



Original Article: **Selection of Biomedical Equipment for public hospitals in Sri Lanka: A stakeholder perspective**

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Abstract

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Background: Health technology is an important component in delivering healthcare services. Healthcare technology can be expensive and often does not align with the unique needs of under-resourced areas. Out of the variety of health technologies, biomedical equipment is one of the major assets for any healthcare institution, and it plays an important role in healthcare delivery.

Unlike developed countries, Sri Lanka lacks a system for choosing effective biomedical equipment for hospitals. This study explored current practices to improve the biomedical equipment selection process.

Purpose: The study aims to assess stakeholders' perceptions of the decision-making process for selecting biomedical equipment in selected line ministry hospitals in the Western Province of Sri Lanka.

Methodology: This cross-sectional study was conducted in four (4) line ministry hospitals,

with each facility representing a specific level identified within the line ministry. A survey using a self-administered Questionnaire (SAQ) and a desk review using a checklist were conducted to assess the stakeholders' perceptions of the decision-making process in selecting biomedical equipment.

Results: The stakeholders' survey revealed low awareness of the unavailability of an HTA policy, institutional guidelines, and essential biomedical equipment list. Equipment requests were mainly paper-based, finalized by a committee, and took over two days to process. Respondents found the decision-making process inconvenient and dissatisfying.

The finalized requests assessed through the checklist revealed that they were incomplete, lacking crucial information, such as the Requesting Officer and infrastructure details, and not accounting for financial, environmental, and equipment demand factors.

Conclusions: The decision-making system practiced was revealed to be inefficient, inconsistent, and noncomprehensive. It was also found to be made without due consideration of factors related to equipment, finance, infrastructure, human resources, and services. Therefore, establishing a proper need assessment and prioritization method with criteria is recommended.

Keywords: Biomedical equipment, need assessment, stakeholders' perception.

Introduction

WHO health systems framework delineates six (6) fundamental building blocks essential for a robust healthcare system [1]. As defined by the WHO medical device is “an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose” and “medical equipment” is “medical devices requiring calibration, maintenance, repair, user training and decommissioning activities usually managed by clinical engineers.” It is often interchangeably known as “Biomedical equipment” [2].

Background

The Alma-Ata Declaration of 1978 emphasized the pivotal role of appropriate and functional medical technology in healthcare delivery. However, in developing countries, over 95% of biomedical equipment is imported, and a concerning revelation is that between 40% and 70% of such equipment is either broken, unused, or unfit for purpose [3]. This high rate of equipment failure adversely affects patient outcomes, health

system efficiency, and healthcare provider workloads.

In developed countries, a well-defined mechanism guides the selection of biomedical equipment [4]. Health Technology Assessment (HTA) is a common practice in countries like the UK and Italy, European Union HTA regulates entry of new medical devices in Europe, ensuring evidence-based selection across member states [5].

WHO's report on “Medical Devices: Managing the Mismatch” highlights the complexities of medical device selection, urging data-driven, public health-focused choices. [6]

In the Sri Lankan healthcare landscape, the process of selecting biomedical equipment warrants a closer examination, particularly concerning instances where such equipment remains unused or uninstalled. This study aims to delve into a comprehensive analysis of the current approach to biomedical equipment selection in Sri Lanka. Amidst the absence of a national HTA policy in Sri Lanka, understanding the processes and practices of health institutions in selecting and prioritizing biomedical equipment requirements becomes crucial.

Purpose of the study

The objective of the study is to assess stakeholders' perceptions of the decision-making process for selecting biomedical equipment in selected line ministry hospitals in the Western Province of Sri Lanka.

Methods

This observational cross-sectional study was conducted in the line ministry hospitals in Western Province, Sri Lanka.

Four line ministry hospitals were randomly selected based on the four levels of hospitals: national hospitals (NH), teaching hospitals (TH), Specialized hospitals, District General hospitals (DGH), and Base hospitals (BH).

The selected hospitals are as follows.

