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Center Of Biomedical Engineering

A Master Thesis

On

Decision Support System for Medical Equipment Standardization

By

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This Thesis Is Submitted To, Addis Ababa University, Addis Ababa Institute Of Technology In Partial Fulfillment Of The Requirements For Degree Of Master Of Science In Biomedical Engineering

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Addis Ababa University

School of Graduate Studies

Declaration

I declare that this thesis report, submitted to center of Biomedical Engineering at Addis Ababa Institute of Technology, Addis Ababa University in partial fulfillment of requirements for degree of Master of Science in Biomedical Engineering is entirely my own work with the exception of paraphrased or quoted work whose sources are appropriately cited and acknowledged in the references.

Name: _____

Signature: _____

Date: _____

This MSc. thesis has been submitted for examination with my approval as an advisor.

_____

Masreshaw Demelash (PhD)

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Certification

This is to certify that the thesis prepared by Tadesse Minalku, entitled '***'Decision Support System for Medical Equipment Standardization''*** submitted in partial fulfillment of requirements for degree of Master of Science in Biomedical Engineering complies with the regulations of University and meets the accepted standards with respect to originality and quality.

Signed by the Examining Committee

Advisor	Signature	Date
Internal Examiner	Signature	Date
External Examiner	Signature	Date

Chief of Department or Graduate Program Coordinator

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Abstract

Decision Support System for Medical Equipment Standardization (MES)

Introduction: *Healthcare technology in general and medical equipment in particular is vital for the healthcare provision. However, today's medical equipment market competition paved a way for existence of lack of Medical Equipment Standardization (MES) in hospitals. Consequently, decision making in MES and managing of medical equipment appropriateness become complex practices. Similarly, although the exact problem in Ethiopia is not yet known, only 72% and 50% of medical equipment in Addis Ababa and regional public hospitals respectively are functional which raise equipment appropriateness issues. Moreover, my field observation helped me see professionals who complained about lack of MES. But no attention is given in Ethiopia, and evidences around investigating the needs, challenges, practices and requirements in MES decision making process are limited. So this research aims to investigate the impact of lack of MES in equipment appropriateness and develop a novel decision support system for MES decision making process.*

Methodology: *Mixed study was applied. For this survey, 457 health professionals from 5 Federal hospitals and 6 hospitals from Addis Ababa Health Bureau participated during survey between March and April 2018. To strength this, 4 biomedical engineers (1 EFDA, 3 EPSA) were also interviewed. To analyze the collected data Statistical Package for Social Sciences (SPSS) software version 23 was used. Input-output (IO) approach and sequential water fall model was used to organize and develop the system respectively. Requirements were assessed and validated before the system was developed. Then C-sharp and SQL were used as a programming language. At the end, this novel system was simulated using analytical model and tested using hypothetical values.*

Results and Conclusions*: Descriptive test result of survey indicated that lack of medical equipment standardization has an impact on medical equipment appropriateness. The cross-tabulation test also supports this and on average more than 257 (72.3%) participants agreed on lack of MES existence and its impact on equipment appropriateness. Similarly, chi-square test result also indicated that, there is a statistically significant relationship between existence of lack of MES and its impact on medical equipment appropriateness. Our findings are in agreement with the WHO findings which stated that 30-50% of world economy is wasted by extra spare part and maintenance requirement resulted from lack of MES. In addition based on survey result, physicians' preference, manager-supplier relationship, public procurement law, negative attitude, lack of communication and collaboration are major challenges in MES. Moreover, 337 (94.7%) participants reported they have no system for MES standardization has an impact on equipment appropriateness and supports the need of a new system that facilitates MES decision making process. The overall survey result indicated that lack of medical equipment standardization has an impact on equipment appropriateness and supports the need of a new system that facilitates MES decision making process. Following this, a novel system was developed and tested. The system output can support decision makers in MES decision making process.*

Key Words: *Lack of Medical Equipment Standardization. Medical Equipment Appropriateness, Decision Support System, Input Output Approach, Sequential Water Fall Mode*

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List of Acronyms and Abbreviations

DSS	Decision Support System
EHSTG	Ethiopian Hospital Services Transformation Guidelines
EHSDP	Ethiopian Health Sector Development Plane
FMOH	Federal Minister Of Health
FDA	Food and Drug Admimstration of America
EFDA	Ethiopian Food and Drug Administration
GOE	Government Of Ethiopia
HSTP	Health Sector Transformation Plan
LMES	Lack Of Medical Equipment Standardization
MES	Medical Equipment Standardization
EPSA	Ethiopian Pharmaceuticals Supply Agency
RHBs	Regional Health Bureaus
WorHOs	Woreda Health Office
WHO	World health organization

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Chapter 1 Introduction

1.1. Overview of Healthcare System in Ethiopia

Health provision in Ethiopia is provided through public, private and non-governmental organizations. The public healthcare delivery system is classified as specialized, general, primary hospitals, health centers and health posts. The administration of the health sector is organized as Federal Minister of Health (FMOH), Regional Health Bureaus (RHBs) and Woreda Health Office (WorHOs) with different responsibilities in controlling and implementing of health policies [1, 2].

There are also other organizations which have defined responsibilities under FMOH. These are Ethiopian Public Health Institute (EPHI) that mainly; focuses on health related research and trainings; Ethiopian Pharmaceuticals Supply Agency (EPSA) that focuses on acquisition of medical equipment for public hospitals; Ethiopia Food and Drug Administration (EFDA) responsible for regulatory issues, such as premarket, on market and post market surveillance. Moreover, Blood Bank (BB) focuses on availing supply of blood and Federal HIV/AIDS prevention and control office mainly focuses on HIV prevention [2].

Generally health system and health provision is a complex task which consists of institutions, resources and people, whose primary purpose is to increase the quality of health services. According to World Health Organization (WHO), establishing an effective indicated healthcare system and health provision requires human resource, health management information system, and finance and health technology management as the pillars [3, 4]. Under the health technology management, improving regulatory system, medical equipment standardization (MES), supply chain and logistics management, research and evidence for decision making and use of technology are issues raised by WHO.

1.2. Healthcare Technology Management (HTM)

Healthcare technology management (HTM) is a systematic approach which involves collecting compressive and reliable information about your equipment, planning your technology needs acquisition (selection and procurement) of suitable models and utilizing them by providing

sufficient resources for training, maintainace and replacement [4]. Medical equipment management is a complex task. Therefore decision makers need to take a decision on medical equipment management in general and acquisition in particular based on compressive and reliable information with the whole medical equipment management life cycle [4, 5, 6].

Generally medical equipment management life cycle has three phases.

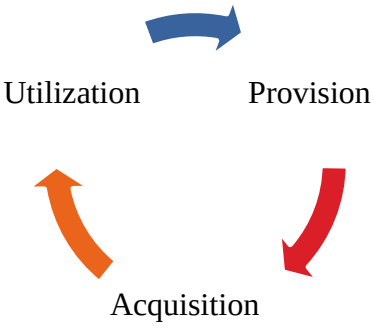


Figure1. Life cycle management for medical equipment *[4, 5, 6]*

Provision

Although all the three phases of medical equipment management cycle are continues and not separable, separate description is provided here. Provisions of the medical equipment mainly begin with technology and strategic planning. Cost, technology and social expectation are the main driving force towards planning. Hence planning is closely linked with the overall vision of healthcare service [7]. The strategic plan involves clinical and nonclinical factors in determining the healthcare organizational direction/vision. Therefore, planning is the first step in medical equipment management life cycle. In this step, distinct policies on acquisition, utilization and maintenance of medical equipment are clearly outlined. Need assessment, prioritization and budget allocation are the main activities in planning phase.

Acquisition

Medical equipment acquisition has basically two parts. These are evaluation and procurement. In evaluation process medical equipment is selected by considering different factors such as appropriateness (effectiveness, safety and acceptability, affordability, serviceability) of the medical equipment and its standardization potential because considering medical equipment

standardization (MES) limits wide variety of makes and models of equipment in a hospital Availability of spare parts, trainings and manuals (technical and operation) are considered in procurement process [8]. In addition, medical equipment should be compatible with existing equipment and appropriate for the level of service provided by your facility. Parallely, procured medical equipment should be familiar to staff and acceptable to patients as well as to the equipments user. Standardization of medical equipments is not simple. But having compressive national Standard Medical Equipment List(SMEL) and Medical Equipment Inventory(MEI) has significant impacts increasing the quality of MES decision making process as it restricts purchases to those equipments that meet these standards [4, 5].

Utilization

Utilization encompasses different activities such as monitoring and inspection, replacement and decommissioning of equipments. In addition utilization consists of having compressive inventory because of inventory has significant value for medical equipment standardization.

1.3. Medical Equipment Management in Ethiopia

In Ethiopia, the public procurement law allows almost all makes of medical equipments that comply with the minimum quality standards to be imported. As a result different brands of medical equipment with the same function are currently available in hospitals. This can limit the efficiency of medical equipment management systems and healthcare providers. Improving quality of care and optimize acquisition and utilization cost, managing all the life cycle of medical equipments should be the primary objective of each actor.

Classical equipment management system involves life cycle management that starts from research and development to disposal and replacement phase to provide reliable and quality health service [9]. This traditional equipment management system approach is a not holistic and is dependent on a single stakeholder who is not enough to achieve demand for quality and optimization of cost. Today following the need for medical equipment and the increasing variation of medical equipment brands/models, it is not possible to manage them using traditional approaches, rather collaborated and a new approach that helps to simplify the management system should be developed.

FMOH indicated the challenges in relation to managing the health technologies and the future directions in its annual reports. According to the Annual Report of Ethiopian Health Sector Development Plan (HSDP) IV 2010/11 and Health Sector Transformation Plan V (HSTP) of Ethiopia (2015/16 up to 2019/20), lack of medical equipment standardization and maintenance system are areas which require serious attention in the country [10, 11]. To overcome such problems and to implement future directions, the three medical equipment management actors FMOH, EFDA and EPSA are responsible. But major problem arises from communication barrier between them as indicated in their intersection point. As Ashenafi Hussein indicated in his thesis one of the problems was uncoordinated management system [12].

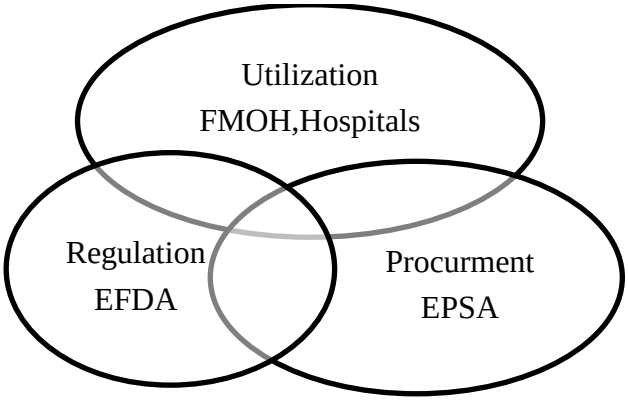


Figure 2: The three medical equipment management actors in Ethiopia (source, researcher own model from literature)

Therefore, to solve the above mentioned and other related challenges and problems in which the healthcare providers and technical persons are facing; all stakeholders should struggle and find out a new approach. To find real and tangible information related to the problem, they should do a research or should refer to researches which have been done. But since there are limited researches in the past, the challenges and the impacts become tough

1.4. Statement of the Problem

Healthcare technology has a significant impact on quality of healthcare service provision. Following this high proportion of healthcare cost is consumed by healthcare technology in general and medical equipment in particular. In 2008, EPSA distributed wide ranges of medical equipments, pharmaceutical and medical supplies with a total worth of 18.87 billon ETB all over the country from different manufacturers [11]. Medical equipment accounts the majority of this worth. This wide range of equipment cause lack of standardization and increase burdens on medical equipment management which may contribute for medical equipment to be not functional. Although the exact problem is not yet known, only 72% and 50% of medical equipment in Addis Ababa and Regional public hospitals respectively are functional which results appropriateness issue [13].

Moreover, medical equipment is heavily required in all aspects of health interventions. There are around 6,000 distinct device types and 750,000 brands and models on the market, available from over 12,000 manufacturers worldwide [4]. As a result a single hospital can have hundreds of different brands and models of similar functioning equipments. This shows lack of medical equipment standardization. Consequently, medical equipment management may become more complex in developing countries like Ethiopia which impacts equipment appropriateness. Beside this, my filed observation also helped me see different professionals who complained about lack of MES.

Even though several issues and complains were raised regarding lack of MES and its negative impacts on medical equipment appropriateness, it is known that decision making to prioritize medical equipments has become a difficult and complex task which requires real data. Evidences are also limited in Ethiopia in indicating those issues and complains are true and in investigating impacts,existing practices, needs, challenges, and requirements in MES decision making process. Furthermore, no attention is given to how prioritize and make a decision when wide variety of brands and models of equipment are available. This results in acquisition of equipment which may be no longer appropriate. So the focus of this research is to investigate the impact of lack of MES in equipment appropriateness and develop a decision support system for standardization decision making process.

1.5. Research Questions

1. Is there a significant relationship between lack of MES existence and its impact on medical equipment appropriateness?
2. How do the different professionals feel the impacts?
3. What are existing practices and challenges in MES decision making process?

1.6. Objective of the Research

1.6.1. General Objective

To investigate impacts of lack of medical equipment standardization (MES) on equipment appropriateness and design a decision support system for MES.

1.6.2. Specific Objectives

Based on the above general objective the study addresses the following issues.

- To investigate if significant relationship exists between lack of MES and impact on equipment appropriateness.
- To compare professionals (biomedical and users) perception on these impacts.
- To investigate the existing practices and challenges in MES decision making process.
- To review and validate requirements for medical equipment standardization.
- To design, develop and test a novel system that can support MES decision making process

1.7. Significance

This particular research is expected to contribute to scientific knowledge and address practical problem. This research will provide a decision support system as an output which is used for supporting decision makers in medical equipment acquisition process by introducing the concepts of MES. We believe that this research can also be used as reference for future researches and as in put to policy and decision makers.

1.8. Scope of the Research

This thesis has basically two sections. We have assessment and system development section. The assessment was focused on investigating impacts of lack of MES on equipment appropriateness, existing practices, challenges in MES decision making process and the needs of decision support system mainly, on hospitals, EFDA, EPSA. The second section was system development only limited for EPSA due to its responsibilities on acquisition of medical equipments for public hospitals [14]. Although medical equipment is very broad, for demonstration purpose less complex and easily replaceable medical equipment such as stethoscopes were not included. Therefore, in this thesis only more complex and expensive (capital) equipment were considered.

1.9. Operational Definition

Appropriateness	It is the overall effectiveness, safety, affordability, acceptability and serviceability of medical equipments [3, 4, 36, 37]**.**
Lack of standardization	The existence of the various models and brands of equipment which have the same function between hospitals or in single hospital
Medical Device	*''An instrument, apparatus or machine that is used in the Prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means'' WHO* [15]
Medical equipment	*''Are medical devices requiring calibration, maintenance, repair, user training, and decommissioning activities usually managed by clinical engineers and used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices'' WHO [15].*

1.10. Thesis Organization

Chapter 1	Presents an overview of the healthcare system, Health technology management (HTM), problem statement, research questions , objectives, significance and scope of the research
Chapter 2	Discusses about general concept of standardization, medical equipment standardization in Ethiopia, overview of DSS are reviewed
Chapter 3	Presents the research design, system development approach, sampling method and data collection protocol and procedures, data quality assurance procedure, ways of data analysis, and ethical consideration.
Chapter 4	Is all about survey regarding impacts of lack of MES on appropriateness of equipment is presented
Chapter 5	Presents all about the Development
Chapter 6	Conclusion, Recommendations, Limitation and Future Works

Table 1. Organizational structure of the thesis

Chapter 2 Literature Review

2.1. Medical Equipment Standardization (MES) in General

Medical equipment standardization (MES) has different definitions in different context. But for this thesis the definition of WHO is used. ''*Standardization is define as the process of reducing the range of makes and models of equipment available in your stock, by purchasing particular named makes and models''* [3]. From this definition lack of MES is contextualised as the existence of different brands and models of medical equipment which have similar functions in one hospital or department.

Standardization began to be developed after industrial revolution (18^{th} century). It was mainly used in product design and manufacturing. The industrial companies were obligated toward standardization of manufacturing process, raw material and working place. Industries were benefited from standardization in getting cheap labor and the workers to do their job easily in a short period of time [16].

Similarly, standardization was used as the possibility of replacing a component or a sub-assembly by another one with either more functions or including components with higher quality in order to decrease the number of parts. But they found that it is not advantageous in terms of initial product cost, but they found that it is highly efficient in terms of operational cost, supply chain and logistic optimization [16]. Latter standardization was highly used in military that called for standard devices, tools and equipments [17].

