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COLLEGE OF SCIENCE AND
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Regional Centre of Excellence in Biomedical Engineering and e-Health (CEBE)

ASSESSMENT OF EFFECTS OF HOSPITAL POLICIES ON MEDICAL EQUIPMENT SAFETY AND PERFORMANCE

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A Dissertation Submitted to the Regional Centre of Excellence in Biomedical Engineering and e-Health (CEBE), University of Rwanda as partial fulfilment of the requirements for the Master's Degree in Biomedical Engineering.

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DECLARATION

I, Vestine TUYISENGE, declare that this dissertation entitled “**Assessment of Effects of Hospital Policies on Medical Equipment Safety and Performance.**” is my original work based on research and prototype and has not been submitted for any other degree or professional qualification.

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CERTIFICATE

This is to certify that the project entitled “**Assessment of Effects of Hospital Policies on Medical Equipment Safety and Performance.**” is a record of original work done by Vestine TUYISENGE (221028724), a MSc. Degree student in Biomedical Engineering.

This work has been submitted under the guidance of Prof. Khalaf Abdelbaset and Dr. Omar Gatera.

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ABSTRACT

In many countries worldwide, advancement in healthcare technology continues to accelerate. It is in this regards that the implementation of effective policies becomes crucial to ensure the reliability and safety of medical devices and equipment. Many developing countries are doing their level best to enhance their healthcare system. The main objective of this study is to access the effects of hospital policies on medical equipment safety and performance. To achieve its objective, this study examines different effects of policies on the medical equipment lifecycle, especially in the deployment phase, where it discusses the impact of utilization policies on training programs, user compliance, and ongoing monitoring, for the sake of mitigation of potential risks associated with medical equipment adoption. It accesses the availability and implementation of policies in different health institutions, the impact of policies implementation on the safety and performance of medical equipment, the role of clinical staff in ensuring safety and performance of medical equipment, and the positive and negative effects of those policies on medical equipment safety and o performance. This study was conducted through collecting data from four different hospitals, where the clinical staff especially medical equipment users gave responses to the questions asked. This study used random purposive sampling method to sample 60 clinical staff from 4 different hospitals. A questionnaire was used to collect data from respondents. 60 responses from respondents were retrieved and analyzed with the use of STATA Vesion17.0 software. Some of obtained results were displayed on tables. According to the study findings, different clinical staff agreed that there are policies regarding medical equipment being implemented in their respective institutions, and these policies, together with the responsibility of medical equipment users, contribute in improving medical equipment safety and performance. This brings many effects on medical equipment safety and performance, including both positive and negative effects. This proves that the implementation of different policies regarding medical equipment in hospitals will have a great role in the improvement of medical equipment safety and performance. The study found that in Rwandan health institutions, different medical equipment users are trained about policies regarding medical equipment, and are trained about medical equipment their use in their daily work.

Keywords: Policies; guidelines; medical equipment; safety; performance.

LIST OF ACRONYMS

BMET: Biomedical Engineers and Technicians

CHUB: Centre Hospitalier Universitaire de Butare (Butare University Teaching Hospital)

CM: Corrective Maintenance

CT: Computed Tomography

FDA: Food and Drug Authority

GHTF: Global Harmonization Task Force

GIHT: Global Initiative for Health Technologies

HT: Healthcare Technology

HTM: Health Technology Management

IEC: International Electrotechnical Commission

IMDRF: International Medical Device Regulations Forum

ISO: International Organization for Standardization

IVDR: In-Vitro Diagnostic Regulation

JICA: Japanese International Corporation Agency

K4C: Knowledge For Change

KFH: King Faisal Hospital

MDGs: Millennium Development Goals

MDR: Medical Device Regulation

ME: Medical Equipment

MEHT: Medical Equipment and Health Technology

MoH: Ministry of Health

MRI: Magnetic Resonance Imaging

OMH: Omani ministry of Health

PHC: Primary Health Care

PM: Preventive Maintenance

QMS: Quality Management System

QSR: Quality System Regulation

RBC: Rwanda Biomedical Center

SDGs: Sustainable Development Goals

SOP: Standards Operating Procedures

UBTS: Ugandan Blood Transfusion Services

UHC: Universal Health Coverage

WHA: World Health Assembly

WHO: World Health Organization

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CHAPTER 1. GENERAL INTRODUCTION

1.1 Introduction

Globally, and particularly in Africa, there is a challenge to the delivery of health services and the achievement of the Sustainable Development Goals (SDGs) due to the weakness in the health system. The challenge originates from different factors including inadequate health policies, inadequate staff, and backward health technology coupled with poor levels of service delivery [1]. The efforts are being made to boost this status of health system in order to improve service delivery. It is in this regard that the World Health Organization (WHO) has continuously identified and advised that policies regarding medical equipment should be revised in order to enable the health systems globally and to handle emerging needs for the equipment in managing the health conditions [2]. Our country, Rwanda, through SDGs, is doing its level best to emerge technology in different sectors including health. Specifically, in health sector, there is a goal of achieving the best quality healthcare services through efficient use of healthcare resources. Apart from SDGs, Rwanda is working hard to achieve access to Universal Health Coverage (UHC) which aim at providing high quality healthcare that is Accountable, Affordable, Accessible, and Reliable [3]. To achieve this, there is need of clear guidelines and policies in line with WHO guidelines on the utilization of medical resources, including medical equipment. In addition, there is need of hospital policies regarding medical equipment, which will enable clinical users to understand how to effectively and efficiently utilize medical equipment, for the sake of their performance optimization, and safety concerns on the sides of both patient and medical equipment users.

Medical equipment is among resources that play a great importance in the provision of healthcare service. Effective utilization of these medical equipment may result not only on their good performance, but also on the safety of both patient and user. Through design, development, and implementation of proper regulations and/or policies, this can be achieved. This is because creating and maintaining comprehensive medical equipment policies is crucial for the efficient and safe operation of healthcare facilities, ensuring that medical devices and equipment are used in compliance with standards and regulatory requirements. In different countries worldwide, and particularly in Africa, medical devices and equipment present a significant proportion of national healthcare expenditure.

Despite this, not enough attention is paid to equipment use and maintenance, which lead to inefficient and ineffective follow up and maintenance of medical equipment [4].

According to Rwanda FDA's regulations of medical devices, medical equipment need to be used as intended by the manufacturer, and need to be effective during their usage lifetime, in order to ensure health and safety of a patient, user or other person[5] . One among the best approaches to ensure optimal performance and durability of medical equipment as well as its safe use is development of policies to govern health professionals, because this improves accessibility to quality health services [6].

1.2 Problem statement

Globally, and specifically in Africa, the health system is still weak in providing quality health service delivery to patients, and this hinders the achievement of millennium development goals, sustainable development goals, and other goals as well. This weakness has roots in inadequate staff capacity building, poor state of health equipment, poor quality of care, lack of enough medical equipment maintenance personnel, inadequate health policies, and poor monitoring and evaluation of these policies [1]. In addition to this, medical equipment management policies are needed in different health institutions in order to facilitate them to deal with medical equipment, from the procurement process up to disposal process. The presence of these policies will help in reducing the weaknesses occurring in the healthcare service delivery, and improving the safety and performance of medical equipment [7].

1.3 Research Questions (Hypotheses)

- What is the level of awareness of clinical staff/medical equipment users on the national and hospital policies?
- Do both national and hospital policies implemented in the healthcare institutions ensure safety and performance of medical equipment?
- What is the role of medical equipment users in ensuring safety and performance of medical equipment?
- Are there some effects brought by these policies on medical equipment safety and performance in comparison to national and international standards?

1.4 Objectives

1.4.1 General Objective

This project aims to assess the effects of hospital policies on medical equipment safety and performance.

1.4.2 Specific Objectives

To achieve the general objective of this project, the following specific objectives are used as guiding points.

- To assess awareness of clinical staff on the availability of policies in their institution;
- To assess the policies implementation for safety purposes and performance purposes;
- To evaluate the role of medical equipment users in ensuring medical equipment safety and performance.
- To evaluate the positive and negative effects of policies in comparison to existing policies at national level and international level.

1.5 Study Scope

This study focused on Rwandan healthcare institutions which provide healthcare services by using large amount of medical equipment in the diagnosis, treatment, and rehabilitation process. As it deals with medical equipment and policies, some among the critical medical equipment were selected, including Patient Monitor, Ultrasound Machines and Imaging machines (X-ray or CT scan). The assessment will be done from four different hospitals including 1 Level1 university teaching hospital, King Faisal Hospital, 1 Level2 University Teaching Hospital, and 1 Referral Hospital in order to get general overview, reliable data and compare the findings.

1.6 Significance of the Study

This research study, as it assesses different effects of hospital policies on medical equipment safety and performance from different health institutions, it is significant in improving patient outcomes and satisfaction, enhancing the quality of health care delivery, ensuring regulatory compliance, advancing clinical staff' knowledge through capacity building, and managing costs associated with the use of medical equipment in health care service delivery. In addition to this, this study will facilitate health institutions to manage risks which may result from medical equipment failures or errors, and it will contribute to future policy development and assure best practices in healthcare delivery.

Findings from this study can be used as decision support tool to help, not only to Rwandan health institutions, but also the Ministry of Health, as part of policy makers, to identify gaps in policy implementation and evaluation and reformulate the appropriate policies regarding medical equipment, to identify key areas which need intervention, so as to enhance medical equipment safety and performance, in order to optimally utilize medical equipment and improve productivity.

1.7 Organization

Chapter one gives the introduction and background information to the study, Chapter two discusses the state of the art, where it discusses different literatures related to the study. In chapter three, the methods and materials used in conducting this study were presented. Chapter four presents the findings and results got from the research followed by discussion, and finally Chapter five concludes the research study, discusses challenges, and recommendations from the research study.

1.8 Summary

According to WHO, different countries are encouraged to have and revise health policies as one among the ways of improving healthcare sector. Implementation and evaluation of policies related to medical equipment in various health institutions will help to ensure safe use and optimal performance of medical equipment. This will comprehend various dimensions including patient safety, quality of care, cost efficiency, staff training, and risk management. The assessment of effects of these policies in healthcare institutions will help to improve overall healthcare outcomes, and inform evidence-based decision making among clinical staff.

CHAPTER 2. STATE OF THE ART (RECENTLY RELATED LITERATURE)

2.1. Literature Review

According to the World Health Organization Report presented in 2008, medical equipment and pharmaceutical industries are considered as major economic forces, whereby Global expenditure on medical equipment and devices is growing year by year, and in Sub-saran Africa, it is presenting a market with much potential for expansion. In different countries, the annual growth rate of the equipment market is over 10% a year. To improve primary health care, there are many things to consider, but putting people first is the most important thing. To ensure improved health and social outcomes, effectiveness and safety should not be considered as technical matters, but an issue to pay much attention on by healthcare service providers. In addition, public policies are needed in health sector because, together with those in other sectors, they have a huge potential to secure health communities. Policies represent an important complement to universal coverage and service delivery reforms. It is in this regard that public policies are encouraged to be strengthened and aligned with the goals pursued by Primary Health care (PHC). People expect their governments to put into place an array of public policies, including policies required to make health systems function properly, and policies that can contribute to health and a sense of security [8].

The ISO 13485 standard, published in 2016 specifies requirements for a Quality Management System (QMS) for organizations involved in one or more stages of the life-cycle of a medical device, including design, development, production, storage and distribution, installation, servicing, and final decommissioning and disposal of medical devices and related services. This standard emphasized that the quality management system requirements specified in this international standard are complementary to the technical requirements for products that are necessary to meet customer and applicable regulatory requirements for safety and performance. The organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. It is in this regard that organization shall establish implement and maintain any requirement, procedure, activity or arrangement required to be documented by this international standard or applicable regulatory requirements. It shall also document the roles undertaken by the organization under the applicable regulatory requirements [9].

2.2. Existing policies and guidelines related to medical devices and equipment

According to WHA (World Health Assembly), there are issues that have been discovered arising from the inappropriate deployment and use of health technologies, specifically medical device and/or equipment. It is in this regards that it requested WHO (World Health Organization) to take specific actions to support its member state in achieving its health-related development goals. Member states were urged to formulate appropriate national strategies and plans for assessment and management of medical devices/equipment, and WHO was requested to provide technical guidance to its member states in implementing policies on health technologies. Within the context of robust health system, policies strategies, and action plans ensure access to safe, effective, and high-quality medical devices that prevent, diagnose, and treat diseases and injury, and assist patients in their rehabilitation. The WHA resolution document presented different examples illustrating how policies on medical devices/equipment can fit within a national overarching health policy [2], [10].

These examples are the following:

- Regulations of medical devices minimize risk to the population
- Safe use and availability of medical devices improve health service delivery
- Affordability of medical devices increases health service coverage
- Telemedicine enhances patient centered care
- Health technology assessment provide basis for priority setting and informed decision making
- Needs assessment helps in the rational allocation of resources
- Research and innovations respond to the needs of a particular health system and population

One among the critical components towards achieving the Millennium Development Goals (MDGs) is the work of achieving equitable access to, and optimal use of medical devices/equipment. Medical devices are particularly important in achieving goals 4,5, and 6.

A survey was designed by Global Initiative for Health Technologies (GIHT) to determine the availability of policies, guidelines, standards and services for the assessment, management and regulation of health technology in member states and associate members [2]. WHO strongly encourages the development of national health policy framework that, when implemented, leads to reduced morbidity and mortality, reduced risks and threats to health, and reduced inequity in health.

The policies need to be adapted to the individual health sector functions in order to guarantee the best use of resources and serve the unique needs of the population according to local or national priorities [10].

Various countries across the world have established regulatory bodies that guide the medical device industry, in order to ensure safety and effectiveness of medical devices from the production to the marketing phase. In Africa, there are medical devices regulations in different countries, which have been designed based on the ISO standards, and which differ from one country to another. This document focused on African countries with the highest GDP including Kenya, Nigeria, Egypt, Sudan, Morocco, Angola, Algeria, Tanzania, Ethiopia and South Africa, where it presents the responsible bodies in charge of the medical device regulations of these countries, as well as the implications for the development of their medical device industries. It is in this regard that African countries are encouraged to play a leading role in encouraging the development of their domestic medical device industries, not only by establishing medical device regulations, and providing adequate resources for their implementation, but also through broader policy considerations [11]. Policies are among strategies to improve medical devices lifecycle, once they are well designed, developed, and implemented, which lead to improved quality of health care and health systems' effectiveness [12].