1. Colombo South Teaching hospital (CSTH), Kalubowila
2. National Cancer Institute (NCI), Maharagama (a specialized hospital)
3. District General Hospital, Negombo
4. Colombo East Base Hospital (CEBH), Mulleriyawa

Data collection

Data was collected through a desk review and a survey of stakeholders.

Desk Review

A desk review was conducted using a checklist to evaluate all requests submitted

to the BES unit by the selected hospitals between April 2022 and April 2023.

Self-administered questionnaire (SAQ)

A validated, pre-tested SAQ was used to assess the perception of the selected stakeholders involved in selecting biomedical equipment. The stakeholders are as follows:

- Hospital Directors / Deputy Directors
- Clinical Consultants of all wards and units forwarding requests to BES
- Medical Officers (MO) Planning
- Officers in charge of units (Unit heads) involved in requesting biomedical equipment (Matrons/ Sisters / Nursing Officers/ Chief Pharmacist/ Surgical Pharmacist/ Chief Radiographers)

Results

Desk review of two hundred and five Biomedical Equipment requests from June 2022 to Dec 2022 revealed the following.

Table 1: Distribution of factors included in the Biomedical Equipment requests according to the hospitals

Factors	CSTH	NCI Maharagama	Negombo	CEBH Mulleriyawa	Total
Unit / Ward	63%	66%	85%	50%	70%
Requesting Officer's Name	3%	6%	35%	40%	17%
Requesting Officer's Designation	3%	6%	28%	40%	14%
Equipment related Factors					
Age of the Replacing Equipment (If Replacement)	0%	0%	0%	0%	0%
Equipment Name	100%	100%	100%	100%	100%
Purpose	8%	43%	17%	20%	18%
Need of the Equipment	0%	0%	4%	0%	1%

Existing Similar Equipment	0%	3%	4%	0%	2%
Requesting Equipment – Specification / Features	0%	3%	4%	0%	2%
Infrastructure					
Space	6%	0%	0%	0%	2%
Electricity with a Backup	0%	0%	0%	0%	0%
A/C and Humidity Controlling System	6%	0%	0%	0%	2%
Water Disposal	6%	0%	0%	0%	2%
Medical Gas Supply	7%	23%	6%	10%	9%
Water Line (Distilled Water /DI Water / Line Water)	7%	3%	4%	10%	5%
Data Management System	6%	0%	0%	0%	2%
Other Necessary Equipment for Function	6%	0%	0%	0%	2%
Human Resources Details of the requesting unit	1%	3%	3%	0%	2%
No of tests/Cases done per month	2%	6%	13%	10%	7%
No of tests/cases are required to be done per month	2%	6%	8%	10%	5%
Environment Impact	0%	0%	0%	0%	0%
Economic factors	0%	0%	0%	0%	0%
Demand (political/social) for the equipment	0%	0%	0%	0%	0%

Table 2: Distribution of the Respondents

Type of Respondents	CSTH Kalubowila	DGH Negambo	NCI Maharagama	CEBH Mulleriyawa	Total
Director	3	2	2	2	9
Consultant & Medical Offer	75	35	37	10	157
Unit Heads	53	31	35	12	131
Total	131	68	74	24	297

Although the equipment name was included in all the requests, other important information was lacking in most of them (Table 1).

Survey results of the SAQ

The survey results of the SAQ are as follows (Table 2).

The majority of the respondents were consultants and medical officers (Table 2).

Table 3: Perception of stakeholders regarding the critical information related to the selection of Medical Equipment

Critical Information	No	Don't Know	Yes
Is there a Policy for the Health Technology Assessment (HTA) in Sri Lanka?	34.6%	34.6%	30.9%
Do you have Guidelines developed for Medical Equipment Assessment at your hospital?	38.2%	22.0%	39.8%
Do you have an Essential Biomedical Equipment list developed for your hospital?	36.1%	15.2%	48.7%
Do you think that the current Biomedical Equipment Selection process in the hospital is efficient?	76.9%	0.0%	23.1%
Do you use a format to request for Biomedical equipment in the hospital?	25.6%	20.4%	54.0%
Do you have a mechanism to prioritize the requests made for Biomedical equipment in the hospital?	34.6%	34.6%	30.9%

