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EVIDENCE-BASED MAINTENANCE APPROACH FOR MEDICAL EQUIPMENT IN RWANDA

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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 fulfillment of the requirements for the Master's Degree in Biomedical Engineering.

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DECLARATION

I, Raissa GATANGANWA, declare that this dissertation entitled "Evidence-based maintenance approach for medical equipment in Rwanda" 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 "Evidence-based maintenance approach for medical equipment in Rwanda" is a record of original work done by Raissa GATANGANWA (220020564), a MSc. Degree student in Biomedical Engineering.

This work has been submitted under the guidance of Eng. Jean NGOIE and Prof. Celestin TWIZERE

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ABSTRACT

Medical Equipment is essential for safe and effective patient care and has a significant impact on the financial viability and accreditation of healthcare organizations. Maintenance is a key component of medical equipment life cycle management. For this reason, equipment maintenance requires adequate planning, implementation, and monitoring. In Rwanda, healthcare organizations have a duty to reduce the cost and the dependency on external parties while ensuring that the medical equipment is safe, accurate, and operating at the required level of performance. The first objective of this work was to study medical equipment maintenance programs in Rwanda and evaluate if they comply with international standards for medical equipment maintenance programs. A questionnaire adapted from international standards was used to study the current maintenance procedures in Rwanda. Three data sources were hospital administration; the biomedical engineering department and end users. The results showed a low level of compliance with international standards regarding the availability of resources, procedures, and services. The second objective was to improve the Rwandan health care service delivery system by suggesting an evidence-based maintenance approach for planning, implementing, and monitoring medical equipment maintenance in Rwanda. Factors influencing effective maintenance planning, implementation and monitoring were reviewed. Therefore, an evidence-based approach has been proposed to support and enhance the management of medical equipment maintenance in Rwanda. Long-time solutions for medical equipment maintenance program strengthening involve availing physical resources (standardized workshops, testing, and maintenance tools), increasing the number of biomedical technicians and engineers, and enhancement of training programs. In addition, it will be critical to set a national policy for maintenance programs. These steps could produce a high impact on risk reduction and contribute to the allocation of available resources, especially in low- and middle-income countries (LMIC) such as Rwanda. This present finding should encourage ongoing research on factors that affect standards compliance and the correlation between those factors.

Keywords: Medical equipment; Maintenance; International standards; Quality Improvement

LIST OF ACRONYMS

BMET: Biomedical Engineering Technician

CE: Clinical Engineering

CHUB: University Teaching Hospital of Butare

CM: Corrective Maintenance

CMMS: Computerized Maintenance Management System

HTM: Healthcare Technology Management

ISO: International Standard Organization

JCAHO: Joint Commission on Accreditation of Health

LAN: Local Area Network

ME: Medical Equipment

MOH Ministry of Health

PDCA: Plan Do Check Act

PESTE: Political Economic Social Technology Legal Environment

RBC: Rwanda Biomedical Center

SPI: Safety and Performance Inspection

SWOT: Strengthens Weakness opportunity and Threats

WHO: World Health Organization

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CHAPTER 1. INTRODUCTION

Today's healthcare is highly dependent on various types of medical equipment to assist in the diagnosis, monitoring, and treatment of patients. It is impractical to provide healthcare services without these technologies as recognized by the World Health Organization (WHO)[1]. Despite the key role of medical equipment, numerous hospitals in low-income and middle-income countries (LMICs) experience considerable shortcomings with regards to medical equipment management. According to WHO, an estimated 50% of medical devices in LMICs are not functional, are used incorrectly, or are not maintained properly due to the absence of an effective management policy. Practical methods and powerful management strategies are required to meet these challenges[2].

The sustainability of medical equipment maintenance in government hospitals in LMICs is critical to delivering effective healthcare services and a Quality management system should be applied to optimize the proper management of medical equipment. Implications of failing medical equipment include wasting healthcare funds, delays in patient treatment, and poorer healthcare outcomes for patients[3].