2.2.1. Medical devices management policy

Medical device/equipment management policy is designed to assist clinical staff in the management of medical devices. It encompasses each aspect of the medical device life cycle including purchasing and commissioning, use and management, maintenance and support, condemnation and replacement [13]. In addition to this, medical device management policy ensures that risks associated with the use of medical equipment are minimized, and that medical equipment is fit for purpose, maintained appropriately and operated in accordance with instruction by staff with appropriate knowledge and necessary competency, in order to minimize risk and maximize safety for all concerned parties [14]. This management policy complies with the WHO high 5s project, which dealt with standardization in patient safety, to reflect to the challenges through implementation of evidence-based interventions [15].

2.2.2. Medical device maintenance policy

The medical device/equipment maintenance policy is designed to facilitate clinical personnel in striving for effective and efficient maintenance of medical equipment used for diagnosis, treatment, and prognosis and monitoring purposes.

This policy provides a broad logical framework of decisions to be taken for guiding certain actions that are useful in prolonging the active life of equipment in ensuring that the equipment provides accurate results. In addition, it ensures that medical equipment is stored, deployed, and maintained in such a way that the risks associated with its use are minimized, and ensures the maximum availability of equipment that provide accurate and reliable results [16]. The adequate medical equipment preventive maintenance results in in high standards of diagnosis and treatment, and reduces the costs of maintenance of a medical equipment, and this helps to ensure medical equipment efficiency, as one among factors which are frequently overlooked by the management in order to increase yield [17].

2.2.3. Medical device procurement policy

The medical device/equipment procurement policy is designed with the purpose of describing the actions required to minimize the risks which may appear or occur due to inadequate planning and consultation of medical equipment. This helps in decision making about the purchase of optimal equipment that is fit for purpose and that comply with international or national safety standards. In addition to this, medical equipment procurement policy describes different requirements to be taken into consideration during medical equipment procurement planning, medical equipment contract formation, and medical equipment contract management [18].

2.3. Available health policies in Rwanda

In our country, the Ministry of Health (MoH) is in charge of designing, developing and distributing policies related to health. There is mainly the Health Sector Policy which has the overall aim of ensuring universal accessibility to equitable and affordable quality health services for all Rwandans. This Health Sector Policy sets the health sector's objectives, identifies the priority health interventions for meeting these objectives, outline the roles of each level in the health system, and provides guidelines for improved planning and evaluation of activities in the health sector [6].

In addition to this health sector policy, there are other policies that complement to it, ensuring safety of patient, for example, National Pharmacy Policy which aims to provide and continuously improve upon the equitable availability of essential and affordable medications, health commodities and technologies that are of high quality and effective for patients.

From these policies, health institutions design and develop specific guidelines and standard operating procedures which will guide their workers in their daily works.

Some of the guidelines regarding medical equipment are necessary in order to govern medical equipment users on how to properly and properly use and manage the medical equipment.

They include guidelines for good storage and distribution of medical products, guidelines for registration of medical devices, guidelines for health care equipment donations, guidelines for decommissioning and disposing healthcare equipment, etc.

2.4 Examples of international medical equipment policies

International medical equipment policies include guidelines which help to ensure that medical devices are safe, effective, and accessible worldwide, and which address specific regional needs and regulatory requirements. They vary significantly based on the organizations or regions which develop them. They all aim at guiding the regulation, standardization, and distribution of medical equipment globally.

2.4.1 International Organization for Standardization (ISO) Standards

They include ISO 13485 standard which specifies requirements for a quality management system, where organizations need to demonstrate its ability to provide medical devices and related services that consistently meet customer and regulatory requirements [19]. They also include ISO 14971 standard which outlines the process of risk management for medical devices, helping manufacturers identify and mitigate potential hazards associated with medical devices [20].

2.4.2 European Union Medical Device Regulations (MDR) and In-Vitro Diagnostic Regulation (IVDR)

They include MDR 2017/745 regulation which applies to medical devices sold within the European Union, and includes stringent requirements for safety and performance, including detailed clinical evaluations and post-market surveillance [21], and MDR 2017/746 regulation which governs in-vitro diagnostic medical devices, emphasizing the need for rigorous evidence of performance and safety [22].

2.4.3 U.S. Food and Drug Administration (FDA) Regulations

They include 21CFR Part 820 regulation which pertains to Quality System Regulations (QSR) for medical devices, establishing the standards for design, production, and post-market monitoring. This is part of the FDA's code of Federal Regulations [23]. They also include FDA's 510(k) Process which is a premarket submission process that allows manufacturers to demonstrate that their new device is substantially equivalent to an existing device which is already approved by the FDA.

2.4.4 World Health Organization (WHO) Guidelines.

They include WHO guidelines provided for technical specifications and quality assurance of medical devices, especially for use in low and middle-income countries [24]. They also include WHO Medical Device Regulations which help countries to develop their own regulatory frameworks for medical device, with the aim of improving access to safe and effective technologies [19].

2.4.5 International Electro technical Commission (IEC) Standards

The IEC60601 Series are standards which specify safety and performance requirements for medical electrical equipment [25].

2.4.6 Global Harmonization Task Force (GHTF)/ International Medical Device Regulators Forum (IMDRF)

The IMDRF guidelines work towards the harmonization of medical device regulations. They provide guidelines which help to streamline international regulatory processes and promote global trade [26].

2.5 Management and utilization of medical equipment

In many health institutions, it is often the nurses and doctors who are the primary users of medical devices and equipment. However, some of them are not educated well enough to handle and use the equipment.

When it comes to medical devices and equipment used in intensive care unit and/or operating room, it becomes a crucial thing to be considered, because some incidents which occurred were due to incorrect operation and maintenance, which would consequently harm patients. This issue should be mitigated by clinical engineers as their most important and difficult task to regularly train equipment users to operate medical equipment effectively and safely. To ensure safety, standardization of equipment can solve many user problems, and the training and continuing education are important components of standardization which may help a lot [27]. The enhancement of skills of medical equipment users has proven to be a key focus in promoting the utilization of medical equipment. In low resource settings, the most frequently mentioned barriers to health technologies include: Lack of spare parts, lack of consumables, lack of reliable power supply, lack of user training, and lack of technical personnel. To solve some among these barriers, this study aimed at demonstrating the efficacy of an intervention model involving ongoing skills enhancement of medical equipment users, Biomedical Engineers and Technicians (BMETs) in enhancing the utilization of medical laboratory equipment in low resource settings.

Among the selected medical equipment, the users and BMETs were mentored and trained in the use and preventive maintenance for different medical equipment, whereas for other equipment, intervention program was not involved. They were thus assessed for comparison. This is because it has been estimated by The Japanese International Corporation Agency (JICA) that 20% of all equipment failures can be prevented by user training, and 60% can be prevented by routine preventive maintenance. This study was conducted in 2018, by Knowledge for Change (K4C) in Ugandan Blood Transfusion Services (UBTS), where different BMETs and medical equipment users were trained and mentored, in order to strengthen the capacity of health. During the study, three training courses were given which include health technology management, medical equipment qualification, calibration and validation, and finally the role of senior management in health technology management training. The pieces of medical equipment which were used in the study (in both intervention group and second group) were classified into categories, from A (Equipment in good working condition and in use) to F (Equipment out of use, to be replaced) according to their conditions.

At the end of the study, the result has proven that medical equipment in the intervention group were likely to be in good working condition and in use, than the equipment in the second group. This imply that about 90% of medical equipment can be maintained in good working condition and in use through routine mentoring and training of users and BMETs to promote proper use and planned preventive maintenance.

These intervention training were prior to other trainings which were previously provided to UBTS by medical equipment manufacturers, distributors (vendors), other partners or internally organized training sessions. In the conclusion, the study has suggested health facilities in low and middle-income countries to implement this approach involving co-learning and mentorship, because it has proven successfulness. This will help them to fully utilize medical technologies and/or equipment in service delivery. In addition, it suggested that there is need for policies on the inclusion of training on medical technologies in the curricula of health professionals in low resource countries as well as in associated professional development programs [28].

Medical equipment efficiency is one among the factors that are frequently overlooked by the management which can lead to losses by reducing yield. Inadequate preventive maintenance of equipment results in low standards of diagnosis and treatment, and increases the cost of medical equipment maintenance. Nevertheless, an optimum utilization of medical equipment result in optimal patient handling and rapid turnover, minimum possible cost, quality patient care and patient satisfaction [17].

In many countries, the two key objectives of health policy are improving quality and controlling costs of hospital care. These objectives are achieved simultaneously by improving hospital efficiency through elimination of unnecessary procedures and medical errors. Some among medical equipment being used in imaging including CT scan and MRI are considered to be high technology medical equipment that present technology advancement in medical imaging services, and offer important opportunities in improving disease diagnosis and treatment. In addition, they involve significant costs, and their overuse has been increasingly recognized as significant public health problem which can raise serious concerns with wasteful costs and adverse health outcomes. It is in this regard that researchers do their best to examine the relationship or association between hospital efficiency and utilization of these high technology medical equipment. This study contributed to the ongoing health care reform in China, whose policymakers were concerned with public hospital reform, high utilization rates of CT and MRI, and the rapid increase in health care costs [29].

2.6 Factors affecting usability of medical equipment

Some of the factors affecting utilization of medical equipment are training of staff, equipment installed on turnkey basis, preventive maintenance and after-sales services, facility for backup power supply, time scheduling of the hospital, awareness of the facilities, networking of special facility or skill, upgradeability and use coefficient [17].

Different contributors to the effective use of medical equipment include institutional factors, device-related variables, professionally operated aspects, as well as national structure for selection, procurement, usage, and administration. Among the institutional related factors, there are: power interruption, inappropriate place, no repair, no service maintenance performed, limited working hours, poor procurement and management, lack of inventory, no calibration, and lack of bioengineers. Among the professional operating related factors, there are: Lack of training, no demand of use, lack of information about the equipment, and no preventive maintenance. Among the equipment related factors, there are: Lack of safety, equipment not installed, no spare parts, no accessories, equipment lifetimes, no operating procedures/user manuals, lack of software, and need of special conditions. In addition, different significant factors affecting medical equipment utilization efficiency were identified, which include: the form in which the hospital received the equipment, the regularly availability of the equipment, the equipment breakdown in the previous 12 months, the availability of adequate staff operating the equipment with adequate training, performing preventive maintenance according to the manufacturer's instructions and schedule.

This study concluded by requesting hospitals to create an appropriate strategic framework to manage and utilize the available medical equipment, based on their level and demand. This will help to access and utilize medical equipment more efficiently, affordably, and safely, in order to increase patient satisfaction, and provide high quality health care services [30]. The global weakness in the health system is a challenge not only to the delivery of health services, but also to the achievement of the Sustainable Development Goals (SDGs), as well as other health targets at global, regional, and national levels. Some factors that have been identified to be affecting the utilization of medical equipment include human resource capacity development, medical equipment management policy, medical equipment procurement policy, and adherence to service charter [1].

2.7 Implementation and evaluation of medical equipment policies

The medical equipment policies are essential in promoting patient safety, ensuring regulatory compliance, enhancing operational efficiency, managing costs, and promoting continual improvement within healthcare facilities. They contribute to the delivery of high-quality patient care while minimizing risks and maximizing resource utilization.

The implementation of medical equipment policies will help health institutions and clinical staff in different ways as mentioned:

Understanding their roles and responsibilities through training sessions

Establishing standardized processes for acquiring new equipment

Implementing preventive maintenance schedules and quality assurance measures to ensure reliability and performance of medical equipment.

Maintaining comprehensive records of equipment inventory, maintenance activities, safety checks and user training.

The evaluation and monitoring of medical equipment policies will help health institutions and clinical staff to monitor changes in regulations and standards in order to ensure ongoing compliance and adapt to changes in regulations, technology, clinical practices, and organizational needs. In addition, this will help to make continuous improvements to the policies over time, basing on feedback on the effectiveness and usability of policies.

2.8 Summary

The medical equipment policies play a vital role in ensuring effective and safe use of medical equipment. Having seen that some among key challenges of healthcare service delivery in developing countries include lack of adequate policies and lack of enough trained personnel about medical equipment, the world health organization urges and advises its member states to revise policies regarding medical equipment in order to enable health systems globally and to handle emerging needs for the equipment. This will help to manage health conditions of the patients being subjected to medical equipment during the diagnosis or treatment of diseases [2]. It is in this regard that this study sought to assess the effects brought by presence of medical equipment related policies on medical equipment safety and performance.

CHAPTER 3. RESEARCH METHODOLOGY

This chapter elaborates on the methods and approaches which have been used to conduct the survey, including the methods used to collect and analyze relevant data for the study, the steps which were undertaken to complete the study, the system design methodology and the tools which have been used during data collection. The elements covered in this chapter include research process, research design method, and the summary.

3.1 Research Process

This study sought to assess different effects of hospital policies on medical equipment safety and performance. This study comprehend to other studies which investigated about factors which influence medical equipment utilization, including human resource capacity development, medical equipment management policy, medical equipment procurement policy, and adherence to service charter [1], or the study which sought to investigate factors associated with efficient utilization of medical equipment, including professional operating related factors, institutional related factors and equipment related factors [31]. In addition to this, this study is in line with the WHO report specifying medical devices regulations and policies dealing with medical devices and equipment within their whole lifecycle, from development and manufacturing up to disposal phase, where it details about metrics of medical equipment effectiveness/performance [19].

This study assesses effects of hospital policies on medical equipment safety and performance through different steps presented in the figure below.

