and dental equipment used in hospitals and other primary health care (PHC) facilities.

Likewise, the document contains relevant strategies for health facilities' infrastructure and utilities, which are essential for supporting the proper operation and use of medical equipment and devices.

This Policy and Strategy document touches on organizational shifts in the MOHS at the national level and at the health facility level in charge of maintenance and management, establishing clear mandates, duties and responsibilities complemented by specific guidelines and recommendations required to ensure the safe, efficient and effective use of medical equipment and devices.

In addition, these policies and strategies focus on the various stages of the technology management cycle applied to medical equipment and devices, with an emphasis on the principles of 'lifecycle costing'.

Other major equipment in the hospital and other health facilities, such as ambulances, land motor vehicles, IT and communication equipment and facilities, waste management equipment, electric generators and water supply pumps, buildings and structures, hospital beds, medical and hospital furniture, and office furniture and equipment are deemed to be beyond the scope of this document.

# 2. SITUATIONAL ANALYSIS

Quality health service delivery requires a multifaceted approach to achieve positive outcomes. There is no magic potion or silver bullet to cure all its deficiencies. However, the challenges in the delivery of quality health services can be addressed effectively using practical and doable strategies. In most resource-challenged countries such as Sierra Leone, the management and maintenance of medical equipment and devices is an area where appropriate and suitable policies, strategies and practical interventions can have a big positive impact on health service delivery. Environmental scanning is the first step in formulating policies and strategies. Below are some of the strengths and challenges identified in the system.

# Strengths:

- a) There are suitable Directorates in the MOHS to take on the responsibility for the management and maintenance of medical equipment and devices.
- b) MOHS key management personnel have increasingly been sensitized on the gaps in the management and maintenance of medical equipment and devices.
- c) At the health facility level, nearly all 16 district and tertiary regional hospitals have a health facility maintenance unit (HFMU) with at least one pin-coded Medical Equipment Technician (MET).
- d) The MET is usually complemented by volunteers with different skill levels.
- e) The majority of health facilities have a maintenance workshop.
- f) Health partners, international nongovernmental organizations (NGOs) and development agencies are expanding their support to include management and maintenance issues for donated medical equipment and devices
- g) UNICEF-Sierra Leone is providing technical support to build the management and maintenance capacity of the HFMUs for the SCBUs and other hospital departments.
- h) UNICEF-Sierra Leone is gradually providing basic maintenance tools and equipment to the HFMUs as part of capacity building.

# Challenges:

a) There is a lack of management and maintenance advocacy at the MOHS at the national level and lack of a clear mandate and responsibilities to influence critical decisions relevant to the management and maintenance of medical equipment and devices.

- b) Operational budgets for maintenance at the hospital level are low; many devices remain unrepaired because of a lack of spare parts to fix them. Low priority and, by extension, low input resources are given to medical equipment management and maintenance.
- c) The management and maintenance information system for medical equipment and devices is inadequate at the national and facility levels. Consequently, there is no basis for the realistic and appropriate planning, budgeting, procurement and management of these assets and the related human resources development.<sup>7</sup>
- d) The majority of the METs (Heads of HFMUs) have had no formal training in the maintenance and repair of medical equipment and devices and in managing a maintenance unit and the maintenance itself.<sup>8</sup>
- e) A few hospitals do not even have a maintenance workshop, for example, Kenema Government Hospital, Jui Hospital, Rokupa Hospital, Kinghaman Road Maternity Hospital, Koidu Government, and Port Loko Government Hospital. Furthermore, the majority of the maintenance units lack, among other things, basic tools and equipment for the technicians to carry out basic maintenance services.
- f) In instances where there is a maintenance workshop in the hospital, it is inappropriately located at the back of the hospital. As a result, the supervision and monitoring of the maintenance unit is usually an afterthought.
- g) Many maintenance posts are unfilled, resulting in an insufficient number of technical personnel to meet service demand on the ground.<sup>9</sup>
- h) The absence of preventive maintenance measures has significantly shortened the lifespan of medical devices and their safety. In general, maintenance is wrongly understood as purely a 'repair and restoration' activity. Consequently, preventive maintenance strategies are overlooked.
- i) There are no comprehensive training programmes for technicians (METs) or equipment users (doctors, nurses, paramedics).
- j) 'Maintenance culture' is weak in the public health facility system. The procurement and replacement of medical equipment and devices seems to be the main strategy for improving their availability.
- k) Donations of medical devices and technology usually lack coordination on the part of the recipients. Such donations are usually motivated by donors' 'good intentions', but lack the benefit of a proper needs assessment. There are no clear guidelines to assist facilities that are seeking or accepting donations.<sup>10</sup>
- Boarding off/decommissioning and disposing of dilapidated, unrepairable medical devices can pose hazards to the environment and community. The absence of clear guidelines and criteria makes the disposal exercise difficult. As a result, unusable, unsafe and disposable devices are stored and kept for a long time, unnecessarily eating up space in the health facility, usually in the maintenance workshop.

# 3. POLICY AND STRATEGY FRAMEWORK

The MOHS's Vision and Mission statements are used as the overarching guide when developing policies and strategies, considering other current and future health strategies, programmes and projects. Accordingly, this Policy's Vision/Mission statements and goal are aligned with the MOHS's broader Vision/Mission statements. Furthermore, these management and maintenance policies and strategies are subordinated to and aligned with the MOHS's other policies and broader concerns, such as UHC, PHC, etc., for the purpose of efficiency and effectiveness.

# **MOHS** Vision

The MOHS believes that access to sound health is a human right. Its vision is to ensure a functional national health system delivering efficient, acceptable, quality health care services that are accessible, equitable and

<sup>&</sup>lt;sup>7</sup> National Health Technology Assessment Unit, inventory and maintenance (pp. 174–5, 480). In: Global Atlas of medical devices. WHO medical devices technical series. Geneva: World Health Organization; 2017 (https://www.who.int/medical\_devices/publications/global\_atlas\_meddev2017/en/).