The mission of Rwanda's Health Sector is to provide and continually improve affordable promotive, preventive, curative, and rehabilitative healthcare services of the highest quality. A broad range of medical equipment is essential in achieving this mission. According to the Ministry of Health Strategic Plan, special attention is needed for timely planning of effective implementation, and expansion of reliable maintenance systems that emphasize preventive maintenance. In addition, one of the priorities of the strategic plan of the Ministry of Health is to reinforce compliance with policies, laws, and regulations[4].

Rwanda is also promoting Medical Tourism and one of the key factors that will determine whether Rwanda succeeds in building medical tourism will be to develop world-class specialty health services[5]. The proper functioning and maintenance of medical equipment which follow international standards can contribute to the achievement of international accreditation of Rwanda's public hospitals and build trust with patients; this is essential in achieving this vision of Medical Tourism in Rwanda.

The Government of Rwanda spends about four (4) billions Rwandan francs per year purchasing medical equipment. Therefore, the maintenance of medical equipment must be efficient so that the equipment can reliably be used safely and appropriately; from this perspective, the

management of biomedical equipment requires appropriate planning, implementation, and monitoring processes. An evidence-based management approach is indispensable for providing quality health services while saving resources**.**[6]

Rwanda currently has different programs and plans as mentioned above which intend to increase the efficient delivery of healthcare services, however, Rwandan healthcare organizations still face constraints in delivering effective and timely maintenance of medical equipment.

Reviewing the existing studies, it is very important to have policies and procedures regarding medical equipment maintenance. This is the context of this research work, which intends to assess the current maintenance program of medical equipment and provide an evidence-based approach for developing and implementing medical equipment maintenance in a Rwandan healthcare organization and integrating a cost-effective decision for it.

1.1. Problem Statement

As in many LMIC countries, biomedical departments in Rwandan healthcare organizations are challenged with assuring the availability, efficiency, and safety of equipment as well as optimizing the use of available resources.

There is no national policy concerning medical equipment maintenance. As result, there is no proper program for medical equipment maintenance and management of medical equipment itself in most Rwandan hospitals.

Insufficient skills in biomedical departments and a shortage of Clinical Engineering Professionals (CEP) within hospitals can lead to ineffective procedures related to risk management, medical equipment maintenance programs and cost management.

1.2. Research questions

The following four (4) questions are the baselines which guided this study:

1. What are the current procedures for medical equipment maintenance management in Rwanda?

2. Do the current procedures for medical equipment maintenance in Rwandan public hospitals comply with international standards and guideline?

3. What are the factors affecting medical equipment maintenance in Rwandan public hospitals?

4. Are there any strategies or procedures for optimizing medical equipment maintenance Planning, implementation and monitoring?

1.3. Study Objectives

General Objective

The main objective of this work is to provide an evidence-based approach that will support and enhance the planning, implementation, and monitoring of medical equipment maintenance in Rwanda.

Specific Objectives

- Study biomedical equipment maintenance programs in hospitals and identify their level of compliance with international guidelines for medical equipment maintenance programs,
- Assess procedures, standards, and strategies to optimize the management of medical equipment maintenance in Rwandan healthcare organizations,
- Provide an evidence-based maintenance approach for medical equipment in Rwanda

1.4. Study Scope

Rwanda is divided into four (4) provinces (Northern, Southern, Western and Eastern provinces) plus Kigali city. Healthcare services in Rwanda are provided through the public sector, government-assisted health facilities, and private healthcare facilities. This study focuses on public facilities. The public sector is organized into different levels which are the central level, referral Hospitals, Provincial Hospitals, District Hospitals, and health centers. Rwanda Biomedical Center (RBC) and hospitals are targeted in this study. RBC was included because it is responsible for Healthcare Technology Management (HTM), supervision, and assistance in the engineering of healthcare infrastructure. This study targeted at least one hospital in each province, Hospitals were targeted because they have a large number of services compared to health centers, and they have a large number and varieties of medical equipment. Hospitals included one (1) teaching hospital as a national reference hospital whose mission is to provide quality healthcare services at the same time providing education and conducting research.