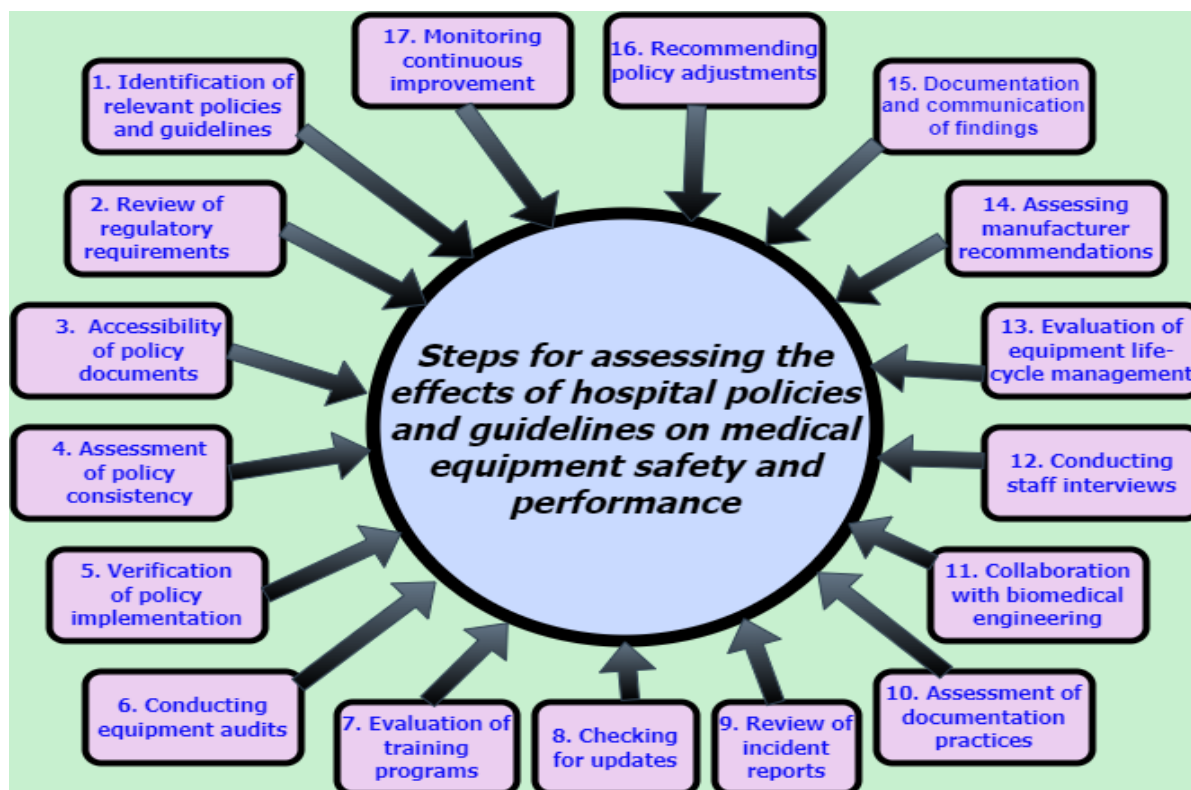


Figure 1: Steps of assessing the effects of hospital policies on medical equipment safety and performance

3.2 Research Design Method

This research adopted the descriptive survey aimed at assessing the effects of hospital policies on medical equipment safety and performance within 4 hospitals including referral hospital, level 1 and level 2 university teaching hospitals. This descriptive survey design is adopted when the researcher intends to collect data in order to test the hypothesis of the study. This study sought to test various hypotheses based on effects of hospital policies on medical equipment safety and performance. The researcher, being interested in policies implementation in different health institution, and how those policies reflect to the medical equipment usability, this lead to the choosing of this study design.

3.2.1 Target Population and sample size

The target population enumerates all elements that the researcher is interested in while conducting the study. In this study, the target population consisted of different clinical staff from 4 different hospitals, and it included Biomedical Technicians and Engineers, Doctors, Nurses, and Radiologists. This is because they are part of clinical staff using medical equipment.

The sampling method adopted in this study is the purposive sampling method which involves the selection of participants intentionally, based on their ability to contribute to relevant information to the study. The population sample size was randomly selected based on purpose, because it had a focus on clinical staff who use medical equipment, specifically the ultrasound machine, x-ray, patient monitor, and biomedical team who deal with various medical equipment. In total, the population sample for this study was 60 clinical staff including Biomedical technicians (17) and engineers (3), doctors (15), nurses (10) and radiologists (15) from the specified hospitals. They are presented in the table below.

Table 1: Respondents' professions and their institutions

Respondent profession	Respondent institution				Total
	KFH	Level1UTH	Level2UTH	Referral H	
Allied Health Professional	3	2	5	5	15
Biomedical Engineer	1	2	0	0	3
Biomedical Technician	5	4	5	3	17
Doctor	1	6	4	4	15
Nurse	2	1	4	3	10
Total	12	15	18	15	60

3.2.2 Research tools

Primary data was collected using a questionnaire, which included some structured questions. The questionnaire was divided into two parts, where the first part covered the descriptive information of the respondents, and the second part covering the variables specific information.

To test the hypotheses of the study, different clinical staff including medical equipment users were approached and interviewed through questionnaire, to evaluate their awareness about the availability and implementation of policies in their institutions, their practical knowledge and skills about the medical equipment they use in their daily work, and their role in ensuring high performance of medical equipment, and promoting safety.

3.2.3 Data processing and analysis

The data collected from different clinical staff with the use of a questionnaire, was examined for completeness and adequacy for analysis. Before analysis was carried out, the data were imported into STATA Version17. The analysis of data involved Descriptive statistics, which included frequency distribution, percentages, and Pearson's value.

Given that the dependent variables (Medical equipment safety and medical equipment performance) was binary and the explanatory variables were categorical in nature, the study adopted a binary logistic regression analysis to investigate different effects of medical equipment related policies and practices on medical equipment safety and performance.

While examining different independent variables, the variables with a P-value less than 0.05 were considered as predictors of medical equipment safety and performance while those with p-values greater than 0.05 were not predictors of medical equipment safety and performance.

3.2.4 Ethical considerations

At first, the researcher obtained an ethical review letter from the Center of Excellence in Biomedical Engineering and E-Health (CEBE), through the college of Medicine and Human Sciences (CMHS). The researcher used this review letter to apply for data collection permit from different health institutions. After investigating different ethical considerations including respondents consent and confidentiality of the data. The data collection was permitted to the researcher from 4 different hospitals, and data collection approval letters were provided to the researcher. During data collection, the respondents were assured that the data collected were treated with confidentiality they deserve, and no information about the respondent were provided, like names, phone numbers, and emails.

3.3 Summary

This study sought to assess about medical equipment policies being implemented in different hospitals, their effects on the safety and performance of medical equipment, and the role of medical equipment users in ensuring good performance and safety of medical equipment. The study adopted a qualitative/descriptive method to conduct a survey from different clinical staff based on the purpose of being medical equipment users. A total number of 60 respondents have given responses to the questionnaire, and the collected data was analyzed using STATA Version 17.0. Different findings were presented in the tables.

During assessment, medical equipment policies are the priority in this study, and they cover different areas as presented in the following figure:

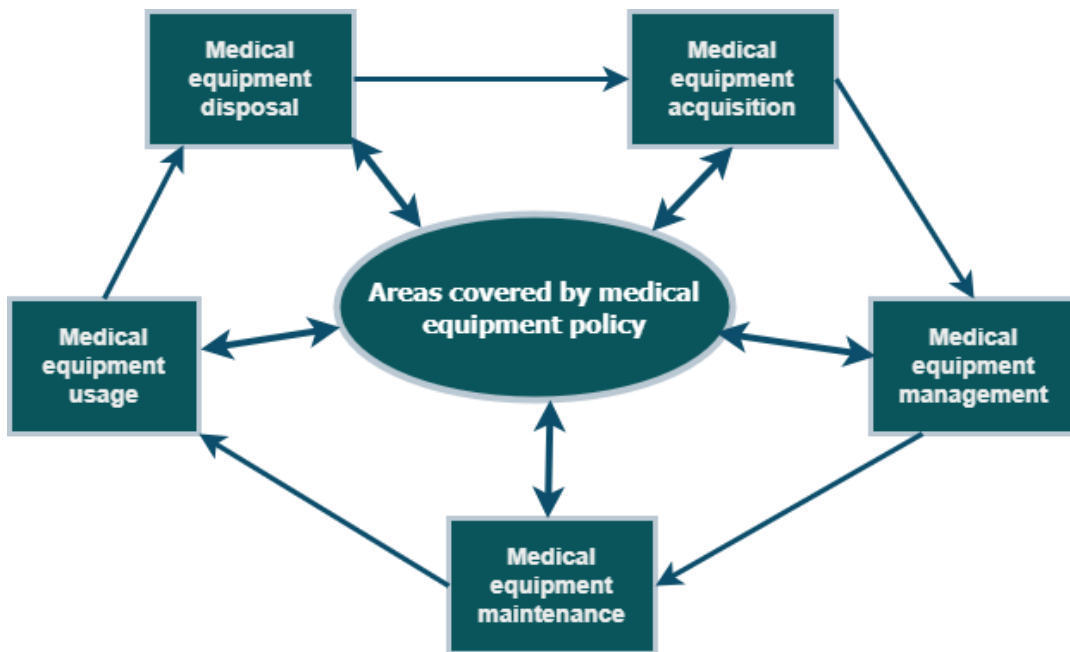


Figure 2: Areas covered by medical equipment policies

CHAPTER 4. THE PROJECT RESULTS AND DISCUSSION

This chapter presents the research findings and discussion. The study sought to assess the effects of hospital policies on medical equipment safety and performance in different health institutions. The data, which have been collected, were analyzed using descriptive statistics. The findings were presented in the form of tables with associated explanations

4.1 Response rate

This study sought to establish the response rate on the questionnaire distributed to the respondents. The researcher delivered the questionnaire link to respondents, of which 60 were adequately filled for analysis. This presents 100% of the sample size describes in the previous chapter.

4.2 Demographic Characteristics of the study population

This includes population features of the respondents who participated in this study. The major demographic variables considered in this study include age, profession, education, and experience. Regarding age, those aged between 20-29 years were 8 (13.33%), those aged between 30-39 years were 35 (58.33%), those aged between 40-49 were 15 (25.00%) and those aged 50 years and above were 2 (3.33%). The majority of age groups are in the range of 30-39 years. With their majority, being youthful, the study concludes that they are energetic and should be contributing to optimal utilization of medical equipment, hence improving their performance. The study also examined the profession of the respondents.

Among the respondents, 15 (25.00%) were radiologists (making part of the allied health professionals), 3 (5.00%) were biomedical engineers, 17 (28.33%) were biomedical technicians, 15 (25.00%) were doctors and 10 (16.67%) were nurses. The study examined the education level of the respondents. 30 (50.00%) of the respondents possess College education (A1), 29 (48.33%) of the respondent possess Bachelors' degree (A0), while 1 (1.67%) respondent possesses post graduate degree (MSc). Given that majority of the respondent are educated to the university level (A1 and A0), it can be concluded that they possess requisite knowledge for optimal utilization of medical equipment, and how effective polices should be implemented to ensure medical equipment safety and performance. However, this effective utilization of medical equipment does not only require academic qualification, but also experience on job, and continuous training. In addition, this study sought to examine the experience of the respondents in their institutions. Among the respondents, 5 (8.33%) possess the working experience of less than1 year, 18 (30.00%) possess a working experience ranging between 1-3 years, 19 (31.67%), possess a working experience ranging between 3-5 years, 6 (10.00%) possess a working experience ranging between 5-7 years, 8 (13.33%) possess a working experience ranging between 7-9 years and 4 (6.67%) possess a working experience of 10years and above. Having the majority of the respondent having a working experience ranging between 1 and 9 years, this concludes that they are well communicated about hospital policies and understand them much better, so that they will provide their role in ensuring safety and performance of medical equipment, through being governed by hospital policies and guidelines. The findings about the demographic characteristics of the respondents are presented in the table below.

Table 2: Demographic characteristics of study population

Characteristics/Variable	Response	Frequency	Percentage
Age group	20-29	8	13.33
	30-39	35	58.33
	40-49	15	25.00
	50-59	2	3.33
	60 and above	0	0.00
Profession	Allied Health Professionals (Radiologist, Lab scientist, etc...)	15	25.00
	Biomedical Engineer	3	5.00
	Biomedical Technician	17	28.33
	Doctor	15	25.00
	Nurse	10	16.67

Education level	College graduate (A1)	30	50.00
	University graduate (A0)	29	48.33
	University post-graduate (MSc, PhD)	1	1.67
<hr/>			
Experience	Less than 1 year	5	8.33
	1-3 years	18	30.00
	3-5 years	19	31.67
	5-7 years	6	10.00
	7-9 years	8	13.33
	10 years and above	4	6.67
<hr/>			

The Study also carried out a cross tabulation of demographic variables with the dependent variables (medical equipment safety and medical equipment performance). Starting with medical equipment performance, regarding the age, the majority of the respondents (33/60) with the age range of 30-39 years confirmed about contribution of policies on medical equipment performance while 14/60 respondents with age range of 40-49 years also confirmed about this. Regarding the profession, among 15 radiologists, 14 confirmed about contribution of policies on the performance of the medical equipment they mostly use in their daily life, which include X-ray machines and CT scans. Among biomedical engineering team comprising of biomedical engineers and biomedical technicians, 19 of them among 20 confirmed about the contribution of policies on the performance of the medical equipment they deal with in their daily job. Regarding education, for those holding diploma (A1), 28 among 30 responded that policies contribute to the medical equipment performance, while for those holding bachelor's education (A0), 27 among 29 respondents confirmed about the contribution of policies on medical equipment performance. The only one respondent holding a university post graduate degree (MSc) also confirmed about polices contribution in ensuring medical equipment performance. Regarding experience, 4 among 5 respondents having n experience of less than 1 year confirmed about the contribution of policies on medical equipment performance. 17 among 18 respondents with experience of 1 to 3 years confirmed about policies contribution on medical equipment performance, 18 among 19 respondents with experience of 3 to 5 years responded that polices play a great contribution in ensuring medical equipment performance, 6 among 6 respondents with experience of 5 to 7 years also confirmed on policies contribution in ensuring medical equipment performance, 8 among 8 respondents having experience of 7 to 9 years added their confirmation about policy contribution to ensuring optimal medical equipment performance.

Finally 3 among 4 respondents with experience of 10 years and above responded that policies have major role in medical performance contribution. With the majority of respondents in each category of employees with various experience confirming about policy contribution on medical equipment performance, this clearly shows that they are aware about policies in their institutions, and contribute to implementing these policies in their daily work. The cross table of demographic variables and medical equipment performance are presented here below.

Table 3: Demographic variables versus Medical equipment performance

Characteristics/Variable	Maybe	No	Yes	Total
Characteristic/Variable	No.	No.	No.	No.
<i>Age group</i>				
20-29	1	0	7	8
30-39	2	0	33	35
40-49	0	1	14	15
50-59	0	0	2	2
Total	3	1	56	60
<i>Profession</i>				
Allied Health Professionals	1	0	14	15
Biomedical Engineer	0	0	3	3
Biomedical Technician	1	0	16	17
Doctor	0	1	14	15
Nurse	1	0	9	10
Total	3	1	56	60
<i>Education level</i>				
College graduate (A1)	2	0	28	30
University graduate (A0)	1	1	27	29
University post-graduate (MSc, PhD)	0	0	1	1
Total	3	1	56	60
<i>Experience</i>				
Less than 1 year	1	0	4	5
1-3 years	1	0	17	18
3-5 years	0	1	18	19
5-7 years	0	0	6	6
7-9 years	0	0	8	8
10 years and above	1	0	3	4
Total	3	1	56	60

Comparing the demographic variables with medical equipment safety, regarding the age, among the 8 respondent with the age range of 20 to 29, 7 responded that there is a positive impact of policy on medical equipment safety. Among the 35 respondents with the age range of 30 to 39, 34 respondent confirmed about policies impact on medical equipment safety.

