PRACTICAL GUIDE

SELECTING BIOMEDICAL EQUIPMENT FOR LINE MINISTRY HOSPITALS IN SRI LANKA

August 2023

PRACTICAL GUIDE

This handbook is one of the final results of the research project "To improve the decision-making process for selecting Biomedical Equipment in selected line ministry hospitals in the Western province, Sri Lanka" carried out as a partial fulfilment of the degree of MD in Medical Administration offered by the Postgraduate Institute of Medicine (PGIM) of the University of Colombo, Sri Lanka.

REVIEW COMMITTEE

(1) Emeritus Prof. Saroj Jayasinghe
Emeritus Professor of Medicine
Founder Head, Department of Medical Humanities
University of Colombo, Sri Lanka
and
Consultant Physician

(2)

(3)

Ministry of Health, Sri Lanka

(4) Eng. S.A.J.Karunathilake
Deputy Director General – Biomedical Engineering Services Division
Ministry of Health, Sri Lanka

(5) Dr. Chandana Wijesinghe
Specialist in Medical Administration
Deputy Director
Teaching Hospital – Peradeniya, Sri Lanka

AUTHOR

Dr.

Email:

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In the pursuit of creating this invaluable handbook on “Selecting Biomedical Equipment for Line Ministry Hospitals in Sri Lanka”, numerous individuals have played pivotal roles and it is with deep gratitude and appreciation that I acknowledge their contributions.

First and foremost, my sincere thanks extend to Dr. Asela Gunawardena, the Director General of Health Services (DGHS) of Ministry of Health, Sri Lanka for granting permission to undertake this significant research project. His support and commitment to advancing healthcare services in Sri Lanka has been instrumental in bringing this handbook to fruition.

I would like to express my profound gratitude to the Review Committee Head, Emeritus Prof. Saroj Jayasinghe. His expertise as an Emeritus Professor of Medicine, Founder Head of the Department of Medical Humanities at the University of Colombo, and as a Consultant Physician, have been invaluable in guiding me through this project.

My gratitude also goes to my esteemed supervisors,

I owe a special debt of gratitude to Dr. Chandana Wijesinghe for his unwavering guidance and support, which has been instrumental in shaping this handbook.

I extend my heartfelt appreciation to Eng. S. A. J. Karunathilake, Deputy Director General of the Biomedical Engineering Services Division (BES) and his dedicated team at BES division. Their commitment to healthcare equipment management has been instrumental in the development of this handbook.

I would like to acknowledge and express my gratitude to Eng. T. V. A. Ruwansiri for his technical support and contributions to the development of the systems involved in this project.

To my family, including my husband, kids and parents, I extend my heartfelt thanks for their unwavering support, understanding and encouragement throughout this challenging journey. Their patience and belief in my work have been a constant source of motivation.

In closing, this handbook represents a collective effort and each individual mentioned above has played a crucial role in its creation. I am sincerely grateful for their contributions and it is my hope that this handbook will make a lasting and positive impact on healthcare services in Sri Lanka, ultimately benefiting the population we serve.

Message from the Director General of Health Services

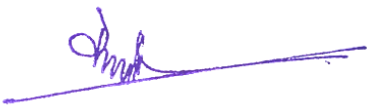
Sri Lanka has witnessed unprecedented growth in healthcare expenditure and this burden falls heavily on our nation. As we navigate through the challenging economic landscape, it is our responsibility to ensure that our investments lead to tangible benefits for our people.

Our healthcare landscape is unique, influenced by our culture, our people, and our values. Therefore, it is vital that our equipment procurement strategy is not only efficient but also tailored to our specific needs.

I am pleased to present to you a comprehensive guide on “Selecting Biomedical Equipment for Line Ministry Hospitals in Sri Lanka", a valuable resource that sheds light on our journey toward more efficient, effective and productive healthcare equipment procurement. This handbook captures the essence of Healthcare Technology Assessment (HTA) and needs assessment, two vital tools that will empower us to make well informed decisions and allocate resources wisely. The handbook underscores the importance of HTA and needs assessment from a Sri Lankan perspective, reminding us that we must use these tools to adapt and evolve with the changing dynamics of our healthcare system.

This handbook marks a turning point in our healthcare journey. It serves as a guide, directing us toward a more strategic, needs based approach to biomedical engineering equipment procurement. By concentrating on the most essential requirements in our government hospitals, we can ensure that every piece of equipment we acquire serves a purpose, addresses a need and contributes to our overarching goal of providing exceptional healthcare to our citizens.

I invite each of you to use this handbook as a powerful tool that will empower our healthcare system, medical professionals and our citizens. Let us together embark on this journey towards a brighter, healthier Sri Lanka, where every rupee spent on healthcare is an investment in our future.



Dr. Asela Gunawardena

Director General of Health Services

Message from the Deputy Director General of the Biomedical Engineering Services Division

In the world of healthcare, we are confronted with a challenging paradox: the demand for medical equipment is seemingly limitless, while the resources at our disposal are finite. I am delighted to introduce this handbook on “Selecting Biomedical Equipment for Line Ministry Hospitals in Sri Lanka". This handbook has been crafted in response to a longstanding need in the field of healthcare management, an effective guide to optimising limited budgets while addressing the ever expanding requirements for medical equipment in government hospitals.

We understand that it is impossible to satisfy all the demands for medical equipment but by adopting a strategic and informed approach, we can make the most of our available resources. This involves the judicious selection of equipment, the avoidance of unnecessary purchases and a steadfast commitment to providing essential requirements.

In today's world, patients rightfully anticipate the best possible care and this includes access to cutting edge medical technologies. This handbook equips decision makers and offers guidance on how to prioritize medical equipment purchases based on clinical need, cost effectiveness, and long term sustainability.

We envision this handbook as an invaluable resource for healthcare administrators, policymakers and procurement professionals. By employing the principles outlined within these pages, we believe that government hospitals cannot only maximise the utility of their budgets but also ensure that patients receive the high quality care they deserve.

Our aspiration is that this handbook will not be confined to library shelves but will be fully utilised in shaping future healthcare activities. By sharing knowledge and expertise, we can collectively enhance healthcare delivery and make meaningful strides toward bridging the gap between resource limitations and patient expectations.

As this handbook will be launched into the hands of decision makers, I am excited to see the positive impact it can have on the healthcare system.

Eng. S.A.J. Karunathilake
Deputy Director General
Biomedical Engineering Services Division

PREFACE

The selection of biomedical equipment for line ministry hospitals in Sri Lanka is a multifaceted endeavour that necessitates careful consideration, meticulous planning, and informed decision-making. This handbook stands as a comprehensive guide to navigate the elaborated process of biomedical equipment selection, procurement and management. Its purpose is to equip healthcare decision makers, administrators and professionals with the knowledge and tools needed to make well thought out choices in the acquisition and maintenance of biomedical equipment.

Healthcare is at the heart of any nation's progress and its effectiveness hinges significantly on the availability and functionality of the medical equipment supporting it. Biomedical equipment plays a pivotal role in healthcare delivery, from diagnostic and therapeutic devices to patient monitoring and laboratory instruments. Thus, ensuring that healthcare facilities are equipped with the right tools is paramount to enhancing the quality of care and optimising resource allocation.

This handbook or guideline is a product of comprehensive research, collaboration and dedication to advancing healthcare services in Sri Lanka. Its development was driven by recognition of the challenges faced in the acquisition, management and maintenance of biomedical equipment. The need for a systematic approach, grounded in data driven decision making, became increasingly evident as the healthcare landscape evolved.

The journey through this handbook begins with the fundamental process of conducting a needs assessment. The needs assessment is a powerful tool that empowers healthcare facilities to identify existing gaps, prioritize activities, and allocate resources efficiently. By collecting baseline information and comparing it to desired standards, healthcare decision makers gain invaluable insights into the specific needs of each facility and the available resources.

The role of prioritization emerges as a central theme. In a landscape of limited resources, prioritization is essential to ensure that healthcare facilities focus on acquiring equipment that will have the most significant impact on patient care and clinical outcomes. The handbook underscores the significance of data driven decision making in this process, encouraging healthcare facilities to rely on comprehensive needs assessments rather than budget constraints or vendor recommendations.

Involving health service providers in the decision-making process emerges as a vital step. Their insights and support are invaluable, as they are the individuals directly involved in implementing and utilizing the chosen equipment. Collaboration with health service providers guarantees that equipment aligns with the specific needs of the healthcare facility and seamlessly integrates into existing operations.

The handbook also delves into the critical phases of procurement, installation, commissioning and training. These phases are indispensable in ensuring that selected equipment is not only acquired but also properly integrated, operated efficiently and maintained throughout its lifespan.

ACRONYMS AND ABBREVIATIONS

BES	Biomedical Engineering Services Division
CPGs	Clinical practice guidelines
DDG	Deputy Director General
DGHS	Director General of Health Services
Dr	Doctor
Eng	Engineer
HB-HTA	hospital-based Health Technology Assessment
HTA	Health Technology Assessment
HTM	Healthcare technology management
IT	Information Technology
M&E	Monitoring and Evaluation
MD	Doctor of Medicine
MEL	Model Equipment List
MoH	Ministry of Health
NAPM	Need Assessment and Prioritization Model
PGIM	Postgraduate Institute of Medicine
Prof	Professor
TCO	Total Cost of Ownership
VfM	Value for Money
WHO	World Health Organization

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Section 1: Background, Objectives, Principles, Use and Structure of the Guide

Background

Health technologies are essential for the effective and proper functioning of a country's health system. Medical equipment as defined by the World Health Organization (WHO) is known as "medical devices requiring calibration, maintenance, repair, user training and decommissioning which are usually managed by biomedical engineers. Further, the equipment can be used alone or in combination with any appropriate accessory, consumable or other piece of medical equipment". This equipment is considered as core assets which are essential in delivering an effective healthcare service.

Biomedical equipment is considered as the set of instruments used in the health sector in the field of biology, pharmacology and medicine. These instruments are designed in a manner to obtain specific information, perform biological and chemical processes and also for treatments. The Biomedical Engineering Services division at the Ministry of Health (MoH) functions as a conduit for greater knowledge gathering of biology through concepts of engineering, servicing the needs of human health. The division is focused on developing new technologies for healthcare purposes focused on medicine and biology. This field is intended to reduce the gap between engineering and medicine and provide effective healthcare treatment which includes diagnosis, monitoring and therapy.

Equipment planning in the healthcare sector is a specialised process which requires a clear understanding of the hospital and clinical needs and also an intricate familiarity and know-how of the building process, budgeting and architectural design.

Procurement of medical equipment in the health sector involves finding, evaluating terms and conditions, acquiring the necessary goods and/or services from an external supplier or service provider usually through a competitive bidding procedure or tender.

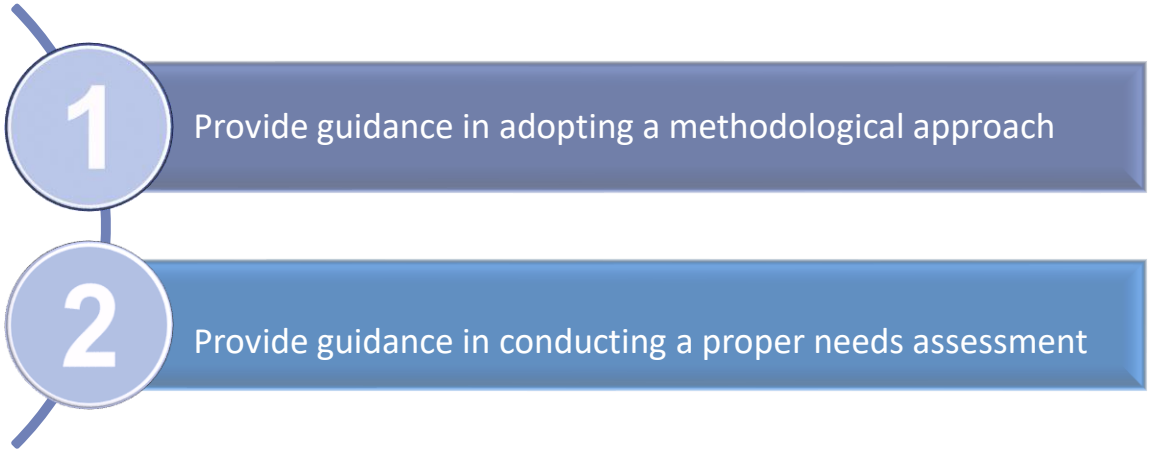
The selection of biomedical equipment to support the needs of a particular health institution is a multifactorial complex process. Though international frameworks and guidelines are available, Sri Lanka does not have an effective and acceptable method for identifying the actual needs of the hospitals to purchase any biomedical equipment. Thus, observations and available data have proven that the equipment is ordered and purchased by the hospitals in an unplanned manner leading to wastage, unproductiveness, inappropriate usage or non-usage, lack of accountability and misuse of public property. In such a backdrop, optimal use of biomedical equipment could be achieved based on a proper needs assessment process.

A needs assessment is a strategic activity which would determine and address the gaps between the current situation and the anticipated state of affairs. This method, adopted as a part of the planning process would help to address and sort out the deficiencies of biomedical equipment requirements at national and local hospitals, in a viable and productive manner. The process of needs assessment (Figure 9) is complex and incorporates several variables, providing information necessary for decision makers to prioritise and choose appropriate medical equipment at national and regional (local) level hospitals.

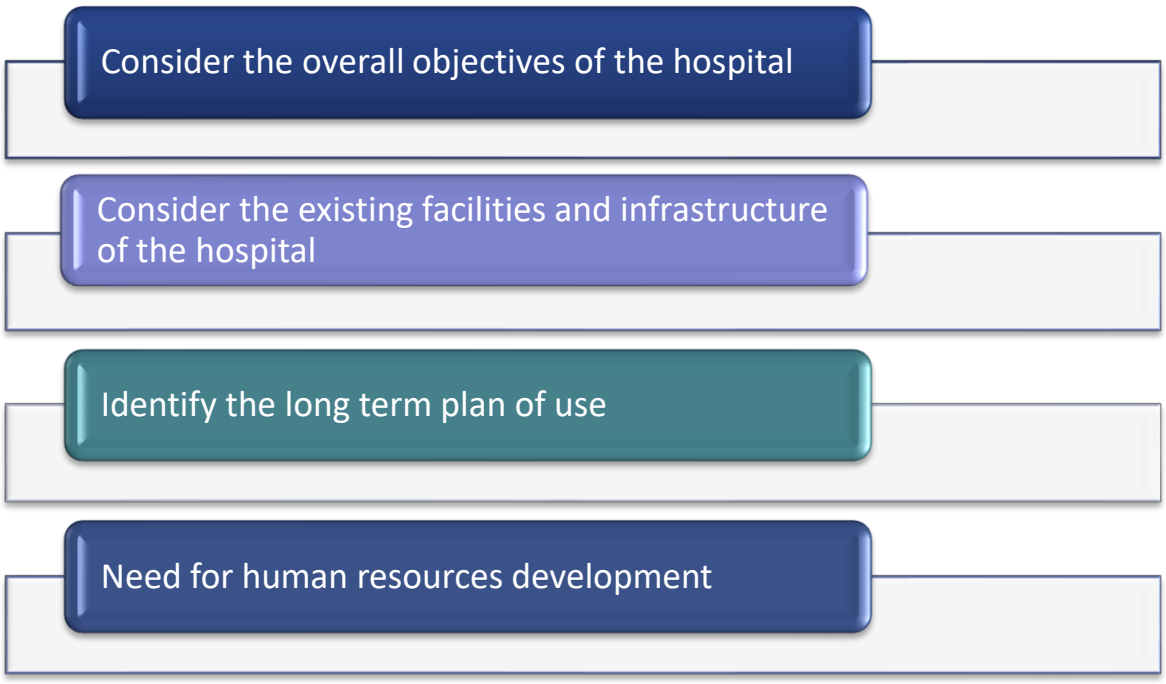
PRACTICAL GUIDE

Objectives

The key objective of this guide is to provide the national and regional (local) hospitals with necessary guidance in implementing a methodological approach in conducting a proper **needs assessment** prior to procuring biomedical equipment.



Guiding principles



Using the guide

Decisions taken with regard to purchasing medical equipment possess unique challenges that are not encountered when purchasing medicines. Hospitals with low resource settings especially at regional or local level encounter many challenges related to medical equipment which influences the proper diagnosis and treatment of patients. These challenges would include lack of essential and functioning equipment and also other aspects such as planning the medical equipment life cycle. This handbook would serve as a guide in overcoming these challenges.