1.5. Significance of the Study

Medical equipment management includes compiling an inventory, conducting regular inspections, performing tests, and conducting preventative and corrective maintenance [7]. In Rwanda there is no internationally accredited public hospital; inefficient medical equipment management creates areas where there are gaps in compliance with international standards. This study quantifies the level of compliance for medical equipment maintenance in Rwandan public hospitals, which has not been done before. Furthermore, the study gathers different international standards and best practices regarding medical equipment maintenance. This study sheds a light on the factors affecting medical equipment maintenance and includes evidence-based suggestions for optimizing medical equipment maintenance in Rwandan public hospitals.

1.6. Organization of the Study

The study report starts with an abstract that summarizes the study, followed by five chapters. The introductory chapter provides background and the motivation of the study, outlines the problem statement, the main and specific objectives, the study hypothesis, and the scope of the study, and concludes with a justification for this research. Chapter two is an in-depth literature review on medical equipment maintenance from a global perspective, and an African perspective and delves into the particular context of the study. The literature review also includes medical equipment international standards and best practices, which this study adapts. The third chapter gives details of the study methods from setting and design, to data collection tools and procedures, and the steps taken for data management and analysis. It also includes the challenges and limitations of this study. In chapter four of the report, all results from data analysis are presented and displayed graphically. It also includes a discussion of the results to highlight the major findings and the outputs of the study. Chapter five provides a summary of conclusions drawn from the study and, most importantly, recommendations to address the discussed issues as well as opportunities for further research.

CHAPTER 2. LITERATURE REVIEW

2.1. Introduction

Maintenance is a key part of overall medical equipment management estimated to cost between 5% and 10% of the purchase cost of equipment year [7]. Across the world, the lacks of continual and systematic medical equipment maintenance continues to indicate gaps in the healthcare system. Consequently, healthcare organizations are likely to waste precious capital resources, increase operational expenditures, reduce patient throughput, and increase unnecessary risks to users and patients and these concerns are changing the attitude of Governments towards medical equipment management which intends to its optimization [8]. The promotion and increase of the productivity and quality of biomedical resources are essential for the success of any healthcare organization because they reduce patient dissatisfaction, facilitate timely patient treatment, reduce risks and mortality during patient care, and reduce dispatch costs.

The proper management of maintenance is a well-planned and implemented program that hospitals can minimize breakdowns of medical equipment. This is specifically very important in developing countries for providing quality healthcare services as well as managing limited resources [9]. Financial management, operational management, personnel management, performance improvement, and performance monitoring are aspects recommended by WHO that should be addressed for proper management of the maintenance program. The performance improvements include identifying the areas of improvement which is the outcome of performance monitoring; identifying best practices and improving performance based on best practices [10]. Despite the role of proper maintenance, the potential to manage and maintain medical equipment in most LMICs remains weak. For instance, higher rates of medical equipment failures are associated with a lack of information about the assessment and planning of medical equipment decisions [2].

Today, Medical equipment maintenance is under the responsibility of the Clinical and Biomedical Engineering (CE/BME) department. This department is also responsible for healthcare asset management and healthcare technology assessment, clinical staff safety, risk, and safety management, and also contrast monitoring and quality improvement[11].

2.2. Definition of medical equipment maintenance

In 2011, The World Health Organization (WHO) cited three major maintenance strategies:

2.2.1. Safety and Performance Inspection (SPI)

The inspection includes the performance and safety inspection, the performance inspections ensure that the equipment works properly within the limits set by the manufacturer or according to the standards in force for that type of equipment. The safety inspection ensures that both patients and users are safe.

2.2.2. Preventive Maintenance (PM)

PM targets to extend the life of the equipment and reduce failure rates, According to C. W. Gits preventive maintenance is potentially effective if it results in lowering the failure rate. Some hidden issues can be easily detected during the scheduled inspection [12], [13].

2.2.3. Corrective Maintenance (CM)

Electrical and mechanical components can be damaged at any time. (CM) restores the operation of a defective device and allows it to be put back into operation in optimal parameters[13].