Among 15 respondents with age range of 40 to 49, 14 of them confirmed about policy impact on medical equipment safety, and finally all 2 respondents with the age range of 50-59 years confirmed their point of view on the contribution of policies on medical equipment safety. This implies that the presence of policies in the institutions and their implementation play a pivotal role in improving the safety of medical equipment as confirmed by major respondents of this study (57/60). Regarding the profession, 14 radiologists among 15 responded that policies contribute in ensuring medical equipment safety. 3 among 3 biomedical engineers and 16 among 17 biomedical technicians also confirmed about policies impact on medical equipment safety. 14 Doctors among 15 also did not go far from agreeing about the policies contribution on medical equipment safety. This also considers 10 nurses among 10 who also agreed that the policies address safety issues on medical equipment. Having the majority of respondents from different departments agreeing on the contribution of policies on safety of medical equipment, it clearly shows that policies are communicated to different clinical staff, and their implementation play a great importance on the safety of medical equipment being used in service delivery. Regarding the education, among 30 respondents holding advanced diploma (A1), 28 of them responded that policies have a contribution in improving medical equipment safety.

Among 29 respondents holding bachelor's degree (A0), 28 of them confirmed about policy impact on medical equipment safety, and the only 1 respondent holding the university post graduate degree (MSc) also confirmed about the impact of policies on medical equipment safety. This implies that policies are having a contribution in ensuring medical equipment safety. Regarding the experience, the respondents with the experience of less than 1 year who confirmed about the impact of policies on medical equipment safety are 4 (6.67%), the respondents with experience of 1 to 3 years who agreed about the impact of policies on medical equipment safety are 17 (28.33%), the respondents with experience of 3-5 years who confirmed about the impact of policies on medical equipment safety are 18 (30.00%), the respondents with experience of 5-7 years who supported that policies have impact on medical equipment safety are 6 (10.00%), the respondents with experience of 7-9 years who are supporting that the policies have impact on medical equipment safety are 8 (13.33%) and the respondents with experience of 10 years and above who are supporting the policy impact on medical equipment safety are 4 (6.67%). The majority of respondents having agreed that there are impacts brought by policies on medical equipment safety confirms about the contribution of medical equipment policies in ensuring medical equipment safety.

Table 4: Demographic variables versus Medical equipment safety

Characteristics/Variable	Maybe	No	Yes	Total
Characteristic/Variable	No.	No.	No.	No.
<i>Age group</i>				
20-29	1	0	7	8
30-39	1	0	34	35
40-49	0	1	14	15
50-59	0	0	2	2
Total	2	1	57	60
<i>Profession</i>				
Allied Health Professionals	1	0	14	15
Biomedical Engineer	0	0	3	3
Biomedical Technician	1	0	16	17
Doctor	0	1	14	15
Nurse	0	0	10	10
Total	2	1	57	60
<i>Education level</i>				
College graduate (A1)	2	0	28	30
University graduate (A0)	0	1	28	29
University post-graduate (MSc, PhD)	0	0	1	1
Total	2	1	57	60
<i>Experience</i>				
Less than 1 year	1	0	4	5
1-3 years	1	0	17	18
3-5 years	0	1	18	19
5-7 years	0	0	6	6
7-9 years	0	0	8	8
10 years and above	0	0	4	4
Total	2	1	57	60

The results presented in table 3 and table 4 reveal that in most of Rwandan health institutions, policies are available, well communicated and implemented in hospitals, and their implementation presents major effects on medical equipment safety and performance. This is because major of the respondent have confirmed that the presence of medical equipment policies in their institution and the performance of facts demonstrated in medical equipment policies including training, good management, and following of procedures involve in ensuring medical equipment safety and performance. The findings reveal that having majority of young workforce in health institutions, and majority of the educated clinical staff with enough experience, shows that the clinical staff are well knowledgeable about medical equipment policies, and contribute with their role in implementing those policies to better optimize medical equipment performance and ensure that the medical equipment is used safely.

These findings are in agreement with Edosa Tesfaye Geta, (2023) who stated that among the factors affecting the utilization of medical equipment, there are professional operating factors [31], and who stated that human capacity development is one among factors that affect medical equipment utilization, leading to their optimal performance [1].

4.3 Descriptive analysis of study variables

This research adopted descriptive statistics to examine the study variables. The responses are in three categories, including the “Yes” responses, the “No” responses, and the “Maybe” responses. The study utilized STATA Version17.0 to generate frequency distribution and percentages for each statement about the study variable. The study’s independent variables included policies availability in hospitals, respecting of policies by clinical staff, policies being communicated and understood by staff, noticeable improvement brought by policies, policy impact on error reduction, policies which need to be enhanced, training of clinical staff about policies, provision of user manuals for new medical equipment, availability and accessibility of user manuals to clinical staff, performing of medical equipment calibration, preventive maintenance and corrective maintenance, and the dependent variables included medical equipment safety and medical equipment performance.

Table 5: Cross tabulation of medical equipment performance and independent variables

	Medical equipment performance			
	Maybe	No	Yes	Total
	No. (%)	No. (%)	No. (%)	No. (%)
<i>Policies availability in hospital</i>				
Maybe	1(100.00)	0(0.00)	0(0.00)	1(100.00)
No	0(0.00)	1(100.00)	0(0.00)	1(100.00)
Yes	2(3.45)	0(0.00)	56(96.55)	58(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)
Pearson chi2(4) = 79.3103 Pr = 0.000				
<i>Respect of policies by clinical staff</i>				
Maybe	3(100.00)	0(0.00)	0(0.00)	3(100.00)
No	0(0.00)	1(50.00)	1(50.00)	2(100.00)
Yes	0(0.00)	0(0.00)	55(100.00)	55(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)
Pearson chi2(4) = 89.4643 Pr = 0.000				
<i>Policies being communicated and understood by staff</i>				
Maybe	2(40.00)	0(0.00)	3(60.00)	5(100.00)
No	1(100.00)	0(0.00)	0(0.00)	1(100.00)
Yes	0(0.00)	1(1.85)	53(98.15)	54(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)
Pearson chi2(4) = 34.7738 Pr = 0.000				
<i>Noticeable improvement</i>				

Maybe	3(60.00)	0(0.00)	2(40.00)	5(100.00)
No	0(0.00)	0(0.00)	0(0.00)	0(0.00)
Yes	0(0.00)	1(1.82)	54(98.18)	55(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)

Pearson chi2(2) = 34.7532 Pr = 0.000

Policy impact on error reduction

Maybe	3(100.00)	0(0.00)	0(0.00)	3(100.00)
No	0(0.00)	0(0.00)	1(100.00)	1(100.00)
Yes	0(0.00)	1(1.79)	55(98.21)	56(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)

Pearson chi2(4) = 60.0191 Pr = 0.000

Policies need to be enhanced

Maybe	1(20.00)	0(0.00)	4(80.00)	5(100.00)
No	0(0.00)	0(0.00)	25(100.00)	25(100.00)
Yes	2(6.67)	1(3.33)	27(90.00)	30(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)

Pearson chi2(4) = 4.9167 Pr = 0.296

Training about policies

Maybe	0(0.00)	1(20.00)	4(80.00)	5(100.00)
No	1(50.00)	0(0.00)	1(50.00)	2(100.00)
Yes	2(3.77)	0(0.00)	51(96.23)	53(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)

Pearson chi2(2) = 42.9372 Pr = 0.000

Provision of user manuals for new

ME

Maybe	1(100.00)	0(0.00)	0(0.00)	1(100.00)
No	0(0.00)	0(0.00)	0(0.00)	0(0.00)
Yes	2(3.39)	1(1.69)	56(94.92)	59(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)

Pearson chi2(2) = 19.3220 Pr = 0.000

Availability and accessibility of user manual to clinical staff

Maybe	2(40.00)	0(0.00)	3(60.00)	5(100.00)
No	1(33.33)	0(0.00)	2(66.67)	3(100.00)
Yes	0(0.00)	1(1.92)	51(98.08)	52(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)

Pearson chi2(4) = 20.7697 Pr = 0.000

Performing of ME Calibration

Maybe	2(33.33)	0(0.00)	4(66.67)	6(100.00)
No	0(0.00)	0(0.00)	2(100.00)	2(100.00)
Yes	1(1.92)	1(1.92)	50(96.15)	52(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)

Pearson chi2(4) = 11.3828 Pr = 0.023

Performing Preventive maintenance of Medical equipment

Based on ME criticality	1(2.27)	0(0.00)	43(97.73)	44(100.00)
Based on ME history and performance	0(0.00)	0(0.00)	1(100.00)	1(100.00)
Based on manufacturer recommendati	2(13.33)	1(6.67)	12(80.00)	15(100.00)

Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)
Pearson chi2(4) = 6.1694 Pr = 0.187				
<i>Performing Corrective maintenance of Medical equipment</i>				
Based on adverse incident reports	1(50.00)	0(0.00)	1(50.00)	2(100.00)
Based on critical equipment failure	1(9.09)	0(0.00)	10(90.01)	11(100.00)
Based on equipment malfunction	1(2.27)	0(0.00)	43(97.73)	44(100.00)
Based on equipment recalls and alerts	0(0.00)	0(0.00)	1(100.00)	1(100.00)
Based on error messages or alarms	0(0.00)	1(50.00)	1(50.00)	2(100.00)
Total	3(5.00)	1(1.67)	56(93.33)	60(100.00)
Pearson chi2(8) = 39.1802 Pr = 0.000				

The bivariate cross tabulation used Pearson chi² and the p value (<0.05) to assess significance between medical equipment performance and other variables. The results revealed that many of the variables showed statistical significance, with the p value < 0.05. According to the findings, the study revealed that medical equipment policies are available in the hospitals, clinical staff are trained about policies, they are communicated and understood by clinical staff, they are respected by clinical staff, there is an observed noticeable improvement brought by policies on medical equipment performance, there is an impact of policies on error reduction, and in line with these policies, other confounding factors affecting medical equipment performance, there is provision of user manuals to medical equipment users, availability and accessibility of user manuals to clinical staff, performing of medical equipment calibration, preventive maintenance and corrective maintenance, as also part of the factors which help to improve medical equipment performance.

Table 6: Cross tabulation of medical equipment safety and independent variables

	Medical equipment safety			
	Maybe	No	Yes	Total
	No. (%)	No. (%)	No. (%)	No. (%)
<i>Policies availability in hospital</i>				
Maybe	1(100.00)	0(0.00)	0(0.00)	1(100.00)
No	0(0.00)	1(100.00)	0(0.00)	1(100.00)
Yes	1(1.72)	0(0.00)	57(98.28)	58(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)
Pearson chi2(4) = 89.4828 Pr = 0.000				
<i>Respect of policies by clinical staff</i>				
Maybe	2(66.67)	0(0.00)	1(33.33)	3(100.00)
No	0(0.00)	1(50.00)	1(50.00)	2(100.00)
Yes	0(0.00)	0(0.00)	55(100.00)	55(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)
Pearson chi2(4) = 68.7719 Pr = 0.000				
<i>Policies being communicated and understood by staff</i>				
Maybe	2(40.00)	0(0.00)	3(60.00)	5(100.00)

No	0(0.00)	0(0.00)	1(100.00)	1(100.00)
Yes	0(0.00)	1(1.85)	53(98.15)	54(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)
Pearson chi2(4) = 22.8148 Pr = 0.000				
<i>Noticeable improvement</i>				
Maybe	2(40.00)	0(0.00)	3(60.00)	5(100.00)
No	0(0.00)	0(0.00)	0(0.00)	0(0.00)
Yes	0(0.00)	1(1.82)	54(98.18)	55(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)
Pearson chi2(2) = 22.7943 Pr = 0.000				
<i>Policy impact on error reduction</i>				
Maybe	2(66.67)	0(0.00)	1(33.33)	3(100.00)
No	0(0.00)	0(0.00)	1(100.00)	1(100.00)
Yes	0(0.00)	1(1.79)	55(98.21)	56(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)
Pearson chi2(4) = 60.0191 Pr = 0.000				
<i>Policies need to be enhanced</i>				
Maybe	0(0.00)	0(0.00)	5(100.00)	5(100.00)
No	0(0.00)	0(0.00)	25(100.00)	25(100.00)
Yes	2(6.67)	1(3.33)	27(90.00)	30(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)
Pearson chi2(4) = 3.1579 Pr = 0.532				
<i>Training about policies</i>				
Maybe	0(0.00)	1(20.00)	4(80.00)	5(100.00)
No	0(0.00)	0(0.00)	2(100.00)	2(100.00)
Yes	2(3.77)	0(0.00)	51(96.23)	53(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)
Pearson chi2(4) = 11.3962 Pr = 0.022				
<i>Provision of user manuals for new ME</i>				
Maybe	0(0.00)	0(0.00)	1(100.00)	1(100.00)
No	0(0.00)	0(0.00)	0(0.00)	0(0.00)
Yes	2(3.39)	1(1.69)	56(94.92)	59(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)
Pearson chi2(2) = 0.0535 Pr = 0.974				
<i>Availability and accessibility of user manual to clinical staff</i>				
Maybe	2(40.00)	0(0.00)	3(60.00)	5(100.00)
No	0(0.00)	0(0.00)	3(100.00)	3(100.00)
Yes	0(0.00)	1(1.92)	51(98.08)	54(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)
Pearson chi2(4) = 22.8583 Pr = 0.000				
<i>Performing of ME Calibration</i>				
Maybe	1(16.67)	0(0.00)	5(83.33)	6(100.00)
No	0(0.00)	0(0.00)	2(100.00)	2(100.00)
Yes	1(1.92)	1(1.92)	50(96.15)	52(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)
Pearson chi2(4) = 3.8293 Pr = 0.430				

Performing Preventive maintenance of Medical equipment

Based on ME criticality	1(2.27)	0(0.00)	43(97.73)	44(100.00)
Based on ME history and performance	0(0.00)	0(0.00)	1(100.00)	1(100.00)
Based on manufacturer recommendati	1(6.67)	1(6.67)	13(86.67)	15(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)

Pearson chi2(4) = 6.1694 Pr = 0.187

Performing Corrective maintenance of Medical equipment

Based on adverse incident reports	1(50.00)	0(0.00)	1(50.00)	1(100.00)
Based on critical equipment failure	0(0.00)	0(0.00)	11(100.00)	11(100.00)
Based on equipment malfunction	1(2.27)	0(0.00)	43(97.73)	44(100.00)
Based on equipment recalls and alerts	0(0.00)	0(0.00)	1(100.00)	1(100.00)
Based on error messages or alarms	0(0.00)	1(50.00)	1(50.00)	2(100.00)
Total	2(3.33)	1(1.67)	57(95.00)	60(100.00)

Pearson chi2(8) = 39.1802 Pr = 0.000

The bivariate cross tabulation used pearson chi² and the p value (<0.05) to assess significance between medical equipment safety and other variables. The results revealed that many of the variables showed statistical significance, with the p value < 0.05. According to the findings, the study revealed that medical equipment policies are available in the hospitals, clinical staff are trained about policies, they are communicated and understood by clinical staff, they are respected by clinical staff, there is an observed noticeable improvement brought by policies on medical equipment safety, there is an impact of policies on error reduction, and in line with these policies, other confounding factors affecting medical equipment performance, there is provision of user manuals to medical equipment users, availability and accessibility of user manuals to clinical staff, performing of medical equipment calibration, preventive maintenance and corrective maintenance, as also part of the factors which help to improve medical equipment performance.