<sup>&</sup>lt;sup>8</sup> Biomedical engineering professionals per 10,000 population: SLE < 0.01; along with COD, GHA, TZA, BFA, RWA, KEN, NAM, SWZ, TCD, CMR, BEN, UGA. Human resources for medical devices: the role of biomedical engineers. WHO medical devices technical series. Geneva: World Health Organization; 2017 (https://www.who.int/medical\_devices/publications/hr\_med\_dev\_bio-engineers/en/).

<sup>&</sup>lt;sup>9</sup> For example, there is a limited number of technical personnel to meet service demand at Connaught Hospital.

<sup>&</sup>lt;sup>10</sup> Most of the equipment supplied by donors is obsolete and/or out-of-order.

affordable for everybody in Sierra Leone, and the overall goal is to maintain and improve the health of its citizens.

### **MOHS Mission**

To contribute to socio-economic development by promoting and ensuring quality health for the Sierra Leone population.

To this end, the GoSL's battle cry is stated in the Sierra Leone National Health Policy Statement:

"Sierra Leone adopted the Primary Health Care (PHC) strategy for health service delivery. The primary objective is to improve the health status of the Sierra Leone nation through the provision of quality services that are equitable and client focused, leading to a healthy, productive and prosperous society." <sup>11</sup>

In the context of the effective management and maintenance of medical equipment and devices, the Vision and Mission statements are stated as follows:

VISION: Available quality, safe and appropriate medical equipment and devices at all levels of the MOHS health facility system by 2025

MISSION: To establish a sustainable management and maintenance system for medical equipment and devices in the MOHS, in collaboration with key stakeholders and partners.

# 4. GUIDING PRINCIPLES

The MOHS's policies and strategies are developed through consensus-building and consultation exercises with key relevant cadres, MOHS staff, health partners and stakeholders. The following are the basic guiding principles:

- The policies and strategies in general shall be consistent and in conformity with the existing policies, rules, procedures and direction of the GoSL, specifically the MOHS.
- This set of policies and strategies is intended as a reference and guide only for MOHS management and decision-makers, health facility managers, and maintenance managers and supervisors for making decisions pertaining to the management and maintenance of medical equipment and devices. It shall not in any way be considered mandatory, unless otherwise made so by the MOHS.
- In the case of ambiguity or conflict with existing norms and good practices, the onus of responsibility falls on the final decision-maker.
- The policies and strategies below shall be reviewed, revised and, if necessary, updated every two years.
- The designated Office/Unit in the MOHS charged with the management and maintenance of medical equipment shall take the lead and monitor the implementation of these policies and strategies, and see to it that they are adhered to as much as is practical.
- The concept of technology management cycle shall be the overriding consideration in the management and maintenance of medical equipment and devices. In addition, the 'iceberg effect' in medical technology is highlighted so that decision-makers avoid the pitfalls of technology's hidden costs
- Professional (career path) and personal development opportunities for key maintenance unit staff should be the normal consequence of these policies and strategies.
- Key MOHS Directorates will be critical to the success of these policies and strategies, i.e., CMO, Budget and Finance, Human Resources for Health (HRH) and the Directorate of Policy, Planning and Information (DPPI), with the backing and support of donor partners.

# 4.1. **Goal**

Functioning, efficient and effective management and maintenance of medical equipment and devices in public health systems to support the MOHS's quality health service delivery by 2025.

<sup>&</sup>lt;sup>11</sup> National Health Sector Strategic Plan 2017–2021. Freetown: Sierra Leone Ministry of Health and Sanitation; 2017 (<a href="https://extranet.who.int/countryplanningcycles/sites/default/files/planning\_cycle\_repository/sierra\_leone/sierra\_leone\_nbssp\_2017-21\_final\_sept2017.pdf">https://extranet.who.int/countryplanningcycles/sites/default/files/planning\_cycle\_repository/sierra\_leone/sierra\_leone\_nbssp\_2017-21\_final\_sept2017.pdf</a>).

# 4.2. Objectives

With the guidance and support of MOHS top management, various health partners and other government agencies, these policies and strategies envisage:

- Standardizing approaches and potential outcomes of decision-making relevant to the management and maintenance of medical equipment and devices, i.e., planning, acquisition, installation and testing, training, use, maintenance, risk assessment, disposal and replacement;
- Strengthening the management and maintenance units and organizations at all levels of the MOHS, as a means to optimize and protect the investments in medical equipment and devices, e.g., the number and qualification standards of technicians, standardized maintenance workshop facilities, tools and equipment;
- Helping to achieve an acceptable level of quality health service delivery and supporting the goals of the NHSSP, UHC, PHC, etc. through proper maintenance management;
- Better managing the maintenance of medical equipment and devices by establishing a suitable digital database (computerized maintenance management system [CMMS]) for evidence-based planning and (maintenance) management; piloting the SBCUs, and expanding to other assets in the public health system;
- Institutionalizing inspection and preventive maintenance (IPM) and corrective maintenance (CM) programmes as a means to improve the availability of medical equipment and devices;
- Improving the availability of adequate numbers and supply of suitably qualified and trained hospital, medical equipment engineers and technicians in the job market by providing a reasonable career path in the public health sector;
- Ensuring that the users of medical devices are trained adequately in their safe and effective use and motivated to carry out day-to-day first-line maintenance;
- Co-operating with, encouraging and guiding government agencies, private contractors, and donor and health partners in the acquisition, development, capacity building, training, use, maintenance and disposal of medical devices.

# 4.3. **Implementation**

The implementation of these policies and strategies involves the establishment of the following:

- Managerial and technical structures;
- Functional analyses of installed systems;
- Procurement and acquisition systems;
- Information systems and financing systems;
- Appropriate health facility design and infrastructure;
- Training of users and maintenance personnel;
- Preventive maintenance measures, risk assessment, training, and other strategies geared towards promoting awareness of maintenance or developing a maintenance culture;
- Decommissioning and disposal protocols.