The operational requirements (or end user needs) and limitations are often inadequately considered during the planning and procurement process of medical equipment. Due to ad hoc and improper assessment in planning the procurements, significant number of equipment failures tend to impact the patients' well-being and the overall healthcare services.

The key purpose of this guide is to provide practical guidance and assistance to the relevant officials in the hospitals and Ministry of Health, engaged in facilitating the requests of procurement of biomedical equipment. Using the main process in this guide will confirm that a consistent and strong need assessment process is followed.

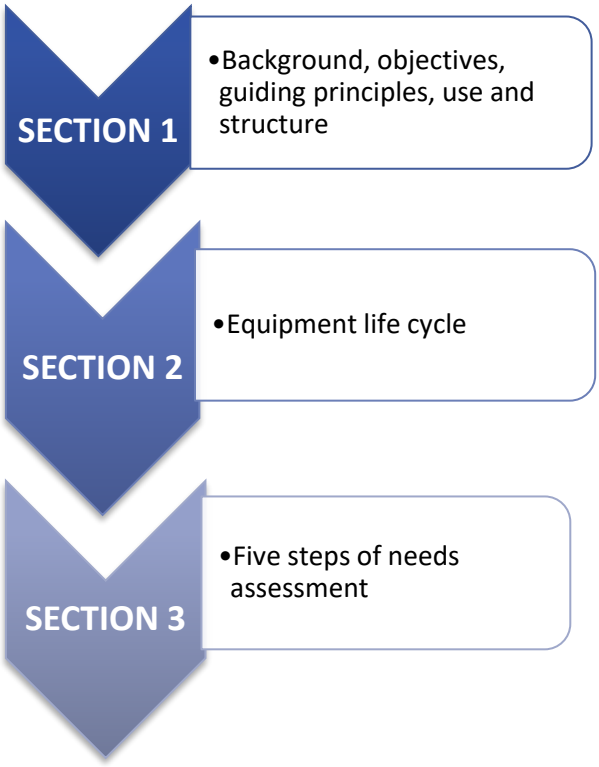
The guide would assist the need assessment process to be implemented in a manner to ensure that required equipment needed to perform a specific activity is selected, provided (or supplied) and ready for usage in an effective, efficient and sustainable manner. Further, it would also support the government's resource constrained health systems and procurement teams to implement a need assessment, when planning and procuring new medical equipment for hospitals.

A multidisciplinary team of officials and stakeholders need to be involved in establishing the effectiveness of the process in terms of analysing and assessing the actual need; evaluating the available options and deciding on the necessity to proceed with the procurement. The team or officials involved in the planning and procuring of medical equipment will need to coordinate and seek input and support from internal and external stakeholders of the particular hospital namely, government ministers, MoH officials, suppliers, regulators, manufacturers, technical agencies, financiers, donors etc. Implementing a need based assessment process would ensure an efficient and effective selection of medical equipment that would be best suited to the end users supporting the healthcare services. This guide is developed in a manner to support the health sector officials involved in procurement planning to facilitate the ordering and supplying of medical equipment to sustain the country's government health system.

PRACTICAL GUIDE

Structure of the guide

This practical guide on selecting biomedical equipment for line ministry hospitals in Sri Lanka has three (3) sections.



Usefulness of the guide

Numerous activities necessitate a multi-disciplinary approach, making it essential to create diverse teams comprising members from planning, financial, clinical, technical and logistical domains.

This guide is suitable and useful for the following:

- Health planners and policymakers
- Government staff in charge of regulating and supervising health systems
- Technical and maintenance staff at the different levels of the HTM service
- Health management teams including medical practitioners
- External support agency/institution staff

Other categories of staff

- Managers and administrators
- Human resource managers
- Finance officers
- Equipment users
- Purchasing officers

Section 2: Equipment life cycle

Health Technology Assessment (HTA)

Health Technology Assessment (HTA) is a comprehensive process that systematically evaluates the broader implications of health technologies, ensuring safety, effectiveness and alignment with patient needs. HTA delivers evidence-based insights to guide healthcare policies, aiming to achieve optimal value while working within resource limitations. HTA, in essence, is research driven and practice oriented assessment. It encompasses a thorough examination of all available knowledge regarding both direct and intended effects of health technologies, as well as their indirect and unintended consequences.

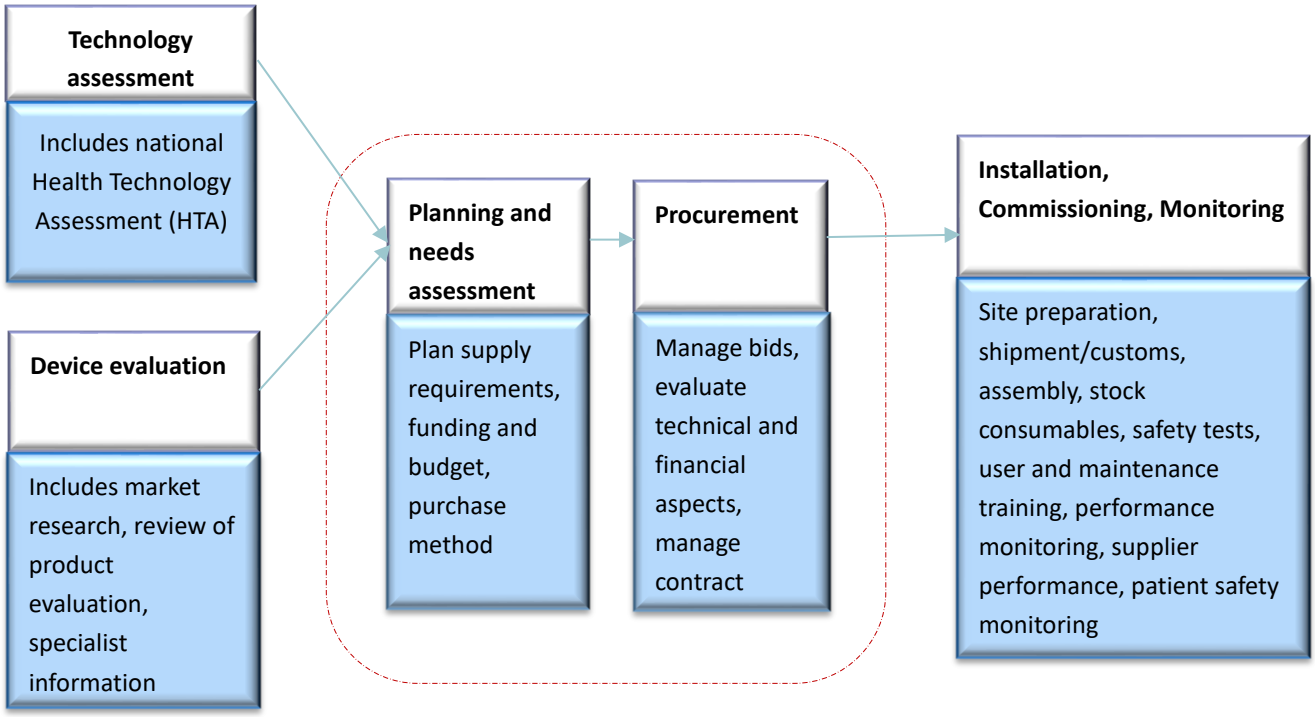


Figure 1: Overview of purchasing medical equipment (specific focus of the review within dashed lines)
Source: Hinrichs-Krapels, et al., 2021 [Items in each step taken from WHO procurement process guide.]

In Sri Lanka, the practice of HTA holds a crucial position in promoting evidence based decision making and the equitable distribution of healthcare funding, especially in the pursuit of Universal Health Coverage. Nonetheless, the absence of a unified HTA policy poses challenges in the introduction and oversight of new biomedical equipment within the healthcare system. This underscores the necessity for a comprehensive HTA framework to address these issues effectively.

Hospital based Health Technology Assessment (HB-HTA)

The procurement of medical devices and equipment is just one facet of hospital operations, intersecting with various other functions such as health technology management, materials management and supply chain logistics. This practical handbook primarily concentrates on what is commonly referred to as the acquisition process. This process initiates as soon as the need for a new or replacement medical device or equipment arises and continues until the equipment is installed and ready for use, as illustrated in Figure 1.

Within the hospital context, HTA performed for managerial decision-making purposes is referred to as hospital-based Health Technology Assessment (HB-HTA). While HB-HTA is typically carried out within hospital premises, it is not confined to this setting. HB-HTA serves as a means to address inquiries posed by hospital managers regarding the implementation of new technologies, including biomedical equipment, within their respective healthcare facilities, among other related matters.

Healthcare technology management (HTM)

Healthcare technology management, known by various terms such as Biomed, biomedical engineering, clinical engineering and medical equipment management, is a critical aspect of overseeing and upkeeping medical devices utilized or intended for use across diverse healthcare environments. These environments range from home care and field settings to doctor's offices and hospitals. Ensuring equitable, quality and efficient healthcare relies on a well balanced and effectively managed set of resources (Figure 2). Among these essential inputs, healthcare technology, encompassing fixed assets and consumables, plays a pivotal role.

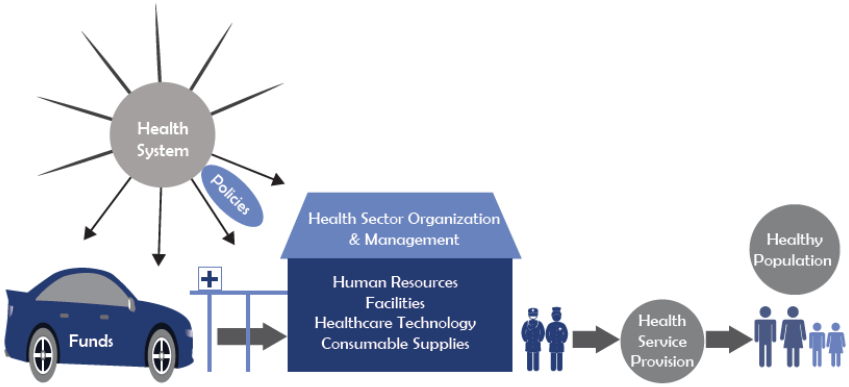


Figure 2: Healthcare technology management (HTM) in the health system
Source: Temple Bird, et al., 2005

Healthcare technology management (HTM) encompasses the coordination and organisation of various activities aimed at effectively managing physical hardware components. These activities are essential for ensuring the smooth operation and maintenance of healthcare technology and also requires a wide range of skills or competencies to manage the related areas of work (Figure 3).

ACTIVITIES

- Collecting pertinent information about the equipment
- Strategizing technology needs and allocating adequate funds
- Acquiring suitable models and proficiently installing them
- Allocating ample resources for optimal use
- Operating the equipment efficiently and safely
- Maintaining and repairing the equipment promptly
- Decommissioning, disposing and replace unsafe and outdated items
- Equipping staff with the necessary skills to maximise equipment utilisation.

Requires a wide range of skills in managing a number of areas including:

- purchasing procedures
- finances
- stores supply and control
- technical problems
- workshops
- staff development

Figure 3: Healthcare technology management – essential activities and skills Source: Lenel, et al., 2005

Healthcare technology plays a crucial role in modern healthcare and it cannot be overlooked. Indeed, healthcare technology management encompasses a series of activities forming a life cycle for equipment, depicted in Figure 4.

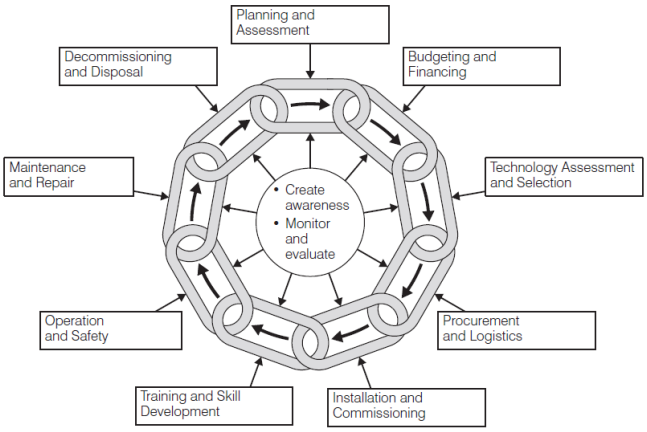


Figure 4: The Healthcare Technology Management Cycle
Source: Temple Bird, et al., 2005

In order to offer an effective HTM service, it is required to provide sufficient inputs and only upon doing so the required necessary outputs and benefits could be obtained as illustrated in Figure 5.

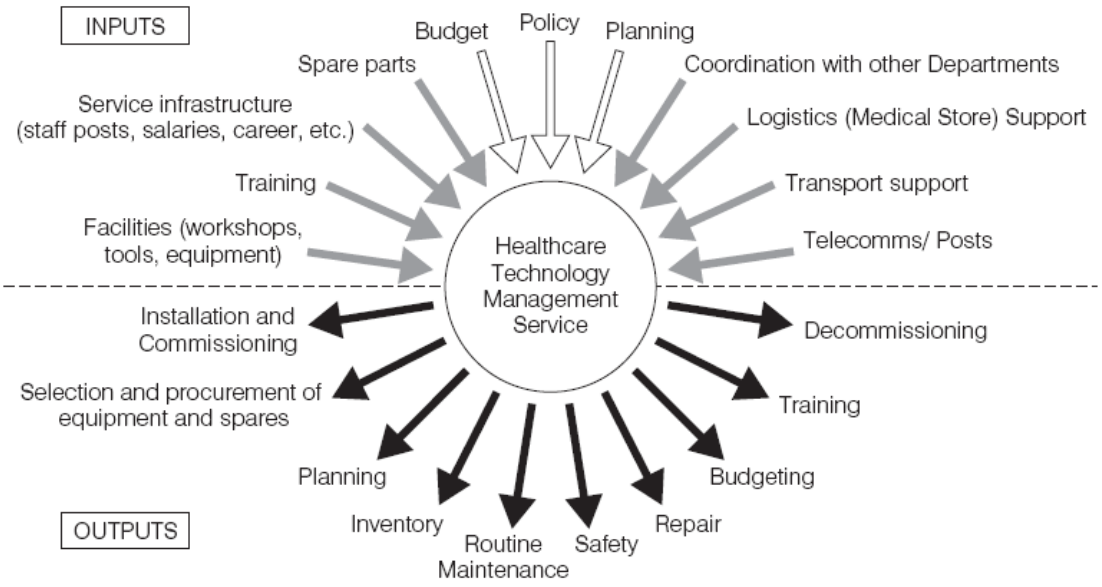


Figure 5: HTM service inputs and outputs
Source: Andreas, et al., 2005 [Extracted from WHO, 1987 "Inter-regional meeting on the maintenance and repair of health care equipment: Nicosia, Cyprus, 24-28 November1986, Geneva, Switzerland, WHO/SHS/NHP/87.5]

Technology serves as the foundation for healthcare delivery and forms the basis for all health interventions. Facilities and healthcare technology represent the most significant capital expenditure in any health sector.

Consequently, it is financially prudent to handle these valuable resources with care and ensure that healthcare technology is managed in the following manner (Figure 6).

Appropriate selection — Choosing healthcare technology that aligns with the specific needs of the healthcare system is crucial.

- Entails careful consideration of factors like the patient population, healthcare services offered and the organisation's goals. By making well-informed selections, healthcare providers can optimise the impact of the investments.

Proper utilisation — Efficiently utilising healthcare technology is essential for maximizing its benefits.

- Training healthcare staff on the correct usage of equipment and systems ensures that they are employed to the full potential. Avoiding misuse or underutilisation helps in providing better care and reducing unnecessary costs.

Maximising lifespan — Healthcare technology should be maintained and serviced regularly to extend its lifespan.

- By implementing preventive maintenance schedules and promptly addressing issues, healthcare facilities can prolong the operational life of the technology, minimising the need for premature replacements.

Figure 6: The Healthcare Technology Management Cycle
Source: Author developed (Reference: Temple-Bird, et al., 2005)

A comprehensive and strategic approach to managing physical resources, particularly healthcare technology, is fundamental to achieving a more equitable, higher quality and efficient healthcare system. Through careful selection, proper utilisation and maintenance, healthcare providers can optimise the resources and deliver improved patient care.

Based on the broader terminology or definition of WHO, the various equipment and technologies associated with health facilities would be referred to as “healthcare technology” in this handbook. Accordingly, medical equipment is considered under healthcare technology and it is important to clarify the following (Figure 7) in assessing the actual needs.