Recently in 2021, Corciova et al cited another category of medical equipment maintenance that is currently used in practice, ***Design-out maintenance*** defined as an aspect of medical equipment maintenance that consists of improving the operation, reliability, or capacity of the equipment in place. Practically it involves studies, construction, installation, start-up, and tuning. it is also named plant improvement maintenance[13].

2.3. Key standards Relevant to Medical equipment maintenance

Standards are defined as documents that set out best practices and minimum performance criteria of a device or a system; they cover detailed specifications of a device and management processes. Hence, standards help assure quality, safety, and functionality. ISO 55000, a standard that focuses on asset management, requires healthcare organizations to plan how preventive and corrective work should be carried out and adherence to any standard [14].

2.3.1. Quality management system

K. Willson et al. defined quality as how well an organization's services or products meet user needs; an organization can assure quality to their customers in two steps. To begin with, define a set of quality standards that demonstrate their commitment to meeting customer requirements. This includes regular review of needs, monitoring performance and compliance with internal and external standards, providing an appropriate environment, and taking preventive and correction

actions. In addition, the organization should provide an integrated document that contains policies and procedures to work with to deliver a service to the agreed standard [7].

For continuous improvement of healthcare organizations different quality systems such as ISO 9001, ISO 13485, and Six Sigma, have been proposed for quality management systems that can be used by an organization involved in one or more stages of the life cycle of medical equipment including maintenance services.

According to ISO 13485 Elaborated in 2016 devices- quality management systems requirements for a regulatory purpose, the healthcare organization is required to identify and implement any change necessary to ensure and maintain the continued suitability, adequacy, and effectiveness of the quality management system as well as medical devices safety through the use of the [15]:

- The quality policy includes the establishment of quality policies and communicating them
- Quality planning includes quality objectives and plans for achieving them, Actions to address risks and opportunities, and planning of changes.
- Determine criteria and methods needed to ensure process execution and effectiveness of process management
- Monitoring, measurement of resources, and evaluation performance mean.

ISO 9001 set out a generic quality system standard applicable to all equipment management processes including medical equipment maintenance. It promotes the process approach that includes the Plan-Do-Check-Act (PDCA) cycle shown in Figure 2.1 and risk-based thinking. In medical equipment maintenance processes, the PDCA cycle allows the biomedical department to ensure that its processes are effectively resourced and managed, and the opportunities for improvement are identified and acted on. Risk-based thinking allows us to determine the factors that could cause the processes and quality management system to deviate from the planned results and to put in place mitigation measures[16].