The policies provide specific steps for MOHS management, other government stakeholders, and health partners to take in order to improve the quality of health service delivery.

The recently equipped SCBUs provide an ideal microcosm in which to test the policies and strategies. The SCBUs have a wide array of medical equipment and devices that are representative of those that might be used in other departments; hospital technicians (METs) have received basic training and tools to carry out IPM and CM; and a supply chain of spare parts and accessories may be made available through the support of MOHS partners.

The SCBUs may be used as a model through which to gather data to help validate the impact of managed maintenance services on the availability of medical equipment and devices, and, by extension, the quality of health service delivery.

# 5. POLICIES AND STRATEGIES

# 5.1. Policy and strategy statements

The policies and strategies outlined here are based on resolution WHA60.29, adopted at the 60th World Health Assembly in May 2007. The resolution addresses issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. The management of health technologies ensures that these assets are available, accessible, affordable, appropriate and used safely. Appropriate management is expected to lead to improved health outcomes through optimal use of the resources.

Figure 1 depicts a simplified version of WHO's health care technology management (HTM) philosophy, presented as a chain. The components of the chain are linked together in a circle, representing a continuum of interconnected activities and processes. These components are: planning and needs assessment; budgeting and financing; selection; procurement (through direct acquisition or donation) and logistics; installation and commissioning; training and skills development; operation and safety; preventive and corrective maintenance; and decommissioning and disposal. Each component supports the next link/component in order to achieve the desired end result: "effective asset management". The linchpin of the circular chain is "creation of awareness" and "monitoring and evaluation", which ensure continuity and support from all key stakeholders.

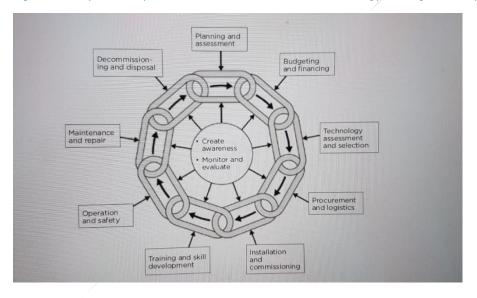


Figure 1. Simplified depiction of WHO's health care technology management cycle

Each component of the management cycle encompasses a wide range of activities, including conferring with stakeholders, assessing facilities, benchmarking, calculating lifetime cost-effectiveness projections, negotiating and monitoring service delivery contracts, establishing a supply chain of spare parts and consumables, conducting financial valuations, developing and managing human resources, record-keeping, managing inventory, managing waste, and implementing safety protocols.<sup>12</sup> The policies and strategies that are proposed in this document describe improvements to many, if not all, of these activities. The targeted areas of improvement are:

- 1. Organization and leadership
- 2. Procurement (through direct acquisition or donation), and safe decommissioning and disposal
- 3. IPM and CM

<sup>&</sup>lt;sup>12</sup> Global Atlas of medical devices. WHO medical devices technical series. Geneva: World Health Organization; 2017;p.44 (<a href="https://www.who.int/medical devices/publications/global atlas meddev2017/en/">https://www.who.int/medical devices/publications/global atlas meddev2017/en/</a>).

- 4. Human resources
- 5. Asset management

# Policy 1. Strengthen organization and leadership

Strategy 1.1: Consolidate and integrate management and maintenance responsibilities for medical equipment and devices under one Directorate in the MOHS organogram:

- The MOHS's national leadership will identify a Directorate at the national level with the technical line supervision over the maintenance units at the health facility level, with a clear mandate and responsibilities to manage and maintain medical equipment and devices.
- The Directorate will carry out a sensitization programme for all relevant stakeholders and key players, donors and partners, and advocate to facilitate effective and efficient acquisition of medical equipment and devices.
- The Directorate will strengthen the maintenance workforce and promote a maintenance culture and awareness by hosting quarterly regional maintenance unit performance evaluation meetings and annual planning meetings.

Strategy 1.2: Establish five (5) strategically located Referral Maintenance Unit (RMU) workshops to carry out the IPM and CM of complex and sophisticated medical equipment beyond the capacity of health facility maintenance units (HFMUs) and peripheral health units (PHUs) in contiguous areas:

• The Directorate shall endeavour to establish suitable, well-equipped RMU workshops with operating budgets and transport service. Recommended locations include Port Loko, Kenema, Bo, and Makeni Government Hospitals and Connaught Hospital. The Directorate shall recruit additional technical staff (METs) for the RMUs.

Strategy 1.3: Institutionalize quality assurance/quality improvement mechanisms for productivity and safety enhancement in all health facility maintenance systems:

- Integrate quality improvement/assurance concepts in maintenance activities.
- Promote the 5S-Kaizen-TQM approach<sup>13</sup> in the HFMU workshops and maintenance activities.

Strategy 1.4: Develop a flexible organizational model for the HFMUs, considering available technology, economic factors and practicality. Suggestions for components of the model are as follows:

- In-house personnel model wherein maintenance activities are executed solely and wholly by the HFMUs, including the management of a supply chain for spare parts and contracts with distributors and service providers;
- Mixed model wherein the MOHS stipulates contracts regarding the servicing and maintenance of medical equipment and devices. The MOHS decides if this service should be performed by the original equipment manufacturer (OEM), by a third party such as an independent service organization (ISO) or by a mix of the two. The management of contracts by the manufacturer and the provisioning of spare parts and other high-level activities are carried out by in-house personnel;
- Third-party multi-vendor service model wherein the MOHS stipulates that an ISO should service the full risk maintenance activities and carry out other maintenance services. In this way, the hospital does not need to be concerned with the management of sophisticated test equipment and medical devices.

Strategy 1.5: Strengthen organization at the health facility level:

- Regularly increase and improve the capacity of the HFMUs to meet the work demand in terms of the number of pin-coded staff, skills development through in-service training, provisioning of tools and equipment, spare parts and a functional workshop facility.
- Standardize and update the unit's mandate and roles, with clear duties and responsibilities for its staff.