Figure 7: Equipment requirement analysis
Source: Author developed (Reference: Temple-Bird, et al., 2005)

Advantages of healthcare technology management

Box 1: Advantages of proper healthcare technology management

- Health facilities can ensure uninterrupted service delivery through well-functioning healthcare technology.
- Proper utilisation, maintenance and protection of equipment is prioritised.
- Staff would maximise equipment usage by adhering to written procedures and best practices.
- Health service providers would receive comprehensive, timely and reliable information on:
  - Equipment functional status
  - Performance of maintenance services
  - Operational skills and practices of equipment user departments
  - Skills and practices of staff responsible for equipment related activities in various departments, including finance, purchasing, stores and human resources
- Staff can exercise control over the substantial financial investment in equipment, leading to a more effective and efficient healthcare service.

Source: Author developed

Equipment life cycle

Various aspects of the HTM concerns the management of the medical equipment life cycle, which would be from planning to purchase, installation, operation all the way through decommissioning and disposal. The Equipment Life Cycle as often used in HTM details the four (4) phases and the chain of activities identified under nine (9) different key areas (Figure 8).

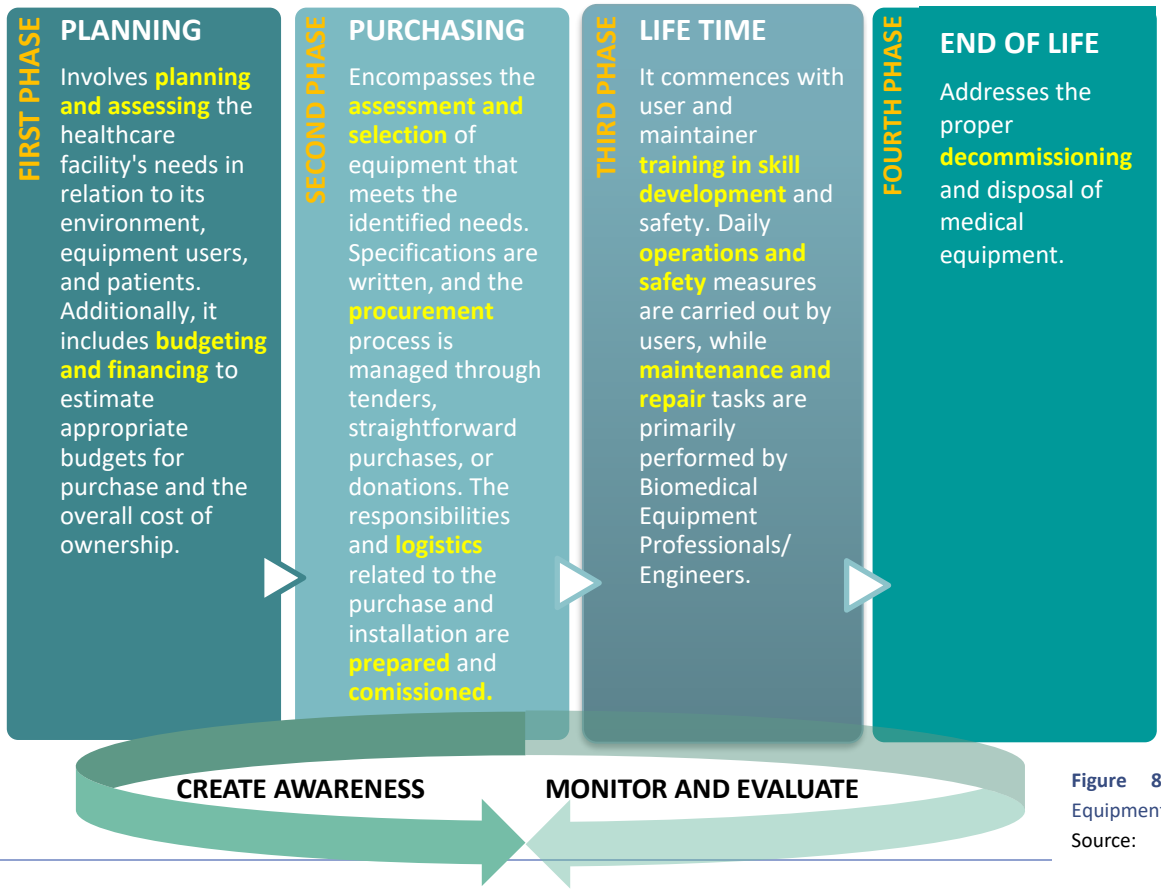


Figure 8: Phases of the Equipment Life Cycle
Source: Author developed

Throughout the entire life cycle, “create awareness” and “monitor and evaluate” are ongoing elements. Raising awareness among all involved stakeholders, including users, maintainers, administrators and politicians, is crucial to enhance systems and improve biomedical and healthcare practices. Monitoring and evaluating the equipment's life cycle facilitate the review and improvement of processes, as well as the sharing of successes and lessons learned.

Section 3: Five steps of needs assessment

Needs assessment

Once a biomedical problem has been identified, conducting a comprehensive **needs assessment** becomes imperative. The procurement of biomedical equipment necessitates a well executed needs assessment, which involves identifying and defining prioritised requirements while considering potential impacts on users with the ultimate goal of enhancing health or health service delivery. In the context of health technology design, a robust needs assessment plays a pivotal role in problem identification and guides design choices to address engineering questions and solve the identified problem effectively.

The process of choosing biomedical equipment is intricate and demands a transparent approach based on rationality, evidence and assessment of prioritized public health needs. Poor choices can lead to inappropriate utilisation or non-use of medical equipment, resulting in resource wastage. In a needs assessment, it is crucial to consider unique diagnostic, treatment and preventive approaches within the specific problem context and its solutions. Health technology must align with local circumstances, taking into account available national resources, infrastructure, knowledge and skills. Conducting a location specific needs assessment is vital to ensure that the selected technologies are not only effective and suitable but also cost-effective, without compromising resources in other critical healthcare areas.

The guide outlines a **five-step planning** process (Figure 9), offering practical activities and quantitative and qualitative methods to ensure a systematic and robust assessment of biomedical equipment procurement requirements, leading to tangible outcomes. The gathered information can significantly enhance healthcare technology management (HTM) services and health outcomes for both targeted populations and the overall health sector.

This process aids relevant officials in identifying and prioritising biomedical equipment requirements and reaching a consensus on appropriate interventions for positive change. In this guide, needs assessment refers to identifying and defining prioritized requirements related to biomedical equipment. A thorough assessment takes into account the potential impact on the performance of biomedical equipment users and the delivery of services within the context of health system capabilities and service delivery priorities. It also considers the overall objectives of the institution, existing facilities and infrastructure, long-term usage plans and human resources development before procuring biomedical equipment. Involving end users in the assessment process is of critical importance.

The needs assessment can be conducted in various scenarios and circumstances. It is a regular part of an effective medical equipment maintenance programme and occurs during updates to medical equipment inventories, service re-evaluations or equipment replacements. Effective medical equipment maintenance and management play a significant role in reducing unnecessary expenses and contribute to efficient service delivery and financial management in hospitals.

In performing a needs assessment, the general approach involves examining the available resources at the facility, national or local level and comparing them to what should be available, considering the specific demand and situation of the target area or group. The assessment can be carried out at national, regional, local or hospital/ facility levels and it is also crucial before the construction of any new health facility (e.g. hospital).

Needs assessment at a glance

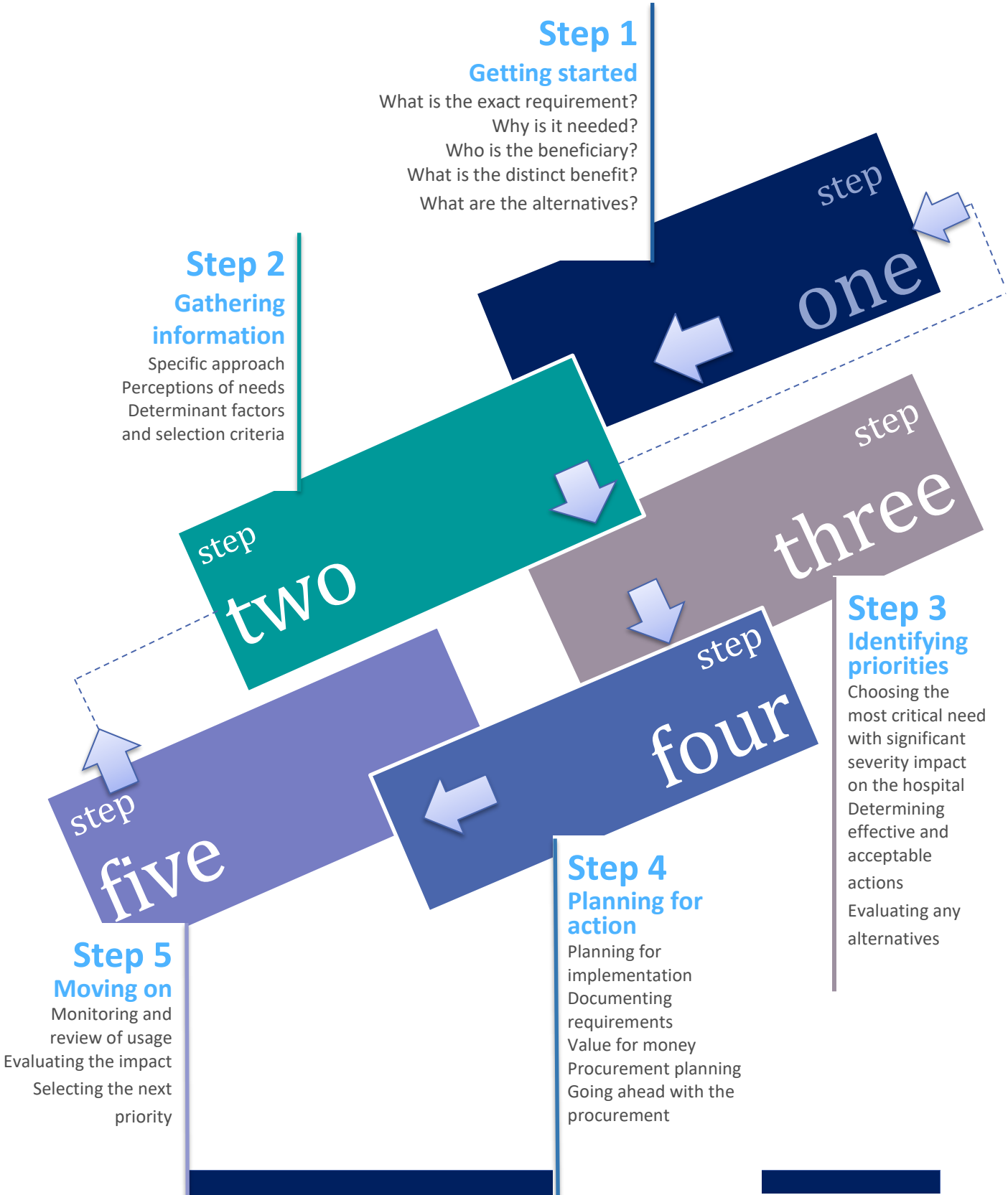


Figure 9: Needs assessment – summary

Source: Author developed, Reference: Cavanagh & Chadwick, 2005 and based on the model outlined by Hooper and Longworth (2002),

STEP 1
Getting started

1.1 Requirement identification

A suggested iterative approach is employed for the identification of requirements related to biomedical equipment and conducting needs assessments. In practice, these steps are closely interconnected and not distinctly separable (Figure 10).

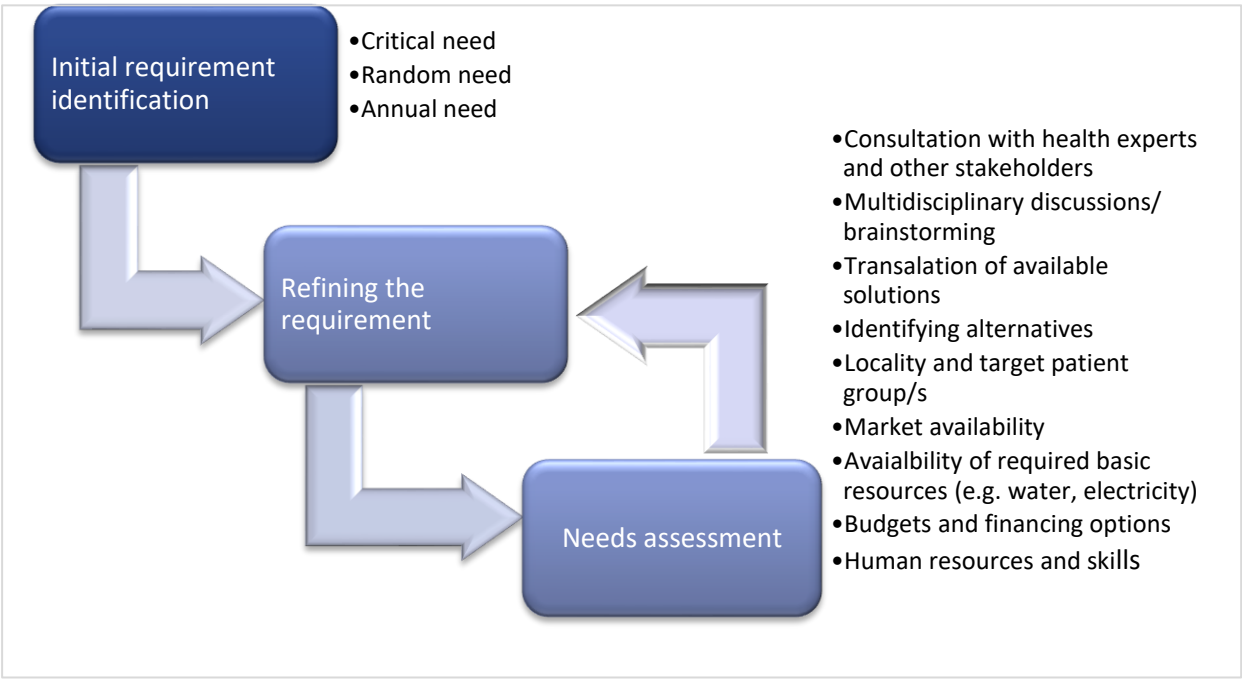


Figure 10: Requirement identification and needs assessment
Source: Author developed, Reference: Saidi, et al., 2019

A crucial skill that necessitates training and practice is the capability to recognise a biomedical equipment need and conduct a thorough and multi-disciplinary local needs assessment for that particular requirement. Understanding user needs holds paramount importance, as complex health technologies may prove impractical and unfeasible in resource limited environments. Accurately identifying the requirement and conducting a comprehensive needs assessment can significantly reduce wasteful and unsuitable utilisation of scarce local resources.

1.2 Equipment planning

Healthcare equipment planning is a highly specialised process that demands not only a comprehensive understanding of the clinical requirements but also a detailed knowledge of budgeting, architectural design and the building process. The planning process is meticulously developed and executed to ensure that the equipment needed for specific activities is carefully selected, supplied and made ready for efficient and effective use.

Biomedical equipment planning and procurement are integral parts of the HTM processes during the acquisition stage. Subsequent to the acquisition stage, HTM progresses to the utilisation stage. Table 1 provides examples of activities that fall under the planning phase during the acquisition stage of HTM.

Table 1: Examples of processes and activities for HTM's medical equipment acquisition stage

MEDICAL EQUIPMENT ACQUISITION STAGE	
Process	**Activity (examples)**
Biomedical equipment planning	♦ **Needs assessment** ♦ Health technology assessments ♦ Health system strengthening ♦ Budgeting/ financing for total cost of ownership (TCO) ♦ Feasibility appraisal ♦ Value for money appraisal ♦ Market analysis ♦ Technical requirement identification

Source: Author adapted, Reference: Access and Delivery Partnership (ADP), 2020

1.3 Exact requirement

It is important to assess the current situation in order to identify the difference between **what is needed and what exists**. Conducting a thorough assessment of the current situation is imperative to discern the disparity between the existing resources and the actual requirements. For effective management of biomedical equipment stock, it is essential to have a comprehensive understanding of the current stock and supplies, as managing unknown inventory proves to be challenging. It is crucial to be mindful of the following points (Figure 11).