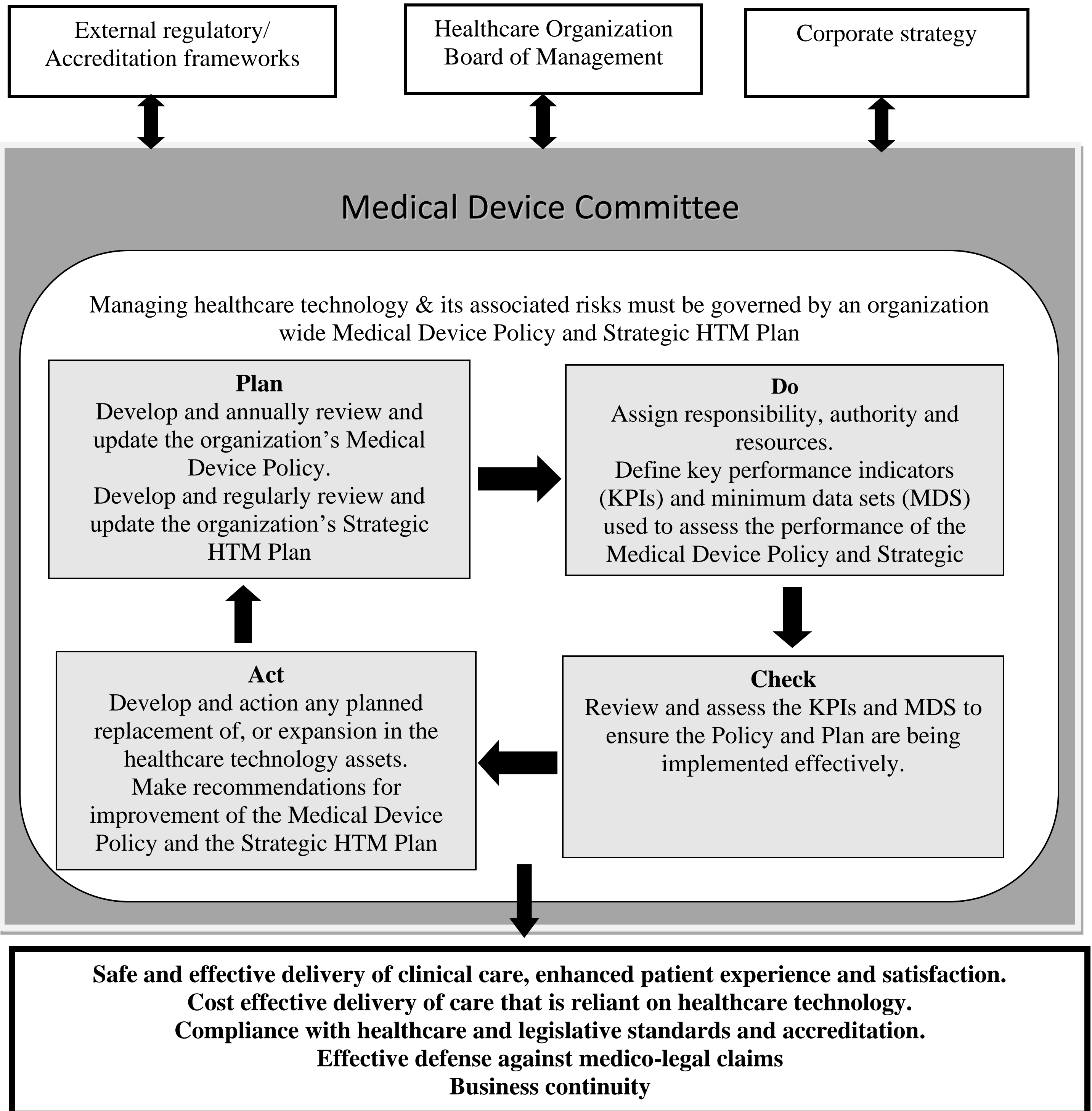

Figure 2.1. PDCA cycle

2.3.2. Quality control and performance testing

Performance testing can be defined as providing objective evidence that medical equipment fulfills the manufacturer's specifications which includes the accuracy, precision, and other qualities of the equipment that allows it to meet the requirements of its intended use.

Performance testing can help to decide if the equipment can continue to be used and can identify equipment that needs attention before being used again. During performance testing, variables that can lead to medical equipment failure can be detected and therefore preventive maintenance is performed to insure the reliability of the equipment. Performance testing after maintenance has fundamental importance [7].

According to the American standard of medical device risk management, the organization must ensure that medical equipment safety and performance are constantly maintained. Some of the tests which apply to medical equipment required by the American standard are specifically to check for risk hazards such as electrical shock and fire; this may include the inspections of power mains supply; measuring the ground, patient, and earth leakage current and mains contact current [17].

2.4. Practical Approach and Best Practice for medical equipment maintenance

2.4.1. Medical equipment maintenance Planning

In 2004, when the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) one of the major driving forces for the practice of clinical engineering (CE) introduced the medical equipment management accreditation standard, the hospitals were required to identify suitable inspection and maintenance strategies for all equipment in their inventory for achieving effective, safe, and reliable operation [18]. The challenges with this are to find the appropriate strategy to care for each piece of equipment and the man power to accomplish this level of effort[8][10]. In 2006, JCAHO reviewed the standard and made a cost-effective improvement in allowing hospitals to plan inspection and maintenance tasks based on patient risk and mission criticality [18]. This means that the modern approach to medical equipment maintenance comprises periodic inspection procedures to which preventive maintenance (PM) and corrective maintenance (CM) are added when necessary [13].