<sup>&</sup>lt;sup>13</sup> Kuramitsu M. 5S-KAIZEN-TQM: ten years in the application of 5S-KAIZEN-TQM QI approach in African health services. 4th Global Forum on Human Resources for Health, 13–17 November 2017, Dublin, Ireland (<a href="https://www.who.int/hrh/Oral-Better-results-How-quality-improvement-empowersHWperformance-Kuramitsu-15Nov-17h30-18h30.pdf">https://www.who.int/hrh/Oral-Better-results-How-quality-improvement-empowersHWperformance-Kuramitsu-15Nov-17h30-18h30.pdf</a>).

- Establish a clear separate line-item budget for the operation and activities of the HFMUs based on health facility prioritization, needs and health indicators.
- Endeavour to create an HFMU identity and motivation, and heighten safety awareness and consciousness through the adoption of working clothes, safety shoes and hat, goggles, gloves, etc.

Strategy 1.6: Institutionalize monitoring and supervision and maintenance performance review exercises at the health facility level:

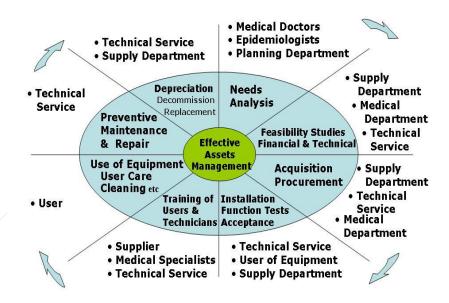
- Carry out the annual planning exercise for hospital management-supported maintenance activities before the start of the new fiscal year in order to formulate a realistic and practical maintenance programme.
- Carry out internal quarterly and semi-annual performance reviews of maintenance activities.
- Establish a computerized documentation and recording system for maintenance activities i.e., CMMS).
- The MOHS and the health facility management (District Health Management Team [DHMT] and Medical Superintendent [MS]) shall carry out regular supportive supervision and monitoring of every HFMU.
- Facilitate sharing of experiences and information on breakthrough technologies among HFMUs within each zone: North, South, East and West.

# Policy 2. Establish evidence-based procurement (direct acquisition or donation)

Strategy 2.1: Use the technology management cycle framework whenever practical, as shown in Figure 2.

Figure 2. Elements of the technology management cycle framework<sup>14</sup>

# **Technology Management Cycle**



- Introduce national-level stakeholders to evidence-based decision-making.
- Educate health partners, donors, national-level stakeholders, and hospital administrators about the 'iceberg effect' in medical technology (Figure 3).<sup>15</sup>

1

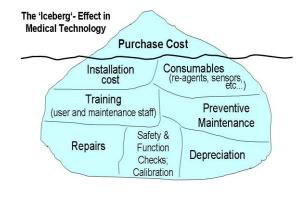
<sup>&</sup>lt;sup>14</sup> By Dieter Horneber, GIZ Consultant; Physical Asset Management; Malawi

<sup>&</sup>lt;sup>15</sup> Sharawi AAER. Quality management system for medical devices: a field study of the reality of some Arab countries. Cairo: Cairo University; 2012. doi:10.13140/RG.2.2.28960.53760.

Figure 3. Depiction of the 'iceberg effect' in medical technology – the hidden costs of technology



# **Hidden Costs of Technology**



- Mandate risk assessment exercises prior to accepting the introduction of any medical equipment or other medical devices.
- Include budget for the running costs of medical equipment during the acquisition process stage, either through the normal procurement process by GoSL or health partners or through donation equivalent to 1–3% of the cost of equipment for spares, reagents and other consumables.
- Lifecycle costing (LCC), whenever practical, shall be the preferred method for evaluating the economic viability, 'quality' and so-called 'total cost of ownership' of medical equipment.
- Enforce compliance to electrical standards, i.e., 230V AC, 50 Hz, BS plug; adaptability to Sierra Leone environment (humidity and temperature), accompanied by common spare parts and consumables/reagents for three years; training of users and technicians; special tools and test equipment if necessary; service manual in English and certification from supplier/manufacturer of its safe and functional status; and installation and commissioning whenever applicable.

Strategy 2.2: Standardize the acquisition of medical equipment and devices:

- Create an independent oversight committee.
- Create a technical working group to develop a standard list of medical devices that will be used as a reference to guide the acquisition of medical devices.
- Standardize the physical infrastructure, i.e., space, volume, noise and utilities (water, electricity supply [400/230V AC, 50 Hz], medical gases), waste disposal, humidity, temperature and other operating conditions in health care facilities.

Strategy 2.3: Establish standard safety and acceptance test protocols for newly acquired medical equipment and other devices:

• Carry out risk assessment exercises for medical equipment acquisitions.

Strategy 2.4: Utilities and infrastructure must be made available before the delivery, installation and commissioning of equipment to the site; maintenance technicians and users should be part of acceptance testing and commissioning exercises:

<sup>&</sup>lt;sup>16</sup> Porter D. Management of medical devices: areas requiring further strengthening. Global Forum on Medical Devices, Bangkok, Thailand, 2010 (<a href="https://www.who.int/medical devices/03 medical devices management david porter.pdf">https://www.who.int/medical devices/03 medical devices management david porter.pdf</a>).

- Facilitate productive coordination and collaboration between the procurement unit and the recipient of the equipment prior to installation and commissioning, with utilities made suitable for the equipment.
- Develop acceptance testing protocols and standards for commissioning, including the training of maintenance technicians and equipment users.

# Policy 3. Institutionalize IPM and CM

Strategy 3.1: Standardize IPM and CM programmes in the public health facilities, including PHUs:

- Carry out sensitization exercises on the importance and benefits of IPM and CM among key stakeholders.
- Carry out annual asset inventory exercises, including all essential DHMT assets.
- Develop reference manuals or guides, maintenance plans and strategies to carry out IPM and CM.
- Allocate financial resources to IPM and CM activities.

Strategy 3.2: Include IPM and CM programmes in the MOHS's annual budget:

- Collaborate with the MOHS Directorate of Finance and Local Council for budgetary support.
- Allocate separate budgets for IPM and CM programmes.