Department of Defense (DOD) in USA reviewed the concept of standardization in 1965[17]. . The four objective of standardization were:

- *''Improving operational readiness of military services by increasing efficiency of design, development, material acquisition and logistics support*
- *Conserving money, manpower, time, facilities and natural resources;*
- *Minimize variety of items, processes and practices which are associated with the design, development, production and logistics support of equipment and supplies''.*

The concept of MES began later after World War II when compatibility of variety of equipments was an issue. According to Ventola, increasing of today's market competition is the cause for variety of brands and models of equipments for the same purpose [18].

Following the existence of wide range of makes and models of medical equipments in the market, different countries are working towards standardization. Botswana is considered to be a model country which provides a solution for the above types of problem. In Botswana all x-ray machine in all primary hospital in the country comes from a single company. At the same time all surgical instruments in primary hospitals supposed to be from a single company. This creates an opportunity for radiologists and surgeons to do their duty with a full of confidence all over country [4]**.**

Because existence of such different brands and models of equipments in market not only increases complexity of decision making process, this can also affects quality of healthcare system by making healthcare provider confused until they become comfortable with different equipment. In the same way, this causes economic loss by decreasing efficiency of maintenance system, vendor/supplier control, logistic, inventory and spar part management.

This overall problem makes managing appropriateness of medical equipments highly challenging. Following this standardization has become an issue and a current agenda in healthcare system in general and medical equipment in particular. Therefore, stakeholders should work hard in order to keep their medical equipments in continuous working conditions and should monitor the quality of healthcare services they deliver.

2.2. Medical Equipment Standardization (MES) in Ethiopia

Ethiopian Hospitals Management Initiative, which started in 2006, is a pioneer initiative to introduce a standardized healthcare provision. Standardizing of medical equipments in perspective department is an option to achieve the initiative. To implement this guidelines and initiatives were developed by FMHO as a tool [19]. But this heavily depends on the available real data, level of communication between the three medical equipment actors and enhanced by computerized decision support system.

As indicated in Ethiopian hospital services transformation guidelines (EHSTG), health technology management is a great issue today. Hence medical equipment management is among areas included in healthcare sector transformation plan (HSTP) (2008-2012 EC) [1, 10]. Moreover, compressive and proper management of medical equipment is the result of effective medical equipment life cycle management strategy; which is a continuous process consists of provision, acquisition, and utilization [19].

In Ethiopia since medical equipment management is share responsibility of the medical equipment actors, they have significant role in order to consider standardization as a part of medical equipment management. For example, EPSA can consider standardization during acquisition phase (evaluation and procurement). Procurement is define as ‘’the *process of obtaining goods and services through purchase, donation, loan or hire’’* [4]. The research which was conducted by Ventola indicates that a careful evaluation of medical equipment is necessary in any clinical practices at every stage of medical equipment lifecycles even decommissioning and disposable [18].

Generally, MES has significance advantage for all medical equipment management actors by limiting number and types of spare parts, accessories, and consumables that will be keept for different types of equipment. In addition, it is possible to rationalize sources of supply and supply routes, and make savings through bulk purchasing and logistics. Moreover, considering standardization enables in obtaining equipment from a limited range of trusted suppliers and become economical in terms of service visits, spare parts, consumables, and trainings [3, 20, 21].

Professionals agree that users have role for MES that helps to optimize the impact on quality service and cost. However, standardization requires great care because of decision making in acquisition process needs to consider legal issue [20, 22]. On the other hand MES has risks associated with dependence on single supplier in the event of medical equipment failure. Procurement award contracting should reconsider user feedback, service history [3, 22]. Any procurement system should consider reliability and previous performance of equipments, total life cycle cost and standardization of the range of equipment as input [23]. Taking valid technical, clinical and financial constraint in to consideration, procuring similar and up to date model of medical equipment helps to optimize quality of care and economic impacts [24].

According to EHSTG, hospital medical equipment committee is responsible in considering technical as well as clinical evaluation to get appropriate equipment and avoid substandard equipment and optimize varation of brands [13]. Therefore, in medical equipment acquisition process reconsidering vendor qualification for service support, equipment safety and previous service history of related equipment using feedback from technical and clinical staff in makes standardization and equipment selection process easier thereby minimizing the impact of lack of MES on equipment appropriateness.

The effectiveness of modern healthcare service delivery is the result of well MES that will encourage healthcare provider and medical equipment management and maintainace team. Thus both developing and developed countries are struggling in managing and controlling healthcare delivery within the limited resources [7,25].

Lack of efficient and effective planning, management and provision of healthcare service can increase loss of resource and decrease quality of healthcare in hospitals. The demand to increase delivery of high quality healthcare services and minimizing economic loss is highly challenged by inappropriate selection, uncoordinated and disorganized decision making process and absence of effective regulation of medical equipment. Medical equipment planning should be based on priority of public health need. In addition medical equipment planning should incorporate all activities related with, research and development, health technology, need assessment, regulation, standardization and management [26, 27]. This tells importance of integrating medical equipment planning with medical equipment regulation for the provision of quality health service and optimization of economic loss. The medical equipment users are responsible in the hospital in evaluating the medical equipments, safety and performance, which is used as input for medical equipment regulator for post market assessments.

Medical equipment regulation is one of the roles of medical equipment management actors' in establishing a clear and comprehensive national policy on medical devices and ensures product compliances with regulatory requirements. The pre-market control, sales monitoring (placement on market), post-market surveillance (assessment) is the main responsibility of medical equipment regulator [28]. Besides, the role of medical equipment regulator to technological

innovation and market support for manufacturer, it has a significant role in protecting public health and increase quality of care [29].

Pre-market control is performed on the device to ensure the compliance of device with the regulatory requirements. In this stage, performance and safety of the device; quality system of manufacturing, packaging and labeling of the device are regulated. While in case of sale monitoring or placement on-market, vendor activities related with product registration, after sale obligation and advertising systems are controlled. Participating in medical equipment post – market assessment and developing the habit of using feedback and customers compliant from the equipment user is critical to ensure medical equipment appropriateness [28, 30].

The effectiveness of medical equipment can be impacted due to absence of vender regulation. Pre-market review and post-market surveillance (assessment) contributes for equipment control and ensure continuous, safe and effective use of medical equipment's. In this thesis user/customer compliant means *''any written, electronic, oral communication that alleges deficiency, related to the identity, quality, durability, reliability, safety or performance of the medical device/equipments' placed on the market''* [31].

According to the regulation on supervisory management of medical equipment of republic of china, medical equipment with poor quality and safety requirement after re -evaluation during post market assessment are discarded from the market. In addition to this manufacturer is removed from registration file by regulatory organ [32]. These tell us the more we do re-evaluation and post-market assessment the more its probability to increase appropriateness of the medical equipment and it will be easy to implement standardization by limiting the venders/manufacturers.

As indicated in Australian medical equipment regulation guideline, once the equipment has passed pre-market and on market monitoring and ready for supply, regulator should be ready to make post-market assessment and should be confident about equipment safety and reliability. The guide also indicates reconsideration of service life of equipment during post- market assessments. Medical equipment may not be appropriate once its service life is passed. So, any equipment that fail frequently but service life of the device is passed, should not be taken as

problem related with the equipment appropriateness. Only problems during service life should be assessed and considered via post market assessment [33].

Equipment life cycle approach in medical equipment assessments was discovered by Lorraine Nolan. The main idea of this life cycle approach in medical equipment was applying the three medical equipment regulation concepts (pre-market, on market and post-market surveillance) for the whole life cycle of equipments. Lorraine Nolan defined medical equipment lifecycle market surveillance/assessments as ‘’*an approach to market surveillance which involves using data and information from all stages of the lifecycle of a medical device to direct and support the conduct of surveillance activities and investigations. The outcome and findings from these post-market investigations are used to update, develop and reinforce new pre-market requirements’’* [34].

Therefore, assessing and evaluating available medical equipments in the market or hospitals by collecting relevant information regarding their appropriateness by post-market surveillance (assessment) and incorporating a result as a feedback in decision making process for regulation, procurement and utilization can bring a significant effect in reducing inappropriate medical equipments as well as manufacturers from the market. This can limit medical equipment ranges available in hospitals and can reduce cost.

2.3. Medical Equipment Appropriateness

In modern healthcare service provision, medical equipment plays irreplaceable role in making healthcare systems more reliable via enabling health professionals to diagnose, treat, monitor and provide therapy to patients [15]. Healthcare system is reliable when all elements in healthcare systems (medical equipment, healthcare providers, and technical personnels etc) are appropriate and can do failure free performance [35].

Appropriateness of medical equipment can be viewed indifferent contexts and dimensions in different literatures. This makes defining and contextualizing appropriateness of medical equipment as important. Hence appropriateness refers to *‘’ methods, procedures, techniques, and equipment that are scientifically valid, adapted to local needs, acceptable to both patient and healthcare personnel and that can be utilized and maintained with resources the community or country can afford’’*[36].

Moreover, appropriate health technology *is defined by using* key criterion as'' *effective (both in theory and in practical use), safe and not easy to use incorrectly, affordable (in initial and recurrent cost), acceptable (to all who are affected by it), serviceable/sustainable (can be maintained, repaired and re-supplied)''* [37]. Thus two definitions indicate that during any medical equipment selection processes effectiveness, safety, affordability, acceptability and serviceability are the key criterion to be considered.

Effectiveness of medical equipment can be expressed and measured in different way. Some considered effectiveness with operational performance [38, 39]. A study was conducted to investigate the relationship between MES and operational performance of medical equipment in Hyderabad public sector hospitals. Accordingly, the result was different from nurse and biomedical perspective. For nurses and physicians varation of medical equipment brands is not such great problematic and no significant relationship but for biomedical engineering standardization has a positive relationship as it affects efficiency of maintenance system [38]. Tesfaye Seifu also indicated that MES has the potential to increase performance of equipments. For example, for laboratory MES helps to get sustainable and cost effective laboratory service; allows to use and share reagent and instrument when there is shortage of stock or when equipment fails [40].

But, most frequently effectiveness is measured mathematically, by using availability and reliability of medical equipment. In this case reliability is considered as an inclusive. Moreover, reliability can have different view from different perspective. Equipment reliability from user and supplier perspective has different definition but the same implication. From equipment users perspectives; reliability can be measured and defined in terms of the ability of equipment to give long, failure free, operation. Hence they perceived that having long failure free operation can increase service quality. Similarly, this can minimize the need of spare parts and human power required and reduces cost. Moreover, reliability for vendors/suppliers may be giving of failure free warranty period under specified operating conditions [41]. Accordingly, selecting the one with better reliability is recommended [41, 42]. In addition, reliability is characterized by the probability in which equipment does not fail for specified equipment life time and it is measured by mean time between failures [39].

Moreover, reliability can be defined as the ability of equipment to perform its required function without failure for specified conditions and equipment life time. Based on the definition given by working conditions may vary from equipment to equipment. For example life support equipments in hospitals are supposed to work continuously without failing for a long time [43].

Serviceability describes how medical equipment is serviced or repaired and become available. Serviceability measures the rate of equpment becoming functional after its breaks down. This depends on availability of spare parts; trainings for all brands/models of equipment and information, knowledge and skill exchange between biomedical engineers. Hence standardizing of medical equipment reduce error and making training easier which allows staff to get more time to provide service to the patients.

Affordability of the medical equipment is measured using total life cycle cost related with purchasing and operation. Equipment is affordable if its life cycle cost is optimal. Moreover, standardization can maximize inter changeability of equipment and components, minimize down time, maximize operational readiness and availability of equipment, reduce total life cycle and logistic costs, maximize reliability, maintainability and safety of the equipment [44]. Efficient maintenance system is also an advantage of medical equipment standardization [20, 45, 46]. Standardization also optimizes time needed for training, to adapt the operation principle of different equipment and facilitate knowledge sharing between professionals [47]. Defense standardization program office indicated in the guide, interchangeability and total ownership cost reduction are advantages gained from MES. It can enhance inter and intra- departmental cooperation, spare parts and regents interchangeability, enhance availability of spar part and reduce varation of parts in the inventory [48].

In addition to this, Hockel stated that MES can increase interoperability of equipment that helps to reduce expense and enables new equipments to run continuously and reduce loss of data for patients and work interruption[49].

As stated by Dhillon, in engineering maintainace, interchangeability of equipment either physically or functionally has a positive impacts to increase appropriateness of equipment by removing and replacing parts and reducing down of the equipment. In addition to this

interchangeability can create positive impact in spare part and inventory control. Hence facilitate serviceability of equipment which increases equipment reliability [50]. Similarly standardization is used as tools in getting appropriate equipment, reduction of complexity of inventories. It has a significant economic impact by lowering of spare parts prices or costs required for training more individuals on one type of technology [20, 45, 46].

Borges *et al* indicated that, having equipment from the same manufacturer and limiting the range of equipment can have significance effect in optimizing costs related with maintainace, spare part, inventory, logistics and supplier control and negotiations [47]. The following conceptual framework was developed based on the literature. As can be seen lack of MES was considered independent variable while appropriateness of medical equipment is dependent variables.

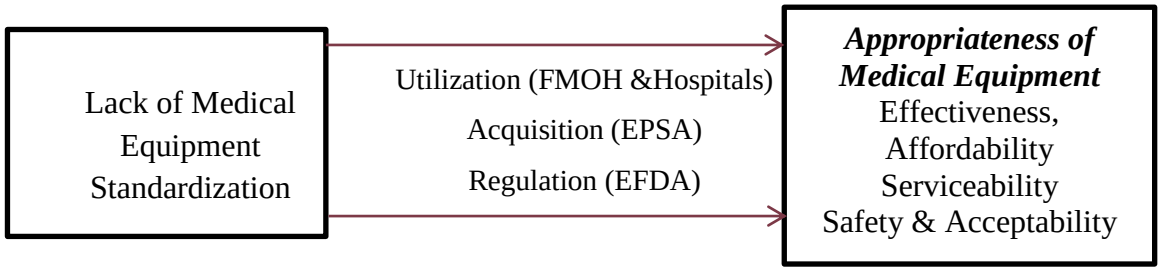


Figure 3. Conceptual frame works of relationship between dependent and independent variables (source - researcher owns model from literature)

Thus lack of MES is the cause of changing the dependent variables. The appropriateness of medical equipment is measured by equipment effectiveness, serviceability, safety, acceptability and affordability.

Appropriateness of medical equipment	**Attributes**
Effectiveness of equipment	Durability ,Down time, Reliability Compatibility with existed equipment Inter-operability of equipment's performance of equipment
Serviceability	Frequency of repair under warranty Efficiency of maintainace system, Time for user training Speed of delivering information
Safety and Acceptability	Time to be familiar with equipment Knowledge and skill transferability Medical error Varation of health care delivery, Service quality Opportunity of risk, Clinical competency Technical and procedural skill Operational procedure complexity Challenges to improve staff performance Confusion of user to adapt different types of equipment
Affordability	Purchasing cost of equipment Operational cost (Maintainace,inventory,spar part,training,logistic) equipment Opportunity of getting spare Parts Opportunity of volume discount Efficiency of logistic management

Table 2. Appropriateness of equipment and their attribute [3, 4, 21, 36, 37]

2.4. Review of Decision Support

According to Ventola, decision making in MES is challenging and complex processes which need collaboration of different stakeholders [18]. At the same time, the rapid increasing of medical equipment market competition in healthcare institute has proven inefficiency of traditional approaches such as; payment cap model, formulary model and bulk purchase or local contracting which was used as medical equipment standardization tools [51].

Those empirical approaches have a limitation and are no longer enough in order to standardize variety of medical equipment in hospitals, since different hospital request in different time and

make these empirical approaches in general and bulk or group purchasing in particular difficult in Ethiopia.

Good decision is impossible without having compressive and reliable information. The need for information has resulted in development of technologies that integrate information from multiple, disparate operational systems to support problem solving [52, 53]. Khoo *et al* indicated that availability of large amount of data and existence of dis-integrated decision making system makes decision making more complex and the actors have to use the support of science and technology to be more efficient [54].

But short review of definition and concept of DSS system would be very important before we go to this particular decision support system. Hence, based on the existed literature there is no single definition and context for DSS. According to Juhani Heilala *et al*, DSS is integrated use of communication technology, data, documents, knowledge or model to identify and solve problem related with the quality of decision making process using computerized system [55]. Moreover, common and generally agreed definition of DSS is computer based system that help decision makers confront ill-structured problems through providing organized data, direct interaction with data and analytical models [56, 57, 58].

Any decision support system has basically three main components. The first component is data management which enables to uses one or more data to provide relevant information. The data can be internal which is already stored in database and used by retrieving the data. But data can be also given externally by the user which is called external data. The second component is model management, a software package including mathematical model that helps to access and analysis relevant information from the database. The information can be either quantative or qualitative or both. The third and the last component of any DSS system is interface which is used as a communication channel between the system and the decision makers. This is very important since the information supplied determines what data need to be extracted from the data sources. All the three components of DSS system are interconnected for the full functionality of any designed system [58].