4.3.1 Medical equipment performance

Medical equipment performance refers to how effectively and efficiently medical devices and systems operate to fulfill their intended purposes. Among the key aspects of medical equipment performance including accuracy and precision, reliability and durability, safety, usability, efficiency, functionality, compliance with standards, maintenance and calibration, and technological integration, this study sought to examine some among them which include medical equipment maintenance (Corrective maintenance and preventive maintenance) and calibration.

Regarding preventive maintenance, the study findings revealed that among the medical equipment which have been investigated, the preventive maintenance is done, based on different conditions or factors as presented in the table below. The fact that preventive maintenance is done based on equipment criticality was supported by 44 (73.33%) respondents, the fact that preventive maintenance is done based on equipment history and performance was supported by 1 (1.67%) respondent, and the fact that preventive maintenance is done based on manufacturer’s recommendation was supported by 15 (25.00%) respondents. Regarding corrective maintenance, the study findings revealed that among medical equipment which have been investigated, the corrective maintenance is done based on different factors or conditions. The fact that corrective maintenance is done based on equipment malfunction was supported by 44 (73.33%) respondents, the fact that corrective maintenance is done based on error messages or alarms was supported by 2 (3.33%) respondents, the fact that corrective maintenance is done based on equipment recalls and alerts was supported by 1 (1.67%) respondent, the fact that corrective maintenance is done based on adverse incident reports was supported by 2 (3.33%) respondents, and finally, the fact that corrective maintenance is done based on critical equipment failure was supported by 11 (18.33%) respondents. Regarding calibration, 52 (86.67%) respondents supported that calibration of medical equipment is done, with a “Yes” response, while 2 (3.33%) respondents who responded with a “No” response and 6 (10.00%) respondents who responded with a “Maybe” response.

All these aspects are part of policies which deal with medical equipment policies which details how medical equipment must be utilized and managed in the institutions.

Table 7: Performing of medical equipment PM, CM, and calibration

Variable	Response	Frequency	Percentage
Performing PM	Based on equipment criticality	44	73.33
	Based on equipment history and performance	1	1.67
	Based on manufacturer’s recommendation	15	25.00
Total		60	100.00
Performing CM	Based on adverse incident reports	2	3.33
	Based on critical equipment failure	11	18.33
	Based on equipment malfunction	44	73.33
	Based on equipment recalls and alerts	1	1.67
	Based on error messages or alarms	2	3.33
Total		60	100.00
Performing calibration	Maybe	6	10.00
	No	2	3.33
	Yes	52	86.67
Total		60	100.00

4.3.2 Medical equipment safety

Medical equipment safety refers to the measures and practices that ensure that medical devices, during their use, do not pose any risks to patients, healthcare providers, or environment. This study sought to examine some of the key aspects of medical equipment safety including user safety, patient safety, maintenance and calibration, and environmental considerations. Regarding maintenance and calibration, the study findings revealed that in different institutions, medical equipment maintenance, and calibration are done in effective way to ensure safety of medical equipment as presented in the table above. In addition to this, regular scheduled maintenance must be done to medical equipment to ensure ongoing safe operation of medical equipment. Calibration also must be done regularly in order to maintain accuracy and functionality of medical equipment, which prevents unsafe conditions. Regarding user and patient safety, the study findings revealed that most of the medical equipment user (58 respondents) wear personal protective equipment (PPE) while using medical equipment. This is done as one of medical equipment users' role in ensuring safety of medical equipment as a safety protocol.

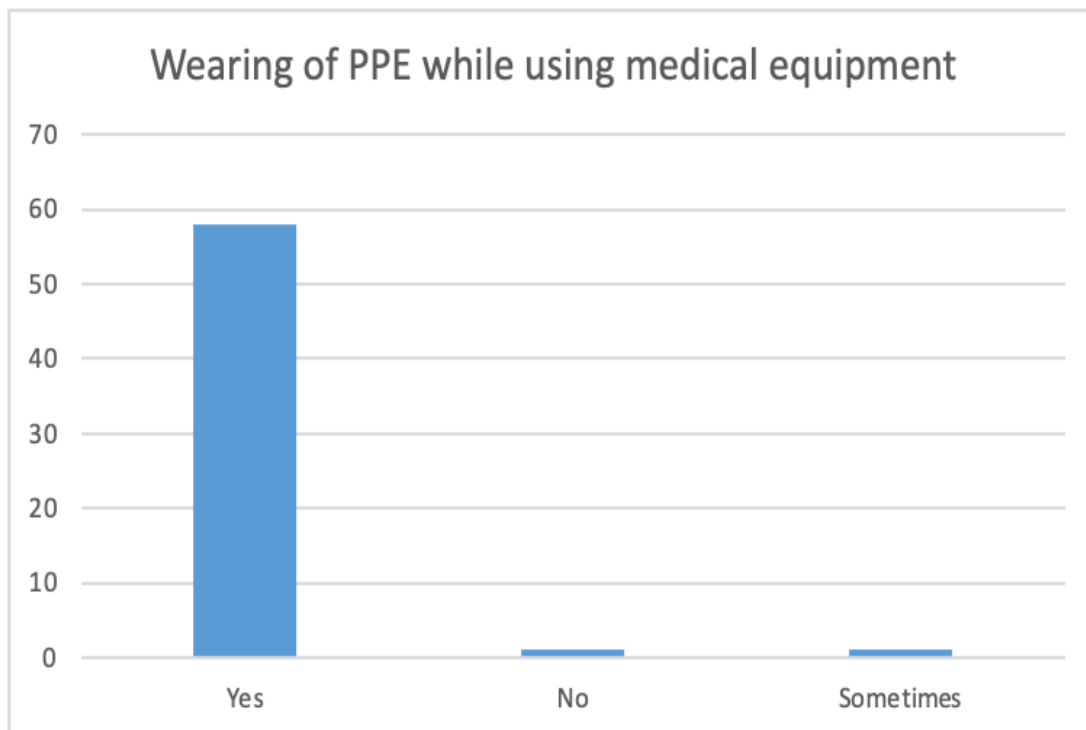


Figure 3: Wearing of PPE while using medical equipment

In addition to this, to ensure patient safety, there are different procedures which are followed to ensure safe and effective use of medical equipment.

These procedures include pre-use checks (responded by 53 out of 60), calibration (responded by 21 out of 60), patient identification (responded 8 by out of 60), patient preparation (responded 12 by out of 60), setting configuration (responded by 41 out of 60), safety checks (responded 19 by out of 60), continuous monitoring (responded by out 50 of 60), cleaning and sterilization (responded by 10 out of 60), and others (responded by 1 out of 60). The findings are presented in the figure below.

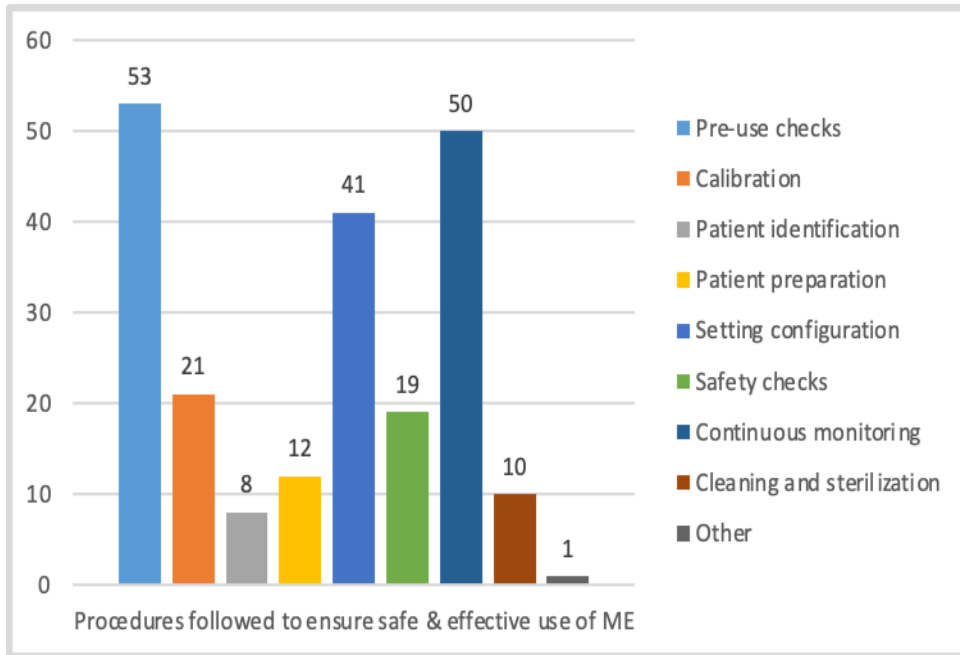


Figure 4: Procedures followed to ensure safe and effective use of medical equipment

4.3.3 Medical equipment policies

The research also sought to establish different hospital policies dealing with medical equipment in 4 different institutions. The respondents were presented with the number of statements which they were required to respond with a No, Maybe, or a Yes . The findings of these statements are presented in table__. The statement that there are policies and other guidelines being implemented in hospitals was supported by 58 (96.67%) respondents while 2 respondents responded with a No and a Yes respectively. This implies that there are policies regarding medical equipment being implemented in hospitals. The statement that clinical staff are trained and informed about policies was supported by 53 respondents (88.33%), 2 (3.33) responded with “No”, whereas 5 (8.33%) responded with “Maybe”, The statement that policies are well communicated and understood by staff was supported by 54 (90.00%) respondents, against 1 who responded with “No” and 4 who responded with “Maybe”.

The statement that policies are respected and followed by clinical staff was agreed upon by 55 (91.67%) respondents, against the remaining 5 respondents with “Maybe” and “No” responses, meaning that policies are policies are respected and followed by clinical staff.

The researcher also sought to establish whether policies being implemented have brought positive impacts on the safety of medical equipment. This statement was supported by 57 respondents with a “Yes” response, against the 3 remaining with “Maybe” and “No” responses. The statement about policy contribution in maintaining optimal performance of medical equipment was supported by 56 (93.33%) respondents against 4 remaining respondents with “No” and “Maybe” responses. The statement that policies implementation present effects on medical equipment performance was supported by 56 (93.33%) respondents against the 4 remaining ones with “No” and “Maybe” responses. The statement that policies address potential risk associated with medical equipment safety was agreed upon by 49 respondents, against 8 respondents who responded with “Maybe” and 3 who responded with “No”. The statement that since the implementation of policies, there are noticeable improvement on medical equipment reliability and performance was supported by 55 (91.67%) respondent with “Yes” against the 5 (8.33%) respondents with “Maybe” responses. The statement about policies impacts on reducing equipment related errors was supported by 56 (93.33%) respondents with “Yes”, against the remaining 4 respondents with a “No” and “Maybe” responses. The statement that there is a need of additional training and resources to better align clinical staff with medical equipment policies was supported by 57 (95.00) respondents against the remaining 3 respondents with” Maybe” and “No” responses.

The statement that there are specific policies which need to be enhanced to improve the safety and performance of medical equipment was agreed upon by 30 (50.00%) respondents, against 25 (41.67%) respondents with a “No” response and 5 (8.33%) respondents with a “Maybe” response.

Table 8: Statements about medical equipment policies

Statements		Frequency	Percentage
There are policies and other guidelines in the hospital	Maybe	1	1.67
	No	1	1.67
	Yes	58	96.67
	Total	60	100.00
Clinical staff are being trained about policies	Maybe	5	8.33
	No	2	3.33
	Yes	53	88.33
	Total	60	100.00
Policies are well communicated and understood by staff	Maybe	5	8.33

	No	1	1.67
	Yes	54	90.00
	Total	60	100.00
Policies are respected and followed by clinical staff	Maybe	3	5.00
	No	2	3.33
	Yes	55	91.67
	Total	60	100.00
Policies positively impacted the safety of ME	Maybe	2	3.33
	No	1	1.67
	Yes	57	95.00
	Total	60	100.00
Policies contribute to maintaining performance of ME	Maybe	3	5.00
	No	1	1.67
	Yes	56	93.33
	Total	60	100.00
Policies implementation show effects on ME safety	Maybe	1	1.67
	No	3	5.00
	Yes	56	93.33
	Total	60	100.00
Policies address potential risks associated with ME	Maybe	8	13.33
	No	3	5.00
	Yes	49	81.66
	Total	60	100.00
Noticeable improvement on performance and ME reliability	Maybe	5	8.33
	No	0	0.00
	Yes	55	91.67
	Total	60	100.00
Policies impact on reducing equipment related errors	Maybe	3	5.00
	No	1	1.67
	Yes	56	93.33
	Total	60	100.00
Need of additional training to align staff with ME policies	Maybe	1	1.67
	No	2	3.33
	Yes	57	95.00
	Total	60	100.00
Specific policies to be enhanced to ensure ME performance and safety	Maybe	5	8.33
	No	25	41.67
	Yes	30	50.00
	Total	60	100.00

4.3.4 The effects of medical equipment policies on medical equipment safety

Medical equipment policies encompass regulations, standards, and guidelines that address various aspects of the design, manufacture, use, and maintenance of medical equipment. They have impact on ensuring and enhancing medical equipment safety. In health institutions, these policies address aspects of use, management, and maintenance of medical equipment.