Strategy 3.3: Expand IPM and CM programmes:

- Monitor IPM and CM programmes and improve as needed.
- Review IPM and CM reports quarterly and use information to guide annual budgeting processes.
- Establish/improve regional and district health facility maintenance workshops.

Strategy 3.4: Establish a CMMS, work order system, and IPM and CM checklists/guides to document activities:

- Establish a CMMS, provision software and hardware, and users/technicians.
- Train maintenance staff on the CMMS and establish a work order system as part of all HFMU operations.

# Policy 4. Improve human resources

Strategy 4.1: Increase the number of qualified and trained maintenance technicians:

- Collaborate with HRH to increase the number of hospital maintenance technicians on the payroll.
- Establish academic and performance-based career paths for biomedical engineers and technicians.
- Develop diploma and degree courses for biomedical engineers and technicians.
- Create a pipeline of technicians by inviting students from trade schools to volunteer as apprentices.

Strategy 4.2: Promote in-service skills development and education programmes for biomedical technicians and clinical staff:

- Collaborate and advocate with the district health team's human resources personnel to conduct regular in-service medical equipment user training.
- Mandate weekly sharing of outputs from the work order and scheduling system among the technical staff.

# Policy 5. Standardize asset management from needs assessment to decommissioning and disposal

Strategy 5.1: Promote the establishment of a national asset registry and CMMS in the public health sector for planning, budgeting, management and maintenance:

- Establish a virtual library of all assets in the public health care system.
- Establish a work order documentation and reporting system.

• Standardize the introduction of medical equipment and other devices through evidence-based methods.

Strategy 5.2: Establish decommissioning and disposal procedures:

- Establish guidelines and protocols for decommissioning and disposal of medical equipment and devices.
- Establish a medical equipment and device replacement programme.

Strategy 5.3: Develop a culture of engagement and collaboration and coordination with key health facility staff throughout the lifecycle of the medical equipment and devices:

- Optimize the vast expertise and skills of various available human resources in the health facility organizations through consultation, collaboration and co-optation.
- Whenever practical, create a multidisciplinary steering and technical working group within the health facility to recommend courses of action pertaining to equipment lifecycle.

Strategy 5.4: Co-operate with, encourage and guide government agencies, private contractors, donors and other health partners in the management and maintenance of medical equipment and other devices:

- Generate up-to-date evidence on clinical interventions, technical specifications, procurement practices, maintenance protocols, and decommissioning practices.
- Carry out market surveys of suppliers and distributors of medical equipment and devices, as well as relevant third-party service contractors in Sierra Leone and elsewhere.
- Validate procurement, distribution, maintenance and other management practices proposed by partners.
- Perform due diligence and establish accreditation standards for third-party service providers.

# 6. IMPLEMENTATION PLAN

The policies and strategies for the management and maintenance of medical equipment and devices at the health facility level shall be integrated into the Annual Planning exercise, which will be initiated by UNICEF. The MOHS HSS, Directorate in charge of the management and maintenance of medical equipment, and DPPI shall take the lead in this effort. Monitoring and supervision shall also be undertaken by the same MOHS Offices and UNICEF.

UNICEF will encourage and collaborate with HSS and DPPI to develop an implementation plan, including the dissemination of this document after revision through consultation with relevant staff and health partners.

UNICEF shall also collaborate with other health partners as advocates to promote the policies through dissemination, circulation and sensitization among a wide audience of stakeholders.

The Implementation Plan associated with this Policy and Strategy, which will be developed after the dissemination and circulation of this document, includes: (1) budgetary estimates for HFMU operation, (2) IPM and repair procedures, (3) staffing patterns for HFMUs (including job descriptions and training plans), (4) Acceptance Safety Test Protocols, (5) work order system, (6) guidelines on medical equipment donation and other devices, and (7) guidelines for decommissioning medical equipment and other devices.

The above shall be initiated, developed and formulated by the HSS, DPPI and the office in charge of medical equipment maintenance and management through separate forums and consultation exercises, with the participation of specific MOHS staff on the ground and experts in the abovementioned fields and related functions.

# **ANNEXES**

Annex I HFMU Mandates, Duties, Responsibilities and Tasks

Annex II Ideal Maintenance Workshop (layout)

Annex III Components of Medical Equipment Acquisition, Management and Maintenance

Annex IV Guidelines on Acquisition and Disposal of Medical Equipment

Annex V M&E, Benchmarks, Way Forward and Next Steps

Annex VI Consultation Workshop, 16–18 December 2020, Golden Tulip Hotel, Freetown

# Annex I. Health Facility Maintenance Unit (HFMU) Mandates, Duties, Responsibilities and Tasks

## Mandate

- 1. Technical and management advisory services on matters of hospital engineering and maintenance;
- 2. Consultancy services on hospital engineering and maintenance to hospital management and other health facilities;
- 3. Direct provision of preventive and corrective maintenance services;
- 4. Development and maintenance of maintenance management system;
- 5. Standards and system development;
- 6. Education and training of engineering and maintenance unit as well as medical and nursing services;
- 7. Research and development in health physical assets;
- 8. Risk management of health physical assets.

# **Duties and Responsibilities**

- 1. Ensure that hospital facilities, utilities, equipment, communication system, and other health physical assets are available, safe, accurate, and in functional condition at reasonable cost;
- 2. Ensure adequate and timely provision of the required purity medical gases in the hospital;
- 3. Ensure in-service education and training of hospital staff on maintenance and engineering issues, including operation and basic maintenance of medical equipment;
- 4. Ensure the adequate, timely and quality provision of water and electric power in the hospital;
- 5. Maintain the cleanliness, safety and security of the hospital facilities and utility plants;
- 6. Establish a communication network with the hospital management and medical and nursing services;
- 7. Maintain an adequate number of motivated and highly skilled technicians and artisans in the HFMU;
- 8. Establish standards for hospital physical asset management and availability.