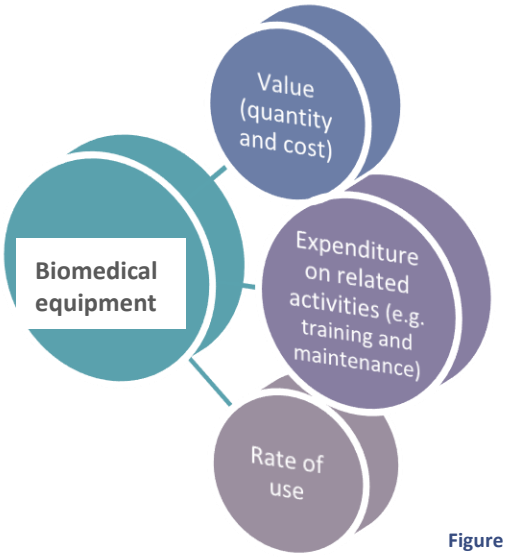


Figure 11: Key aspects for consideration to manage the Biomedical equipment stock

Source: Author adopted, Reference: Temple-Bird, et al., 2005

To conduct an effective analysis of the equipment situation and establish a starting point for planning, utilising essential "planning tools" can be valuable. The following tools can aid in determining the baseline data:

- Maintaining an up-to-date biomedical equipment inventory
- Understanding the value of the stock of biomedical equipment
- Ensuring budget lines that accurately reflect biomedical equipment and related expenditure
- Identifying the rate of utilisation of biomedical equipment

1.4 Model Equipment List

A Model Equipment List (MEL) serves as a valuable tool in the planning process and can be described as follows:

• It is a comprehensive compilation of biomedical equipment typically required for each healthcare intervention, encompassing various healthcare functions, activities or procedures (e.g. anaesthesia machine, aspiration/suction pump, autoclave / sterilizer etc.).

• The list is organised based on the activity space or room, such as reception areas or treatment rooms and further categorised by unit or department.

• MEL is tailored for different levels of healthcare delivery, including national, regional and district levels, as the equipment needs may vary depending on the hospital's objectives and the scope of healthcare services offered.

• It includes a wide range of items making it a practical resource for planners, architects, engineers and purchasers.

• One of its primary purposes is to assess the economic viability of the hospital's objectives or vision, ensuring that the required resources, including biomedical equipment, can be feasibly accommodated.

It is important that any suggested biomedical equipment need identified for procurement should confirm to the following (Figure 12) or should be “system fit”. Due to these factors, MELs will vary within the regions/ districts/ areas/localities.

Figure 12: Analysing the “system fit” of suggested biomedical equipment need identified for procurement
Source: Author adopted, Reference: Temple-Bird, et al., 2005

The MEL must be a true reflection of the technological level of the equipment, specifically describing technology that the facility can feasibly sustain. In other words, the MEL should encompass equipment that can be operated and maintained by the existing staff and for which there are sufficient resources available for its effective use. It is important to ensure that the MEL aligns with the facility's capabilities, to avoid impractical or unmanageable equipment choices and to promote the successful integration and utilisation of biomedical technology within the healthcare setting.

1.4.1 Usefulness of the model equipment list

To effectively plan the procurement of equipment, hospital authorities and officials at the Ministry of Health (MoH) must be informed about any deficiencies in biomedical equipment. To identify such shortfalls, a crucial step involves comparing the equipment inventory with the available model equipment list. This comparison allows officers to discern whether any essential equipment is in excess, extravagant, currently missing or needs to be purchased (Figure 13). Such proactive analysis ensures that the hospital remains well equipped and able to deliver optimal healthcare services.

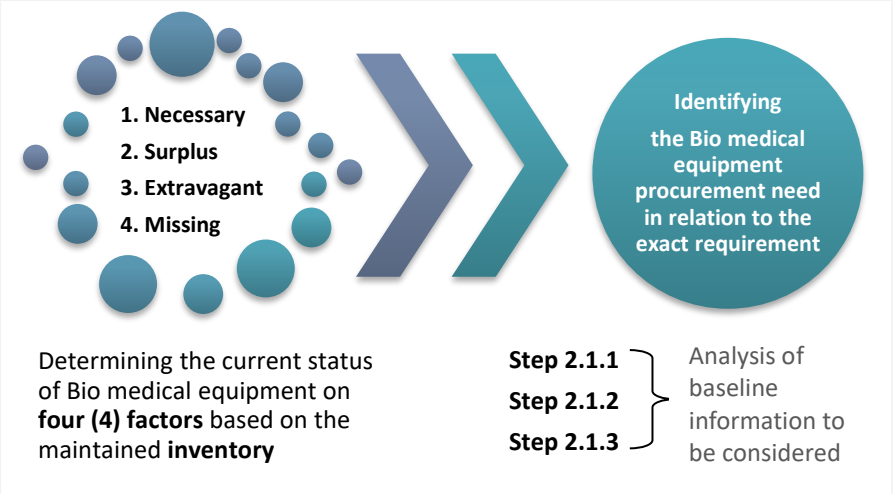


Figure 13: Framework to analyse the shortfall in biomedical equipment
Source: Author adopted, Reference: Temple-Bird, et al., 2005 and World Health Organization , 2011

1.4.2 Responsibility for developing the model equipment lists

The equipment planning cycle ideally involves the collaboration of diverse stakeholders, including MoH officials, hospital directors, medical practitioners, biomedical engineers, maintenance staff, administrators, senior equipment users, procurement, finance personnel and others. This collective engagement enables evidence based decision making throughout each stage of the biomedical equipment's life cycle. One of the pivotal functions of this group is the acquisition of new biomedical equipment, whether through procurement or donations.

It is paramount that this task is carried out by a multidisciplinary team to ensure that decisions benefit from the expertise and perspectives of all disciplines, rather than relying solely on the insights of a limited few. By involving various stakeholders, the equipment planning process becomes more comprehensive and effective, resulting in optimised management of biomedical equipment and improved healthcare services.

1.5 Biomedical equipment needs profiling

The profiling of biomedical equipment needs based on its intended use, system fit, current practice, user profiles and environment provides necessary feedback and detailed clarifications or answers under **Step 1** (Getting started) for questions such as;

- Why is it needed?
- Who is the beneficiary?
- What is the distinct benefit?
- What are the alternatives?

The below Table 2 lists instances of procurement product profile content from facilities that characterise the health, user and facility need.

Table 2: Facility-level information analysis in procurement of biomedical equipment

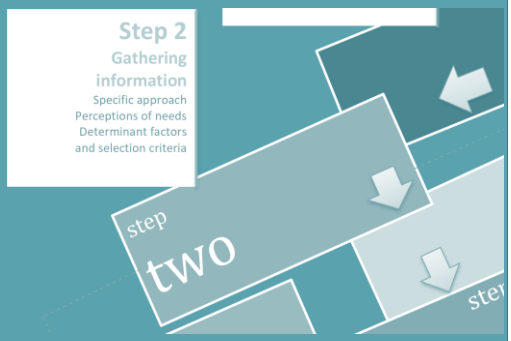
BIOMEDICAL EQUIPMENT NEEDS PROFILING	
Profile sections	**Potential questions**
Intended use	• What will be the primary application of this medical equipment (description and purpose)? • How will this medical equipment support healthcare tasks (name, goal, frequency, flexibility, dependencies, inputs, outputs)? • Which patient population or health programme will benefit from the utilisation of this equipment and at what specific point in the treatment or care continuum will it be employed? • What is the estimated number of patients who will require access to this equipment within a given time period (or any alternative metric used to assess the equipment's demand)?
System fit	• How will the integration of this equipment occur within the clinical system, process, or package of care? • Can this equipment serve multiple health programmes or meet various healthcare needs? • Are there existing clinical guidelines that specifically address the utilisation of this equipment? • Are additional equipment or resources necessary for the proper functioning of this equipment, such as cold chain systems for reagents, patient trolleys or networked computers? • Will the implementation of this equipment improve access to healthcare services for underserved or at-risk populations?
Current practice	• What medical equipment is presently utilized to address the healthcare need, and what are the associated operational costs? • How does the facility fund the maintenance of medical equipment? • Have alternative equipment, services or solutions been employed in the past to address similar needs? • Are patients referred to other facilities to access health services that necessitate this medical equipment and if so, where is this facility located?
User profiles	• Who will be the intended users of the medical equipment and what are their specific designations and the required number of staff to operate it? • Who will assume the responsibility for maintenance, inspection and repair of the medical equipment? • How many users and technicians are expected to be involved and what are their existing skill levels? • What are the anticipated advantages and benefits for users resulting from the implementation of the new medical equipment? • How is the current practice for on-boarding new staff and providing on-the-job training handled?
Profile sections	**Potential questions**
Environment	• Is there a designated secure area with sufficient dimensions to facilitate access and installation of the equipment? • What are the expected ambient conditions at the hospital, including factors like temperature, humidity, elevation, dust, saltwater exposure, flooding and winds? • How accessible is the hospital and will there be any challenges in transporting and servicing the equipment? • What is the availability and quality of electricity at the hospital? (Indicate any seasonal differences, any issues related to maintaining electrical equipment etc.) • Are there solar powered systems in place at the hospital? • Does the hospital have a reliable supply of potable water? (Indicate seasonal differences – if any) • Does the hospital have an established healthcare waste management system? (If yes, provide a description of the system in place)

Source: Author adopted, Reference: Access and Delivery Partnership (ADP), 2020

Biomedical engineering, clinical, laboratory and other technical experts will carefully examine the facility and end-user details to collaborate with procurement teams in formulating functional, performance and design requirements.

Additionally, these experts will provide valuable insights into other vital considerations, including adherence to recognised quality standards, provision of reference materials and conducting training activities in local languages. The collective expertise will contribute significantly to the successful procurement process, ensuring that the equipment meets the necessary criteria and aligns with the facility's specific needs.

STEP 2
Gathering information



2.1 Specific approach

As a specific approach Step 2 summarises the detailed information gathering and analysis steps of the needs assessment process. Before embarking on any planning process, it is crucial to determine the initial state. Therefore, analysing baseline data will provide valuable insights into the current status of biomedical equipment. This information serves as a foundation for informed decision making and effective planning activities.

The following **Step 2.1.1** is critically important as it directly refers to the health situation of the population of the identified or target locality.

Step 2.1.1 Baseline information on health service requirements

Table 3: Information on health service requirements

Local geographical and public health conditions	Considerations	Result
• **Population density of the target region/ district/ area of the locality of the hospital (healthcare services)** • **Major disease burden, common sicknesses and health issues**	• Population issues (demography/ economic concerns/ patient rate) • Epidemiological needs (disease priorities)/ medical needs • Prioritisation of healthcare concerns • Clinical practice guidelines (CPGs)/ protocols/ national and/or local recommendations • Internationally recognised standards on diagnosis and treatment of different diseases and medical conditions	• Appropriate health service delivery requirements

Source: Author adopted, Reference: World Health Organization , 2011

Step 2.1.2 Baseline information on health service availability

Table 4: Information on health service availability

Service delivery situation	Considerations	Result
• **Services available and offered by the hospital (e.g. surgical, maternal and child health, dental, etc.)** • **Available facilities in the region/ district/ area (e.g. hospitals, clinics, etc.)** • **Availability of human resources and required skills**	• Present or prevalent status of health service availability and accessibility • Views on health service from the target group of patients • Views on health service delivery from service providers/ related stake holders • Types of facilities available, conditions, numbers/amounts • Existing staffing levels	• Overview of the availability of health service • Facility availability map (or facility map)

Source: Author adopted, Reference: World Health Organization , 2011

Based on Step 2.1.1 (Table 3) and Step 2.1.2 (Table 4) some of the key information to be collected includes the following:

Availability of health services		
Knowing what is available:		
Knowing	♦ Where	*hospital (s) location*
	♦ What type	*health services available at the facility*
	♦ What range	*hospital (s) patients' details in terms of age, gender, geographical area/ distribution etc.*
	♦ What specific needs are met	*facility (and its services)*
	♦ How does	*facility receive referrals and from who*
	♦ How many	*patients seen each week/ month/ quarter/ year*
	♦ How long is the stay	*On average for how long do the patients remain or stay at the hospital (s)*
	♦ What are the reasons for leaving	*discharge, onward referral etc.*
	♦ What is the caseload	*staff*
	♦ How many full time staff does the hospital (s) employ	*time they have available each week to attend to patient appointments*
	♦ What information is available	*regarding staff satisfaction or facility user satisfaction obtained by way of surveys*
	♦ How does existing patients access the hospital (s)	*public transport, by walking, private transport etc.*
	♦ How accessible is the service	*by public transportation*
Having	♦ Some way of updating the information	*accuracy and analytical*

Step 2.1.3 Baseline information on Biomedical equipment

Table 5: Information on biomedical equipment

Medical device situation	Considerations	Result
• **Availability and condition of medical devices (including type, number, location and physical condition)** • **Status of water, electrical and waste disposal systems related to use of Biomedical equipment**	• Inventory of Biomedical equipment including status and condition • Current status of HTM infrastructure (or lack of thereof)	• Facility availability map (or facility map) • Biomedical equipment inventory (qualitative and quantitative) • Outline of HTM infrastructure

Source: Author adopted, Reference: World Health Organization , 2011

This step holds utmost significance in the health technology process, aiming to ascertain the availability of biomedical equipment and related infrastructure, along with the current condition. An essential planning tool utilised for this purpose is an equipment inventory. It is vital to gather comprehensive and reliable information during this inventory process, as any alterations, corrections or enhancements can significantly affect financial and human resources, as well as the overall environment. Thorough data collection ensures well informed decision making and contributes to effective resource management in the healthcare setting.

Taking Step 2.1.3 (Table 5) into account, some of the key information to be collected includes the following:

Availability and condition of Biomedical equipment			
Knowing what is available:			
Knowing	-	What is there	*type/brand/model/ serial number*
	-	How much is there	*quantity*
	-	Where is it	*location (hospital/unit/ department)*
	-	When was it	*installation date*
	-	What condition is it in	*status (in operation/ out of order/ repairable)*
	-	How far is it in its life cycle	*year of manufacture/ age/ expected life*
	-	What type of after sales	*spare parts required/ available for repair*
	-	What type of support	*tools available for inspection, maintenance and repair*
	-	What is the history	*medical equipment history if available (operation/use time, maintenance/ repair)*
Having	-	Some way of updating the information	*accuracy*

Step 2.1.4 Baseline information on human resources

Table 6: Information on human resources

Human resources	Considerations	Result
• **The necessary qualifications and the quantity of human resources needed to meet the specified healthcare demand (as determined by the outcomes of Step 2.1.1)**	• The presence, capability and capacity of existing human resources skilled and knowledgeable in biomedical equipment and related planning [Minimum information should be available with regard to: ♦ Current positions and job specifications ♦ Quantity of unfilled positions ♦ Condition and accessibility of: » Primary, advanced or vocational education » Ongoing education » On-site training » Human resource planning]	• Data on human resources (staffing plan) • Education and training roadmap

Source: Author adopted, Reference: World Health Organization, 2011

Step 2.1.5 Baseline information on finances

Table 7: Information on finances

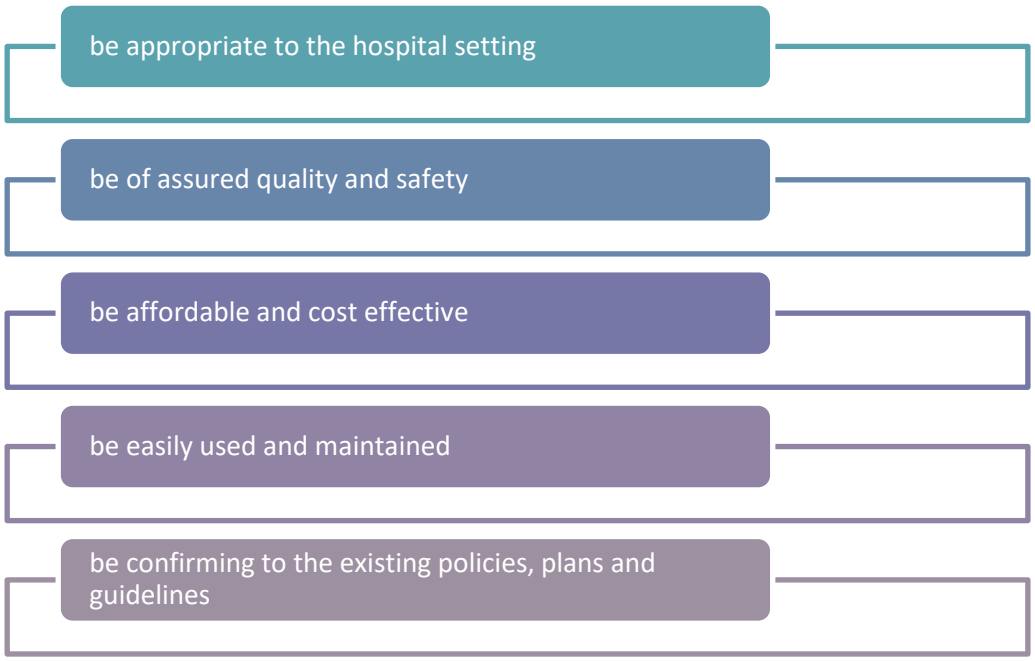
Financial situation	Considerations	Result
• **The ability to fund the comprehensive operation of the procurement, operations and maintenance of the biomedical equipment encompassing healthcare services, health technology, and infrastructure (as outlined in Steps 2.1.2 and 2.1.3 above).**	• Financial resources or funding [minimum information required for collection and evaluation includes: • Budget and expenses from previous periods/ years • Current budget/ estimates • System of monitoring/controlling budget.]	• Budget and estimates

Source: Author adopted, Reference: World Health Organization, 2011

When all the information has been collected, one can proceed with the analysis, interpretation and drawing of conclusions. The analysis and interpretation should directly stem from the data gathered in accordance with the previously outlined steps. It is essential to recognise that employing an inadequate methodology during the information gathering phases will diminish the capacity to formulate sound interpretations of the situation. Ultimately, this deficiency will impact the quality of the conclusions and by extension, the recommendations aimed at addressing the needs of the serving and target population (e.g. patients of the hospital).