When enforced and being implemented, regulatory bodies and healthcare organizations ensure that medical equipment is safe for use, which protect not only patients, but also healthcare providers and the public in general from potential harm.

In this study, after examining different factors of medical equipment utilization, and implementation of policies in health institutions, the findings have revealed different effects of policies on medical equipment safety. The reduced rate of errors is the first effect which has been supported by 51 respondents. Other effects include improved quality of service which was supported by 26 respondents, improved patient safety which has been supported by 29 respondents, reduced maintenance costs which has been supported by 6 respondents, optimal patient satisfaction which was supported by 25 respondents, and finally, effective and efficient performance of medical equipment which was supported by 45 respondents. The findings are presented in the figure below.

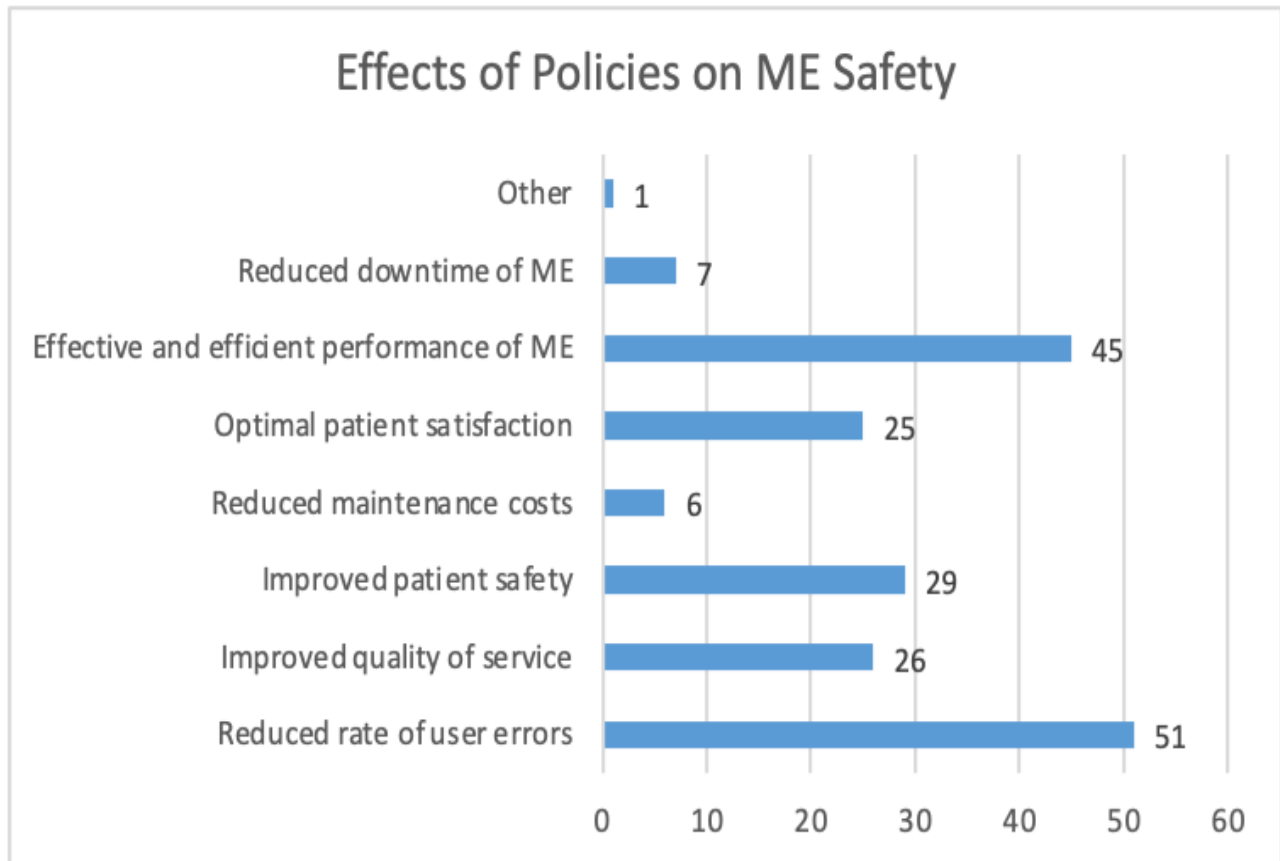


Figure 5: Effects of policies on medical equipment safety

In addition to the effects of policies on medical equipment safety, the clinical staff, and particularly medical equipment users, have the responsibility to ensure that medical equipment they use are optimally used.

In this study, the respondents have agreed that their role and contribution in ensuring optimal performance of medical equipment include continuous education on medical equipment (supported by 58 respondents), reading and following of user manuals (supported by 46 respondents), following of procedures for medical equipment setup, operation, and shutdown (supported by 52 respondents), routine calibration and maintenance (supported by 26 respondents), and infection control (supported by 25 respondents), and in others, one respondent suggested that for X-ray machines linen or tissues on bed should be of single use, in order to avoid cracks on X-ray couch, and another respondent suggested to advise policy makers to follow up and make changes where needed.

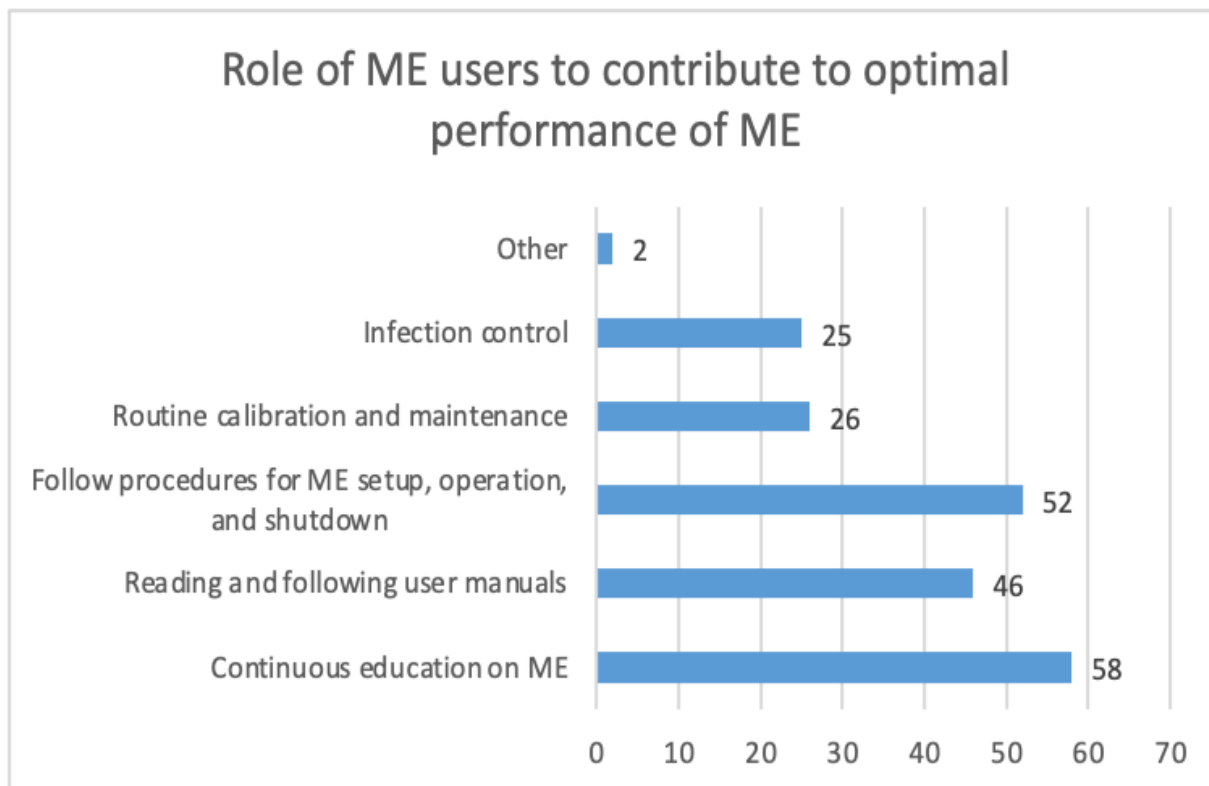


Figure 6: The role of medical equipment users to contribute to their optimal performance

4.4 Positive and negative effects of policies on medical equipment safety and performance

This study sought to evaluate the positive and negative effects of policies on medical equipment safety and performance in comparison to existing policies at national level and international level.

4.4.1 Positive effects

Within the health institutions, while policies are available, accessible, affordable, implemented and evaluated, there are a couple of positive effects, which they may bring to the health institutions in general, and specifically on medical equipment. These positive effects include:

- **Enhanced safety:** The enhanced safety results from policies which mandate routine maintenance and calibration to ensure that medical equipment operate accurately and safely, which reduces the risks of malfunctions that could harm patients. The policies also include safety protocols for equipment use, which minimize the risk of operator error and equipment-related incidents.
- **Improved performance:** Through continuous monitoring and evaluation of equipment performance, any medical equipment issues are identified and addressed, which ensures optimal functioning of medical equipment. Policies can standardize equipment usage and procedures across the hospital, and this ensures consistent performance and reduces variability in patient care.
- **Effective training and competency:** Training policies require regular training and competency assessments for staff and ensure that health professionals are well informed about the correct use and limitation of medical equipment, which ensures optimal functioning of medical equipment. They also ensure that operators are certified and have up-to-date knowledge which helps in maintaining high standards in equipment use.
- **Risk management:** Policies related to risk assessment help in management of potential risks associated with medical equipment. They also encourage the reporting of equipment related incidents, which help in identification of potential safety issues and implementation of corrective actions.
- **Compliance and quality assurance:** Aligning hospital policies with national and international standards contributes to safety and quality assurance, through ensuring that medical equipment meet regulatory requirements. In addition to this, conducting internal audits and medical equipment inspections, safety and performance standards are achieved.
- **Patient safety:** Policies for management recalls ensure that only medical equipment in good conditions are in use, and ensures that defective and potentially hazardous devices are removed from use. This, together with policies related to cleaning, sterilization, and disinfection of medical equipment, help to prevent the transmission of infections, and improve patient safety.
- **Efficient resource management:** Effective policies for inventory management ensure that equipment is well maintained, adequately stocked, and readily available in case of need, which enhances the medical equipment operational efficiency.

In addition to this, management of the lifecycle of equipment from its acquisition to disposal phase ensures that medical equipment is replaced or upgraded at appropriate time, which maintains high performance.

- **Support for innovation and improvement:** This is achieved through adoption of best practices which encourage the use of best practices and incorporates advancement in medical technologies into hospital policies, in order to improve the overall quality of care. In addition, inclusion of mechanisms for staff to provide feedback on medical equipment performance in the policies, lead to continuous improvement and adoption of new technologies that enhance patient care.

4.4.2 Negative effects

However, there are some negative effects of policies on medical equipment safety and performance, which are can be brought by implementation of medical equipment policies. Moreover, in the rapidly evolving technological landscapes, medical equipment policies may pose significant challenges to small companies, or health institutions. These negative effects include:

- **Resource allocation or Budget constraints:** Policies aimed at reducing costs result in the purchase of cheaper, lower quality equipment that may not perform as well or that may fail often. Additionally, budget constraint may cause delaying of the replacement of medical equipment, which may compromise performance and safety.
- **Inconsistent implementation:** Some countries like developing countries may struggle to meet international standards due to limited resources and infrastructure, and different interpretations and implementation of international guidelines in different countries lead to inconsistency in medical equipment safety and performance.
- **Communication gaps:** these gaps result from policies which do not facilitate effective communication among departments, which can lead to misunderstanding and mishandling of medical equipment. Inadequate documentation also results in missed maintenance schedules, loss of incident reports, and overall decrease in equipment reliability.

4.5 Discussion

The first objective of this study was to assess awareness of clinical staff on the availability of policies in their institution.

The medical equipment users and biomedical technicians and engineers were interviewed about the presence of policies in their respective institutions, the training about policies, availability and accessibility on those policies, communication of policies and understanding of clinical staff about policies. The results of the analysis indicated that policies are available, communicated to, accessible, trained, and understood by clinical staff from different health institutions as indicated by the majority of the respondents (over 85%). This implies that the presence of policies are among the key factors of improving medical equipment safety and performance. The results were significant at 5% level of significance.

The findings are in agreement with B. Gbadago et al., (2017) who agreed that presence of policies in hospitals bring more benefits not only to employees but also to patients [32]. In addition to this, the study is also in agreement with R. Rosa et al., (2016) who agreed that the presence of standard operating procedures (SOPs) lead to decrease of problems regarding patients and prioritization of the quality of care [33].

The second objective of the study was to assess the policies implementation for safety purposes and performance purposes. The medical equipment users and biomedical technicians and engineers were interviewed about the implementation of policies in their respective institutions, the contribution of policies on maintaining the optimal performance of medical equipment, the positive impacts of policies on medical equipment safety, the effects on medical equipment safety observed since the implementation of policies, improvement in overall performance and reliability of medical equipment due to policies implementation, and the measurable impact of policies on reducing medical equipment related incidents or errors. The results of the analysis indicated that there is a major role of policies being implemented on medical equipment safety and performance. The results were significant at 5% of significance level. The findings are in agreement with R. Rosa et al., (2016) who agreed that it is important to have qualified staff to implement the SOPs and other guidelines or policies, for the sake of improving the quality of care and the patient safety. She agreed that implementation of SOPs provides improved health practices [33]. In addition to this, this study also is in agreement with M. Lingg et al., (2017) who suggested that it is the role of policymakers to foster the regulation, assessment, and management in order to improve quality of delivered healthcare. The suggestion was made based to the factor that policies related to medical equipment are essential to assure equitable access to high quality and affordable devices and their appropriate use [34]. The study also agrees with Luke Bailey, (2018) who found that the use of standard operating procedures increase staff level of confidence, which will improve the staff' ability to operate efficiently, consistently, and correctly [35].

The third objective of the study was to evaluate the role of medical equipment users in ensuring medical equipment safety and performance. Different respondents of this study in different health institutions supported their contribution in ensuring the safe use of medical equipment, and improving the optimal performance of medical equipment. Their role in this include following of procedures and wearing of PPE when using medical equipment, reading and following of user manuals, continuous education on medical equipment, routine calibration and maintenance, infection control, trainings, and performing medical equipment inventory, and other best practices. The result of findings indicated that the clinical staff are responsible for handling and taking good care of their medical equipment to ensure safety and performance. The results were significant at 5% level of significance.