### Tasks

These tasks comprise the essential work necessary to accomplish the duties and responsibilities, for example:

- 1. Carry out an integrated planned preventive maintenance programme for essential and priority facilities, utilities, power and water supply plants, and medical and laboratory equipment;
- 2. Manage, monitor and supervise service contracts entered into by the hospital pertaining to engineering and maintenance;
- 3. Restore broken down physical assets to a safe and functional status at minimal cost;
- 4. Carry out education and training programmes for medical and nursing services staff;
- 5. Develop a skills development training programme for HFMU staff;
- 6. Hold regular HFMU meetings;
- 7. Establish a physical assets register and other workable maintenance documentation and reporting systems;
- 8. Regularly update hospital management on maintenance activities and accomplishments;
- 9. Conduct monitoring and evaluation of HFMU performance;
- 10. Conduct research on equipment and user performance;
- 11. Develop safety and risk management evaluation of hospital and other health physical assets.

# List of cadres for typical regional government hospital:

- 3 biomedical equipment technicians (BMETs), including head of the maintenance unit
- 1 AC technician
- 1 carpenter/painter

- 2 electricians
- 2 plumbers
- 1 mechanic with welding skills

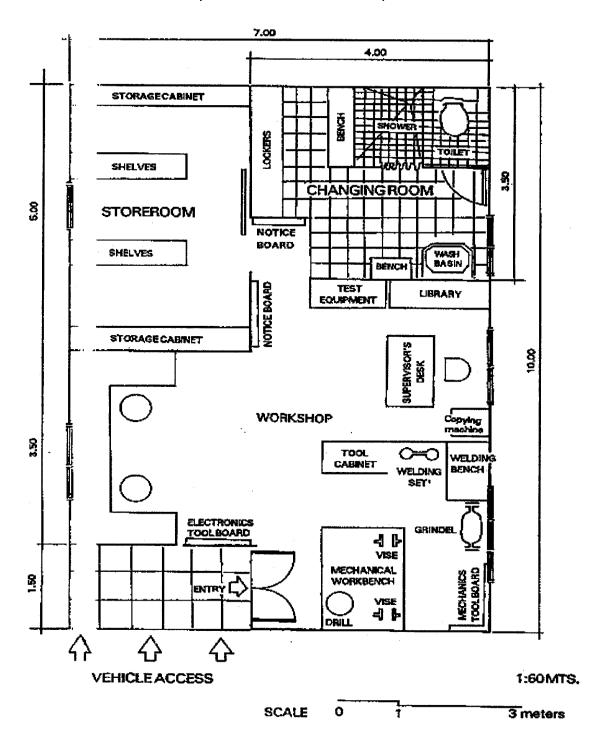
# NOTE:

For Connaught Hospital, ODCH/PCMH and potentially the Referral Maintenance Units, additional staff/technicians should be considered:

- 1 head of the maintenance unit
- 1 office manager/secretary
- 1 more BMET
- 1 more electrician for a 24-hour shifting schedule and plant operations
- 1 more plumber
- 1 more carpenter

On-the-job trainees/apprentices from trade schools/volunteers may be accepted, provided there are specific job descriptions and training plans for them geared towards the needs of the maintenance works of the health facility.

Annex II. Ideal Health Facility Maintenance Workshop



# Annex III. Components of Medical Equipment Acquisition, Management and Maintenance

- a) **Selection** of medical devices and technology shall conform to the minimum requirements by type and sophistication with respect to the standard and level of health care service delivery.
- b) Standardization of medical devices shall be done based on agreed levels of appropriate and suitable technology, interchangeability of spares and consumables, training needs, installation and commissioning requirements, etc. and *not solely* based on makes or models. *Generic specifications* based on need shall be used, including aspects of technical design and standard components and accessories.
- c) Cost-effectiveness means that all **related costs** shall be weighed against the benefits accruing from the equipment: the **'cost of ownership'**. Below are the components of cost of ownership.
  - The **investment** cost or purchase price
  - **Installation** and transportation costs where applicable
  - **Running** costs, which include the consumables needed for the equipment's utilization (e.g., reagents, fuel, disposables)
  - Costs of specialized user personnel and their training
  - Maintenance costs, which include spares (availability) and personnel needed for servicing
  - **Depreciation** costs, which refers to the cost of replacing the equipment at the end of its lifespan
  - Disposal costs where applicable.
- d) All health care technology acquired shall conform to the **standards** of the following institutions:
  - International Organization for Standardization (ISO)
  - International Electrotechnical Commission (IEC) for medical equipment/devices
  - European Economic Community (EEC)
  - European Certification (CE) marked products
  - ENEC (European Norms Electrical Certification); also known as EN
  - British Standard (BS)
  - Deutsche Industrie Norm (DIN)
  - Japan International Norm (JIN)
  - Underwriters Laboratory (UL); synonymous with the CE marking organization.

With the exception of ISO standards, other national or international standards that denote equal or better quality can be taken into consideration.

- e) All electrical medical devices acquired and procured shall be suitable for use in the Sierra Leone electrical system and environment:
  - Power source: 240V / 50Hz (single phase) or 415V / 50Hz (three phase) mains supply

➤ Ambient temperature: max. 50°C
 ➤ Humidity: max. 70–85%
 ➤ Male plug and sockets: BS, 3-pin prong

- f) Voltage fluctuations and frequent outages are harmful to all sensitive electrical medical devices. Voltage stabilizers of sufficient capacity and range or time-delayed automatic switches should be part of the procurement in order to protect equipment from damage. A centralized voltage stabilizer of sufficient capacity may be installed at the source of power to each socket for electrical medical devices in an area, unit or department, i.e., SBCU, OT, ICU, etc.
- g) All marking and labels on electrical medical devices and all accompanying literature (e.g., manuals) shall be in English.
- h) Acquisition **contracts** of medical devices and technology shall always incorporate adequate training of maintenance personnel and users.