Table 4: Frequency of recording the requests according to the mechanism

Mechanism	Frequency	Percent	Valid Percent	Cumulative Percent
Paper-based only	149	72.3	72.3	72.3
Paper-based and Electronic	57	27.7	27.7	100
Total	206	100.0	100.0	

Table 5: Frequency of finalizing the requests according to the mechanism

Mechanism of finalizing the requests	Frequency	Percent	Valid Percent	Cumulative Percent
Don't Know	26	12.6	12.6	12.6
No mechanism	21	10.2	10.2	22.8
Individually	23	11.2	11.2	34
Through a committee	128	62.1	62.1	96.1
Through a Database	8	3.9	3.9	100
Total	206	100	100	

The survey revealed that the majority of the respondents were not aware of the nonavailability of a policy for HTA. And 76.9% of respondents perceived that the

current selection process was inefficient (Table 3).

The majority (72.3%) of the respondents mentioned that the system for requesting biomedical equipment is paper-based only (Table 4).

According to Table 5, the main mechanism of finalizing the requests made for the biomedical equipment was revealed to be through a committee (62.1%). Only 3.9% used a database to finalize the requests.

It was revealed that 51.9% of the respondents believed that it takes two or more days to obtain the necessary information about the need (Table 6).

The majority (51.5%) of the respondents perceived that the current mechanism leads to delays in the process of selecting biomedical equipment (Table 7).

Table 6: Time duration to obtain the necessary information about the need for the requested biomedical equipment

How long does it take to obtain the necessary information	Frequency	Per cent	Valid Percent	Cumulative Percent
Immediately	0	0.0	0.0	0.0
Within a day	0	0.0	0.0	0.0
Takes two or more days	107	51.9	51.9	51.9
Takes more than one week	48	23.3	23.3	75.2
Takes months	51	24.8	24.8	100
Total	206	100	100	

Table 7: The frequency of delays in selecting biomedical equipment perceived by the respondents

Frequency of delays	Frequency	Percent	Valid Percent	Cumulative Percent
Yes, always	52	25.2	25.2	25.2
Yes, most of the time	106	51.5	51.5	76.7
Yes, sometimes	34	16.5	16.5	93.2
Yes, but rarely	14	6.8	6.8	100.0
No, not at all	0	0	0	100
Total	206	100.0	100.0	100.0

Discussion

Biomedical equipment should be suited to its intended location and purpose to ensure optimal functionality [7]. However, in developing countries, approximately 75%

of such equipment is incompatible with resource-constrained settings, resulting in underutilization [8]. The discrepancy arises due to reasons such as inadequate needs assessment, insufficient infrastructure, shortage of consumables, absence of

trained healthcare staff, etc. These issues are part of a wider problem in many countries [9].

The desk review done, revealed the unavailability of information to make decisions and to set priorities in the process of selecting the necessary biomedical equipment. A systematic review by Barasa et al (2014) emphasized the importance of quality information for decision-making. It was mentioned that the availability and quality of information for decision-making play a crucial role in priority-setting practices. It was found that the lack of information was the most common obstacle in priority-setting, and the hospital decision-makers often lacked sufficient and reliable information to make informed decisions, which resulted in the use of informal and subjective considerations in selecting equipment. The article also mentioned that the decision-makers believed that the availability of quality information would enhance the decision-making process [10].

The analysis of the respondents revealed the following composition. Hospital Directors at 3%, Clinicians at 53%, and the unit heads or in-charge officers' majority who were nursing officers, at 44%. This composition is seen as closely related to a study from Brazil that revealed that those who initiated medical equipment selection were physicians (29.00%), followed by nurses (24.00%), managers (22.00%) and clinical engineers (20.00%). The study reported that patients had not initiated the selection of medical equipment [11] showing the involvement of the clinicians in the decision-making process at the highest level followed by the nurses similar to the conducted study. However, the involvement of the biomedical engineers in the initiation and selection of the

biomedical equipment at the hospital level was not assessed as there were no full-time biomedical engineers at the selected hospitals where the study was conducted.