The results were in agreement with Omoit et al., (2020) who agreed that compliance with guidelines and standard operating procedures is very important in healthcare institutions in order to assist with assessment and treatment, continuity of care, clinical handover, patient safety, clinical quality education, research, evaluation, and others [36]. In addition to this, this study also is in agreement with an NIH Public Access manuscript, (2014) which established a cross national comparative study of approaches to regulations, in order to evaluate medical device effectiveness and safety [37]. The results are also in agreement with Edosa Tesfaye Geta, (2023) who showed about the factors which affect medical equipment utilization which include institutional related factors, equipment related factors and professional operating related factors, and among the professional operating related factors, training and performing of preventive maintenance are the main factors which lead to efficient utilization of medical equipment, hence leading to optimal performance of medical equipment [31]. In addition to this, the medical equipment users have the responsibility of correct usage and operation of medical equipment, daily inspection, issues reporting, documentation, complying with regulations and continuous learning about best practices for medical equipment safety in order to maintain high safety standards and optimal performance of medical equipment.

The fourth objective of the study was to evaluate the positive and negative effects of policies on medical equipment safety and performance in comparison to existing policies at national level and international level. The study findings reveal that many policies existing at hospitals are in line with the national health sector policy and other ministerial instructions which deal with medical equipment utilization in hospitals, with the aim of ensuring universal accessibility to equitable and affordable quality health services to Rwandans [6].

The medical equipment policies have been found to have both positive and negative effects on medical equipment safety and performance, through their design, development, implementation, and/or monitoring and evaluation in regards with international standards.

The findings generated from analysis of data collected through questionnaires revealed that generally, different policies being implemented in hospitals, and being respected by clinical staff as meant to be, bring more benefits to clinical staff, patients being subjected to medical equipment, and to health institutions in general. This is because the descriptive analysis revealed that many of the respondents responded with a “Yes” on most statements regarding policies at the hospital. The research also revealed that the staff at the hospitals need additional training resources to better align them with hospital policies related to medical equipment.

In addition to this, the findings revealed that there are some specific hospital policies which could be enhanced to better ensure safety and performance of medical equipment. They include medical equipment management policy, medical equipment utilization policies, maintenance policy, medical equipment disposal and replacement policy, medical equipment procurement policy, and medical equipment safety policy.

In addition to this, from the findings, respondents suggested on what should be done to improve safety and performance of medical equipment, which include monitoring and evaluation of policies being implemented, inclusion of inputs and ideas of medical equipment users during policy making, provision of more refresher trainings to medical equipment users to improve their knowledge, regulatory compliance of policies with international standards, performing quality control and assurance, training of enough personnel on new technologies, proper management, allocation of biomedical technician in each service/department, increasing of numbers of medical equipment, especially in maternity departments. Performing of regular checkup, and control of electrical safety of medical equipment.

Finally, the existence and implementation of policies at hospital levels has proven to bring some positive effects on medical equipment safety and performance. This agrees with international standards on medical equipment which ensure safety, quality, and effectiveness of medical equipment globally across health systems. They recommend hospitals, manufacturers, and regulators to stay updated with them in order to maintain compliance and to ensure the highest level of patient care. include all standards that ensure that medical equipment is safe, effective, and reliable.

4.6 Summary of Findings

The findings generated from the analysis of data collected through questionnaires revealed that generally, the existence and implementation of medical equipment policies in hospitals is accompanied with safely used and optimally performing medical equipment. The positive association between medical equipment policies and medical equipment safety and performance means that when hospitals adopt policies related to medical equipment, including medical equipment procurement policies, medical equipment management policies, medical equipment maintenance policies, and other national or international policies related to medical equipment, they experience improved utilization rate of medical equipment, through regular maintenance and calibration, efficient inventory management, standardized procurement processes, utilization monitoring and reporting, equipment sharing, prioritization and scheduling, training, procedures and methods, which all provide the best way of ensuring safe use and optimal performance of medical equipment. The research also revealed that policies are available, accessible, being communicated and understood by clinical staff in their respective hospitals. This implies that there is a positive association between policies implementation in the hospitals and the medical equipment safety and performance.

The study further showed that medical equipment users contribute to improving safety and performance of medical equipment through respecting policies, following recommended procedures for medical equipment utilization, and through continuous education on medical equipment they mostly use. This study revealed that medical equipment policies are needed in hospitals in order to help hospital achieve on patient safety, quality assurance, compliance with regulations, cost efficiency, operational efficiency, risk management, staff training and competency. Medical equipment policies are vital for maintaining a high standard for healthcare delivery.

CHAPTER 5. CONCLUSION AND RECOMMENDATION

5.1 Conclusion

The study objective was to assess the effects of hospital policies on medical equipment safety and performance through evaluating the positive and negative effects of policies, in comparison to existing policies at national and international levels. The findings from different health institutions led to a number of conclusions. The study concludes that lack of policies and guidelines in health institutions lead to reduced and ineffective use of medical equipment, which influence their safety and performance. In addition to this, the study concluded that lack of attachment to hospital policies leads to occurrence of incidents or issues related to medical equipment safety. The study also concludes that the existence and implementation of medical related policies in hospitals is associated with optimal performance of medical equipment. The study concludes that medical equipment users' role is also important in ensuring safe use and optimal performance of medical equipment. The study found out that policies related to medical equipment being implemented in hospitals result to positive effects which include enhanced safety, improved performance, effective training and competency, risk management, compliance and quality assurance, patient safety, efficient resource management, and support for innovation and improvement. However, there are some negative effects which may result from hospital policies on medical equipment safety and performance, which include budget constraints, inconsistent implementation, and communication gap. The international standards on medical equipment suggest the good management of medical equipment for the effective use and optimal performance, and for the promotion of patient safety. The study findings are complying with these international standards which aim at reducing possible errors associated with the use of medical equipment, hence promoting safety and performance of medical equipment during the post- market period. This study concludes that whenever hospital is working in accordance with medical equipment related policies being well respected, this hospital will experience optimal performance of medical equipment, hence maintenance costs will be reduced, there will be provision of high-quality services and high patient satisfaction. There will be safe use of medical equipment which will lead to numerous positive outcomes on patient, healthcare providers, and the overall healthcare system. This complies with international standards which are related to medical equipment, and which have the aim of protecting both the patient and medical equipment user or operator against any risks which may be associated with the use of medical equipment, and they aim at providing guidance to the ways of ensuring optimal performance of medical equipment.

In conclusion, the existence and implementation of medical equipment policies in hospitals significantly enhance both the safety and performance of medical devices. This is because these policies ensure regular maintenance, proper training, and their strict adherence to international standards reduce the risk of equipment failure and misuse. Therefore, hospitals are requested to maintain high quality operational efficiency, improve patient outcomes, and ensure that medical equipment consistently meets safety and quality standards, which ultimately lead to a more reliable and effective healthcare environment.

5.2 Recommendations

Based on the findings that the hospital policies have significant effects on medical equipment safety and performance, the study recommends:

The clinical staff to be better aligned with hospital policies and guidelines related to medical equipment.

Health institutions to better communicate and introduce policies to clinical staff for better understanding.

Health institutions to provide thorough refresher trainings to medical equipment users to ensure that they are optimally utilized and safely used.

The ministry of Health to design and develop, implement and monitor policies that address risks associated to the use of medical equipment.

Suggestions for Further Research. The current study was on effects of hospital policies on medical equipment safety and performance in different hospitals. The study has been successfully carried out. However, there are some gaps that can be filled by future research.

The study suggests future researchers to examine factors that may influence policies implementation in hospitals. The study also recommend that future studies may examine other effects of policies on medical equipment safety and performance in addition to the ones assessed according to the scope of the study. The study also recommends future research to examine the impacts of user training on medical equipment safety and performance.

REFERENCES

- [1] G. H. Aliow, T. W. Mwaura, and O. Musa, “Factors Affecting Medical Equipment Utilization in Health Service Delivery in Mandera County Referral Hospital,” vol. 10, no. 4, pp. 13–20, 2021, doi: 10.9790/1959-1004051320.
- [2] World Health Organization, “Development of medical device policies,” *WHO Med. device Tech. Ser.*, p. 45, 2011, [Online]. Available: <https://apps.who.int/iris/bitstream/handle/10665/44600/9789241501637-eng.pdf?sequence=1&isAllowed=y>.
- [3] ILO Social Protection Department, “Rwanda: Progress towards Universal Health Coverage,” *Soc. Prot. Action Build. Soc. Prot. Floors*, vol. 1, no. April, pp. 1–6, 2012, [Online]. Available: <http://www.social-protection.org/gimi/gess/RessourcePDF.action?ressource.ressourceId=53613>.
- [4] P. T. Hounbo, G. J. V. D. Wilt, D. Medenou, L. Y. Dakpanon, J. Bunders, and J. Ruitenber, “Policy and management of medical devices for the public health care sector in Benin,” *IET Semin. Dig.*, vol. 2008, no. 12213, 2008, doi: 10.1049/ic:20080570.
- [5] R. G. Registration, M. Devices, and V. Diagnostics, “REGULATIONS GOVERNING THE REGISTRATION OF MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS,” 2018.
- [6] Rwanda Ministry of Health, “Health Sector Policy,” p. 41, 2015, [Online]. Available: http://www.moh.gov.rw/fileadmin/templates/policies/Health_Sector_Policy___19th_January_2015.pdf.
- [7] M. Ghasemi, E. Mazaheri, M. Hadian, and S. Karimi, “Evaluation of medical equipment management in educational hospitals in Isfahan,” pp. 1–6, 2022, doi: 10.4103/jehp.jehp.
- [8] P. H. Care, “DELIVERY More Than Ever COVERAGE REFORMS,” 2008.
- [9] I. Abuhav, “Iso 13485:2016,” *Iso 134852016*, vol. 2016, 2018, doi: 10.1201/9781351000796.
- [10] “No Title.”
- [11] T. Saidi and T. S. Douglas, “Chapter 19 Medical Device Regulation in Africa,” no. December, 2020.
- [12] M. Lingg, A. Dreser, L. Durán-Arenas, and K. Wyss, “Strategies to improve the medical device life cycle in Mexico,” *Salud Publica Mex.*, vol. 60, no. 4, pp. 462–471, 2018, doi: 10.21149/9060.
- [13] S. Manager and E. Registers, “Medical devices management policy,” no. November 2015,

- pp. 1–26, 2013, [Online]. Available:
<http://www.sussexpartnership.nhs.uk/gps/policies/finish/2021/274>.
- [14] C. Q. Commission *et al.*, “Management of Medical Devices (Equipment) Policy,” 2019.
- [15] A. Leotsakos *et al.*, “Standardization in patient safety : the WHO High 5s project,” vol. 26, no. 2, pp. 109–116, 2014.
- [16] Employee’s State Insurance Corporation, “Medical Equipment Maintenance Policy (2012),” pp. 2–19, 2012.
- [17] “Assessment of Equipment Utilization and Maintenance Schedule at a Dental Institution in Bengaluru , India,” pp. 104–108, 2017.
- [18] P. Statement, “Medical Equipment Procurement Policy 1.,” no. January, pp. 1–5, 2021.
- [19] R. Spotlight, “의료기기 [Medical Device],” vol. 5, no. July 2013, pp. 12–17, 2015.
- [20] “Iso149712019-Modirfa.” .
- [21] T. Union, O. Journal, and E. Union, “(recast) (Text with EEA relevance),” *Ec 2074/2005*, vol. 10, no. December 2016, pp. 1–21, 2017, [Online]. Available:
<http://data.europa.eu/eli/reg/2024/996/oj>.
- [22] The European Parliament and the Council of the European Union, “Regulation (EU) 2017/746 of the European parliament and of the council on in vitro diagnostic medical devices,” *Off. J. Eur. Union*, vol. 5, no. 5, pp. 117–176, 2017.
- [23] Food and Drug Administration, “PART 820 - QUALITY SYSTEM Subpart A - General Provisions,” *Code Feredal Regul. (CFR9*, vol. 82, no. 7, pp. 153–167, 2011, [Online]. Available: <https://www.gpo.gov/fdsys/granule/CFR-2011-title21-vol8/CFR-2011-title21-vol8-part820>.
- [24] WHO, “USER GUIDE : WHO technical specification for medical devices Version 1.1 2014,” pp. 1–24, 2014, [Online]. Available:
http://www.who.int/medical_devices/management_use/mde_tech_spec/en/.
- [25] I. E. Commission, *International Standard IEC60601-1*, vol. 2006. 2006.
- [26] IMDRF Good Regulatory Review Practices Group, “Essential Principles of Safety and Performance of Medical Devices,” *Int. Med. Device Regul. Forum*, 2018.
- [27] B. Paper, “MedicAl devices : MAnAging the Mismatch Increasing complexity of medical technology and consequences for training and outcome of care,” 2010.
- [28] S. Oshabaheebwa, L. K. Namuli, M. S. Tusabe, J. Nantume, L. H. Ackers, and R. T. Ssekitoleko, “Enhancing skills to promote the utilization of medical laboratory equipment in low resource settings,” *Heal. Policy Technol.*, vol. 9, no. 1, pp. 94–101, 2020, doi:

- 10.1016/j.hlpt.2020.01.001.
- [29] Y. Wei, H. Yu, J. Geng, B. Wu, and Z. Guo, “Hospital efficiency and utilization of high-technology medical equipment : A panel data analysis,” no. 138, pp. 65–72, 2018, doi: 10.1016/j.hlpt.2018.01.001.
- [30] W. Zone and O. R. State, “Efficiency of Medical Equipment Utilization and Its Associated Factors at Public Referral Hospitals Efficiency of Medical Equipment Utilization and Its Associated Factors at Public Referral Hospitals in East Wollega Zone , Oromia Regional State , Ethiopia,” 2023, doi: 10.2147/MDER.S401041.
- [31] E. T. Geta, “Efficiency of Medical Equipment Utilization and Its Associated Factors at Public Referral Hospitals in East Wollega Zone , Oromia Regional State , Ethiopia,” no. February, pp. 37–46, 2023.
- [32] B. P. Gbadago, S. N. Amedome, and B. Q. Honyenuga, “The Impact of Occupational Health and Safety Measures on Employee Performance at the South Tongu District Hospital,” vol. 17, no. 5, 2017.
- [33] R. Rosa, M. Helena, H. M. B. De, and F. Weiss, “www.ssoar.info Standard operating procedure in the hospital context: the nurses’ perception,” 2016, doi: 10.9789/2175-5361.
- [34] M. Lingg, A. D. Mansilla, L. Durán-arenas, and K. Wyss, “The regulation , assessment , and management of medical devices in Mexico : How do they shape the quality of delivered healthcare ?,” pp. 1–10, 2017, doi: 10.1186/s40886-017-0055-8.
- [35] L. Bailey, “Standard Operating Procedures and their Effect on Confidence Levels. Master of Science (Clinical Research Management) November 2018 Luke Bailey, B.S.,” no. November, 2018.
- [36] D. F. O. Omoit, G. O. Otieno, and K. K. Rucha, “Measuring the Extent of Compliance to Standard Operating Procedures for Documentation of Medical Records by Healthcare Workers in Kenya,” no. July, 2020, doi: 10.5923/j.phr.20201002.06.
- [37] A. Manuscript, E. Medical, and D. Effectiveness, “NIH Public Access,” vol. 69, no. 1, pp. 1–26, 2014.