- i) Other acquisition schemes, e.g., tie-up, revenue-sharing, rent-to-own, etc., should be considered only upon careful evaluation of relevant costs and benefits in specific departments or equipment, e.g., radiology and laboratory or its specific equipment, MRI, radiotherapy equipment, ultrasound scanner, X-ray machine, auto blood chemistry analyser or whole package (Laboratory and Radiology and Imaging Departments).
- j) **Private—public partnership (PPP)** shall be encouraged whenever applicable and technically and economically viable. Private service contractors shall be engaged after thorough vetting of their technical and financial capacity.
- k) All partners shall be strongly encouraged to include in any procurement of medical devices a provision for the supply of **essential spare parts**, which may be needed for foreseeable future repairs of the equipment for a period of approximately 3–5 years. This means that an average of **5%** of the cost of the new equipment should be provided for the supply of additional spare parts. These may be purchased simultaneously with the equipment or the **cash equivalent** may be provided, to be deposited into a special trust fund of the recipient health facility for the above purpose.
- I) Installation and commissioning of medical devices/equipment shall be duly documented according to current or yet to be established standard protocols, rules and regulations in the MOHS. Medical devices/equipment shall be subjected to thorough safety and reasonable acceptance test protocols.
- m) Likewise, health care technology and other assets tested for acceptance shall be registered and included in the MOHS and health facility asset registry/CMMS.
- n) **Inspection and preventive maintenance (IPM)** shall be the main strategic approach to maintenance service.
- o) A work order system shall be implemented in all hospital/health maintenance units to include job requests, job orders and job reports. It shall be part of the CMMS.
- p) An asset **replacement programme** shall be instituted to ensure the safe and continuous delivery of quality health services.
- q) To minimize service disruptions, **redundancy and spinning reserve techniques** should be implemented for small and common medical devices, when budget allows. These techniques shall be used to replace items undergoing maintenance services.

# Annex IV. Guidelines on Acquisition and Disposal of Medical Equipment

## **Procurement**

All procurement requirements shall be based on clinical needs determined by technology assessments and considering cost—benefit analyses in order to ensure the best value for money and equipment that is fit for purpose.

- a) The National Public Procurement Act shall be strictly followed in the procurement of medical devices.
- b) The National Medical Supplies Agency (NMSA) shall be responsible for processing all service and procurement contracts in coordination with appropriate government offices and agencies with sufficient expertise.
- c) All medical devices shall bear the mark of CE, ISO EN, UL and/or any other quality assurance symbols from reputable countries.
- d) A lifecycle cost (LCC) analysis shall be performed in order to estimate associated costs and the spare parts needed for the procurement of a new medical device/asset.
- e) The procurement of consumables, accessories and spare parts shall be in strict compliance with the recommendations of the manufacturer. Refurbished spare parts shall be avoided unless they can be guaranteed to work safely and satisfactorily by the designated MOHS Management and Maintenance Responsibility Centre. For medical devices that are critical and where no downtime is acceptable, there shall be spare part stock within accessible reach.
- f) Conditions obligating the supplier/manufacturer to provide necessary training to the hospital and biomedical engineering and maintenance unit that is responsible for management and maintenance shall be stated and specified in the procurement process for all medical devices and systems.
- g) All acquired and disposed physical assets shall be encoded/decoded in the asset registry/computerized maintenance management system (CMMS) of the MOHS and the respective health facility.
- h) Medical equipment shall only be written off from health facilities after thorough economic and technical assessment by the designated qualified office or committee.

# **Donations**

Donations of medical devices are helpful in many respects, especially in resource-challenged countries. However, recipients should be mindful that, in some instances, donations can cause more problems than their intended benefits. Donations must therefore comply with the same policies and standards as new medical devices/assets being procured.

The following regulations shall apply to all donations:

- All donations (new or old) shall conform to the aforementioned standards and procedures for the procurement and acquisition of health physical assets. They shall be subject to the same scrutiny and vetting process used for other forms of acquisitions and planning before acceptance.
- Acceptance testing and registration should be conducted on all donated medical devices, and they should be included in the asset registry and CMMS.

- Old, broken, outdated and redundant medical devices for which spare parts and consumables are no longer available, or medical devices that are longer supported by the manufacturer should not be accepted as donations.
- A National Donation Plan shall be available indicating which medical devices are desired and which technical support is available for specific types and brands.
- WHO medical equipment donation guidelines<sup>17</sup> may be used in making decisions pertaining to medical equipment donation.

# Management of Medical Devices and Systems

The management of health physical assets encompasses a complex range of aspects and components, which all together are referred to as the "technology cycle". The typical components of a health care technology management cycle are:

- **Needs assessment**, e.g., based on epidemiology, mortality/morbidity, etc.;
- Assessment and selection of appropriate technology;
- Strategic technology planning (clinical, infrastructural, technological, financial);
- Selection and procurement, installation and commissioning, and documentation (asset registry and information system);
- User training and technician training (post-commissioning exercise);
- Utilization, calibration, maintenance and repair, testing and re-commissioning, and documentation (source of maintenance and procurement/acquisition information for the maintenance management information system);
- Performance analysis, risk assessment, lifecycle analysis and documentation (bases for decisions in the next procurement cycle);
- Decommissioning and disposal and documentation (bases for replacement programme).

## Acceptance Testing for Medical Devices

The aim of an acceptance test is to ensure that a medical device has been delivered according to the contract and fulfils the safety criteria. All newly acquired medical devices must pass an acceptance test before they can be used on patients. The MOHS Management and Maintenance Responsibility Centre must develop guidelines and procedures to ensure that this requirement is enforced. The following procedures shall apply:

- a) Acceptance testing protocols shall be performed by a <u>biomedical technician in the presence of the supplier/vendor</u>. These protocols should include, among other things, performing delivery checks, conducting appropriate tests in accordance with the equipment's intended use and description in the user manual, and marking the medical device with an inventory tag before it is approved for use (diagnosis or therapy).
- b) All approved medical devices bearing an inventory tag with a unique identifier shall be registered in the CMMS.
- c) Likewise, donated medical devices shall undergo acceptance safety testing and other protocols enumerated in this Policy before they are put online.