Table 2.1. Maintenance program inclusion criteria

		Patient Risks		
		High	Medium	Low
Mission criticality	Critical	Include	Include	Include
	Important	Include	Optional	Exclude
	Necessary	Include	Exclude	Exclude

2.4.2. Medical equipment maintenance Implementation

After the selection of the inclusion model most appropriate to each type of equipment, the next challenge is to determine the appropriate maintenance implementation strategies for the included equipment. The implementation requires different types of resources: 1) Human resources which include enough skilled staff; 2) financial resources to purchase maintenance and replacement parts; 3) Physical (material) resources which include physical space, workbenches, test and measurement tools, necessary to perform the inspections, preventive maintenance, and collective maintenance; 4) documentation which includes operating and service manuals, software programs, parts lists, electronic and mechanical drawings. This is valuable for both users and biomedical technicians. WHO recommends that each hospital determine during the planning and found all resources which will be required to operate its clinical department to achieve a level of service that meets the standards[8][10].

According to B. Wang, Practical approach for planned maintenance can be implemented in two (2) types of tasks: proactive and reactive. The first type includes planned replacement, predictive (or on-condition) maintenance, and planned discard. The second type includes failure-finding tasks, recalibration, and redesign.

According to K. Willson et al. the maintenance is carried out by in-house services and external services (manufacturer or third party). The decision of choosing which service is required for equipment and how it will be provided requires regular attention to maintenance efficiency, cost-effective maintenance, risk reduction, and the increased uptime of medical equipment [7]. It is very essential to monitor the performance of service providers[10]

2.4.3. Medical equipment maintenance and effective monitoring

According to WHO, monitoring equipment performance to identify opportunities for improvement is essential for assuring the effective management of maintenance programs [10]. Maintenance is not only the attribution of the Biomedical Engineering unit or Clinical Engineering (CE) department; overall monitoring of the department's performance is needed for improvement. To monitor the overall department a set of key performance indicators should be defined and data should be collected for these indicators[13].

CE department can be monitored in four (4) dimensions: Operational performance, staff learning and growth, user perspective, and financial performance. For each dimension, a performance indicator should be established and monitored. In Operation performance, process indicators

such as preventive maintenance completion rate, average time for reparation, etc., are used to measure the implementation of CE department service strategies. In financial performance, indicators such as ownership costs; management costs; service contracts cost as a percentage of total costs, etc. are used to measure CE department efficiency. From the user perspective, several indicators such as uptime, failure rate, patient incidents, the average time between failures, turnaround time, and the average time for reparation, etc. are used the effectiveness of CE service. Finally in staff learning and growth, indicators such as staff holding rate and employee satisfaction score are used to measure staff motivation and growth potential[8] [19].

According to Wang Insufficiencies detected by indictors should be analyzed carefully to determine their root causes, so appropriate actions can be taken to correct the problem and avoid future reoccurrence. Although correcting and preventing deficiencies is essential for continual improvement, it is not enough. It is necessary to disclose issues that are not being monitored. This requires periodic discussions which involve all stakeholders such as clinical users, administrations, finance, and support departments as well as learning from other hospitals. These can help to add other needed indicators or to remove unnecessary ones for better improvement[8].

Practically, for many years maintenance monitoring focuses on the completion of planned maintenance because it is required by the accreditation organization. It doesn’t provide areas for improvement. On the other side, clinical engineering departments record every part of failure and corrective action taken; such records are useful for manufacturers to determine reliable components and for the clinical department to identify stock parts. However, it does not help in identifying strategies to improve maintenance programs. Therefore, there is a need to better understand better the identified failures of medical equipment; their respective causes, and the potential solutions. Global failure codes that can be used to facilitate the identification of best opportunities for improvement are illustrated in the table below [8].