2.2 Perceptions of needs

To ensure the procurement of equipment that precisely aligns with the requirements of the hospital, it is important for the purchasing and donation policies to explicitly define and adopt the criteria for "good selection". It is important to select equipment only suited to the needs of the hospital or required location. All biomedical equipment to:



2.3 Determinant factors and selection criteria

Should the biomedical equipment not align with these "good selection criteria" (as outlined in Table 8), officials will need to strategize solutions for addressing the ensuing drawbacks. Alternatively, a decision could be made to forego equipment that falls short of the selection criteria and instead opt for a different type, brand or model. Incorporating a degree of standardization in equipment procurement will aid in reducing the extensive array of different makes and models of equipment present in the inventory.

Table 8: Good selection criteria for biomedical equipment

Indicators of appropriateness	Criteria
Appropriate to the hospital setting	Equipment must possess the following attributes: • Appropriateness for the facility's level and service offerings • Acceptability to both staff and patients • Compatibility with the skill level of available operators • Compatibility with the local maintenance support capabilities • Harmony with existing equipment and consumable supplies • Alignment with existing utilities and energy supplies • Adaptability to local climate, geography and conditions • Economical operability using local resources

Indicators of appropriateness	Criteria
Assured quality and safety	Equipment should possess the following characteristics: • Adequate quality to meet your demands and ensure reasonable durability. • Construction from robust and long-lasting materials (e.g. stainless steel over aluminium due to greater resilience). • Fabrication from materials that permit easy cleaning, disinfection or sterilization without susceptibility to rust (e.g. polymerized finish or epoxy coating). • Use of materials resistant to breakage (e.g. polycarbonate instead of glass). • Manufacture adhering to globally recognized safety and performance standards. • Appropriate packaging and labelling to prevent damage during transport and storage. • Sourcing from reputable, dependable, licensed manufacturers or registered suppliers.
Affordable and cost-effective	Equipment must fulfil the following cost-related criteria: • Offer a cost-effective price point, recognising the common relationship between quality and cost (i.e. opting for the cheapest option may lead to poor quality and in the long run, increased expenses). • Remain affordable with regard to expenses such as freight, insurance, import taxes etc. • Maintain affordability throughout installation, commissioning and staff training for operation and maintenance. • Demonstrate affordability in terms of operational costs, encompassing consumables, accessories, spare parts and fuel over its lifespan. • Ensure affordability in terms of maintenance and servicing. • Guarantee affordability in the safe disposal process. • Preserve affordability within the procurement process, including the cost of a procurement agent or foreign exchange. • Sustain affordability in relation to staffing costs, covering any additional personnel or specialised training required.
Ease of use and maintenance	Should select equipment based on the following criteria: • Ensuring the staff possess the requisite skills for operating, cleaning and maintaining. • Availability of instructions and manuals in a suitable language. • Provision of staff training by the supplier. • Access to local after sales support, staffed with genuine technical expertise. • Offering the option of additional technical assistance through service contracts. • Providing a warranty or guarantee that covers a reasonable duration, with a clear understanding of its terms (e.g. coverage for parts, labour). • Ensuring a supply route for equipment related necessities, including consumables, accessories and spare parts. • Ensuring a reliable supply of these necessities for an adequate period, typically up to 10 years.

Indicators of appropriateness	Criteria
Conforms to existing policies, plans and guidelines	Equipment selection should align with the following principles: • Adherence to the established purchasing and donations policy of MoH. • Alignment with the approved standardization policy of MoH. • Conformity to the technological specifications detailed in the *Model Equipment Lists and *Generic Equipment Specifications (**pending finalisation*). • Consideration of suitability, following a thorough review of available literature and product comparisons. • Suitability assessment based on feedback received from prior purchases.

Source: Author adopted, Reference: Temple-Bird, et al., 2005

2.3.1 Replacement and disposal

The primary objective of most biomedical equipment acquisitions is to facilitate the replacement of existing stocks as they reach the end of their operational life. Replacement is a fundamental necessity as all equipment inherently possesses a finite lifespan. The duration of this lifespan is contingent upon the equipment's type and the underlying technology it incorporates. Failing to proactively plan for equipment replacement will inevitably lead to a decline in the quality of healthcare services provided to the public. Neglecting the replacement of equipment at the end of its operational life results in several adverse consequences, including:

- Disparities in reliability levels across the equipment inventory.
- A general deterioration in various aspects, such as:
  - Performance
  - Safety
  - Dependability
  - Availability for use

It is imperative that each healthcare facility undertakes biomedical equipment replacement solely for well-defined and valid reasons (Box 2).

Box 2: Acceptable replacement criteria for biomedical equipment

Acceptable replacement criteria

(1) Equipment replacement will only occur when one of the following valid conditions has been met:

- The equipment is irreparably worn out, having reached the end of its natural lifespan
- The equipment is damaged beyond the possibility of repair
- The equipment exhibits unreliability due to faults, age or safety concerns
- The equipment has become clinically or technologically obsolete
- Spare parts for the equipment are no longer obtainable
- It is no longer cost-effective to repair the equipment

Additionally, one of the following valid conditions must also be met:

- Utilisation statistics are available, demonstrating an ongoing necessity for the equipment
- A documented clinical or operational need remains

(2) Equipment replacement will not be triggered solely because of the following reasons:

- The equipment's age
- Staff preferences or dislikes
- The introduction of a newer model on the market

Determining the appropriate time to retire equipment

Experienced officials in the division of BES and maintenance personnel should assess the biomedical equipment, taking into consideration the following factors:

- Whether the equipment meets any of the valid replacement criteria outlined earlier
- Whether the equipment has surpassed its recommended typical "lifetime", whether it be on an international or local scale
- The equipment's performance history and its current condition, as documented in its service records
- Whether there is a necessity to deviate from the standard expected lifespan, either by retiring the equipment prematurely or extending its operational life

In the case of costly equipment, seeking an evaluation from the supplier may provide valuable insights.

Source: Author adopted, Reference: Temple-Bird, et al., 2005

The approach to achieving the aforementioned objective involves establishing and maintaining a comprehensive inventory of biomedical equipment at both national and local levels. It is essential to implement a standardised biomedical equipment inventory system across the entire government health service. This uniform approach facilitates the efficient compilation of data at both national and local levels, which can then be recorded in a centralised computer or IT system utilising a common software platform developed by the Division of Biomedical Engineering Services of the MoH (https://bmes.lk/). This standardised and centralised system (Figure 14) known as "Need Assessment and Prioritization Model (NAPM)" ensures consistency, accuracy and ease of data management, promoting effective decision making and resource optimisation within the healthcare sector.

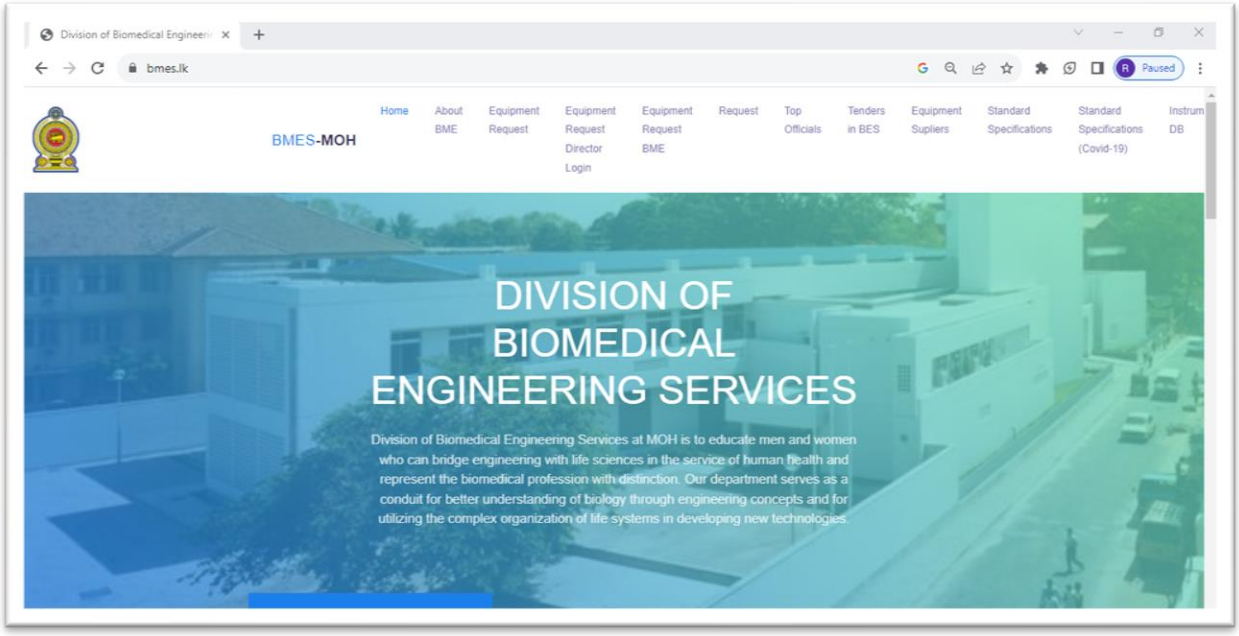


Figure 14: Biomedical Engineering Services website

Source: www.bmes.lk, Biomedical Engineering Services, Ministry of Health, 2023

Biomedical equipment requirements encompass a detailed document outlining the specific functions, performance criteria and essential features necessary to fulfil the end user's needs and achieve the desired health outcomes within the facility, where the equipment will be utilised and maintained (Figure 15).

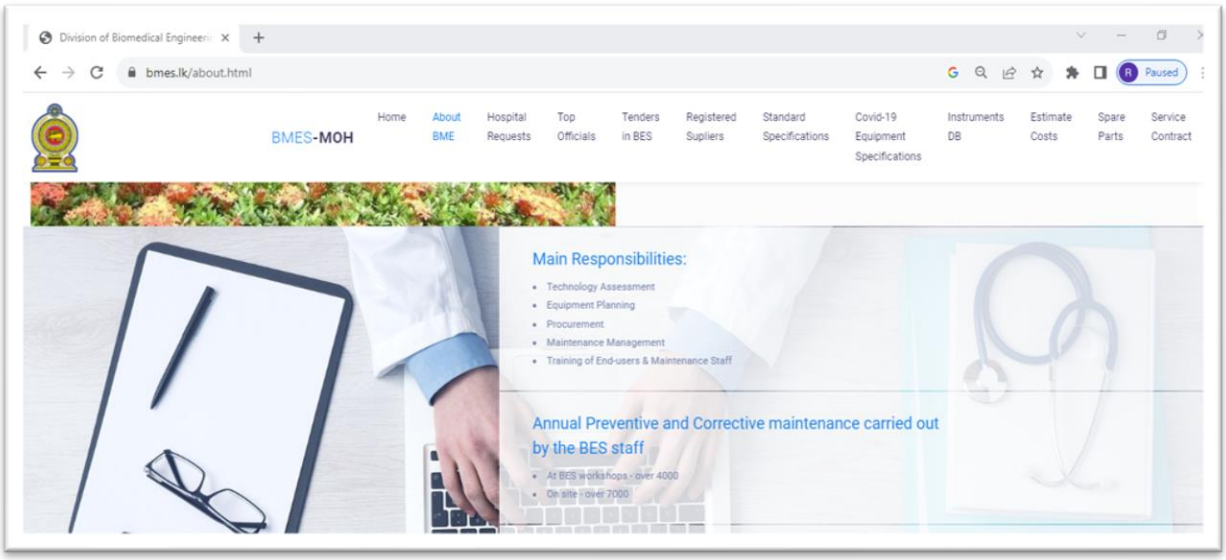
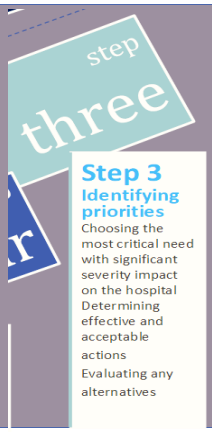


Figure 15: Main responsibilities of BES Division-Ministry of Health
Source: www.bmes.lk, Biomedical Engineering Services, Ministry of Health, 2023

These requirements should effectively communicate what is essential throughout the entire equipment life cycle, encompassing installation, operational utilisation and decommissioning stages. A well defined set of requirements ensures that the equipment meets the intended objectives and remains effective throughout its operational life within the healthcare facility.

STEP 3
Identifying priorities



3.1 Objectives guided priorities

In the context of biomedical equipment procurement and donations, four (4) distinct objectives guide the acquisition process. Each of these objectives serves a unique purpose and influences the timing of equipment acquisition. These objectives can be arranged in the following order (Figure 16) of priority:

First priority: To sustain equipment depreciation

To replace equipment as it nears the end of its operational life and is retired from service. This is an essential step to maintain the current standard of healthcare delivery. The goal here is to ensure that healthcare services can continue without disruption.

Second priority: To fulfill basic standard requirements

It involves acquiring additional equipment items that are essential to meet the basic standard of care. These items are necessary to provide a foundational level of healthcare services, and their acquisition is crucial to enhance the quality of care.

Third priority: To enhance healthcare services

Focuses on obtaining extra equipment items beyond the basic standard requirements. This is done with the aim of elevating the level of healthcare services offered by the hospital. It involves upgrading facilities and services to provide a higher standard of care.

Fourth priority: To comply with external directives

To acquiring additional equipment items not originally planned by the facility itself. These acquisitions are necessitated by directives from central health service provider organizations or national bodies. Such directives may involve high-profile or politically motivated projects that cannot be refused for political reasons.

Figure 16: Objectives guiding the acquisition process of biomedical equipment
Source: Author adopted Reference: World Health Organization , 2011

Within each of these four (4) categories of objectives, priorities must be established. These priorities should be based on measurable indicators that gauge progress toward achieving the respective goals. This systematic approach to biomedical equipment acquisition ensures that resources are allocated efficiently and in alignment with the healthcare facility's overarching objectives.

This framework allows healthcare facilities to make informed decisions about when and why to acquire equipment, ensuring that the actions are guided by a clear understanding of the priorities and the broader healthcare landscape.

Biomedical equipment procurement should be conducted within the framework of a structured and planned equipment procurement process (e.g. annual plan, medium term plan) considering a capital expenditure analysis and budget to ensure a deliberate and well thought out approach. Additionally, any acquisition efforts should be closely aligned with the priorities outlined in the annual action plans of the MoH.

3.2 Prioritization

When there is a scarcity of resources to fulfil all identified needs, which is a common scenario, the process of prioritization becomes crucial. Prioritization is a strategic undertaking typically led by those responsible for the commissioning of services. It is essential to incorporate the perspectives of service users and providers in this decision-making process. While consensus may not always be reached, it is advisable to give precedence to areas where alignment exists with critical needs.

The specific approach to determining priorities can vary based on local circumstances. Often, national priorities and resource availability serve as catalysts for initiating the needs assessment process. Consequently, the primary aim of this step is to precisely outline what actions should be taken, the methodologies involved and the sequence in which they should be executed.