# CMMS/Asset Registry

A CMMS and computerized asset inventory system are essential technical tools in modern health care systems for ensuring efficient monitoring and providing cost-effective health care services, maintenance and capital investment planning. It also simplifies the procedures when it comes to reporting and monitoring adverse

<sup>&</sup>lt;sup>17</sup> Guidelines for health care equipment donations. Geneva: World Health Organization; 2010 (https://www.who.int/medical\_devices/publications/en/Donation\_Guidelines.pdf).

events arising from the use of medical devices. All health care providers within the health sector must therefore develop an inventory system to systematically organize, plan and monitor medical devices/assets that are in clinical use. The devices shall preferably be registered in a CMMS, or if not possible, in a local manual inventory system. The following procedures shall apply:

- a) All medical equipment/devices (standalone or part of a medical devices system) in a hospital and/or health care facility that are in clinical use and working condition.
- b) Medical devices registered in the CMMS shall be classified in accordance with a national standardized nomenclature with a proper generic description of the device, make, model and unique registration number (inventory tag). The nomenclature shall be monitored and updated continuously in order to match new classifications of medical devices.

# **Disposal of Medical Devices**

Medical devices or systems that are deemed unsafe, unreliable, outdated or at the end of their lifecycle shall be taken out of service. Human health and environmental safety must be priorities in the disposal of medical devices, which may contain organic parts, chemicals and fluids, radioactive substances, electrical and electronic parts, batteries and toxic plastics, etc. that are hazardous and may require extra care. In order to ensure environmentally safe disposal of medical devices, the MOHS, through it technical arms, shall ensure that the following regulations and procedures are enforced:

- a) Medical devices that are suspected of having safety deviations/issues should decommissioned.
- b) A designated medical equipment technician/expert shall carry out an investigation on the medical device that is designated for disposal, and the (hospital manager) shall sign a disposal certificate to take the medical device out of service.
- c) Disposal of medical devices, consumables, accessories and single-use items must comply with the country's environmental safety laws and regulations and manufacturers' recommendation, as well as any applicable rules from hospital waste management plans and/or infection prevention and control (IPC) protocols.
- d) Disposal of medical devices shall follow the established health and environmental rules and regulations, as well as the existing national and local environmental laws and ordinances. Medical devices collected for disposal must be dismantled by authorized cadres and stored in a safe location as prescribed under the law, rules and regulations.
- e) Each hospital shall have a waste management plan for disposing of medical devices and ensure that the plan conforms with the national waste management plans and regulations.
- f) The CMMS shall be updated to reflect the new status of the disposed medical devices, and the inventory tag must be removed from the unit.
- g) Special precautions and documented routines shall be taken for safe disassembly of the following items: fluids, mercury-containing components, batteries, circuit boards, cathode ray tubes, liquid crystal displays, components containing radioactive substances, capacitors containing polychlorinated biphenyls, and electrolytic capacitors.

Annex V. Monitoring and Evaluation of the Strategic Plan for the Maintenance and Management of Medical Equipment and Devices; Key Benchmarks, Next Steps and Way Forward

					YEAR	YEAR			
No.	Benchmark	Key Assumptions	2021	2022	2023	2024	2025		
1	Designate an organization/unit to be in charge of the maintenance and management of medical equipment and devices in Sierra Leone at the MOHS level.	<ul> <li>CMO/MOHS can designate a programme or unit under one of the following:</li> <li>1. Directorate of HSS</li> <li>2. Directorate of Hospital and Ambulances</li> </ul>	Q1	-	-	-	-		
2	Build up the capacities and re-engineer the maintenance units (MUs) at the facility (hospital) level.	<ol> <li>HRH commitment, post created, filled posts</li> <li>Support of donors continues</li> <li>Workshops retrofitted</li> </ol>	Q1-Q2 x	X	x	x	X		
			Q2-Q4						
	Integrate maintenance functions at the DHMT level.	MOHS Memo issued	Q2-Q3	X	X	X	X		
				-	-	-	-		
3	Establish HFMUs.  Create a system at the facilities for receiving and dispatching equipment from PHUs.	Funding needs to be secured for the HFMUs  UNICEF to provide funding for basic repair kits	Q1-Q2						
4	Establish national IPM and CM programmes/systems (pilot in SCBUs). Develop and print national IPM and CM guidelines. Provide continuous capacity building training on IPM and CM guidelines for technicians. Revise National IPM and CM guidelines to include other equipment.	Adequate budget allocated  Plan is developed every year to include M&E	x x	x	x	x	x		
5	Institutionalize documentation and recording for performance-based, evidence-based decision-making, i.e., CMMS.	Programme (after firmly establishing the system, discuss integration into the national system with DPPI)  Donors/partners to provide training, desktop computers,	x	x	x	x	x		

		other hardware, access to the Internet					
6	Establish five RMU workshops (Port Loko, Kenema, Makeni, Bo Hospitals and Connaught Hospital).	HFMU/DMU are strengthened already Posts and HR for BMETs are approved	-	X	X	X	X
7	Establish capacity-building training programmes for technicians and users.	In-service training  Academic-based pre-service training programmes (government)	x -	x	x	x	x x
8	Upgrade/retrofit health facilities' electrical systems to reduce electric anomaly-induced equipment breakdowns (pilot in SCBUs).	Donors/partners supplied materials and local labour	Q1-Q2	-	-	-	-
9	Improve medical oxygen supply by installing oxygen plants at four regional hospitals plus two tertiary care hospitals.	Kenema, Bo, Makeni and Port Loko, PCMH and Ola During	х	-	-	-	-
10	Develop Standard Equipment Lists (SELs) for different health care delivery levels.	Created draft for referral hospitals, district hospitals and PHUs (CHCs) - Include clinical and technical cadres (human resources) required to use and maintain the equipment  Consultative meeting and validation with unit heads and specialists	Q2-Q4	Q1	-	-	-