Table 2.2. Failure codes adopted for monitoring maintenance effectiveness

Source	Activity	Code	Code definitions
Equipment	Corrective Maintenance (CM)	UPF	Unpreventable failure, evident to the user, is typically caused by normal wear and tear but is unpredictable.
		PPF	Preventable and predictable failure, evident to the user, typically caused by wear and tear that can be predicted or detected.
		USE	Failures induced by use, e.g., abuse, abnormal wear & tear, accident, or environment issues.
		SIF	Service-induced failure, i.e., failure induced by corrective or scheduled maintenance that was not properly completed or a part that was replaced and had a premature failure
	Planned Maintenance (PM)	PF	Potential failure, i.e., failure is either about to occur or in the process of occurring but has not yet caused equipment to stop working or problems for patients or users.
		EF	Evident failure, i.e., a problem that can be detected but was not reported by the user without running any special tests or using specialized test/measurement equipment.
		HF	Hidden failure, i.e., a problem that could not be detected by the user unless running a special test or using specialized test/measurement equipment.
	CM and PM	NPF	No problem found, including alleged failures that could not be duplicated (''cannot duplicate'' [CND])
Accessories & Network	CM or PM	BATT	ATT Battery failure, ie, battery failed before the scheduled replacement time
		ACC	Other accessory failures, excluding batteries, evident to the user, typically caused by normal wear and tear
		NET	Failure in or caused by network, while the equipment itself is working without problems. Applicable only to networked equipment.

All these failure codes are useful for detailed analysis, but they might be burdensome to the clinical department. For this reason, they can be reduced to three (3) groups as shown in table 2.3 depending on actions that must be taken by the Clinical engineering (CE) department. The first group is direct, which includes actions handled by the CE department without support from others. The second group is indirect which includes actions that can be handled by CE in collaboration with others. The third one is the future which includes actions that can be taken by CE but will have an impact only in the future[20].

Table2.3. Failure codes grouping

Failure code	**Action taken by CE**	**Group**
NPF	None	
UPF	Advise purchasing	Future
ACC	Guide users and purchasing	Indirect
BATT	Guide users and purchasing	Indirect
USE	Guide users and facilities	Indirect
EF	Guide users	Indirect
SIF	Educate staff and advise the original manufacturer	Direct
HF	Review PM program	Direct
PF	Review PM program	Direct
PPF	Review PM program	Direct

2.5. Common factors affecting medical equipment maintenance management in LMICs

2.5.1. Resources Management

2.5.1.1. Physical resources

Maintenance management depends on several physical resources. These include workspace, tools and test equipment, supplies, replacement parts, and operation and service manuals needed to perform maintenance activities. Workspace is one of the main factors in medical equipment maintenance. Various tools and test equipment necessary to perform maintenance activities are also an issue[9][21].

According to the Health Building note which guides the accommodation required for the maintenance of health care buildings and equipment and the operation of engineering services within the Hospital; the provision of a suitable workshop within the hospital estate is necessary to prevent hazardous situations arising during maintenance operations. The workshop should be equipped with specialized test equipment and supplies for the equipment it is expected to maintain; separated areas for storage; a ventilation system; temperature controls for effective calibration; adequate voltage; Changing rooms and toilets among others[22].

2.5.1.2. Human resources

In 2015, the WHO assessed the availability of professional biomedical engineers (BME) by country. According to the findings, the lowest number of biomedical engineers occurred in LMICs, this shows the need for the promotion of educational programs for biomedical engineers in developing health systems [23].

Md. Anwar et al, have identified the shortfall in healthcare technology management (HTM) due to the absence of skilled clinical engineers and biomedical engineering scientists in developing countries, this affects the proper implementation of health technology management. To ensure a safe healthcare system, there is a necessity of understanding the need and the benefit of introducing well-skilled clinical engineers in hospitals for the improvement of health care services [24].