The study revealed the absence of an HTA policy and guidelines for selecting biomedical equipment in Sri Lanka. An article by Dasanayaka (2011) mentioned that the absence of a proper framework with the right technology management policy has resulted in poor performance of healthcare equipment and resource wastage by undermining the quality of healthcare services in Sri Lanka.

A systematic review done by Gamage & Abeysena (2020) has stated that HTA is a policy tool aimed at facilitating informed decision-making processes that support the entry and use of health-related technologies. Further mentioned, the development of HTA has been driven by three main factors that are the growing demand for healthcare services and expectations, the limited availability of resources, and the increasing influx of new technologies into the healthcare market. An article by Sunuwar (2020) mentions that the HTA policy is vital in expanding the healthcare system's concept and methods of value assessment. Even though an HTA policy is absent in Sri Lanka, it is mentioned that most of the Asian countries have introduced the HTA at the government level. South Korea, Taiwan, Thailand, Japan, and neighbouring countries such as India, China, and Bhutan have already established HTA. The Health Intervention and Technology Assessment Program (HITAP) in Thailand and the UK (NICE) were identified as two of the best examples in the world where HTA has been incorporated into the decision-making process [12]. Therefore, the absence of an HTA policy can be pointed out as a main

drawback in the decision-making process in selecting biomedical equipment for health institutions. Another article shows that in developed countries such as England, France, Germany, and Sweden the decision-makers had a long experience of more than two decades in the implementation of HTA [13].

The respondents perceived that there was no proper mechanism for performing a needs assessment and prioritization. Another author confirmed this finding, recommending the importance of developing a procedure or mechanism for better, more transparent, and accountable management of biomedical equipment [14].

A 2013 study emphasized the importance of gathering relevant information in decision-making. Medical equipment is required to correspond to local clinical needs, be accurate and reliable in the environment, and ensure the effectiveness of providing health care [15].

The desk review revealed that important factors in the deployment setting are inadequately considered. An article mentions that biomedical equipment for LMIC presents unique challenges not seen in developed markets. According to the WHO, an estimated 70% of equipment coming from developed countries does not function in developing countries due to a lack of trained staff, infrastructure limitations, and lack of support and spare parts [16].

The majority of the respondents of the current study perceived that the current selection mechanism was inefficient. Similarly, a study conducted in Russia uncovered that hospitals and authorities did not properly prioritize or evaluate new technologies as the process of gathering information was disorganized, leading to

inefficiencies in the selection of equipment [17].

This is further confirmed by the findings of a study done in Ethiopia, that showed a higher level in the absence of considering the hospital setting in planning for procuring biomedical equipment. The article further showed a positive correlation between the functionality of the equipment and the procurement practices [18].

It was also revealed that there were no selection guidelines or criteria to evaluate the requirement for biomedical equipment. A similar finding was revealed from a cross-sectional study done in Kalutara [19], Sri Lanka, which stated that all hospitals studied were found to be without guidelines for acquiring equipment.

A study from Iran showed that in 80% of hospitals, there were no procedures for purchasing medical equipment, which meant that there were no formal and internal policies and procedures [20]. The study suggests an effective control system to address these shortcomings by designing a mechanism to make decision-making more efficient based on the hospital's requirements.

In conclusion, the absence of a national HTA policy, institutional guidelines, and an essential biomedical equipment list leads to deficiencies in decision-making in selecting biomedical equipment in hospitals [21]. Further, it is revealed that there is no proper system to perform a need assessment in selecting the required biomedical equipment. A study revealed that considering the status of the hospital setting in the decision-making process in selecting biomedical equipment ensures proper utilization [18]. Therefore, hospitals require to establish specific criteria for decision-

making when selecting medical equipment [22].

It is recommended that a proper need assessment mechanism be established at the hospital level to identify the hospital's biomedical equipment requirements.

Conflict of Interest

Not declared.

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