Chapter 3 Methodology

3.1. Research Design

The study was mixed research both quantitative and qualitative. Quantitative survey approach takes the greater weight of this research. Different scholars defined and agree on quantitative research as an approach relay up on examining the relationship among variables (dependent and independent variables) which can be measured typically on an instrument so that numerical data can be analyzed using statistical procedure [59]. In this research study, qualitative research approach was used to strengthen the quantitative research. Questionnaire was prepared using survey design. This design approach was used because it provides quantitative or numerical description of trend, aptitudes or opinions of a population by studying sample [60, 61].

3.2. System Development Approach

System development approach is a bridge which used to fill gaps and serve as a frame work of comprehensive methodology for DSS development. Based on requirements they need, different types of approaches existed but most of them are complicated [58, 62]. In this research, a sequential water fall model was used to design this novel system.

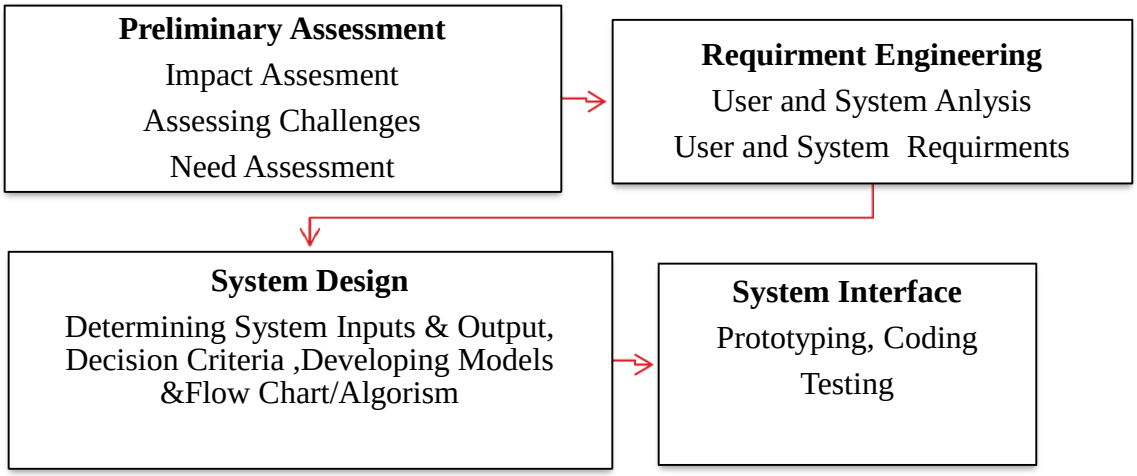


Figure 4: Water fall mode system development phase [58,62]

Additionally, this model was selected because it is simple to understand and use. Therefore, requirements were well understood and determined by the survey assessments. In this model, the system follows a series of phases (preliminary assessment, requirement engineering, system design and testing). Each phase has well defined activities.

3.3. Decision Support System Design Tool

Mostly decision support tools are viewed as software, frame works or models which are important to design a DSS and used to give a clear direction for researchers. Data and modeling are basic decision support tools [62]. In this thesis data was used as input for decision support system which required prioritizing medical equipment's based on medical equipment priority index (MEPI). Compressive and relevant data was collected and analyzed. For database design SQL server and SQL (Structured Query Language) was used as a programing tool. Moreover, Visual Studio 2013 and C-sharp were used as a platform and a system programing tool respectively.

To describe and organize the collected data and make meaningful for model, input-output (IO) approach was used. Input-output approach is the process in which information flow from one region to another region or within the same region and often used as a decision support tool in economic impact assessment and analysis. In addition, this approach is also applicable in healthcare systems in general and in healthcare technology management in particular [57].

Finally analytical model was used as a decision support tool in order to access data through analytical process and test decision support system by considering pre-determined assumptions.

3.4. Population and Sample Size Determination

The sample was determined from the three medical equipment actors (utilization, regulation and procurement). Hospital, EFDA and EPSA were from utilization, regulation and procurement respectively. Sampling techniques are different for quantitative and qualitative approaches. For quantitative approach probability sampling technique was used. In this sampling technique samples were selected from total population in random way.

Therefore, main participants from utilization side were equipment users and technical personnels (biomedical engineers/biomedical technicians).The sample size was determined using a well-known Yamane formula [63].

$$n=N/(1+N*e^2)$$

Where n = the sample size, N = Population size, and e= margin of error.

Since there was no specifically determined value of marginal error for such types of research, the most commonly used marginal error value was taken as 5% (0.05). Using the total population (*8,055*) from Table *3* and using the above formula, sample size (n) of **381** was obtained. But to increase accuracy 20% contingency was used and **457** questionnaires were distributed to the respondents. But the sample size of qualitative approach was determined from EPSA and EFDA purposively, such that only biomedical engineers were involved during interview process. Since the need of qualitative research was just to support the quantitative research and only 4 biomedical engineers (1 EFDA, 3 EPSA) were selected.

Hospital Name In Addis Ababa	**Number of professionals**
Black Lion Specialized Hospital	1836
St. Paul Hospital Millinum Medical College	1700
St.peter Specialized Hospital	750
ALERT Hospital	530
Amanuel Specialized Hospital	460
Yekatit 12 Medical College Hospital	744
Minilik II Referral Hospital	523
Zewditu Memorial Hospital	479
Gandi Memorial Hospital	360
Tirunesh Benjig Hospital	345
Ras Desta Damtew Memorial Hospital	328
Total Number of Health Professionals	***N= 8,055***

Table 3: - Total number of health professionals in public hospital, Addis Ababa (source: - human resource office of perspective hospital)

3.5. Inclusion and Exclusion Criteria

The participants of this research study were only healthcare professionals including biomedical engineers/technicians with minimum of one year of experience working as permanent or part-time staff.

3.6. Data Quality Assurance

Data quality assurance is a systematic procedure of assuring and granting the goodness of the data in research. Validity and reliability are the common points in the data quality assurance.

3.6.1. Validity

Validity is the extent of the measuring instrument in measure the intended concept. Basically there are two types of validity. Internal validity (how the score obtained from the research will actually quantifies what it designed to measure) and external validity (how accurately the measures obtained from the sample will describe the reference population) [64, 65, 66]. As part of research, evaluating the validity is primarily important before questionnaire is given to actual respondents. So panel of experts were used in order to know how the questionnaire enough to get the required data easily. Then, the researcher was tried to do test of validity of questionnaire by averaging the suggestions of three subject matter specialists (medical equipment management and researcher). Based on this, the survey questionnaire was given to the three judges to evaluate the questionnaire using two questions.

The first questions was ‘’*are the questions clear and strong in measuring the variables’’* and the second question was *’’ how much are they clear and strong in measuring the variable’’*? For the first question three alternatives (Yes, Not Certain, No) were given and for the second question five alternatives in likert scale (Poor, Fair, Good, Very Good, Not Good) were given.

The judges were also asked to check contents, grammar, coherence and relevance of the questions for the research objective. The experts involved in judging the survey questionnaire are listed in Table 4 below. After the experts closely reviewed the questionnaire and rate items, they were also invited to add any opinions and questions they need.

Accordingly the three judges gave their comments. Consequently, Eng. Henock said that technical terms were not clear and may confuse respondents. He also added that care should be taken when the same brands but different models with the similar functioned equipments exist. Based on this, the technical terms were replaced with simple but synonyms words.

Feedbacks were also given on the number of questions, suitability of questions for statistical analysis, selection of target group and the mechanism of choosing equipment list to get

equipment data by Eng. Ashenafi. Based on these feedbacks, the survey was redesigned. The third judge was Dr.Eng. Wondwosson and he offered ideas on the general points to be considered in research process and advised to reevaluate the survey questionnaire accordingly. Lastly, the survey which is designed based on feedback obtained from three judges was given to the advisors.

No	Position	Field of Study	Sex	Qualification
1	Director, research and industry linkage of AAU,researcher,lecturer	Mechanical engineering	Male	PhD
2	President, Ethiopian Biomedical Engineers and Technologist Society, lecture, Addis Ababa	Biomedical engineering	Male	MSc
3	Chief biomedical engineer	Biomedical engineering	Male	MSc candidate

Table 4. Judges participated in evaluating the survey questioners

Moreover, increase data quality, steps such as questionnaire refining, approaching respondents etc was made. In addition, to minimize generalizability of findings exclusive and inclusive criteria were incorporated during sample selection. In any survey based research, participants may not complete all items in the questionnaires. As a result, analyzing data become challenging. So, in this research we were tried to clean incomplete questionnaires using list wise deletion method before data was analyzed. But deleting of incomplete questionnaires require great care and should be systematic [64, 66]. Hence, in this study participants were guided to complete all the questions and only fully completed questionnaires were considered. To minimize effects of deletion, samples size was increased using 20% contingency.

3.6.2. Reliability

Reliability is the measure of consistency (over time, across the items, across different researcher). But the most kind of reliability is internal consistency in which the consistency of respondents across the items on multiple items measure. All items on this measurement are supposed to reflect the same concept and the response of the participant should be correlated. Cronbach's alpha which ranges between 0 and 1 is the most common measure of internal consistency used by different researcher [59, 64, 65]. Therefore, after the survey were reviewed using the ideas from judges and advisors, Cronbach's alpha as a means of measuring of internal

consistency were determined statistically using SPSS and compared with standard accepted values. Hence when the value is closer to 1 the internal consistency and reliability would be higher.

Cronbach's Alpha	**Cronbach's Alpha Based on Standardized Items**
.864	.864

Table 5. Reliability coefficient measuring internal consistency of items

Based on this, the result of this reliability test indicates that Cronbach's alpha value of 0.864 was obtained which is closer to 1 as shown in Table 5 above. This shows that the measurement was 86% reliable and consistent.

3.7. Data Collection Procedure and Instruments

Support letters were obtained from Center of Biomedical Engineering, requesting organizations and individuals their willingness and support to the researcher. I also discussed with participants about the purpose of the research, time required to fill the data and all ethical consideration. To facilitate data collection process and shorten duration of time, I hired three assistants who helped me collecting the data. The researcher gave the required orientation and training to the data collectors.

Then 457 health and biomedical professionals, who work in 5 Federal hospitals and 6 hospitals under Addis Ababa Health Bureau, were given the chance to fill questions from May to April 2018. In addition 4 biomedical engineers from EFDA and EPSA were interviewed during this period.

Questionnaires:-Questionnaires are common data collection methods for quantative research. Thus close ended structured questionnaires were prepared for hospitals.

Interview: - Since qualitative research in this study was used to support quality of survey based quantitative research, interview was used to investigate challenges of MES in the view of EFDA and EPSA. The interview was conducted using interview guiding questions. The designed guiding questions were open ended that drive the respondents to talk more and provide more information to the researcher.

3.8. Method of Data Analysis

After the survey was collected using survey questionnaire, it was analyzed using Statistical Package for Social Sciences (SPSS) software version 23. The analysis has three sections. For the first section, the descriptive statistics test was used to show whether or not lack of MES has an impact on equipment appropriateness. To strength this, Cross Tabulation analysis was used as a means of investigating the relationship between lack of MES existence and equipment appropriateness. Chi-square test was also used to test the relationship is statistically significant or not. In addition to this, independent sample t-test was used for the second section to compare professionals' perceptions on lack of MES and its impacts. In the third section, descriptive statistics test was used to present results of existing practices, need, challenges and requirements assessment for MES.

3.9. Ethical Consideration

In any research ethical consideration is the most important and significant step that should not be neglected. For this research ethical approval and clearance were obtained from hospital managers. Respondents' identities were kept confidential and data analysis was done by coding. In order to make respondents free, interested and willing to give appropriate response, the researcher gave them a short, but clear over view of research purpose, the value of their response for the researcher, the amount of time they would stay while giving response, why they were selected and why others were excluded. The participants were informed as they would be guaranteed as their names were not to be exposed or disclosed during and while the process of research is conducted. They were also informed that this research does not have a short term financial benefit to any participant as an individual or as a group, but in the long run it will help concerned organizations and policy makers to have a policy consideration, direction and formulation of strategies. In addition they were told that DSS would be designed and recommendation would be provided.

Chapter 4 Survey Result and Discussion

Survey assessment is a critical and the first step prior to design of decision support system. It is a process of collecting actual data, identifying existing practices and problems, user's requirements and challenges in decision making process. The questionnaires used in this research are presented in appendix II.

4.1. General Information about Participants

To conduct the survey, 457 questionnaires were distributed to the respondents and only 394 were collected. For data quality assurance purpose, all incomplete questionnaires were rejected and only 356 (93%) fully completed questionnaires were considered in the data analysis. As shown in Table 6 and Figure 5 below, the number of male and female participants were 202 (56.7%) and 154(43.3%) respectively. From these participants 148(41.6%) were nurses and 57 (16%) were medical doctors. Biomedical engineers and others (psychiatrists, radiography) take 37(10.4%) and 32 (9%) the participants respectively. The remaining participants were 21(5.9%) pharmacists 12(3.4%) radiology technologists 22 (6.2%) laboratory technologists and 27(7.6%) midwiferies. 119(33.4%) and 80 (22.5%) of the respondents had 1-2 years and 2-3 years of experience respectively whereas 54(15.2%) and 103(28.9%) of respondents had 3-4 years and >4 years of experiences. In addition, looking at educational level of the respondents 53(14.9 %) and 230 (64.6%) were diploma and first degree holders. Moreover, 20(5.6%) and 53(14.9%) were master's degree and MD (Subspecialty) respectively. The responsibility of the participants were also asked and majorities of respondents were medical equipment users (90.7%) followed by technical personnel that accounts (9.0%). Managers (1(0.3%)) were the least.

Back Ground Information	Levels	Frequency	Percentage
Gender	Female	154	43.3%
	Male	202	56.7%
Profession	Biomedical Engineer	32	9.0%
	Medical Doctors	57	16.0%
	Nurse	148	41.6%
	Pharmacist	21	5.9%
	Radiologist	12	3.4%
	Laboratory Technologist	22	6.2%
	Midwifery	27	7.6%
	Others, please specify	37	10.4%
Working experience	1- 2 years	119	33.4%
	2-3 years	80	22.5%
	3-4 years	54	15.2%
	>4 years	103	28.9%
Educational level	Diploma	53	14.9%
	First Degree	230	64.6%
	Master Degree	20	5.6%
	MD (Subspecialty)	53	14.9%
Role in the hospital	Hospital manager	1	0.3%
	Medical director	0.0	0.0%
	Equipment user	323	90.7%
	Technical personnel (Equipment Management)	32	9.0%

Table 6.General background information of participants

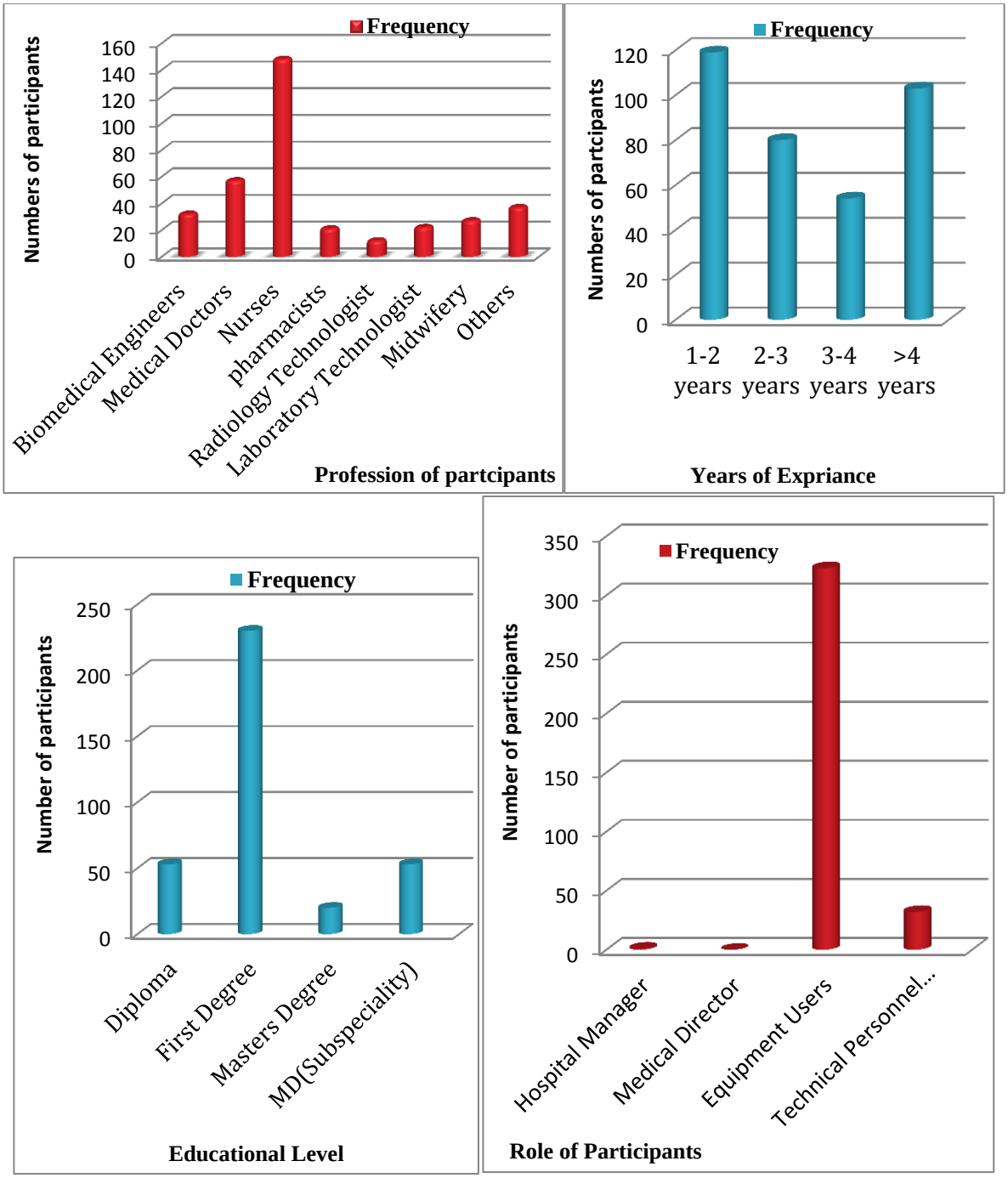


Figure 5, Graphical descriptions of background information of participant

4.2. Impacts of Lack of MES on Medical Equipment Appropriateness

Assessing impacts of lack of MES on equipment appropriateness was one of the objectives of this thesis. Table7 and Figure 6 below show the survey result.