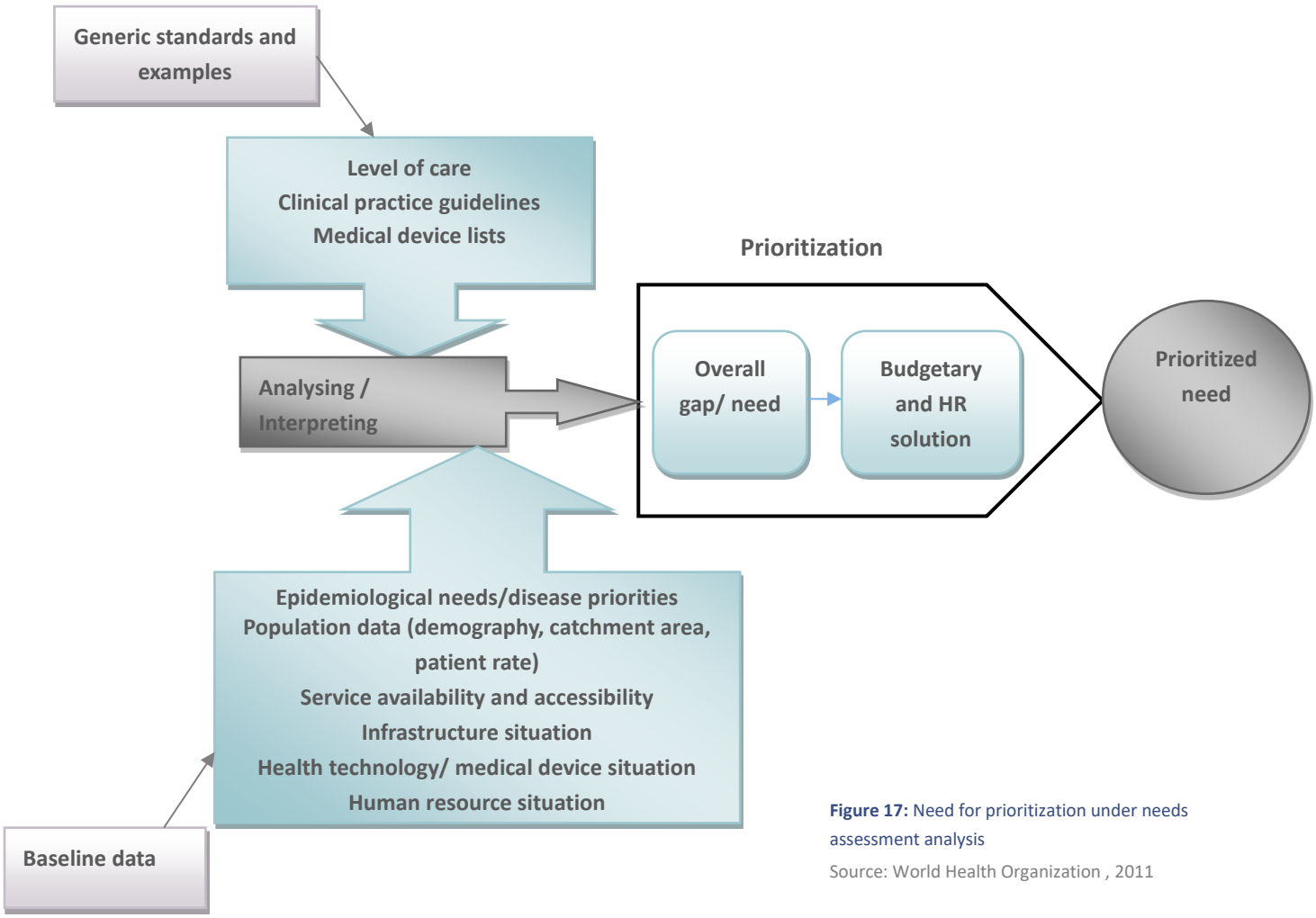


Figure 17: Need for prioritization under needs assessment analysis

Source: World Health Organization , 2011

3.2.1 Interrelated critical activities

Following the comprehensive analysis of the data collected in the earlier phases of the needs assessment process and after arriving at informed conclusions, a reasonably clear understanding of the hospital's needs should emerge. Subsequent decisions on the course of action to take will depend on several critical and closely interrelated activities. These activities encompass:

- **Prioritization:** In cases where available resources are insufficient to address all identified needs, it becomes necessary to establish a ranking order. This ranking will determine which needs should be addressed as a priority and which can be addressed at a later stage.
- **Option appraisal:** It is essential to recognize that there may be multiple approaches to fulfilling the identified needs. Therefore, it is crucial to consider various options and carefully evaluate the evidence supporting each option.
- **Implementation:** Once a consensus has been reached regarding how to address the identified needs an action plan and schedule should be developed. This plan should include a strategy for allocating the necessary resources.

In practice, the tasks of prioritization and option appraisal are intricately connected and should be approached together to ensure effective decision-making.

3.2.2 Option appraisal

In majority of situations, multiple approaches can be considered for addressing the identified needs. Option appraisal (Figure 18) is another critical aspect of this decision making process in responding to the identified biomedical equipment needs. The selection of these options is contingent upon various factors, including:

- The manner in which the needs are ranked in terms of priority
- The anticipated impact of each option
- The accessibility of resources required for implementation

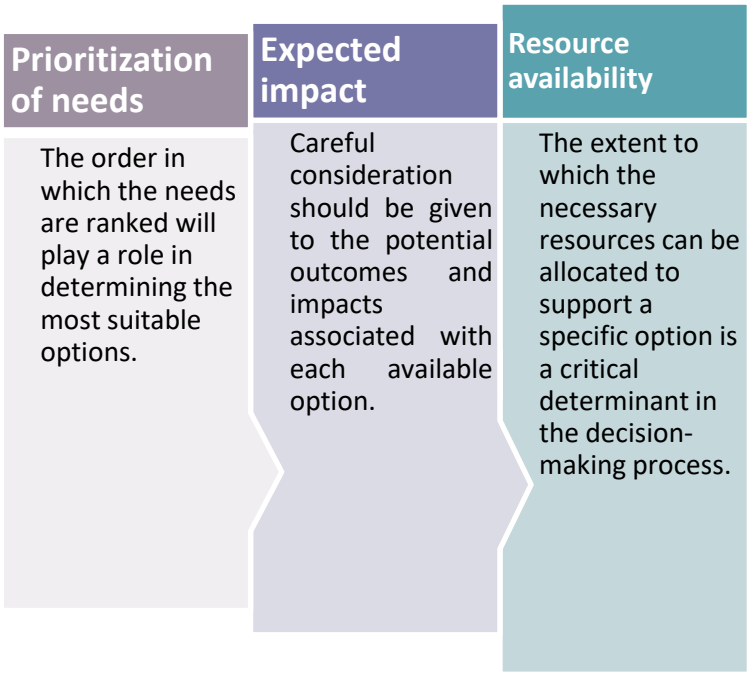


Figure 18: Option appraisal to identify biomedical equipment needs

Source: Author adopted, Reference: Temple-Bird, et al., 2005

3.2.3 Prioritization matrix

The primary objective is to prioritise actions that can significantly enhance the ability to deliver optimal services to the target population while demanding minimal additional resources. As shown in the Prioritization matrix (Table 9), in the middle are actions that can bring about substantial improvements but also require significant resources. Typically, these would not be chosen for immediate implementation but considered as long-term strategies. Similarly, "soft targets" represent actions that necessitate minimal resources yet are essential for providing the necessary biomedical medical devices to support the realisation of these priorities.

Table 9: Prioritization matrix

Finances/resources required to implement change	Likely impact of change	
	Low	High
Low	Soft target: Wait	Win: Go
High	Refrain or wait	Challenging: Wait

Source: World Health Organization , 2011

When assessing options and prioritizing needs post a needs assessment, it's essential to consider several key questions. These questions revolve around impact, feasibility of change, acceptability and resource availability. In the context of health technology needs assessment, the answers to these key questions along with the matrix, helps to guide the evaluation process.

STEP 4
Planning for action

4.1 Planning for implementation

After reaching a consensus on priorities and the corresponding strategies for addressing them, the subsequent phase involves the formulation of an implementation plan. This plan should possess several key attributes:

- **Realistic:** It must be grounded in reality, considering the actual circumstances and resources available.
- **Achievability:** Goals and objectives set in the plan should be feasible within the given context.
- **Adequate funding:** Financial considerations should be accounted for, ensuring that the plan is adequately funded to support its execution.
- **Clarity:** The plan should provide clear and comprehensive details regarding the various stages and steps involved in the implementation process.

The implementation plan serves as a practical roadmap, guiding the execution of actions and strategies to achieve the established priorities effectively.

4.2 Documenting the requirements

In the needs assessment and procurement of medical equipment, a comprehensive requirements document plays a pivotal role in describing the essential functions, performance criteria and features imperative to fulfil the end user's healthcare needs. It serves as the key document for achieving the desired health outcomes within the healthcare facility where the equipment will be deployed and maintained. These requirements extend across the entire equipment life cycle, encompassing installation, operational phases and culminating in the decommissioning stage.

This critical documentation encompasses three (3) distinct yet interconnected components (Figure 19), each serving a unique purpose and varying in the level of detail they provide:

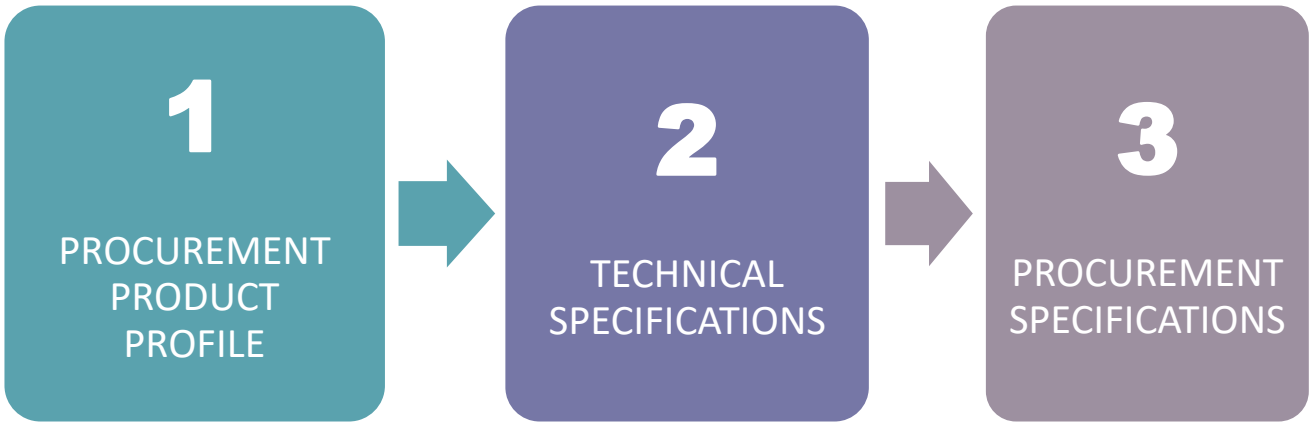


Figure 19: Interconnected components in documentation of biomedical requirements
Source: Author adopted, Reference: The Access and Delivery Partnership (PATH), 2020

- **Procurement product profiles:** These profiles serve as a foundational framework, outlining the overarching product specifications. They provide a high-level perspective of the equipment's intended purpose and core features.

- **Technical specifications:** These terms offer an overview of the equipment's functional aspects. They specify the definite technical requirements necessary for flawless integration and operation.

- **Procurement specifications (bidding or tender documents):** The most detailed of the three, procurement specifications leave no room for ambiguity. They provide exhaustive documentation regarding the equipment's specifications, functionality and performance expectations. These documents are instrumental in the procurement process.

It is paramount to highlight that incomplete or inaccurate medical equipment requirements can have dire consequences. They can lead to the procurement of equipment that falls short of addressing critical healthcare needs, resulting in:

- **Inadequate health provision:** Equipment that does not align with healthcare requirements fails to meet specific objectives or fulfil the hospital and health service needs.
- **Operational challenges:** Incorrectly installed or commissioned equipment poses operational challenges, hindering its effective utilization.
- **Energy and resource shortages:** Inaccurate requirements may lead to equipment that lacks access to the necessary quantity or quality of energy, impeding its functionality.
- **Maintenance and sustainability issues:** Untrained users or technicians may inadvertently damage the equipment, and calibration and maintenance may deviate from the manufacturer's recommendations, jeopardizing sustainability within the facility's existing budget.
- **Financial implications:** Equipment procured without accurate requirements may strain the facility's finances, leading to unexpected budgetary pressures.
- **Inefficient decommissioning:** Inadequate documentation can result in equipment that is not decommissioned or disposed of properly at the end of its economically viable lifetime, creating inefficiencies in the facility's asset management.

In essence, the quality and accuracy of medical equipment requirements profoundly impact the entire procurement process. Rigorous attention to detail and precision are imperative to ensure that the acquired equipment aligns with healthcare objectives and functions seamlessly within the facility's ecosystem, ultimately enhancing the quality of patient care.

4.3 Value for money analysis

Value-based procurement (VBP) involves assessing potential products, services and solutions with the aim of optimising the overall value or Value for Money (VfM) provided for the cost incurred, rather than solely concentrating on the lowest purchase price.

The VBP approach involves recognising and taking into account not just the essential health outcomes and cost factors during the planning and procurement stages but also the potential advantages for patients, providers and the overall national healthcare and HTM systems. Within the scope of VBP, a framework for analysing Value for Money (VfM) can be implemented to aid in decision making processes that assess wider benefits and long-term equipment and management expenses.

A VfM assessment framework (Figure 20) typically takes into account five (5) essential components: economy, effectiveness, efficiency, equity and sustainability.

Figure 20: Value for Money (VFM) assessment framework
Source: The Access and Delivery Partnership (PATH), 2020

- **Economy:** Evaluates whether the biomedical equipment offers the necessary health services at the lowest overall cost of ownership (TCO)
- **Effectiveness:** Assesses the equipment's ability to effectively contribute to improved health outcomes
- **Efficiency:** Examines whether the equipment or service model maximizes benefits for patients, clinicians or the health system in comparison to other equipment or service alternatives
- **Equity:** Considers whether the equipment supports the healthcare needs of all population groups

  Sustainability: Determines whether a health facility, programme or system can maintain the equipment or service model over the long term

4.3.1 Initiating the process

Incorporating input from healthcare providers is vital when shaping the implementation plan. Procurement, in the context of the Biomedical Engineering (BME) website, is a meticulously structured process.

4.3.2 Biomedical engineering web interface system - "Need Assessment and Prioritization Model" (NAPM)

The BME website serves as a pivotal platform for initiating and processing of procurement needs systematically through its web interface system (Figure 21). This insightful system named as the "Need Assessment and Prioritization Model" (NAPM), is adept at capturing and analysing the essential requisites at various procurement stages. Its focus primarily revolves around streamlining the procurement process, harnessing the power of data analysis to drive decisions.

By leveraging the BME website's web interface information technology (IT) system, the emphasis lies in facilitating an efficient and structured procurement journey.

This comprehensive approach integrates advanced analytical capabilities, enabling users to navigate the details of procurement effortlessly. The system's user-friendly design empowers stakeholders to make data driven decisions at every juncture, optimising the procurement process for enhanced efficiency and effectiveness.

The BME software or the IT system which is facilitating the procurement process of biomedical equipment consists of two (2) main interphases (Figure 21) as follows.