APPENDICES

Appendix 1: Mode of Data Collection (The Questionnaire)

SURVEY

QUESTIONNAIRE

Dear

respondent,

I am Ms. Vestine TUYISENGE, a Master's student in Biomedical Engineering, of the Regional Center of Excellence in Biomedical Engineering and E-Health (CEBE) hosted in the University of Rwanda (UR). I am conducting academic research for my master's thesis entitled: "Assessment of effects of Hospital Policies on Medical Equipment Safety and Performance". It is in this regard that I am writing this questionnaire to collect data which will help me to fulfill the requirements of MSc project in Biomedical Engineering. The data which I will get from this questionnaire will be only used for academic purposes in my thesis project, and it will allow me to better understand the current management and utilization of medical equipment in the different health institutions in Rwanda and the influence of hospital policies on this management and utilization of medical equipment. Your participation in this research is voluntary and privacy of the respondent is ensured. The data you will provide in this research will be kept confidential and secure until the research is complete. At the completion of the research, the provided data will be disposed.

This questionnaire will take around 10 minutes of your time to answer. (Tick in front of the name or appropriate response)

1. Do you agree to voluntarily participate in this research?

I agree

I disagree

2. What is your profession?

Doctor

Nurse

Biomedical engineer

Biomedical technician

Allied health professional (Radiologist, Lab scientist, etc.)

3. What is your institution/hospital?

Referral Hospital

Level 2 University Teaching Hospital

Level 1 University Teaching Hospital

King Faisal Hospital (KFH)

4. How old are you?

20-29

30-39

40-49

50-59

60-65

5. What is your highest educational level?

Secondary school (A2)

College graduate (A1)

University graduate (A0)

University post-graduate (MSc, PhD)

6. How long have you been working in your institution?

Less than 1 year

1-3 years

3-5 years

5-7 years

7-9 years

10 years and above

7. Which medical equipment do you use mostly among these?

Patient monitor

Ultrasound machine

X-ray or CT scan

8. Are you informed or trained about medical equipment policies and/or guidelines related to your job?

Yes

No

Maybe

9. At what extent does your institution receive medical equipment (new equipment or replacement of the existing one)?

0-1 times per year

2-3 times per year

4-5 times per year

0-1 times in three years

2-3 times in three years

Once beyond three years

10. Do the clinical staff get trained on the new purchased medical equipment?

Yes

No

Maybe

11. If Yes, do all medical equipment users get the opportunity to be trained on such equipment?

Yes, all are trained

No, some of them

12. If No, how do you get skills on how to use those medical equipment?

Self-documentation

From Biomedical Engineers/technicians

From other clinical staff

From Others

I don't get new skills

13. Do you have refresher trainings on medical equipment?

Yes

No

14. If Yes, how often?

Once per year

Once per 2 years

Once per 3 years

15. Who are in charge of providing those refresher trainings?

Biomedical engineers/technicians

License holder

Medical equipment manufacturers

Rwanda Biomedical Center

Ministry of Health

16. Are medical equipment calibrated as specified by the manufacturers?

Yes

No

Maybe

17. When do you perform medical equipment preventive maintenance?

Based on equipment criticality

Based on equipment history and performance

Based on feedback from users

Based on manufacturer's recommendation

18. When do you perform medical equipment corrective maintenance?

Based on equipment malfunction

Based on error messages or alarms

Based on equipment recalls and alerts

Based on adverse incident reports

Based on critical equipment failure

19. Do you wear personal protective equipment (PPE) while using medical equipment?

Yes

No

Sometimes

20. What procedures among these do you follow to ensure safe and effective use of medical equipment?

Pre-use checks

Calibration

Patient identification

Patient preparation

Setting configuration

Safety checks

Continuous monitoring

Cleaning and sterilization

21. How are medical equipment managed in your institution/hospital?

Very well

Well

Fairly

Poorly

22. Justify the answer provided on the previous question

Enter your answer

23. Do the medical equipment perform what they are intended for?

Yes

No

Sometimes

24. If yes, explain your answer.

Enter your answer

25. How do you deploy medical equipment among departments?

Enter your answer

26. Do the manufacturer/license holder provide user manual for the new purchased medical equipment?

Yes

No

Maybe

27. Are user manuals available and accessible to all medical equipment users?

Yes

No

Maybe

28. Apart from user manuals, what other guideline documents are used to ensure proper management and use of medical equipment?

Standard Operating Procedures (SOPs)

Hospital guidelines

29. Do you have hospital policies, Standard Operating Procedures or guidelines implemented in your institution to govern you in your daily work?

- Yes
- No
- Maybe

30. If yes, are they respected and followed by all clinical staff as they were meant to be?

- Yes
- No
- Maybe

31. In the last year, have the hospital policies implemented positively impacted the safety of medical equipment?

- Yes
- No
- Maybe

32. Do you believe that the current hospital policies contribute to maintaining the optimal performance of medical equipment?

- Yes
- No
- Maybe

33. Since the implementation of the recent hospital policies, have you observed any effects on medical equipment safety?

- Yes
- No
- Maybe

34. If yes, Which ones among these?

- Reduced rate of user errors
- Improved quality of service
- Improved patient safety
- Reduced maintenance costs
- Optimal patient satisfaction
- Effective and efficient performance of medical equipment
- Reduced downtime of medical equipment

35. Have you ever faced any incidents or issues related to medical equipment safety that can be associated with the lack of attachment to hospital policies?

- Yes
- No
- Maybe

36. Do you think the existing hospital policies adequately address potential risks associated with medical equipment?

Yes

No

Maybe

37. Do you feel confident that hospital policies are effectively communicated and understood by staff, in order to promote the safe use of medical equipment?

Yes

No

Maybe

38. Following the implementation of recent hospital policies, has there been a noticeable improvement in the overall performance and reliability of medical equipment?

Yes

No

Maybe

39. Does compliance with hospital policies have a measurable impact on reducing equipment-related incidents or errors?

Yes

No

Maybe

40. Do you believe that there is a need of additional training or resources to better align staff with hospital policies related to medical equipment?

Yes

No

Maybe

41. Are there any specific hospital policies that you believe could be enhanced to better ensure safety and performance of medical equipment?

Yes

No

Maybe

42. If yes, which one?

Enter your answer

43. What do you think can be done by medical equipment user to contribute to optimal performance of medical equipment?

Continuous education on medical equipment

Reading and following user manuals

Follow procedures for equipment setup, operation, and shutdown

Routine calibration and maintenance

Infection control

44. What factors among these do you think may influence policy review, validation, and update?

Technology and organization changes

Incident or audit findings

Policy effectiveness evaluation

Legal and compliance changes

Ethical considerations

Regular scheduled review period

45. At what time interval do you perform regular scheduled review of policies?

Quarterly

Bi-annually

Annually

46. What are the existing national policies dealing with medical equipment in your institution?

Health sector policy

Health sector research policy

Rwanda national health sector policy

Inspection tool

Ministerial instructions

47. What else do you think should be done to improve safety and performance of medical equipment?

Enter your answer

Appendix 2: Ethical Clearance



UNIVERSITY of
RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES
DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 28/12/2022

Ref: CMHS/IRB/610/2022

Vestine TUYISENGE
Masters of Biomedical Engineering,
College of Sciences and Technology, CEBE, UR

Dear Vestine TUYISENGE,

RE: ETHICAL CLEARANCE

Reference is made to your application for ethical clearance for the study entitled *“Effects of Health Technology Utilization Policies on Medical Equipment Safety and Performance”*

Having reviewed your application and been satisfied with your protocol, your study is hereby granted ethical clearance. The ethical clearance is valid for one year starting from the date it is issued and shall be renewed on request. You will be required to submit the progress report and any major changes made in the proposal during the implementation stage. In addition, at the end, the IRB shall need to be given the final report of your study.

We wish you success in this important study.


Assoc. Prof. Stefan Jansen (PhD)
Acting Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate studies, UR

Appendix 3. Kibuye Hospital approval letter

Kibuye, October 13, 2023

REPUBLIC OF RWANDA



WESTERN PROVINCE
KARONGI DISTRICT
KIBUYE REFERRAL HOSPITAL
BP: 44 KIBUYE
TEL: 0780442626
Email: kibuyereferralhospital53@gmail.com

To: TUYISENGE Vestine
Phone: 0783604588

Research Ethic Approval Notice

Dear Vestine,

Reference is made to your letter dated on 18th August 22, 2023 requesting the authorization to collect data as a part of your research topic entitled “**Effect of health technology utilization policy on medical equipment and performance**”. Furthermore, referencing to our accreditation procedures, after reviewing your pledge to ensure that all provided information will be used for academic purpose. And also, will be used in the strict to ethical principles and full respected, **approval has been granted to your topic work.**

You are required to present the result of your study in KRH Research Ethic Committee before publication

Please note that the present approval is valid for 6 months after receiving this letter.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Japhet'.

UKURIKIYINEZA Japhet



Chairperson, Research Ethic Committee

Cc:

- Director General, Kibuye referral hospital
- Clinical Director, Kibuye Referral Hospital
- Director of Nursing and Midwifery, Kibuye Referral Hospital
- Chairperson of Education Research committee
- Biomedical Technician

Appendix 4: King Faisal Hospital Approval letter



KING FAISAL HOSPITAL RWANDA INSTITUTIONAL REVIEW BOARD

Patient Centered Care

IRB Notification of Approval

Ref: KFH/2023/ 114/IRB

Date: March 20, 2024

Protocol Title: ASSESSMENT OF EFFECTS OF HOSPITAL POLICIES ON MEDICAL EQUIPMENT SAFETY AND PERFORMANCE.

Principal Investigator:

Vestine TUYISENGE **Email:** tuyivest@gmail.com

Protocol Reference #: KFH/2023/ 114/IRB

Date of IRB Initial Review: October 10, 2023

Review Type: Full Review

IRB Review Decision: **Approved**

Date of Effectiveness: March 20, 2024

Date of Expiry: March 19, 2025

Dear Vestine TUYISENGE,

King Faisal Hospital Rwanda's Institutional Review Board (KFH IRB) reviewed your protocol resubmission. This letter is to notify you that the KFH IRB approved your resubmission, and this approval is valid for one (1) year and then must be renewed according to the KFH IRB Standard Operating Procedures.

Please note the following considerations:

1. Please review the KFH IRB Standard Operating Procedures and ensure compliance with all requirements, including participant content, changes or amendments to the protocol, and reporting requirements.
2. All project materials, including signed consent forms, must be retained and are subject to review in case of a routine audit
3. Notify the KFH Directorate of Research once data collection is completed
4. The Principal Investigator is requested to submit a hard copy of his/her final manuscript to the Directorate of Research upon completion.
5. Principal Investigators must follow the appropriate study continuing review and closure procedures as indicated in the Standard Operating Procedures Manual.

Please contact us at irb@kfhkigali.com in case of any questions or clarifications.

Sincerely,

Dr. Jean Marie Vianney Dushimiyimana
Consultant ENT Surgeon
Chair, Institutional Review Board



Appendix 5: Butare University Teaching Hospital (CHUB) Approval Letter



chub.rw

CLINICAL EDUCATION AND RESEARCH DIVISION

Huye, November 16, 2023

RESEARCH DIRECTORATE: RESEARCH -ETHICS COMMITTEE

Approval Notice: No: REC/UTHB/097/2023

Dear Vestine Tuyisenge
Email: tuyinvest@gmail.com

Reference is made to your letter requesting for ethical clearance renew of your study entitled: " **Effect of Health Technology utilization policy on medical Equipment Safety and performance**"

Having reviewed your application and been satisfied with your protocol, your study is hereby granted ethical clearance renew and should be conducted within University Teaching Hospital of Butare. Please note that approval of the protocol and consent form is valid for one year starting on the issue date and shall be renewed on request. You are responsible to fulfilling the following requirements:

- Changes, amendments and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes
- Only approved consent forms are to be used in the enrollment of participants
- All consent forms signed by subjects should be retained on file. The committee may conduct audits of all study records. Consent documentation may be part of such audits
- A continuing review application must be submitted to the committee in a timely fashion and before expiry of this approval
- Failure to submit continuing review application result in termination of study
- Notify the committee once the study is finished
- Identification of participants must be kept confidential for the duration of the study

Sincerely

Dr. HABIMANA Emmanuel
Chairperson of Ethics Committee/CHUB

Cc: - Director General
- Head of Clinical Education and Research Division
- Head of Clinical Service Division
- Director of Research
- Director of Infrastructure and maintenance



Appendix 6: Ruhengeri Hospital Approval Letter

<p>REPUBLIC OF RWANDA</p>  <p>MINISTRY OF HEALTH</p>	<p>RUHENGERI LEVEL TWO TEACHING HOSPITAL Po.Box: 57, MUSANZE Website : rrh.gov.rw ruhengeri.hospital@moh.gov.rw</p>	<p>Client centered Service Integrity Teamwork Innovation</p>
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Musanze, 15 DEC 2023

Ref. 995/RL2TH/DG/2023

Vestine TUYISENGE
C/O UNIVERSITY OF RWANDA
Tele: 0783604588

Re: Your request for data Collection

Dear TUYISENGE;

Reference is made to your letter dated on 9th August , 2023 applying permission for data collection for the research project entitled “*Effects of health Technology Utilization policies on Medical Equipment safety and performance*”.

We have the pleasure to inform you that you are allowed to conduct the above mentioned research project .However you're obliged to have all the required equipments for use and the final project report will be shared with Ruhengeri Level II Teaching Hospital.

Best regards.


Dr MUHIRE Philbert
Director General of Ruhengeri Level Two Teaching Hospital

Cc:

-Chair of ethic committee