Effectiveness: - A total of 356 respondents were completed the questionnaires and a mean score of (M=16.4871, SD= 3.04452) were obtained. When the obtained result compared with visually expected average score (mid-range) result (12.6) a mean score was greater. This implies that lack of MES has an impact on effectiveness of medical equipment. Compared to literature the result of this thesis has similar implication. Thus limiting varation of equipment with the same function and implementing standardization has valuable impacts. Therefore, MES can maximize effectiveness in general and availability, durability and reliability of medical equipment in particular [44].

In addition five years experienced biomedical engineer in medical equipment registration in EFDA stated that lack of MES not only impacts effectiveness of medical equipments, but the overall healthcare performance can be also affected.

The chief biomedical engineer and team leader in EPSA added that effectiveness of medical equipment can be increased by standardizing and selecting appropriate medical equipment. Moreover, lack of MES had direct impacts on effectiveness of medical equipment (medical equipment forecasting and specification officers, EPSA). Therefore, the survey result suggests that lack of MES really have an impact on effectiveness of medical equipments.

Serviceability: Serviceability of medical equipment is the ability of medical equipment to be maintained and resupplied in continuous and stable manner [50]. Looking Table 7 and Figure 6 below a mean score of (M=16.1298, SD=3.84226) were obtained. Comparing mean score with expected average score (mid-range) (12.6), the mean score were higher. This indicates lack of MES within the hospitals/departments has an impact on serviceability of the equipments. Information obtained from biomedical engineers in EFDA and EPSA also indicated that lack of MES has an impact on serviceability of medical equipment.

The participants from EFDA and EPSA explained that as medical equipment varieties increase the number of venders also increases. This ultimately increases the complexity of managing spare parts and venders for service support. Therefore, this affects serviceability of medical equipments. But if medical equipments in hospitals were standardized all the above problem can be minimized, while serviceability of equipment can be increased.

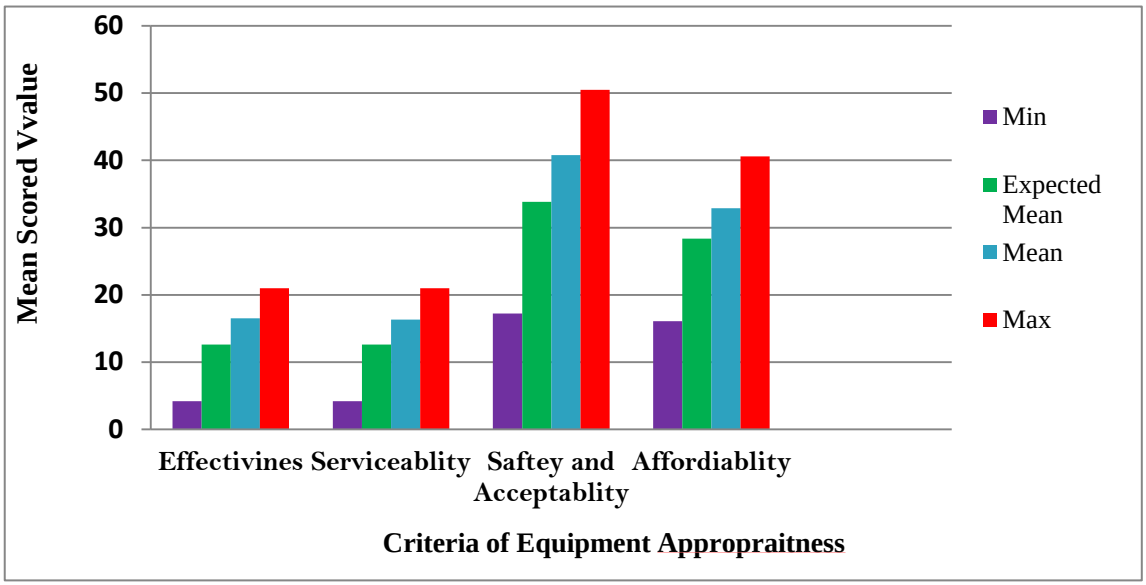
Our survey results support the literature. Various literatures show that lack of MES cost the government hospital in different way. WHO reported that 30-50% of world economic is wasted related with lack of medical equipment standardization [3, 4]. One of these was difficulty of getting spare parts which can increase serviceability of medical equipments. Hence, the ability of equipments to be maintained and repaired with the existed resource can be affected by lack of MES. That means the higher the degree of MES, the higher the probability of medical equipment to be serviceable.

Appropriateness Dimensions	N	Min	Max	Mean	Std. Deviation
Effectiveness	356	4.20	21.00	16.4871	3.04452
Serviceability	356	4.20	21.00	16.1298	3.84226
Safety and Acceptability	356	17.18	50.45	40.7987	7.61420
Affordability	356	16.11	40.56	32.8780	5.76930

Table 7: Summary of impact assessments of lack of MES on medical equipment appropriateness

Safety &Acceptability: Safety is uncompromised in medical system and evaluated by equipment users. The equipment users are persons who spend full time of spending using it. Different health professionals were complaining during data collection process. The result had proven whether their complains were true or not. The respondents were requested to give their opinion using five likert scales. Accordingly, looking the descriptive statistics test result inTable-7 and Figure 6 above, a mean score (M=40.7987, SD=7.61420) was obtained.

When the mean score compared with expected average score (mid-range) of (33.815) a very higher means score were obtained. Therefore, this tells as LMES has an impact on safety and acceptability



1 = strongly disagree 5- =strongly agree, * Higher mean score value means, the impact of LMES in that particular variable were higher.

Figure6: Lack of MES and its Impact on equipment appropriateness

Parallel to this, one of the participants stated that different medical equipments have different feature and reliability. Some equipment are good for user while some are not good as they fail frequently and reduce their confidence and acceptance. This brought a question of safety and acceptability.

Participant from EFDA (Male, 5-year' experience) strengthened this idea as follows.

''Safety is intolerable from any types of medical equipment. Safety of all medical equipments is regulated through pre-market, on market, and post market assessment. But this requires coordination and collaboration of concerned bodies. However the task becomes complex as variety of medical equipments increase. Therefore, for countries like Ethiopia with limited biomedical professionals with field of expert in the area of safety, the existence of medical equipments with various types of brands and models raises safety and acceptability issues. Additionally, once the medical equipment fail and maintained, it immediately used without any safety check. But as long as safety check is not done after medical equipment is maintained, the equipment is simply electrical equipment. This can be minimized using MES as it reduces serviceability issue''.

Therefore, the overall above result indicated that, lack of MES has negative impact on safety and acceptability. Hence, when there is MES in hospitals or departments, safety and acceptability issue can be optimized. This will have a positive impact on the quality of health care services. The same result was obtained in Netherland, such that existence of variety of similar functioning medical equipment contributed for the occurrence of 39% to 46% percent of adverse event/incident in operation room as it increase probability of misuse of equipment [67].

Affordability: - When equipment is affordable, it has to consider the whole life cycle cost of the equipments. Table-7 and Figure 6 above shows a mean score (M=32.8780, SD=5.76930) which is pretty higher than expected average (mid-range). Parallely, the result of the interview also had the same implication. Thus participants from EFDA and EPSA informed that a huge amount of money can be saved with standardization. A chief biomedical engineer and team leader from EPSA stated that

''We are a supplier and as a medical equipment supplier, we provide different types and quantities of medical equipments for hospitals depending on their need. Since the market is huge, different companies are involved with different brands and models but the same functioning equipments. This causes such variety of equipments to exist within hospitals. This is happened because of different hospitals request at different time. These derive us for different invitation in different time which dramatically increases the variety. At the end getting spare parts, controlling venders, giving user and technical training, becomes difficult and increases the cost. This brought affordability issues. Especially, for laboratory equipment which is not possible to get reagent and consumable easily, lack of MES can increase cost of consumables such as reagent''. Here, the result pointed that lack of standardization will have significant impact on affordability of equipment

Finally, Cross Tabulation and Chi-square test were conducted. The aim of cross tabulation test was to obtain information about the relationship between lack of MES existence and its impact on equipment appropriateness. Hence the result showed a positive relationship. Moreover, this test helps to visualize the number of participants who agreed on the relationship between lack of MES existence and its impact on medical equipment appropriateness. Looking Table 8 below, 292 and 224 participants agree on lack of MES existence and its impact on medical equipment

effectiveness and serviceability respectively. Similarly, 259 and 255 participants also believe in lack of MES existence and its impact on Safety&Acceptability and affordability. Therefore, on average more than 257 (72.3%) participants agreed on lack of MES existence and its impact on medical equipment appropriateness.

	Cross Tabulation Table		Does lack of MES exists?		Chi-Square Tests	
			No	Yes	Chi-Square	Sig
			F	F		
Does it have impact on…?	Effectiveness	No	52	7	273.6	0.000*
		Yes	5	292		
	Serviceability	No	27	75	11.6	0.001*
		Yes	30	224		
	Safety&Acceptability	No	19	40	13.7	0.000*
		Yes	38	259		
	Affordability	No	13	44	2.3	0.027
		Yes	44	255		
. The Chi-square statistic is significant (Sig) at the 0 .05 level. Df (Degree of Freedom)=1,F-Frequency						

Table 8. Cross Tabulation between lack of MES and its impact on equipment appropriateness

Moreover, Chi-Square test was conducted to investigate whether the relationship is significant. As a result, the test result shows statistically significant relationship exists between existence of lack of MES and its impact on medical equipment appropriateness with (chi-square value=273.567,df=1,P<0.05,chi-square value=11.630, df=1, P<0.05; chi-square value=13.688, df=1, P<0.05, chi-square value =2.331, df=1, p<0.05).

4.3. Challenges in MES Decision Making

Looking descriptive result in Table-9 and Figure 7 below mean score (M=3.60, SD=0.952) were obtained while evaluating physicians' preference as major challenge. Hence, physician preference is a major challenge that exists in Ethiopia which affects MES decision making process. The result also shows the mean score for each items were much greater than expected average (mid-range) value. Participants were also asked to give their opinions on manager-supplier relationship as one challenge and a score of (M=3.62, SD=0.966) was obtained.

Last but not least, mean score of (M= 3.64, SD=.950, M=3.80, SD=.884, M=3.56, SD=0.998) were found for public procurement law, lack of communication and collaboration and negative attitude respectively.

Common challenges	N	Min	Max	Mean	Std. D
Physician preference	356	1	5	3.60	0.952
Manager-supplier relationship	356	1	5	3.62	0.966
Public procurement law	356	1	5	3.64	0.950
Lack of communication and collaboration	356	1	5	3.80	0.884
Negative attitude	356	1	5	3.56	0.998

1=strongly disagree; 5=strongly agree

Table 9. Challenges in MES decision making process

This result shows the existence of all the above mentioned challenges but lack of communication and collaboration between stakeholders and public procurement law are the major challenges.

Experts at EFDA and EPSA interviewed. The questions raised to them was '*'what are the challenges during MES decision making process*?'' One of the expert answered that, there is no any formal decision making process for MES. This makes the process complex. Even though, there is a problem, issue of MES started just recently. As he said based on his experience, it was not such important to consider physicians preference as a major challenge. But, public procurement law, financial status of the country and political issues are some of the challenges. The other two biomedical engineers added that poor communication between stakeholders is also major challenge. In general, Table 9 and Figure 7 indicate that higher mean score were obtained on lack of communication and collaboration between medical equipment actors (regulation, procurement and utilization).

Therefore, the overall result indicated that physician preference, manager-supplier relationship, public procurement law, lack of communication and negative attitude as common and major challenges during MES decision making process. Ventola conducted a study on investigating challenges in evaluating and standardizing medical devices in healthcare facilities and similar result was obtained. He also pointed physician preference and lacks of communication as major challenges in MES as indicated in [18].

Participant from EPSA were also asked the following questions ‘*’How is strong the procurement unit in using medical equipment post market assessment(MEPMA) results as input in acquisition process, How much do you give value for equipment and value for money*?’’ Then, a medical equipment forecasting and specification officer responded that, since there is communication barrier, the habit of using feedback from users about medical equipments they use and using it as input was limited. He added that they visit hospitals not to observe about their appropriateness rather they only see whether medical equipment is installed or not.

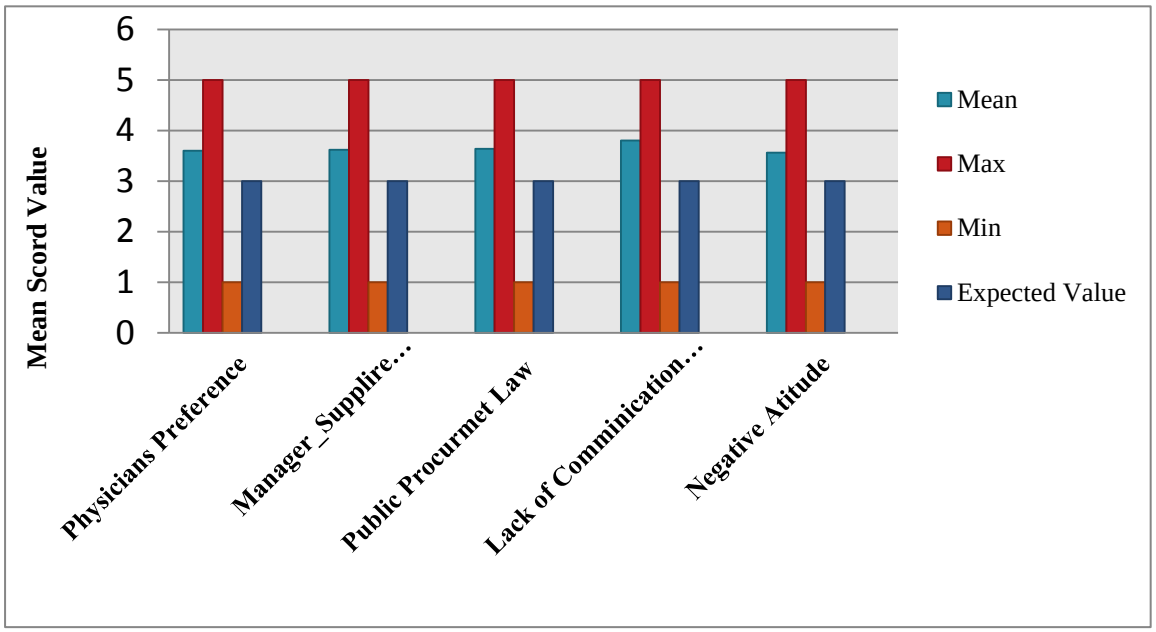


Figure7. Challenges in Medical Equipment Standardization (MES) decision making

One of the participant from EPSA added as ‘’*we do not go much detailed on post market assessment and we do not assess effectiveness, serviceability, safety, acceptability and affordability. But a MEPMA is expected from EPSA. Only when users come with feedback to our office and we try to consider their feedback for the next. Finally he generalized as using users feedback through post market assessment in acquisition process has significant impacts to limit the number of venders involved. But no practical work is done on MEPMA’’.*

Chief biomedical engineer stated that ‘*’during acquisition, there are different stages and it is a multi- decision making process in different stages starting from health facilities. During vendor selection, technical and financial issues are the two major criterions to be considered. He added*

that value for equipment and value for money may be achieved by developing strong specification and platform for MES. But when we look at the existed practices, we did not consider about value for equipment and value for money since we have no any MES platform''.