(1) Requesting Officer login
(2) Director login

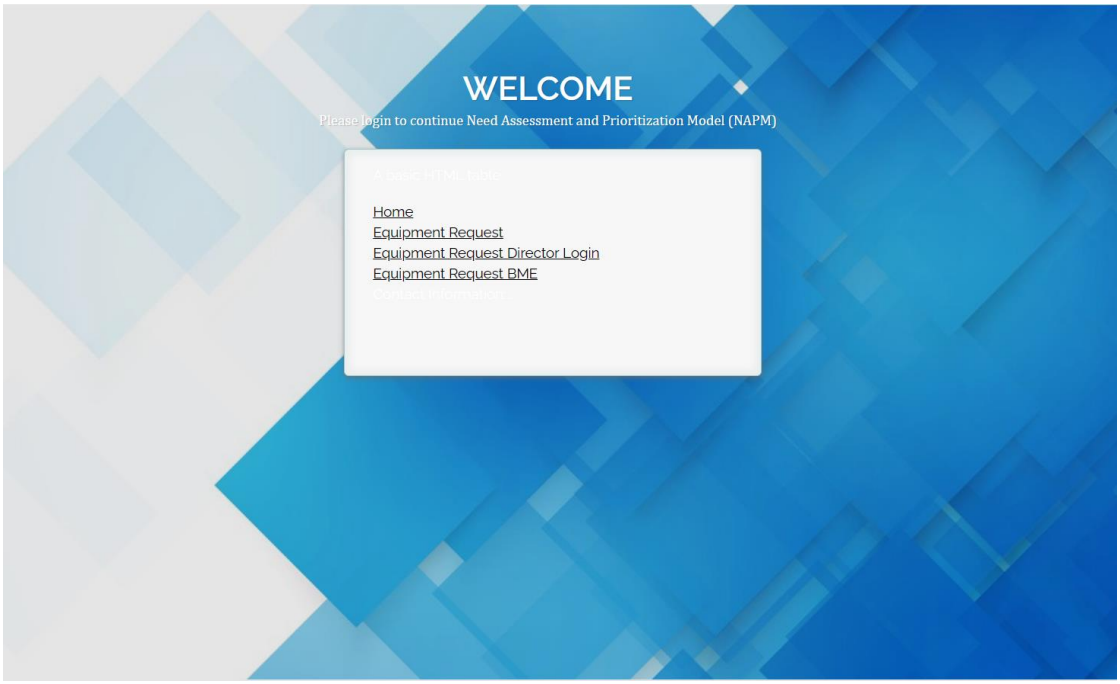


Figure 21: Access or Login page of the BES system - Need Assessment and Prioritization Model (NAPM) for biomedical equipment request

Source: https://bmes.lk/Hospital_Requests/equ_request.html, Biomedical Engineering Services, Ministry of Health, 2023

This system can be used by the following officers/ officials within the approved parameters of accessibility, using unique user names and passwords.

- Hospital Directors
- Consultants/ Specialists/ Medical Officers
- Unit heads (Chief Radiographer, Chief Pharmacist)

➢ Requesting Officer interface

As the first step, the Requesting Officer has to log into the system (Figure 22) which displays key details related equipment requests ensuring a structured and an efficient process.

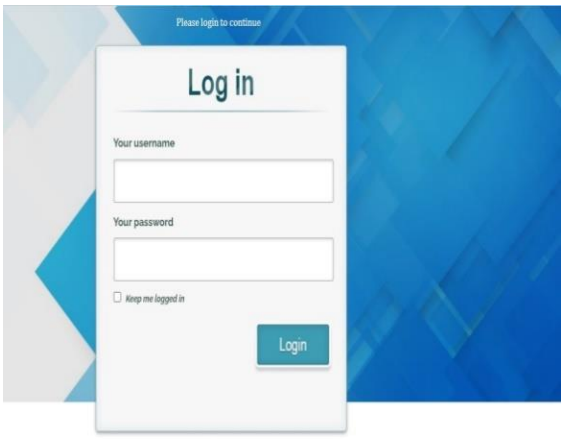


Figure 22: Requesting Officer login interface
Source: https://bmes.lk/Hospital_Requests/login.php, Biomedical Engineering Services, Ministry of Health, 2023

The interface encompasses the following key information (Figure 23) fields:

- Unit/ward details
- Requesting Officer's name
- Requesting Officer's designation
- Age of replacing equipment (if applicable)
- Equipment name
- Purpose
- Need of the equipment
- Existing similar equipment
- Requesting equipment specifications/features

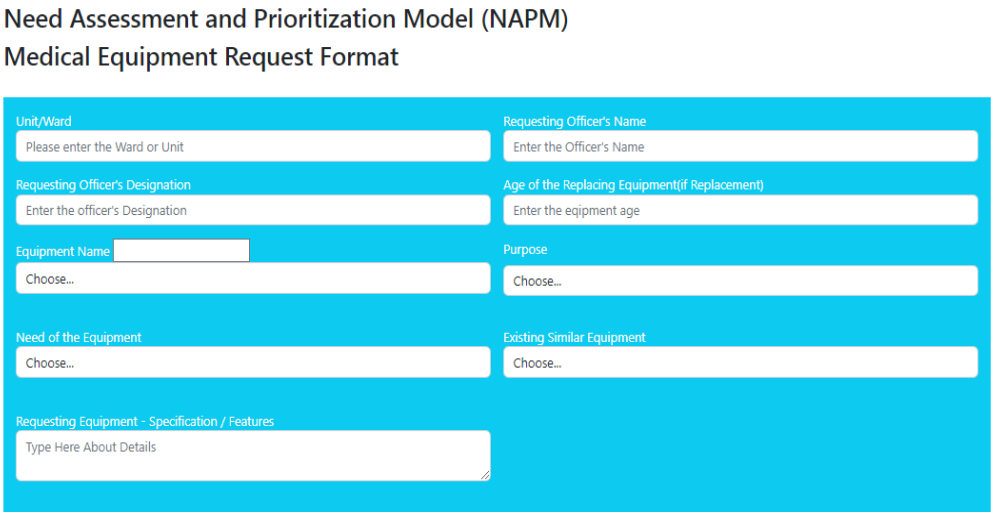


Figure 23: Medical equipment request screen
Source: https://bmes.lk/Hospital_Requests/request.php, Biomedical Engineering Services, Ministry of Health, 2023

In this interface, users have the capability to select equipment details, specify the purpose, outline the need for the equipment and detail existing similar equipment. The interface is thoughtfully designed to enhance efficiency and accuracy in biomedical equipment request submissions.

Key features

- In requesting equipment main details such as unit/ requesting officer's name; requesting officer's designation and equipment name need to be updated.
- "Purpose" provides two (2) options for selection i.e. replacement (Figure 24) or new equipment (Figure 25).

If "**Replacement**" option is selected	If "**New equipment**" option is selected
▪ Additional information with regard to the age of the equipment; age of the equipment; maintenance cost beyond economical value and whether it is a discontinued model needs to be stated. ▪ Further under "Replacement request" additional details related to infrastructure (Figure 26) and human resources (Figure 27) need to be updated with regard to the requested unit. ▪ Additional details such as no. of tests/ cases done per month, no. of tests/cases required to be done per month and the environmental impact (i.e. negligible, minimal, moderate and high) needs to be updated as well (Figure 28).	▪ Additional information with regard to new unit and service expansion of the existing system needs to be updated. ▪ Further under "New equipment" additional details related to infrastructure (Figure 26) and human resources (Figure 27) need to be updated with regard to the requested unit. ▪ Additional details such as no. of tests/ cases done per month, no. of tests/cases required to be done per month and the environmental impact (i.e. negligible, minimal, moderate and high) needs to be updated as well (Figure 28).

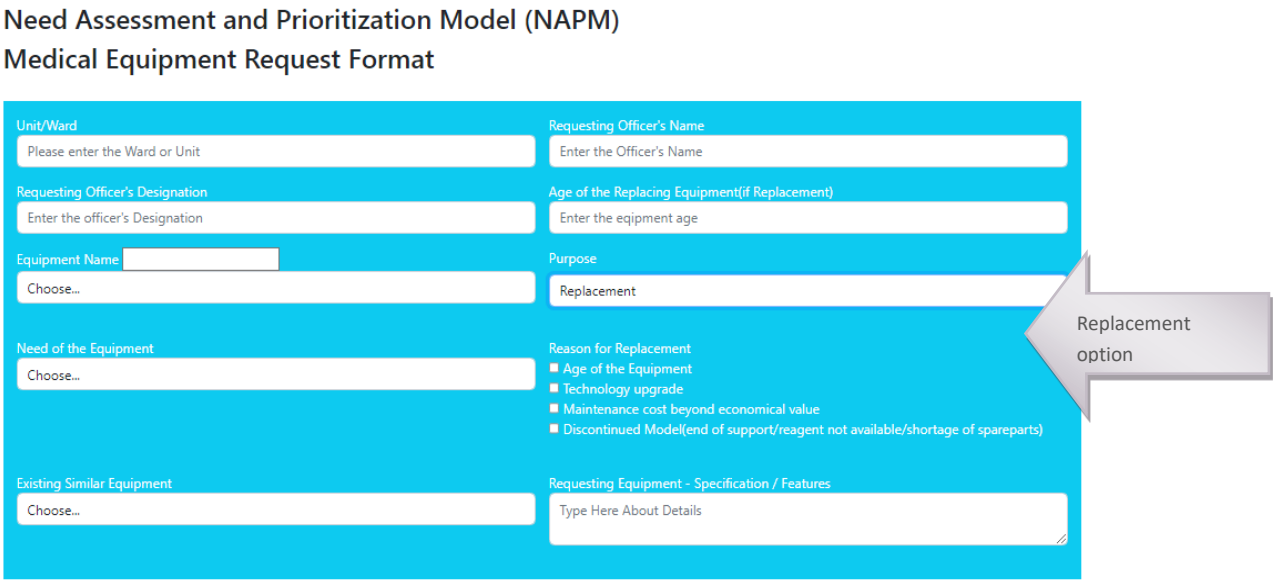


Figure 24: Medical equipment request – Replacement option

Source: https://bmes.lk/Hospital_Requests/request.php, Biomedical Engineering Services, Ministry of Health, 2023

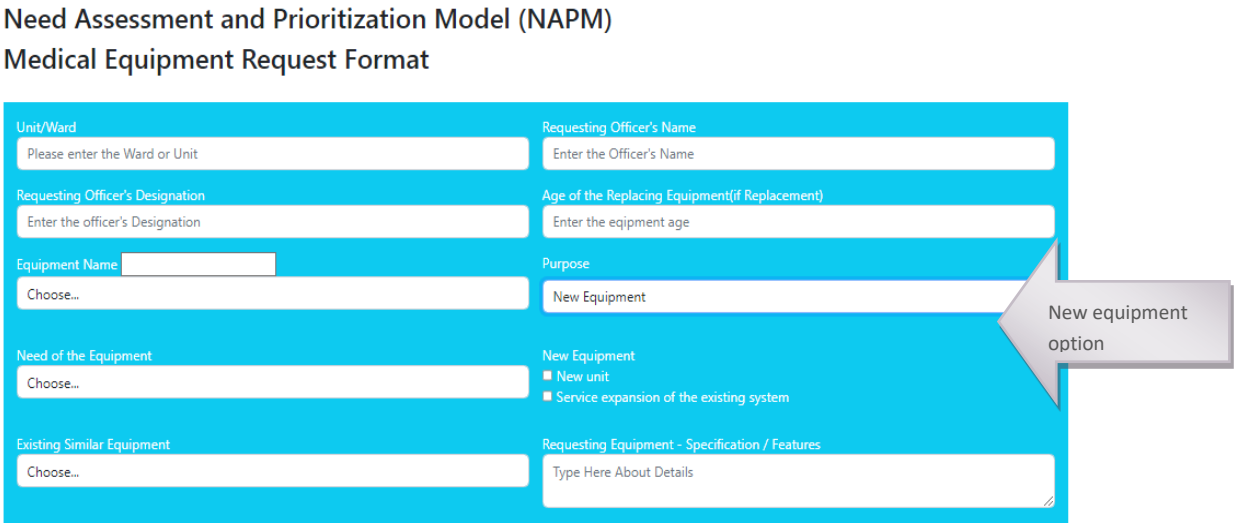


Figure 25: Medical equipment request – New equipment option

Source: https://bmes.lk/Hospital_Requests/request.php, Biomedical Engineering Services, Ministry of Health, 2023

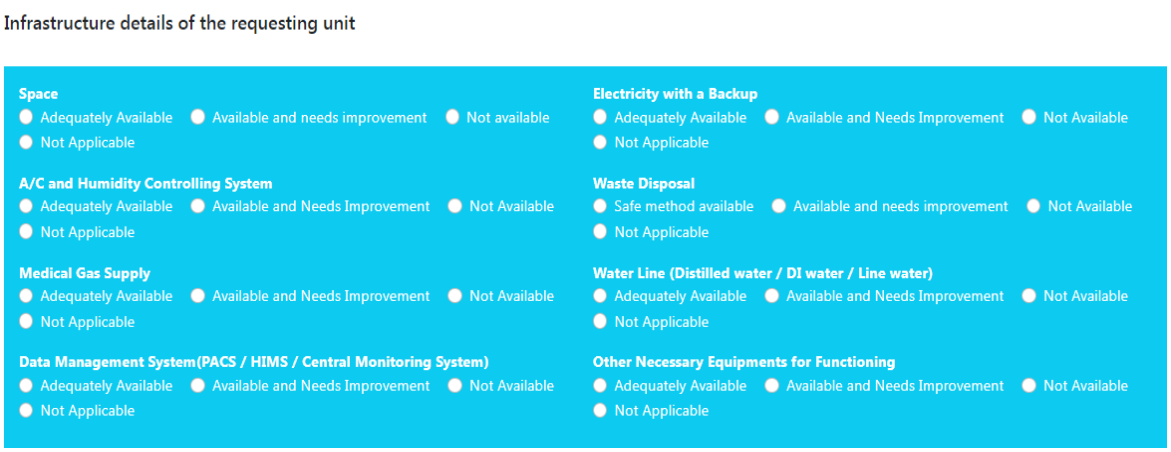


Figure 26: Medical equipment request – Required infrastructure details related to the requested biomedical equipment

Source: https://bmes.lk/Hospital_Requests/request.php, Biomedical Engineering Services, Ministry of Health, 2023

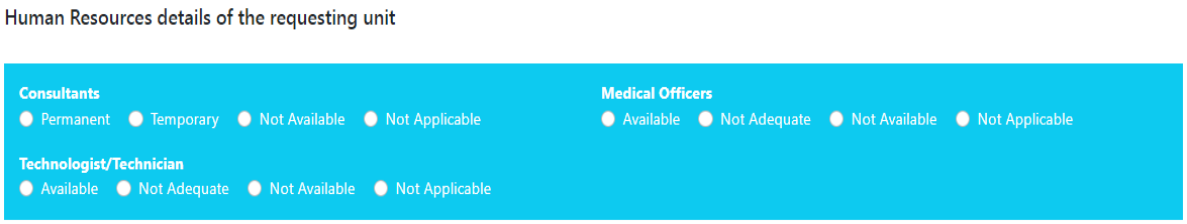


Figure 27: Medical equipment request - Required human resources details related to the requested biomedical equipment
Source: https://bmes.lk/Hospital_Requests/request.php, Biomedical Engineering Services, Ministry of Health, 2023

Figure 28: Medical equipment request – Additional details relevant to assess the need of procurement
Source: https://bmes.lk/Hospital_Requests/request.php
Biomedical Engineering Services, Ministry of Health, 2023

- Under "Existing similar equipment" (Figure 29) if available option is selected additional relevant details of the existing similar equipment such as equipment name; serial no.; state (i.e. working condition or not in working condition, under repair or condemned) needs to be updated. The "Add to table" allows including this information in a structured manner for easy reference and "Clear table" facilitates management of entered data.

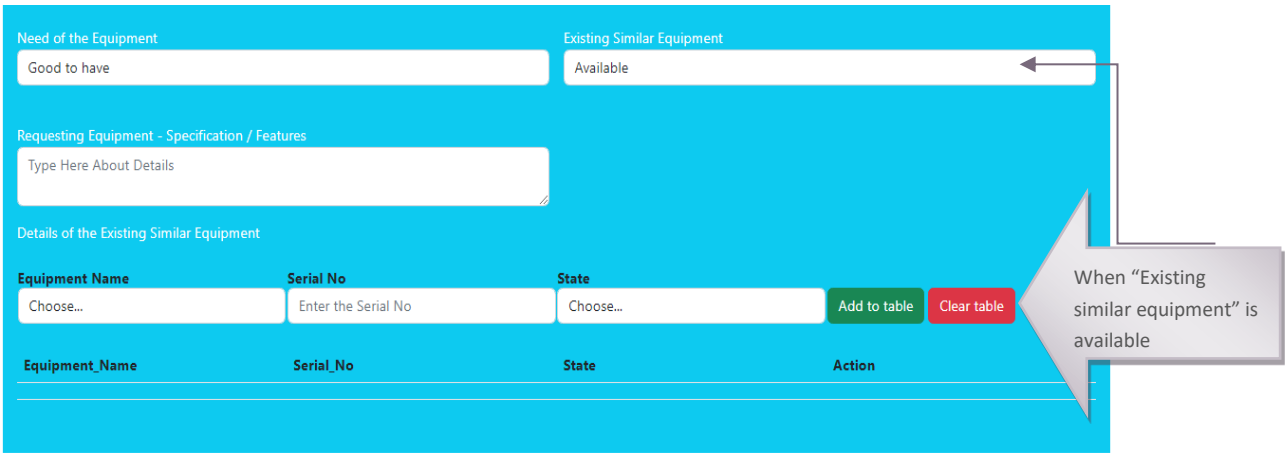


Figure 29: Medical equipment request – Additional details required to be updated when "Existing similar equipment" is available
Source: https://bmes.lk/Hospital_Requests/request.php
Biomedical Engineering Services, Ministry of Health, 2023

- **Director login interface**
  "Need Assessment and Prioritization Model" (NAPM)

As the designated authority, the Director holds exclusive privilege to access and utilise the interface. A concise summary of each request (Figure 30) is prominently displayed for review.