On the other hand biomedical engineer in EFDA stated that *''as a regulatory body we do pre-market, on market and post market surveillance. In pre-market we assess quality, safety and performance. To do this looking good manufacturing practices (GMP), product master file and product dossier, site master file and ISO guide are precondition for registration of products. On market assessment we do two major activities counter fit and substandard control''.*

The biomedical engineer was also asked the question '*'how much time interval does your office do post -market assessment and re-registration of equipment's and vendors*?'' He responded as we do re-registration of product in 4 years' time interval and during this time, if there are variations they will be reviewed again. He added that mostly two types of variations exist. Site, design and equipment changes are considered to be major variations, but name/manufacturer, logo/labeling changes are some of minor changes. Having this into consideration re-registration of product would be done. But according to him, their post-market assessment mostly related with occurrence of adverse event and assessing medical equipment based on their appropriateness is the responsibility of EPSA. In contrary to this, he stated '*'we promote the existence of different manufacturers in order to increase the competitions. Therefore, as long as manufacturers fulfill registration criteria we are happy to register and we don't consider such dimensions of appropriateness''*. He also added that awareness problem from end users, structural problem in hospitals, regulatory structure, lack of professional in this area were major challenges mentioned in case of incident reporting.

4.4. Comparison between Users and Technicians

To investigate whether the impact level is different for equipment users and technical persons statistical t-test was used. This test provides a statistics to evaluate whether the difference between the mean of the two groups is statistically significant or not [59].

Appropriateness	***Groups***	***N***	***M***	***Std. D***	***SE***	***Df***	***t***	***Sig. (2-tailed)***
Effectiveness	Equipment users	324	16.32	2.9	0.16	354	-3.33	0.001
	Technical persons	32	18.17	3.09	0.54			
Serviceability	Equipment users	324	15.93	3.86	0.21	354	-3.06	0.002
	Technical persons	32	18.09	3.01	0.53			
Safety & Acceptability	Equipment users	323	40.90	7.62	0.42	354	0.9	0.395
	Technical persons	32	39.70	7.51	1.32			
Affordability	Equipment users	324	32.70	5.70	0.31	354	-1.81	0.071
	Technical persons	32	34.63	6.20	1.09			
M=Mean, SE=Standard Error,=Df=Degree of Freedom, Sig=Significant level, Std.D=Standard Deviation, N=Number of participants								

Table 10. Comparison between equipment users and technical persons

Accordingly, 324 equipment users and 32 technical personnel were participated as shown in Table-10 above. The result of an independent sample t-test indicated that perception of lack of MES and its impact on medical equipment effectiveness is different between equipment users and technical persons with mean score value of(M=18.17,SD=3.09),t(354)=3.2,p=0.001and (M=16.32,SD=2.9),t(354)=-3.33,p=0.001 respectively. The t-test result also indicated that the difference is statistically significant. When we look at serviceability, similar result was obtained with mean score value of (M=18.09, SD=3.01), t (354) = -3.76, p= .002 for technical personnel and (M=15.93, SD=3.86), t (354) = -3.06, p=0.002 for equipment users. On the ather hand the difference is not statistically significant between equipment users and technical personnel on safety & acceptability and affordability. But the difference still exists and practically the impact level may be significant.

Chapter 5 System Development

This chapter presents about how sequential water fall model shown in figure 4 is implemented to develop this novel decision support system.

5.1. Existing System and Need Assessment

Existing system and need assessments for MES was conducted during survey. The participants were asked if they have computer based system that support MES decision making process and the survey result is presented in Table 11 below**.**

Items	Level	Frequency	Percentage
Does your hospital have any IT system for medical equipment standardization?	No	337	94.7%
	Yes	19	5.3%

Table 11. Existing and Need Assessment for MES

From the total of 356 participants, 337(94.7%) of respondents reported that, there is no any system. The remaining 19 (5.3%) participants responded that medical equipment management committee and biomedical engineers can standardize medical equipment.

Interview result from EFDA and EPSA reported as they have no any system. Hence, biomedical engineer from EPSA said that ‘*’MES is a great challenge and problem. He also added that solving such problem is not simple but requires strong policies. At the same time the problem of MES cannot be solved with EPSA only rather it needs higher government officials' intervention such as FMOH and higher stakeholder*s’’. The other two biomedical engineers and medical equipment forecasting officers stated that, there is no any technological tool and they support the need of a system that can facilitate the decision making process. The former biomedical engineer also added the same thing. Hence, the overall survey and interview results proved that there should be a system for medical equipment standardizations.

5.2. Requirement Engineering

Requirements are conditions needed by users, proposed by them and possessed by the system to solve a specific problem**.** A cooperative, iterative and incremental process which aims to ensure those requirement and conditions become real is called requirements engineering. This requirement engineering process consists of activities such as requirement validation, users' analysis and system analysis [62].

5.2.1. User Requirement and Validation

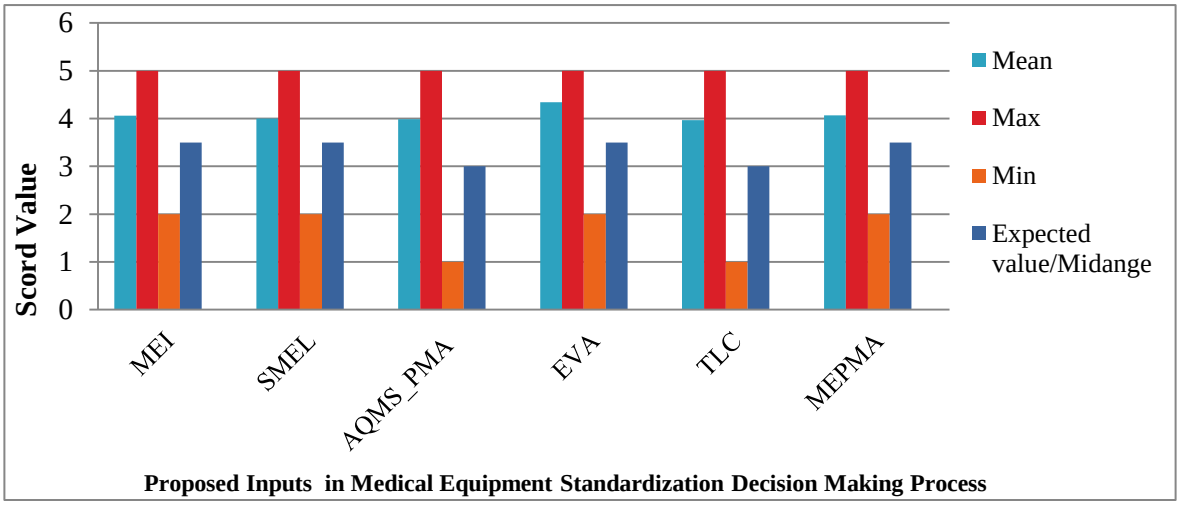
In this research users' requirements were reviewed. Looking Table 12 and Figure 8 below six items were included as user requirements to design this novel system which were compiled from the WHO [15, 21]. But, before these items were used as input, they were validated. To validate 457 participants were involved in measuring the level of appropriateness for such problems and if they are required by users using likert scale. So a mean score higher than expected average mean (mid-range) score were obtained for all items.

ITEMS	***N***	***Min***	***Max***	***Mean***	***SD***
Properly using hospital equipment inventory(MEI)	356	2	5	4.06	0.664
Considering standard medical equipment list (SMEL)	356	2	5	4.00	0.706
Using equipment value analysis (EVA)	356	2	5	4.34	0.623
Considering the total life cycle cost of equipment(TLC)	356	1	5	3.97	0.749
Referring appropriateness of pre-existing medical equipment through post market assessment(MEPMA)	356	2	5	4.07	0.765
Collecting feedback on similar equipment manufacturer & supplier post market assessment(AQMS-PMA)	356	1	5	3.98	0.756

Table 12. Requirement assessment to design the decision support system

Referring to Table 12 and Figure 8, properly using Medical Equipments Inventory (MEI), Standard Medical Equipment List (SMEL), Equipment Value Analysis (EVA), and Medical Equipments Post-Market Assessment (MEPMA) were proposed by users. The finding also showed collecting of users' feedback on similar equipment manufacturer and supplier by post market assessment and considering the total life cycle cost of equipments can be used in MES decision making.

But to design this novel system MEI, SMEL and MEPMA were used as input because they have greater mean score value. Thus inputs can also be easily implemented and accessible.



**** MEI= properly using hospital equipment inventory, SMEL= considering standard medical equipment list, AQMS_PMA= Collecting user feedback about quality similar equipment manufacturer and supplier post market assessment, EVA= Using equipment value analysis, TLC= Total life cycle cost of Equipment, ASBM_PMA= Referring appropriateness of previous similar brands and models throughpostmarketassessment*

Figure 8. **User requirements for Medical Equipment Standardization (MES).**

5.2.2. User Analysis

DSS effectiveness depends on the experience, educational level and responsibilities. So, users of this DSS system are medical equipment managers and experts in EPSA. This public institute has been selected because, it relays on ensuring continues supply of appropriate medical equipments through integrated supply chain, evidence based quantification and inventory management to public hospitals [14].

5.2.3. System Analysis

In decision supports system users always have their own perceptions and understanding. They evaluate the effectiveness of the designed DSS based on their perception and understanding. Therefore, deviation from their perception and understanding may make the system unacceptable and weak. For example, deviation may start from mis-understanding of the definition itself. One user may understand decision support system as final decision maker. The other user may

understand the DSS system as a supporter and optimization tool by providing compressive and relevant information and by guiding the decision making process.

Therefore, the system that would be designed is analyzed to minimize such mis-perception and describe the scope of the decision support system (DSS). Hence this novel system integrates and analysis the MEI, SMEL and MEPMA and generates Medical Equipment Prioritization Index (MEPI) for the existed similar functioning brands and models of medical equipment.

5.3. System Design

System design is the most crucial steps in system development. In this step, a newly proposed system becomes more formal and well structured. Moreover, inputs, outputs, assumptions, criterion, model, programing language are identified.

5.3.1. System Inputs, Processes and Output

Any system is designed to produce an output that has value to its user. But to get a good output, inputs to system also must be good. Therefore, determining the output is the first step in specifying the nature, amount and regularity of the input needed to operate a system.

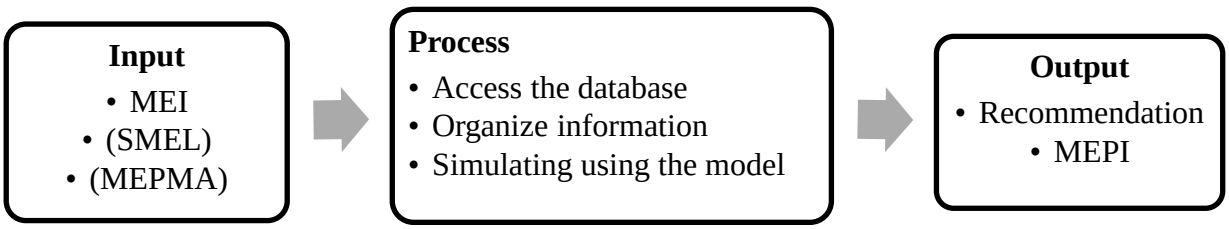


Figure 9: Input output approach for proposed DSS

Output: Are information used for decision makers provided by the system. Therefore, the output of this novel system is the evaluation list of alternatives similar functioning equipment as Medical Equipment Priority Index (MEPI).

Inputs: To get such compressive and reliable information, compressive and reliable input data should be provided. So the quality of decision is highly dependent on quality of input data.

5.3.2. Assumption

Any medical equipment brands/models listed in this research is used only for educational purpose. The researcher has no any intension beyond using for thesis demonstration purpose. The following assumptions were taken while the decision support system was developed. Accordingly**:**

- The procurement is conducted through EPSA and request should come from utilization.
- All equipment should follow single naming system.
- Existence of comprehensive inventory of medical equipment is need
- MEPMA should be done for every medical equipment in the inventory.
- All pre-procured medical equipments are based on national standard medical equipment list
- All similar functioning equipments have the same life time
- All medical equipments have constant failure rate during its service life.

5.3.3. Database Design

Entity Relationship Model (ERM) was used in order to design and show how each database are related. Entity is an object or thing or concepts which can be identified clearly. This model is important tools in order to design large amount of data and relate it with different databases [68]. In this DSS design there are three entities. MEI, SMEL, MEPMA are entities which have their own attributes and relations with each other. SQL was used in order to design database. Relationships between databases were defined by using special keys. This SQL is database computer language that is used for designing and managing of data usually in relational database management system.

5.3.3.1. Entity Relationship Diagram (ERD) and Logical Data Model

Entity relationship diagram is the overall framework of database design process. It is a graphical representation of each entity, attributes and their relationship whereas logical data model is detailed structure of attribute in an entity and the relationships between data attribute [68].

Therefore, to make it clear and visible, the entity relationship table is shown below in Table14

Entities	Attributes
Standard Medical Equipment List (SMEL)	SMEL ID, Name, Purpose, Equipment description, Level of health facility, Service type
Medical Equipment Inventory (MEI)	MEI ID, Name, Manufacturer/brand, Model, Serial number, purchasing date, Year of manufacturing and Expected life time
Medical Equipment Post Market Assessment (MEPMA)	Age, Down time (DT), Number of failure(N), Safety,Acceptability,Interchangablity,Affordability, Serviceability

Table 13. Entity Relationship Table

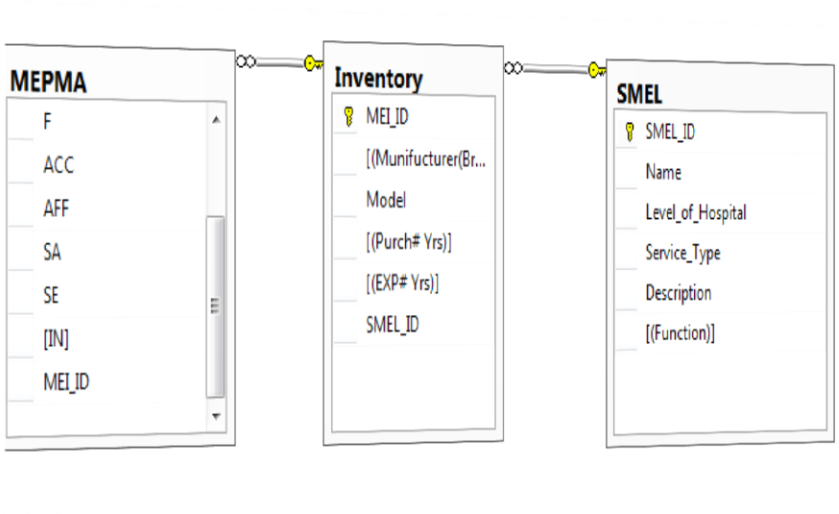


***Figure 10: Logical Data Model*.**

Looking Figure 10 above, the relationship between SMEL and MEI is 1: M. The medical equipment may be found once in the SMEL but may be found at different times based on their brands or models in MEI. Once the medical equipment is registered in MEI, it would be assessed via post market assessment in different time interval. In this case, medical equipment is registered only once in MEI but it can be assessed many times during its life time in MEPMA. Therefore, the relationship MEI and MEPMA is also one to many 1: M.

5.3.4. Decision Criterion

Decision criterion and rating mechanism are the most challenging and critical part in decision support system design. Decision criteria are inputs that can be found by asking the users, or using literature review or using combination of the above two mechanism. DSS criterions were assessed by the researcher during survey and presented in Table 12 and Figure 8. They require both qualitative and quantative responses. From thus requirements, MEI, SMEL and MEPMA were used in system design because they can be implemented easily and accessible in hospitals and central level.

The other challenge was rating mechanism. But, in health technology management likert scale rating mechanism has been used for decision making purpose depends on the decision criteria is either qualitative or quantative [69, 70]. Using this rating mechanism different DSS has been developed in the past [39,71,72]. Therefore, in this DSS design the decision criterion which requires qualitative response were rated accordingly.

Standard Medical Equipment List (SMEL): - is a model list of equipments, based on level of hospital, mode of operation, service type and the type of health interventions (diagnosis, treatment, and care) a facility is expected to carry out. SMEL can be developed at national or health facility level. Moreover, equipment planning and acquisition process should be based on SMEL [4]. Therefore, when EPSA select and procure medical equipment requested by hospitals, it should consider this national SMEL. In Ethiopia national SMEL available from the Ethiopian standard agency depends on healthcare level [74]. The researcher used SMEL as decision criteria and medical equipment acquisition process should be referred with SMEL. SMEL used to make failure free decision when wide variety of brands and models of the same functioning equipment exists and do not know which to choose. In this research, we proposed **yes** or **no** options as Table 14 below.

Level	Value	Description
Yes	1	The equipment is in the standard medical equipment list
No	0	The equipment is not in the standard medical equipment list

Table 14. Scoring mechanism for standards medical equipment list

Medical Equipment Inventory (MEI): - Well organized and designed MEI has significant values in MES. So, having a well-developed inventory can facilitate decision making process in MES [15]. Inventory may be developed by different stakeholders in order to fulfill their need. For example, in our country FMOH, Hospitals, EPSA may have their own MEI.

Medical Equipment Post Market Assessment (MEPMA):- is the process of assessing and evaluating medical equipments when it is in service. Appropriateness of medical equipment is different before and after service. Assessing an equipment inventory trough MEPMA can help to identify potential benefits in standardizing equipment. MEPMA is the backbone of the decision support system as it provides all relevant information such as effectiveness, serviceability, affordability, safety and acceptability.

Serviceability: - it is the degree of existed or procured medical equipment to be maintainable and become available within the available resource [4, 73]. Hence, when stakeholders evaluate and procure any medical equipments and different brands and models available, considering serviceability issue is important for MES. However, evaluating serviceability needs looking of different parameters such as, availability of spare parts, professionals and others conditions. To measure the degree of serviceability 1 to 5 ranges was used as in Table 15.

Level	Value	Description
Very high	5	Medical equipment is fully serviceable
High	4	The equipment is serviceable
Moderate	3	The equipment is serviceable but have different challenges
Low	2	Nearly not serviceable
None	1	Not serviceable

Table 15. Scoring mechanism for medical equipment serviceability

Effectiveness: - measures level of satisfaction gained by equipment users and it is the theoretical and practical value required from equipments. It can be described in different ways but the most commonly used parameters are availability, performance and quality [75, 76].

‘’Effectiveness=Availability*Performance*Quality (1)

But, for medical equipment reliability is important parameters for an equipment to be effective. It

is the ability of medical equipment to work without failure for specified period of time under optimal conditions [77]. Optimal conditions are those conditions required for a single equipment to work at its preset performance and capability. So reliability is an inclusive and we used reliability as a core parameter to determine the effectiveness of equipment. Without loose of the concept of the above equation we added interchangeability as measuring parameter based on the users' requirement. Thus in order to have effective medical equipment, it should also be interchangeable so that effectiveness of medical equipment was described using the following mathematical model.

$$\text{Effectiveness}=\text{Availability}*\text{Reliability}*\text{Interchangeability} \quad (2)$$

$$\text{Reliability}=\exp(-T/\text{MTBF}) \quad (2a)$$

$$\text{Availability}=\text{MTBF}/(\text{MTBF}+\text{DT}) \quad (2b)$$

Where: MTBF=Mean Time between Failure (hrs.), DT=Down Time (hrs.), e=2.718

Number of failure (N): The lower the value of N the higher equipment's reliability. This can minimize effectiveness of equipment. Moreover, the reliability of two medical equipments can be compared with their failure rate. On the other hand, once the medical equipment is maintained and repaired and started to give service, it may fail for the second time. This must be considered and measured using failure rate. But the appropriate word in measuring the reliability of any medical equipment is mean time between failures (MTBF). It is the time measured in which maintained equipment worked properly without fail. Hence, the higher equipment failure rate the lower would be mean time between failures [77]. In this research study, hypothetical value was used for number of failure (N).

Down Time (DT):- This tells the total time in hours in which the equipment was out of service. Medical equipment may be out of service due to one of the following reasons: spare parts, training, consumables and reagent problem. Therefore, DT is measured by considering Time to diagnosis (TD); Time to get spare (TS) and Time to repair (TR) and we used hypothetical value.

$$DT = \text{Time to Diagnosis (TD)} + \text{Time to gate Spare (TS)} + \text{Time to Repair (TR)} \quad (3)$$

Interchangeability(IC): The other most important criteria is interchangeability which measure the probability of exchange spare parts, consumable and reagents. In addition, when equipment fails and if it is not repairable technical personnel use its components as spare part for other similar equipment. Therefore, in this thesis five point probability scales as Table 16,was used in order to measure whether the medical equipment is interchangeable or not with existed medical equipment.

Level	Value	Description
Very high	5	Fully interchangeable
High	4	Interchangeable
Moderate	3	Nearly interchangeable
Low	2	Nearly not interchangeable
None	1	Not inter-changeable

Table 16. Scoring mechanism for medical equipment interchancgablity level

Safety(S): safety measures the outcomes of equipment failure. Safety issues related with the medical equipment are common and serious. Thus issues are directly or indirectly resulted from equipment which is not appropriateness and can be related with user training or maintenance. Therefore, users and patients' safety should never be compromised by inappropriate equipments. In addition lack of MES make equipment users more confused and brings mis- use of equipment and become the causes for safety problem [67]. In order to do this, we proposed five point's measurement scales as presented in Table 17 below.

Level	Value	Description
Very high	1	Death for the patient or user
High	2	Sever and longer time injury
Moderate	3	Inappropriate therapy, mis- diagnostic, loose of monitoring
Low	4	Minimal injury
No risk	5	No effect

Table 17. Scoring mechanism for safety evaluation

Acceptability (AC): acceptability is the very important criteria and used as measurement of appropriateness of equipments. Equipment may not be acceptable by users in different cases, such as frequency of failure, its complexity, poor user interface, and in compatibility with existed

one. On the other hand, biomedical engineers may not accept the equipment because of, reliability, durability, serviceability and intercheangablity issues etc. Moreover, the equipment may not be acceptable compared to the type of service it required

Level	Value	Description
Very high	5	Fully acceptable
High	4	Acceptable
Moderate	3	Nearly acceptable
Low	2	Nearly not acceptable
Very low	1	Not acceptable

Table 18. Scoring mechanism for acceptability

Thus, getting feedback from equipment users had important role in identifying the types of equipment which is not acceptable. The stakeholder should be honest while they evaluate whether the equipment is acceptable or not.

Affordability (AF): - It was used to measure economic impacts of lack of MES. Buying the cheapest item can be a false economy, because it may need repairing or replacing more frequently. This becomes very uneconomical and unaffordable when the varieties of medical equipments increase. It may be more affordable to spend more on appropriate equipment [4].

Level	Value	Description
Very high	5	Fully affordable
High	4	Affordable
Moderate	3	Nearly affordable
Low	2	Nearly not affordable
Very low	1	Not affordable

Table 19. Scoring mechanism for affordability

5.3.5. Model Determination

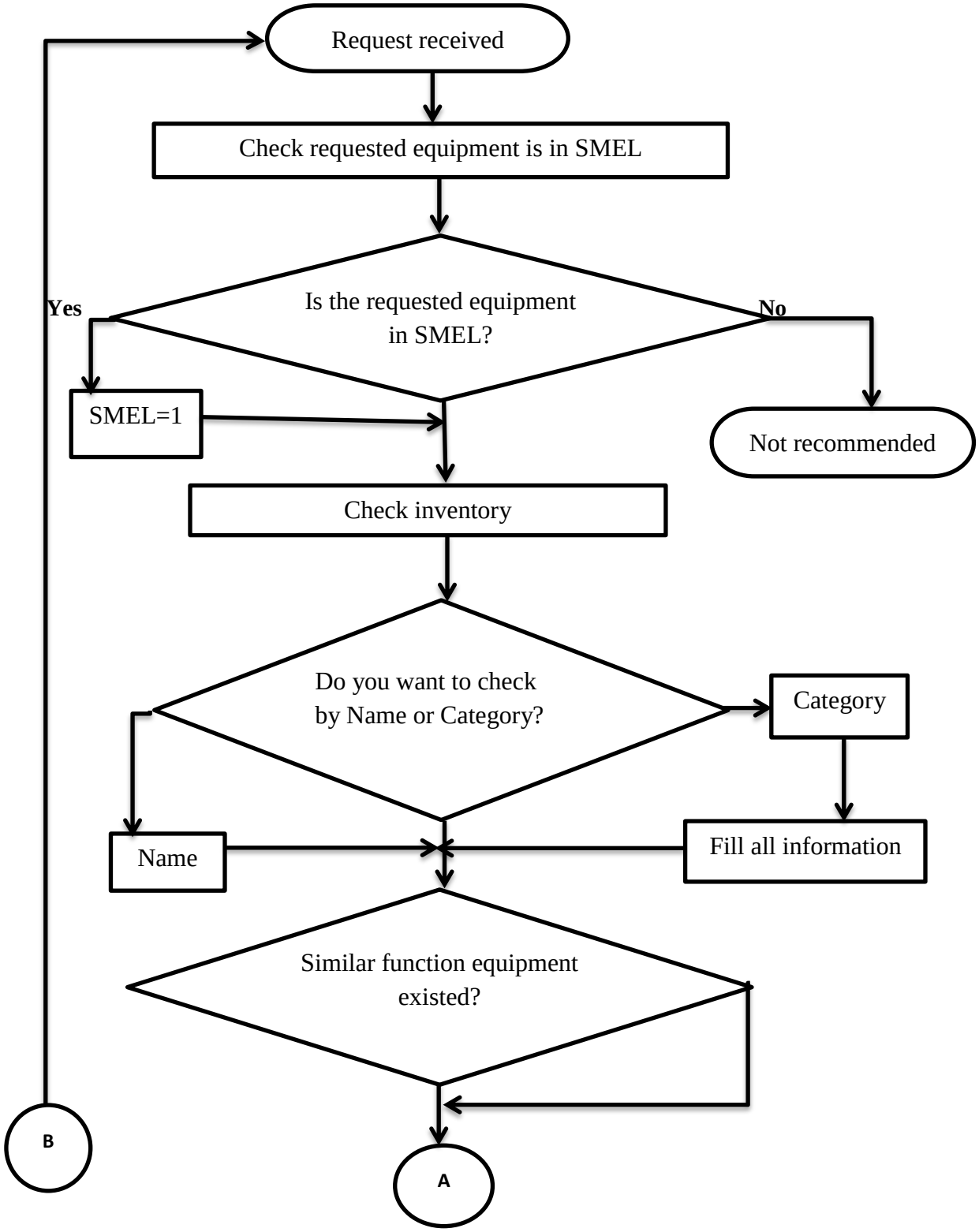
Analytical model was used to simulate the system using hypothetical values. This model is a simple mathematical expression that can generate test result quantitatively. All variables that require quantative and qualitative response are formulated accordingly. Hence the following mathematical model is proposed.

Medical Equipment Priority Index (MEPI) =Effectiveness (EFF)*Serviceability (SE)* Safety (SA)*Acceptability (ACC)*Affordability (AFF)*Standard Medical Equipment List (SMEL) (4)

MEPI is just a number used as reference to prioritize the evaluated list of medical equipment.

5.3.6. System Algorism

System algorism is a complete, unambiguous, with finite number of logical steps. It is a series of steps which are provided in to computer to solve a certain problem. So to develop these system algorisms the following steps were followed by the researcher. First inputs were identified which we gave to the system for each specific problem during the whole decision making process. The second step was identifying of the specific output. The third step was identifying of the operation process and simulates the system. All calculations that can be performed to get the required outputs, was determined in an orderly manner. Lastly, termination point was determined clearly. Figure 11 below shows this series of steps in the form of flow chart.


Request received
Check requested equipment is in SMEL
Is the requested equipment in SMEL?
Yes
No
SMEL=1
Not recommended
Check inventory
Do you want to check by Name or Category?
Category
Name
Fill all information
Similar function equipment existed?
B
A

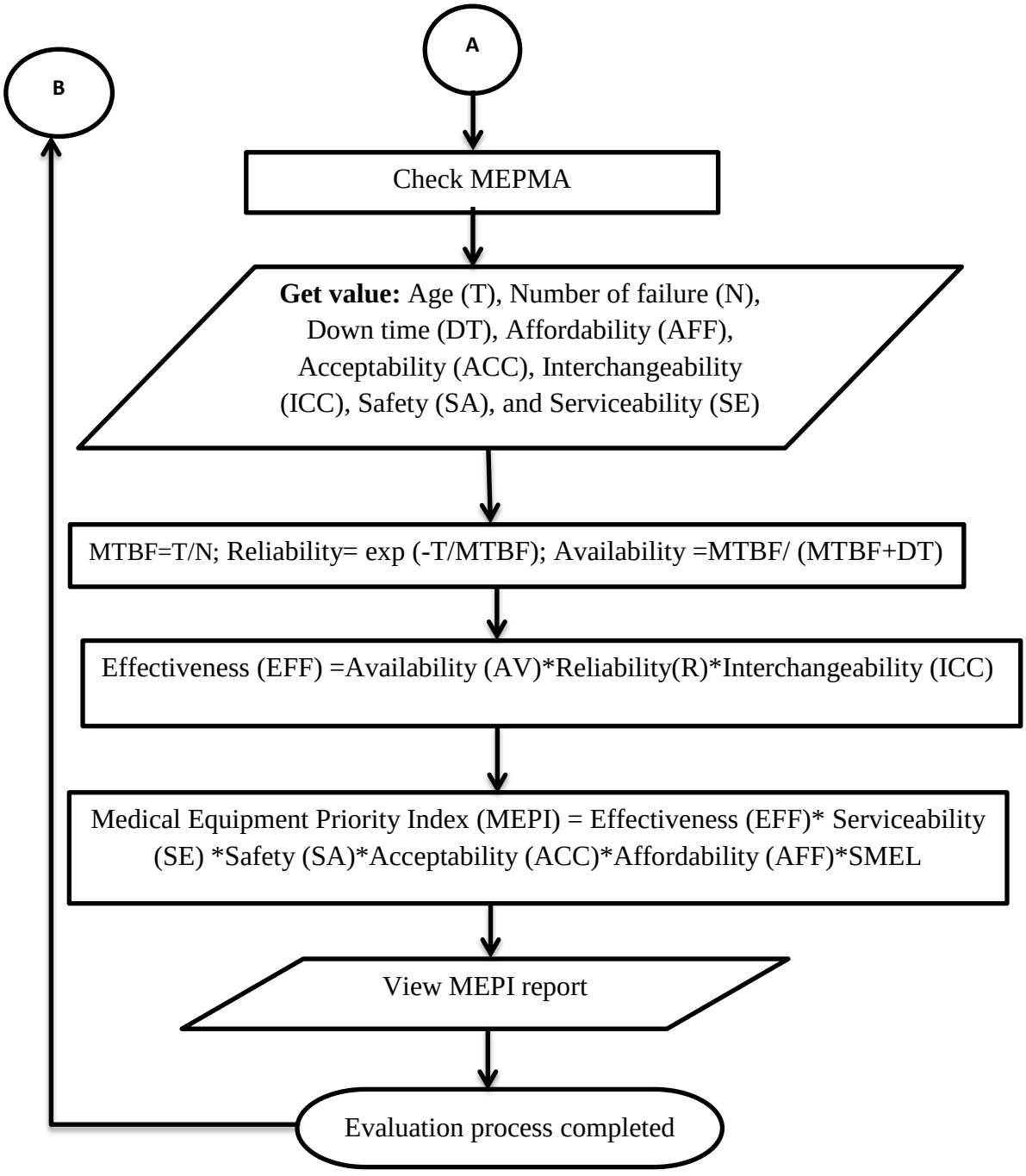


Figure 11: System algorithm flow chart

5.4. System Interface and Testing

5.4.1 System Interface

System interface is a model to simulate the system before we actually implemented. In this section of research, users' requirements are transformed into fruitful product. This helps users to interact with the system and to analyses its result. Hence this novel decision support system would have the following interface.

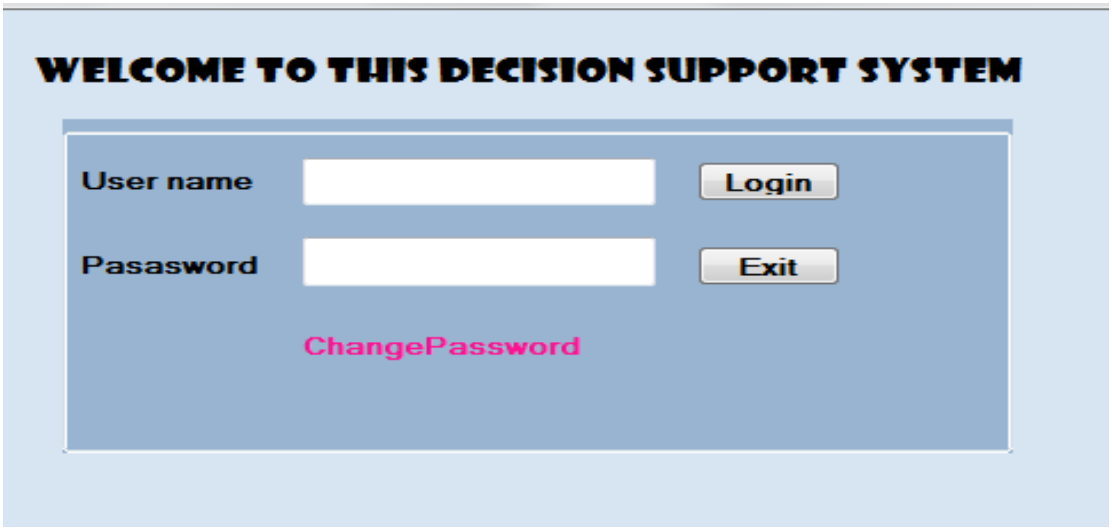


Figure 12: Login page user interface design

As seen in Figure 12 only authorized user with the right user name and password has the right to use the system and access the information required. In addition to this, for security purposes only authorized user can login or change password when required.