Key features

- Main functionalities include the ability to select the status of procurement plans for reagents and consumables, gauge the demand for requested equipment and assess alignment with the Master Plan.

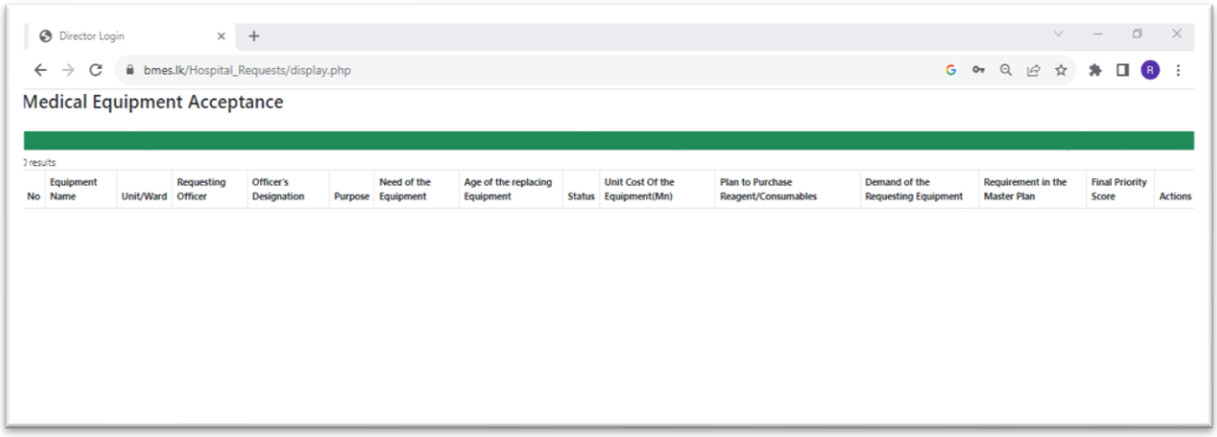


Figure 30: Medical equipment request – Director Login interface
Source: https://bmes.lk/Hospital_Requests/display.php, Biomedical Engineering Services, Ministry of Health, 2023

- Upon selecting the status of the plan, a predefined equation is used to compute the level of priority which is thereafter presented in a structured table format.
- Each criterion and the sub-criteria in the system have been allocated a particular weightage by an expert panel. Accordingly, each request is assigned a score known as "Final Priority Score" which helps to gauge the level of priority.

Figure 31: Medical equipment request plan - Analysis of input or entered data and final priority score
Source: https://bmes.lk/Hospital_Requests/displayall.php

- System facilitates an informed and comprehensive decision making process with regard to each equipment request.
- Based on the overall evaluation the Director is required to provide the final decision in terms of acceptance, revisit for further consideration or rejection (Figure 31).

4.4 Equipment expenditure

Within the area of healthcare technology, there exist numerous expenses, many of which remain concealed beneath the surface, evading easy recognition. To illustrate this intricate web of costs, one can draw a parallel to the enigmatic iceberg, characterized by its deceptively small visible portion above the waterline, while concealing the vast majority of its mass beneath. This entirety of expenditures collectively falls under the umbrella term of “life-cycle costs” for healthcare technology.

The Total Cost of Ownership (TCO) serves as the comprehensive gauge, encompassing both the overt and covert expenses entailed in owning medical equipment. Regrettably, when devising medical equipment strategies and procurement decisions, the focus frequently narrows down to the readily apparent and centrally funded direct costs.

This myopic perspective is akin to fixating on the tip of the iceberg, where only elements such as the purchase price and the expenses associated with delivery are considered, as outline in Figure 32.

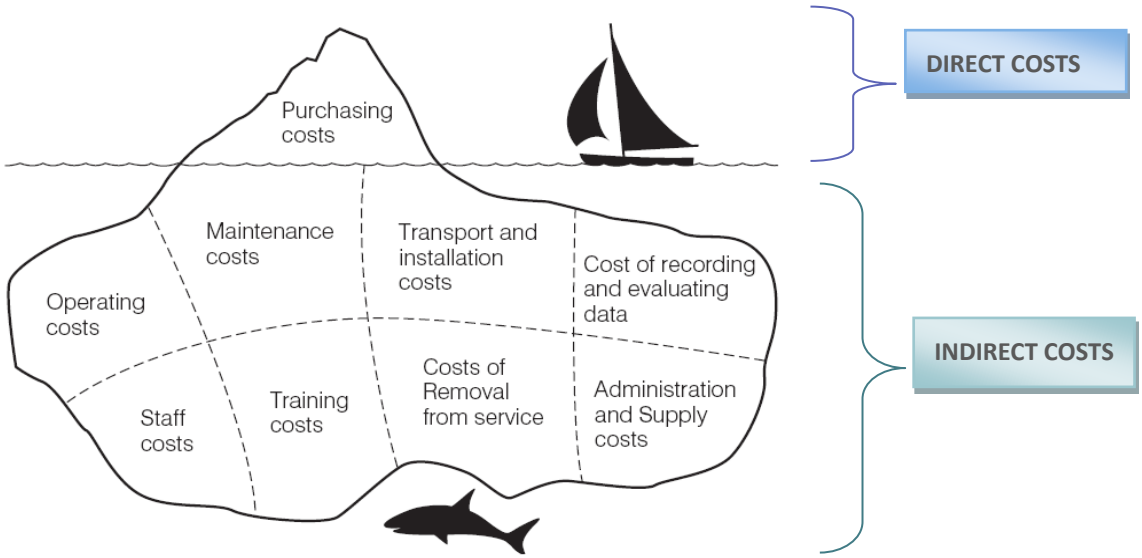


Figure 32: The "Iceberg" model – Direct and indirect costs of procurement of medical equipment

Source: Temple-Bird, et al., 2005

Conversely, indirect costs remain beneath the surface, avoiding easy identification, quantification, prognostication and governance. Often unnoticeable to central healthcare planners, these hidden costs are akin to the submerged mass of the iceberg, as depicted in Figure 32. Should central healthcare planners or benefactors hinge their purchasing and funding verdicts solely on the purchase price or cost the potential of new medical equipment to yield maximal value for money remains largely untapped.

To unfasten the full range of advantages for patients and healthcare systems alike, decisions revolving around equipment acquisition necessitate a comprehensive assessment. This assessment should encompass not only the evident direct costs but also extend to the complex sphere of indirect ownership costs. These encompass an array of aspects, from operating costs, routine maintenance and repair expenditures to the procurement of spare parts, energy consumption, staff costs, training costs, implementation of supportive management systems etc. In embracing this holistic approach, the healthcare ecosystem can ensure that medical equipment investments yield their utmost potential in advancing patient care and fortifying healthcare systems.

4.5 Procurement planning

In the domain of procurement planning, several critical actions come into play:

- Comparative Total Cost of Ownership (TCO): It becomes imperative to undertake a comprehensive evaluation, put together the Total Cost of Ownership (TCO) across different equipment types, models or ownership frameworks.

- Augmenting health system strengthening: Equipped with TCO insights, strategies for strengthening the health system can gain substantial support, guiding equipment planning and prioritization endeavours.

- Exploring maintenance costs: In the pursuit of pragmatic procurement, it is crucial to assess and draw comparisons between the costs of in-house maintenance and third-party equipment maintenance solutions.

4.6 Procurement implementation

During the phase of procurement implementation, the following actions should be taken:

- **Leveraging TCO data for Value for Money (VfM) decisions:** TCO estimates and data furnished by suppliers should be harnessed to facilitate determinations regarding Value for Money (VfM).

- **Optimising equipment selection:** If procurement policies allow, the deployment of TCO can steer the selection process towards medical equipment offerings that boast a lower TCO. This approach proves particularly prudent when faced with the choice between equipment sporting a lower initial purchase price but a higher TCO over its anticipated lifespan.

4.7 Alternative procurement models

In situations necessitating the acquisition of intricate and high-value medical equipment, such as laboratory and diagnostic imaging apparatus, it becomes sensible for healthcare providers and officials to consider the range of options available for procurement. Three (3) fundamental avenues can be identified for acquiring medical equipment:

- **Capital asset purchase:** This involves the outright purchase of medical equipment, categorically designating it as a capital asset.

- **Leasing:** Health projects or plans can opt for leasing arrangements, which can manifest as either a capital lease or an operating lease.

  Rental: The option of renting medical equipment is also available, providing a flexible alternative to acquisition.

4.7.1 Equipment donations

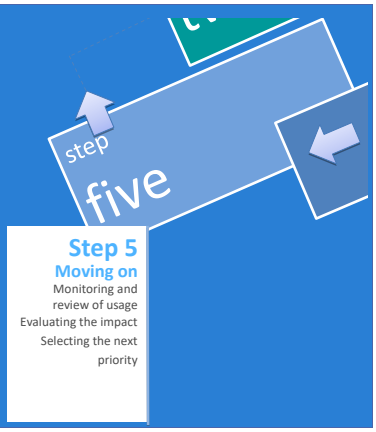
Medical equipment donations do provide valuable assets as medical equipment which help healthcare providers save lives specially at low resource healthcare settings in hospitals. However, it has been noted that several challenges limit the benefits of biomedical equipment donations as these are not made through a value based equipment planning process. Donation of medical equipment needs planning and integration into HTM system and in order to maximize the value of such equipment it is advisable to follow the WHO criteria for “sustainable equipment donations”.

4.8 Equipment installation, commissioning and training

In the lead-up to the installation, commissioning and training phases for medical equipment, a meticulous arrangement is vital. The hospital must ensure the availability of an array of essential components including technicians, trainers, consumables, tools, manuals, protocols and supplies. The objective is to facilitate the seamless execution, verification and documentation of the following key aspects:

- **Installation conforming to manufacturer guidelines:** It is paramount that the installation process aligns meticulously with the recommendations furnished by the equipment manufacturer.
- **Commissioning outcome:** The results of the commissioning phase must be comprehensively documented.
- **Formal acceptance and inventory inclusion:** Formal acceptance into the facility's asset inventory should be confirmed.
- **Initial training for end-users and technicians:** End-users and technicians should receive their initial training sessions.

STEP 5
Moving on



5.1 Monitoring and evaluation

It is important to ensure that monitoring, evaluation and reviewing of the procured biomedical equipment is an ongoing process by establishing relevant systems which are used to gather, manage and analyse data at the start of any new equipment installation. A robust and well throughout monitoring and evaluation (M&E) process will help the hospital and the MoH to understand the effectiveness and productivity of the procured biomedical equipment and also to identify ways to address challenges that arise in the future.

Inadequate operation and maintenance of medical equipment can often lead to premature failures, disruptions in healthcare services and risks to patients. Therefore, it is crucial to prioritize proper training for both end users and technicians who will be responsible for operating and maintaining the equipment. To address this, the procurement process for new medical equipment should include provisions for training services and necessary training materials. This ensures that those who will interact with the equipment receive comprehensive training on its operation and maintenance.

Furthermore, healthcare facilities must establish routine training mechanisms and educational programs to continuously update and refresh the skills of the staff. This includes training for new personnel and ongoing skill development for existing staff. By investing in training and skill development, healthcare facilities can enhance patient safety, improve equipment reliability and optimize the value of their medical equipment.

Ultimately, the integration of training into the procurement and ongoing operational processes is essential to ensure that medical equipment is used effectively, safely and in a manner that aligns with best practices in healthcare delivery.

5.2 Evaluating the impact

In evaluating the impact of the procured biomedical equipment analysing the “life cycle plan of the equipment” would assist in functioning as a database ornately linked with an asset register. It proves invaluable when orchestrating the essential tasks for effective facility, plant or process equipment maintenance. It aids in the formulation of a tailored maintenance programme that spans a defined period. Additionally, it offers clarity in comprehending the asset management process, particularly when gauging the timing for equipment replacements and upgrades.

The overarching purpose of lifecycle planning, as depicted in Figure 33, is to develop optimal strategies for asset utilisation throughout the expected lifespan of biomedical equipment.

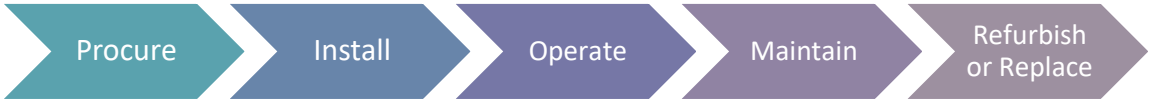


Figure 33: Life cycle process of a biomedical equipment
Source: TAHPI, 2017

The advantages of embracing lifecycle planning for procured biomedical equipment encompass the following.

- **Informed decision making:** It provides a robust foundation for making well-informed decisions concerning investments, maintenance and disposals.
- **Balanced cost consideration:** By explicitly weighing operating and maintenance expenses against capital procurement costs, it ensures the optimal equilibrium is maintained.
- **Holistic capital insight:** Capital costs are assessed within the context of their repercussions on life cycle expenses, allowing for a more comprehensive financial perspective.

5.3 Moving forward

The process of selecting biomedical equipment for line ministry hospitals in Sri Lanka is a complex and multifaceted undertaking. It requires a thorough understanding of the healthcare landscape, the specific needs of each facility and the available resources. This handbook has aimed to provide a comprehensive guide to navigate this intricate journey, emphasising the critical role of a needs assessment process in making informed decisions.

The needs assessment process, as outlined in this handbook, serves as a powerful tool for healthcare decision makers. It begins by collecting baseline information and meticulously analysing the existing healthcare infrastructure and equipment inventory. By comparing this data to desired standards and guidelines, a clear gap analysis emerges, shedding light on areas that require attention and improvement.

One of the fundamental lessons emphasised throughout this handbook is the importance of data-driven decision making. Rather than making equipment choices based solely on budget constraints or vendor recommendations, healthcare facilities are encouraged to rely on **comprehensive needs assessments**. These assessments not only identify the equipment that will have the most significant impact on patient care and clinical outcomes but also help in prioritizing activities and allocating resources efficiently.

Efficiency and cost effectiveness are paramount in the management of healthcare resources. Prioritization, as a key aspect highlighted in this handbook, plays a pivotal role in ensuring that the limited resources are allocated to areas that will have the most substantial positive impact on healthcare delivery.

Furthermore, this guide highlights the significance of healthcare technology assessment (HTA) in making well-informed decisions. HTA, a multidisciplinary process, provides evidence-based insights to inform healthcare policies and procurement strategies. While Sri Lanka has made significant strides in this regard, the absence of a centralized HTA policy for biomedical equipment warrants the need for a comprehensive framework to guide the selection and procurement process.

A crucial aspect often overlooked is the importance of involving health service providers/ officials and relevant stakeholders in the decision making processes. Their insights and support are invaluable as they are the ones directly involved in implementing and utilising the chosen equipment. This collaboration ensures that equipment aligns with the specific needs of the healthcare facility and is seamlessly integrated into existing operations.

This handbook or guidelines touches upon the critical phases of procurement, installation, commissioning and training. These aspects are indispensable in ensuring that the selected equipment is not only acquired but also properly integrated into the healthcare facility, operated efficiently and maintained over its lifespan.

Selecting biomedical equipment for line ministry hospitals in Sri Lanka is a multifaceted process that demands careful planning, informed decision-making and a commitment to delivering high-quality healthcare services. This handbook serves as a guiding light, providing healthcare decision-makers with the knowledge and tools needed to make prudent choices in equipment selection and procurement.

By embracing the principles outlined in this handbook, line ministry hospitals in Sri Lanka can enhance the quality of healthcare services, optimise resource allocation and demonstrate the commitment to responsible and cost effective resource management. As the healthcare landscape continues to evolve, so too must the strategies for selecting and managing biomedical equipment. This handbook represents a significant step toward ensuring that hospitals are equipped with the right tools to provide the best care to patients while safeguarding the prudent use of public funds.

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