5.4.1.1. Case Demonstration

This shows what system users do when different brands and models of equipment are available in the market to standardize the newly required equipment with the existed one. To demonstrate this phenomenon hypothetically, the case of ultrasound equipment was used.

Ultrasound equipment is medical equipment which uses sound wave above the range of human hearing (20 KHz). Medical ultrasound equipment can be used for either diagnostic imaging or therapeutic application. Today, an increasing rate of medical equipment market results importing

of different ultrasound equipments from different manufacturers, wholesalers and suppliers. This makes communication between supplier and recipients very challenging and time consuming. But if ultrasound equipment from a single supplier is acquired, those challenges can be optimized. This phenomenal is hypothetically presented in case I.

Figure 13: System home page interface design

Moreover, ultrasound equipment even from the single supplier are different and have different descriptions depends on level of hospital it required, types of service, function of equipment etc. Therefore, by evaluating and selecting equipment considering the above conditions, standardization potential can be increased. This phenomenon is presented in case II.

Ultrasound equipment generally can be grouped into three from instrumentation, purpose/function and image display mode perspectives. These are simple gray scale, doppler and duplex (a type of ultrasound that makes two kinds of images) ultrasound. It also be used for general purpose or special purpose (for specific application) based on the range of frequency and types of probe it can handle [78]. A general-purpose ultrasound supports a wide variety of transducers and related application software packages allowing for the collection, display and analysis of ultrasound information. Hence, different hospital my need one of them or all of them based on the types of service it delivers. For example, a general hospital radiology service in Ethiopia should consist of duplex and simple gray scale ultrasound for general purpose diagnostic imaging. Specialized hospital radiology service should have duplex ultrasound for

general purpose and duplex ultrasound with cardiac probe (echocardiograph) for special purpose in cardiology [74]. This hypothetical test is presented in case II below.

Case I: - When one needs to know which ultrasound equipment is appropriate and want to limit the numbers of manufacturers, wholesalers and suppliers, it is possible to assess and evaluate all ultrasound equipment by selecting '***'Name''*** option in make analysis button in homepage.

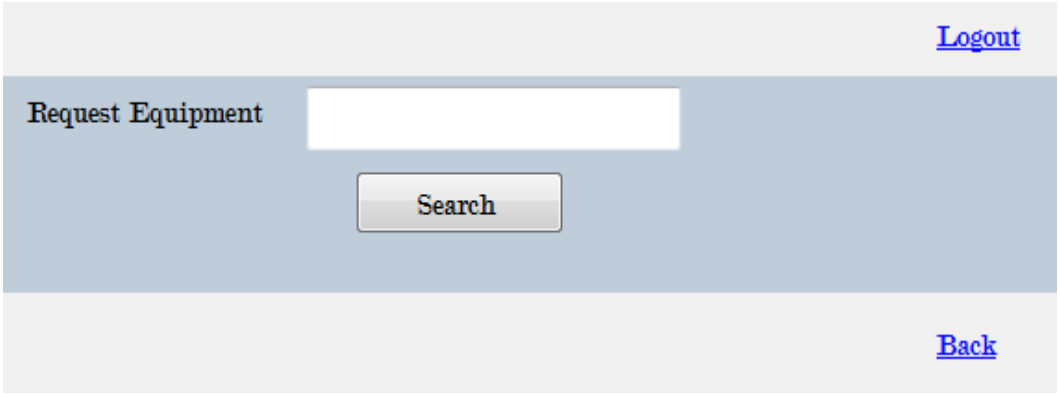


Figure 14: System home page interface design based on equipment name

Name	EFF	ACC	SA	AFF	SE	MEPI
Ultrasound_Datex ohmeda _Capnomac	1.2	2	3	3	2	44.0
Ultrasound_Siemens _Infinity SC	0.848	3	3	3	3	68.7
Ultrasound_Fukuda denshi _Dynascope DS-5300	0.83	3	3	3	3	67.2
Ultrasound_bioengineering _Smart flow	2.236	2	3	2	2	53.7
Ultrasound_Acuson corp_Sequia 256C	0.767	2	3	3	2	27.6
Ultrasound_Esaote_Technos m	1.3	3	3	3	2	70.2
Ultrasound_GE_Stenographe 800T	1.3	2	3	3	2	46.8
Ultrasound_Omasa_ELA-62	2.275	2	3	2	2	54.6
Ultrasound_Philips_IU22	1.33	3	3	3	2	71.0
Ultrasound_HP_Sonos 4500	1.147	3	3	2	2	41.3
Ultrasound_Gilardoni SPA_Caleidon HF	0.429	2	3	3	3	23.0
Ultrasound_Trumpf_5300	0.458	3	3	3	3	37.1
Ultrasound_ Sonicaid _Oxford	0.796	2	3	2	2	19.104
Ultrasound_Verthon _BVI 6100	0.796	3	3	2	3	43.0

***** 1=very low, 2=Low,3=Moderate,4=High,5=Very High, Effectiveness(EFF),Acceptability(ACC),Safety(SA),Affordability (AFF),Serviceability(SE), Medical Equipment Priority Index(MEPI)***

Table 20 Sample analysis of ultrasound machine

By looking the system output in Table 20 and Figure15, Ultrasound_Philips_IU22 has higher Medical Equipment Priority Index (MEPI). Decision makers can standardize thire requirement using such information as input during MES decision making process.

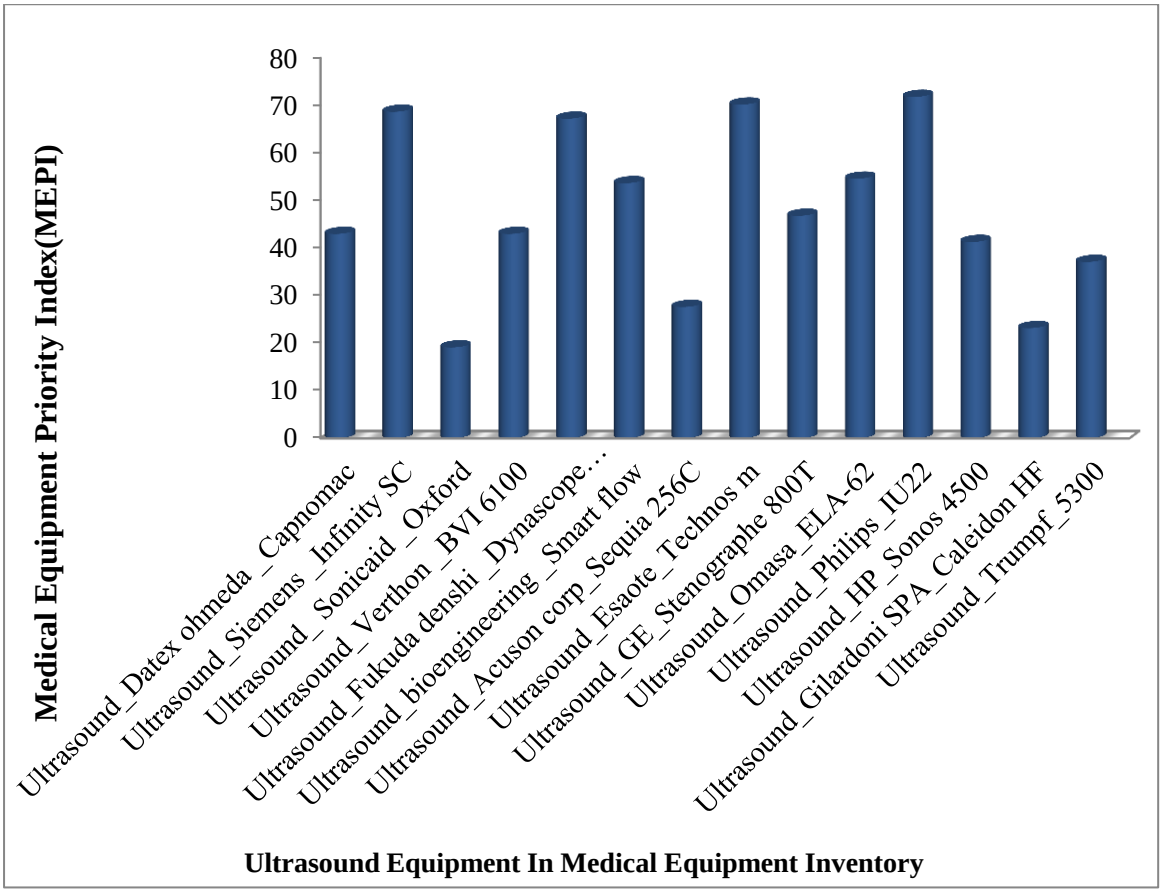


Figure 15: Total analysis for ultrasound machine report

Case II: - In this case, ultrasound equipment is grouped based on the level of (specialized, general or primary); Service type (radiology, cardiology, renal or emergency etc.). Similarly it can be grouped as general purpose duplex, general purpose gray scale, special purpose duplex and Doppler. Based on function ultrasound equipment can be also grouped as diagnostic imaging, therapeutic and diagnostic monitoring.

Then the system automatically selects, analyzes and generates report for ultrasound equipment under this group. The report takes ***Name_ Brand/Manufacturer_ Model*** sequences.

Ultrasound used in general hospital for diagnostic imaging and general purpose duplex in radiology service was requested and the preexisted similar equipment was cross-checked and evaluated. Hence, result indicates ***Ultrasound_ Siemens _Infinity SC*** has higher priority index as indicated in Figure16 and Table22 below.

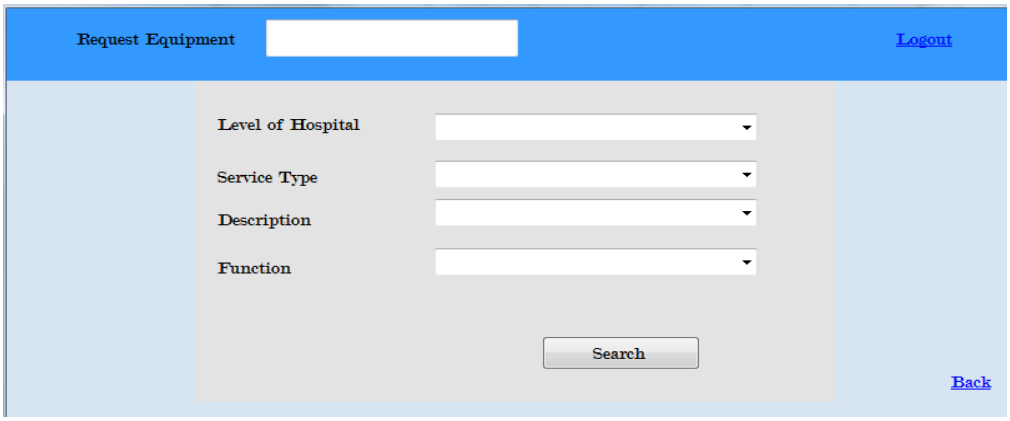


Figure 16: System home page interface design based on equipment group.

Equipment Name	EFF	ACC	SA	AFF	SE	MEPI
Ultrasound_Datex ohmeda _Capnomac	1.194	2	3	3	2	42.98
Ultrasound_Siemens _Infinity SC	0.848	3	3	3	3	68.69
Ultrasound_ Sonicaid _Oxford	0.796	2	3	2	2	19.1

Where: - EFF=Effectiveness, ACC=Acceptability, AFF=Affordability, SA=Safety, SE=Serviceability, IN=Interchangeability

Table 21: Ultrasound equipment for general hospital in radiology for diagnostic imaging purpose

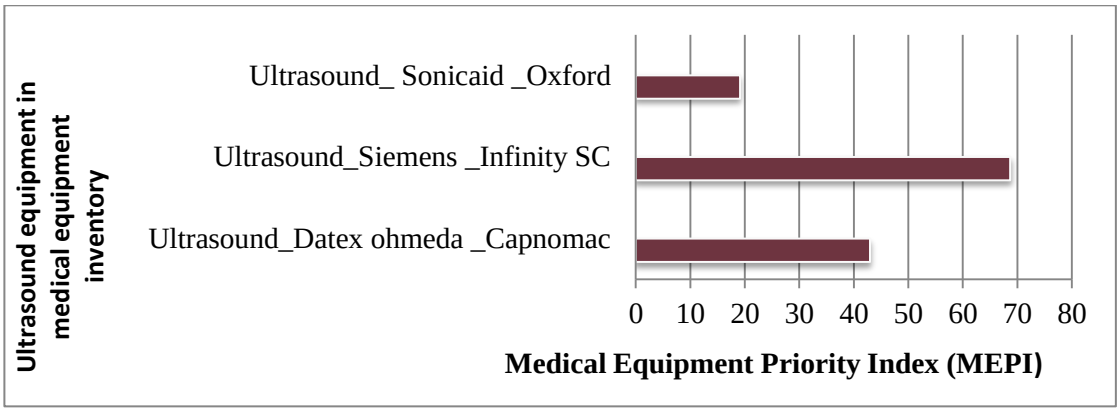


Figure17: Ultrasound equipments for general hospital radiology service for general purpose duplex

Similarly, ultrasound equipment for specialized hospital,in radiology servie and general purpose duplex were also preseneted in Table 22 and Figure 18 below. So,medical equipment priority index(MEPI) for ***Ultrasound_Esaote Technos m*** was higher.

Equipment Name	EFF	ACC	SA	AFF	SE	MEPI
Ultrasound_Acuson corp_Sequia 256C	0.767	2	3	3	2	27.61
Ultrasound_Esaote_Technos m	1.3	3	3	3	2	70.2
Ultrasound_GE_Stenographe 800T	1.3	2	3	3	2	46.8
Ultrasound_Omasa_ELA-62	2.275	2	3	2	2	54.6

Table 22: Ultrasound equipments for specialized hospital radiology service for general purpose duplex

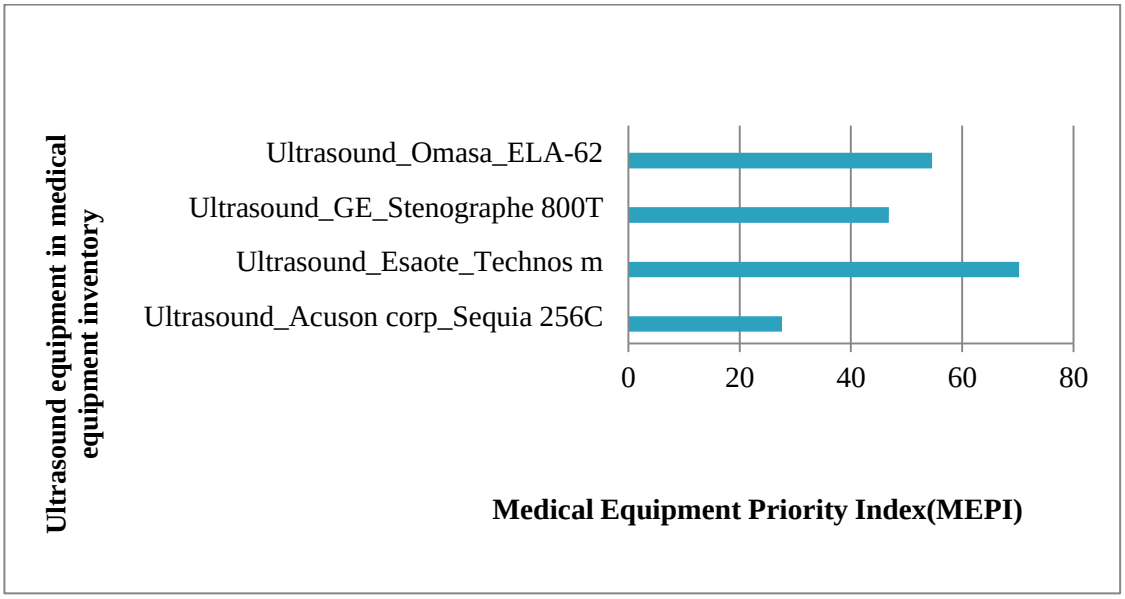


Figure 18: Ultrasound equipments for specialized hospital radiology service for general purpose duplex

Chapter 6 Conclusion, Limitations, Recommendations

6.1. Conclusion

Survey was conducted in all 11 public hospitals in Addis Ababa; 5 from federal hospitals and 6 hospitals from Addis Ababa Health Bureau. For the survey, 457 questionnaires were distributed and 394 were collected. By excluding incomplete questionnaires, only 356 were analyzed. Moreover, 4 biomedical engineers from EFDA and EPSA were interviewed.

The result of the survey showed the lack of MES and its impact equipments appropriateness. From the result, we also observed that majority of respondents agreed on existence of lack of MES and its impact on medical equipment appropriateness. The findings also indicated that physicians' preference, manager-supplier relationship, public procurement low, negative attitude, lack of communication and collaboration between different stakeholders are the existing challenges in MES decisions making process. In addition 337 (94.7%) of respondents reported that they have no any system for MES. The remaining 19 (5.3%) reported that medical equipment management committee and biomedical engineers can make standardization.

The result of the survey indicated the need of Decision Support System (DSS) for medical equipment standardization. Accordingly, requirements were assessed and a novel DSS was designed developed and tested. Requirements were validated before they were used as input to design this novel system. The designed system shows how MES decision making process would be done. The system can give input for decision makers to decide which equipment brands and models are appropriate. Finally the system is tested using ultrasound equipment to show how the novel system works.

Generally, this thesis provides a new contribution for MES. The developed system requires more contribution and work in order to be implemented on the ground. As this stage the system provides simulation for further continuous evaluation and development along with the users' feedback.

6.2. Limitation of the Study

Although this research study has a great contribution for medical equipment management in general and MES in particular, it has its own limitations. To design the system assumptions were taken. So, additional efforts and improvements are expected and recommended to visualize the effect of the system in its actual use.

- Data collection was very difficult and challenges as some users were not motivated and willing.
- Lack of knowledge related with MES made collecting data time consuming and some data may not be valid
- In addition, getting ethical clearance from hospital top managers made data collection process complex.

Moreover, this designed system is highly dependent on the actual existence of these assumptions.

- Existence of comprehensive inventory of medical equipment is need
- MEPMA should be done for every medical equipment in the inventory.
- Any procured medical equipment should be based on standard medical equipment list.
- The other limitation is time to determine reliability and availability of medical equipment. This assumption was made as different medical equipments have different failure rates. Even failure rate of single medical equipment might be different at along its life-cycle. Based on this, useful/service life of medical equipment is used as most equipments have constant failure rate.
- MEPMA should be conducted within 4 (source, EFDA) year interval from it purchased. This was taken as the researcher assumed equipment is in its useful life.
- Furthermore, most time is passed to show how MES decision making process could be done using SMEL, MEI and MEPMA as input.
- Functioning equipment has equal utilization level as failure rate is affected by utilization level.
- Data from literature is sued to simulate the developed system.

6.3. Recommendation

We developed a DSS for EPSA which can be used in MES decision making process. To design this system different assumptions were used and taken as limitations. Hence we would like to recommend that further information is needed and those assumptions should be considered to implement the system. Therefore the following points are recommended for EPSA.

- A well-organized SMEL,MEI and MEPMA are needed for MES decision making process.
- At this stage, the developed system is a proof of concept and it is advisable to take exact data from inventory as well as post market assessment and compare the result for furthers investigation. In addition, further study would be valuable to investigate additional inputs or in order to increase the validity of those inputs of MES.
- The study was conducted in public hospitals in Addis Ababa, EFDA and EPSA. Accordingly, requirements were collected from healthcare professional including biomedical engineers in these institutes. Country-wide study and data is recommended to improve the subjectivity of the developed system.
- Finally the researcher would like to remind that now this novel system should only use as a framework and guidance. When the users of this system see the result, we would like to remember the importance of checking the outcome and cross-checking the reasonability before decision is made

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Appendix I

RELIABILITY TEST FOR ITEM SELECTION

Introduction: - Before trying to collect data from the actual study population, as part of the research process, validating, standardizing and contextualizing the instruments to be employed will have significant value. One of the initiatives in this respect is, enabling evaluators and sound professionals (individuals with the field of experts) to rate each of the items whether or not the question are clear for the respondent. This would have a significant importance in refining the tools, in that items with relatively high scale values will be taken as measuring the variables under investigation. On the other hand, items with relatively low rated values will be dropped as they are irrelevant to measure the variables of interest.

Directions:-Here under, there are list items from the literature used as measuring parameter of the medical equpment appropriateness.. A single key word may have different context. There for, what you are expected to do as a rater of these scales is that you need to concentrate on two important points (equpment quality and economic dimensions).Do these lists of items really clear and measure the research variables (lack of medical equipment standardization and appropriateness)?

- Therefore, for this particular question, three alternative responses are provided as (2) yes (1) No and (0) If you are not certain
- How strong and clear is the item in measuring the aforementioned variables of interest? Therefore, for this particular question four alternative responses are presented as

(4) Excellent, (3) Very Good, (2) Good, (1) fair (0) poor

Remember: - Only if your answer for the first question is ‘’YES’’ so that you are expected to rate the items using the five parameters ((4) Excellent (3) Very Good, (2) Good, (1) fair, (0) poor) from the second questions. It is highly appreciated and acknowledged if you can add any advice/subjects

PART I: IMPACTS ASSESSMENT

		Are the items clear? 2= yes ,1= No 0= not certain			***How much are these items clear?* 4= Excellent,3 =Very Good, 2=Good, 1=fair 0= poor**				
	Items	0	1	2	0	1	2	3	4
A	**Effectiveness:-*How do you feel that lack of medical equipment standardization has impact on…***								
1	Durability of equipment?								
2	Down time of equipment?								
3	Compatibility of equipment?								
4	Reliability of equipment?								
5	Frequency of repair under warranty?								
6	Inter-operability of equipment?								
7	Performance of equipment?								
B	**Sustainability/Serviceability:-*How do you feel that lack of medical equipment standardization negatively affects…***								
8	Efficiency of maintainace system?								
9	Training time for biomedical engineers?								
10	Availability of equipment?								
11	Time to be familiar for different models and brands?								
12	Reduce the availability of spare parts?								
13	Reduce knowledge and skills transferability?								
C	**Safety and Acceptability: - *How do you feel that lack of medical equipment standardization***								
14	Increase regulatory requirement?								
15	Cause varation of healthcare delivery?								
16	Decrease service quality?								
17	Increase opportunity of risk to users?								
18	Increase medical error?								
19	Reduce technical and procedural skill?								
20	Lower clinical competency?								
21	Make operational procedures complex?								
22	Challenges to improve staff performance?								
23	Confused users to adapt different equipment?								
24	Increase work interruption due to failure?								
D	**Affordability:- *How do you feel that lack of***								

	medical equipment standardization …								
25	Increase purchasing cost of equipment?								
26	Increase processing costs?								
27	Minimize efficiency of logistic managements?								
28	Reduce opportunities of share training cost?								
29	Minimize opportunity of volume discount?								
30	Minimize opportunities of gating spare parts?								
31	Increase the cost of inventory management?								
32	Increase maintainace cost?								
33	Increase complexity of spar part management?								

Part II: - Equipment standardization Decision Making.

1. Items listed in table below are used in medical equipment standardization (MES) decision making process.

List of items	**Are items clear? 2= yes ,1= No 0= not certain**			***How much are these items are clear?* 4= Excellent,3 =Very Good, 2=Good, 1=fair 0= poor**				
	0	1	2	0	1	2	3	4
Correctly using hospital equipment inventory								
Considering degree of standardization								
Assessing equipment quality through Post market surveillance								
Assessing the quality of, munifucturer,supplier through Post market surveillance								
Using equipment value analysis result as input								
Considering the total life cycle cost of equipment								
Correctly starting specification from the hospital (users)								
Referring previous performance of similar brand and models equipment								
Correctly looking reliability of previous similar brand and model equipment								
Correctly looking durability of previous similar brand and model equipment								
Using model medical equipment list								
Considering the equpment Serviceability								
Looking the Previous history of equipment with the same brands and model								
Collecting user feedback about the similar equipment,								

munifucterer and supplier								
Correctly Looking the inter-operability of equipment								
Correctly considering interchangeability of new equipment with the existed one.								

Appendix II

ADDIS ABABA UNIVERSITY

ADDIS ABABA INSTITUTE OF TECHNOLOGY

SCHOOL OF MULTIDISCIPLINARY ENGINEERING, CENTER OF BIOMEDICAL ENGINEERING

My name is **Tadesse Minalku**, MSc student at the center of Biomedical Engineering in Addis Ababa Institute of Technology, Addis Ababa University. Currently I am undertaking research in the field of ‘’***Medical Equipment Standardization (MES)*** ‘’ for the partial fulfillment of the requirements for Masters of Science in Biomedical Engineering with support of Addis Ababa University. This study is believed to serve as an input for policy and decision making purpose. It mainly relies on collecting and analyzing responses of focal institutes and experts by administering questionnaires. I, therefore, like to highly appreciate and extend my gratitude for your willingness to respond the following questionnaire genuinely in advance. I promise that I will treat all information you provide as strictly confidential. Your cooperation and assistance is highly valued.

Objective of the Survey

- To assess impacts of lack of medical equipment standardization(MES) in medical equipment appropriateness
- To assess the current practices and challenges of medical equipment standardization (MES) in Ethiopia.

Code: - ----------

Part I: - General information of respondents.

1. Gender A) Female B) Male

2. What is your profession?

A) Biomedical Engineer/Technician B) Medical Doctors(MD) C) Nurse D) Pharmacist E) Radiologist F) Laboratory Technologist G) Midwifery H) others, please specify……

3. How long have been working in the hospital?

A) <1 year B) 1- 2 years C) 2-3 years D) 3-4 years E) >4 years

4. What is your level of education?

A) Diploma B) First Degree C) Master Degree D) MD (specialized) E) PhD F) others, please specify …

5. What is your role in the hospital?

A) Hospital manager
B) Medical director
C) Equipment user
D) Installation and maintenance/Technical personnel
E) Other please specify……

Hint: - ***<u>Lack of medical equipment standardization</u>*** *means the existence of different brands and models of equipment with the same function in one hospital or in one department (e.g. Infant incubator with different brands and models).*

Do you think that lack of medical equipment standardization (MES) existed in your institute?

A) yes **B) no**

Part II: Assessing impacts of lack of medical equipment standardization (MES) in appropriateness of medical equipment (*<u>Effectiveness, Serviceability, Safety, Acceceptablity and Affordable</u>*)

6. The followings items are impacts due to lack of medical equipment standardization (MES). ***Please tick all that apply(✓)***

		Alternative response				
	Items	Agree	Fairly agree	Strongly agree	Disagree	Strongly disagree
A	**Effectiveness:-*How do you feel that lack of medical equipment standardization (MES) has impact on…***					
1	Durability of equipment?					
2	Down time of equipment?					
3	Compatibility of equipment?					
4	Reliability of equipment?					
5	Frequency of repair under warranty?					
6	Inter-operability of equipment?					
7	Performance of equipment?					
B	**Serviceability:-*How do you feel that lack of medical equipment standardization (MES) negatively affects…***					
8	Efficiency of maintenance system?					
9	Training time for biomedical engineers?					
10	Availability of equipment?					
11	The availability of spare parts?					
12	Knowledge and skills transferability?					
C	**Safety and Acceptability: - *How do you feel that lack of medical equipment standardization(MES)***					
13	Increase regulatory requirement?					

14	Cause variation of healthcare delivery?					
15	Decrease service quality?					
16	Increase opportunity of risk to users?					
17	Increase medical error?					
18	Reduce technical and procedural skill?					
19	Lower clinical competency?					
20	Make operational procedures complex?					
21	Challenges to improve staff performance?					
22	Confused users to adapt different equipment?					
23	Increase work interruption due to failure?					
D	**Affordability: - *How do you feel that lack of medical equipment standardization (MES)***					
24	Increase purchasing cost of equipment?					
25	Increase processing costs?					
26	Minimize efficiency of logistic managements?					
27	Reduce opportunities of share training cost?					
28	Minimize opportunity of volume discount?					
29	Minimize opportunities of getting spare parts?					
30	Increase the cost of inventory management?					
31	Increase maintenance cost?					
32	Increase complexity of spar part management?					

Part III: - Medical Equipment Standardization (MES) Decision Making.

7. Does your hospital have any medical equipment standardization (MES) system?

A) *Yes* *B) No*

8. If your answer ‘’**Q10’**’ is ‘’**Yes**’’ what types of system does your hospital has? ……

9. The followings are lists of items that challenge decision makers during medical equipment standardization (MES) decision making process. ***Please tick all that currently exist (✓)***

	Alternative responses				
Items	Agree	Fairly agree	Strongly agree	Dis-agree	Strongly Dis- agree
Physician preference					
Manager-supplier relationship					
Public procurement law					
Lack of communication and collaboration					
Negative attitude					
If other please specify……..					

10. Items listed in table below are used in medical equipment standardization (MES) decision making process. ***Please tick all that exist (✓)***

List of items	***Alternatives response***				
	Agree	Fairly agree	Strongly –agree	Dis-agree	Strongly dis agree
Using hospital equipment inventory(MEI)					
Considering standard medical equipment list (SMEL)					
Assessing the quality of manufacturer and supplier through post market assessment(AQMS-PMA)					
Using equipment value analysis (EVA)					
Considering the total life cycle cost of equipment (TLC)					
Referring appropriateness of pre-existing medical equipment through post market assessment(MEPMA)					

Only Procurements (EPSA) (*filled by biomedical engineers)*

Part I:- Back Ground Questions

What is your title?

What is your responsibility?

How much time do you work in this institute?

How much time do you work in this position?

PART II:- Vendors/Medical Equipment Registration

One of the roles of regulator is to registering vendors and equipment during pre - market assessment and after post-market assessment and post market assessment when the equipment is in-service.

1 Have you ever do re-registration of vendors/equipment? If yes what types of criterion do you use? By how much time interval does your institute do re-registration of venders/equipment?

2 What types of difference have you ever seen related with venders/equipment, between initial registration and during re-registration?

3 How do you think that using feedback from equipment user, related equipment history, and post market surveillance can reduce involvement of low performing vendors and poor quality equipment during re-registration? How do you fell that result of user feedback, equipment history, and post market surveillance for vendors/equipment registration?

Part III:- Post-Market Assessment and Medical Equipment Standardization(MES)

4 What is post-market assessment for you?

5 What activities are done during post-market assessment in your institute?

6 Have you ever do post-market assessment for medical equipment? If yes, what equipment parameter do you assess? How do you do it? How do you communicate with users? If no, why?
7 Do you have any IT system that supports post-market assessment? If yes, what types?
8 How do you think that lack of Medical Equipment Standardization (MES) affects (effectiveness, sustainability and safety acceptability, affordability) of equipment negatively?
9 How do you think that lack of MES has economic impact?
10 Do you think that standardation is challenging? If yes, what are the possible challenges? If not, how is possible?
11 Literature indicated that it is possible to limit the number of venders and varation of brands and standardization of equipment through post market assessment and using for re-registration as input. What is your perception on standardization through post-market assessment?

Part I:- Background Question

What is your title
What is you responsibilities
How much do you work in this institute
How much do you work having this responsibilities

Part II:- Interview Guiding Questions

1. Can you tell me decision making process in acquisition of medical equipment? How much is your communication with hospitals and regulators? What are the points you consider in selecting the venders?
2. In hospital reform guideline, there is a point which state that the medical equipment committee should work toward the standardization of medical equipment. What do you think about standardization?
3. How dose standardization of medical equipment impacts on equipment appropriateness? What are the challenges in medical equipment standardization? How is strong the procurement unit in using feedback from user?
4. How do you use post market surveillance/assessment result as input in the procurement process? How do you think standardization of medical equipment can be achieved? How to give value of equipment and value for money?
5. Generic specification allows the involvement of any interested vendors in competition but standardization leads to limit the numbers of vendors involved. How do you fell about these issues? How can we compromise? Limiting the numbers of vender in competition will cause legal issue. While being dependent only generic specification may leads to choices the vendors with low cost while lower quality equipment. In what way does it is possible to balance them? How we can work toward standardization while not ignoring the generic specification?
6. Usually equipment with low value has lower cost and equipment with best value has high purchasing cost. How do you fell in using the previous equipment performance history (effectiveness, sustainability and safety acceptability, affordability) with similar vendors to limit the involvement of vendors with poor equipment value

Appendix III

Medical Equipment Post Market Assessment Data Collection Form

Purpose: The purpose of this assessment is to know how much the procured medical equipment is appropriate during its service life and used for decision making for newly procured medical equipments. Therefore, to increase the quality of data being honest in giving this information is primary important.

Equipment Name……. Manufacturer/Brand:……, **Model**: ……**Age**……..

Level of Hospitals: ❑ Primary Hospital ❑ General Hospital ❑ Specialized Hospital

Service Type: ❑ Radiology ❑ Cardiology ❑ Renal

❑ Emergency ❑ Others……

Description: ❑ General Purpose-Duplex ❑ Doppler

❑General Purpose-Gray Scale ❑ Special Purpose-Duplex

Function: ❑ Diagnostic-Imaging ❑ Diagnostic-Monitoring

❑ Therapeutic ❑ Life Support

Down Time (DT)…… **Number of Failure** (N)……..

	Very High	High	Medium	Low	Very Low
Level of Serviceability					
Level of Affordability					
Level of Acceptability					
Level of Safety					
Level of Interchangeability					

Appropriateness of medical equipment	**Attributes**
Serviceability	Efficiency of maintainace system, Time for user training Speed of delivering information Time to be familiar with equipment Knowledge and skill transferability

Safety and Acceptability	Medical error Varation of health care delivery, Service quality Opportunity of risk, Clinical competency Technical and procedural skill Operational procedure complexity Challenges to improve staff performance Confusion of user to adapt different types of equipment
Affordability	Purchasing cost of equipment Operationalcost(Maintainace,inventory,spar part,training,logistic) equipment Opportunity of getting spare Parts Opportunity of volume discount Efficiency of logistic management