In addition to the introduction of well-skilled human resources in healthcare facilities, Personnel management is also essential to achieve the program objectives. The personnel should be qualified for the assignments [10]. Typically the CE should have at least an associate's degree in electronics or biomedical technology and desirable to have a bachelor's degree for managers[8]. The most important aspect of personnel management is the ability to ensure adequate training to ensure that technical personnel as well as clinical users are trained and informed on their responsibilities. The best approach to training is to use a combination of techniques matched to the needs of users and clinical staff, with a frequent assessment of progress. Training records should be kept of the outcome of any competence assessment[7]

The human resources management also includes the monitoring services contractors when maintenance is outsourced. Wang reported that the estimated cost of outsourced services is often 50% or more of the hospital's total expenditure on medical equipment maintenance and

management. Therefore it should be well managed in terms of choosing which type of service to be adopted, evaluating the performance of service providers as well as reviewing business relationships [8]

2.5.1.3. Financial Resources

One of the major challenges faced by the CE/Biomedical engineering department is to have detailed control over the finances. The CE manager should not only control the budget for the department but have oversight of all expenses related to the maintenance and management of all medical equipment. The approach for managing financial resources for maintenance should focus on two tasks: monitoring costs and managing the budget. Furthermore, a maintenance program is required for financial planning where the costs and benefits of the current situation and the new proposal can be compared. Therefore, the recording of all expenses associated with maintaining each medical equipment and the hospital's policies for maintenance budget allocations are essential[21].

2.5.2. Documentation Management

In the CE department, formal documentation of policies and procedures has low priority and is even neglected. This is due to CE staff that are normally strong in technical expertise and less skilled with administrative responsibilities and it's time-consuming [8]. Unfortunately, the lack of proper documentation leads to inconsistent implementation and unpredictable outcomes[21].

The practical approach to documentation is done in (4) ways. The first way is providing ME identity (ID); this includes information about the equipment such as specifications, warranty status, service installations, acceptance tests, preventive maintenance, calibration, etc. The second one is the use of local and global evidence which is the constant communication with scientific standard references to be to be informed on international standards and be up to date in the field of medical equipment. The third one is providing a user manual which includes the labeling and operation manuals for each model of ME. The last one is recording executive processes (work order records) that provide documentation of every maintenance task performed on the device; it also includes costs associated with repairs, installation, and calibration[8][21].

2.5.3. Computerized Maintenance Management System (CMMS)

According to WHO, accurate and updated documentation can be achieved through Computerized Maintenance Management System (CMMS) a software tool used by CE departments to manage and maintain equipment inventory, schedule service, record repairs, keep

service records, track expenditures, and produce reports[10]. Ideally, CMMS should be able to help users and CE staff access the information and produce reports. Thereby helping the hospital comply with regulations, codes, and standards[8].

Although CMMS is indispensable for ME maintenance, its usage in not well implemented in developing countries due to several factors such as lack of specialized healthcare staff and specialized personnel for the maintenance of ME; severe problems in the supply chain; absence of strong local regulations and control functions, CMMSs are often designed by international companies that may follow a significantly different standard, a large number of donated ME generating a limited sense of responsibility for its maintenance and limited internet access and unreliable LANs among others [25]

Several other factors affect medical equipment maintenance, and those factors are related to quality management standards and quality control standards. As a result of all factors affecting ME maintenance, many in LMICs fall far behind on the number of maintenance tasks performed when compared to what the need is. A study surveyed the medical equipment management systems in LMICs and demonstrated that 60 % of medical equipment cannot be used for different reasons. Therefore, the consideration of the factors affecting maintenance management is necessary for reducing costs as well as decreasing amortization and failure of ME and disorder in the treatment of patients[9][21].

2.6. Medical equipment maintenance in the context of Rwanda

According to the WHO 2015 survey, Rwanda had a presence of BME professionals less than one (1) per million people [23]. Recently, the Global atlas of medical devices 2022 showed that the number of biomedical increased to 15 biomedical engineers in the country. The survey shows that there is no national policy on health technology and also no national health technology assessment unit[26]. This creates gaps in the management of medical equipment through its life cycle, notably its maintenance

According to a study Robert et al. most BME professionals available in Rwandan hospitals have an advanced high school education; it is rare to find BME professional who has formal education beyond high school in hospitals. Additionally, the BME department suffers from a lack of financial resources, a lack of spare parts and service manuals for donated equipment, and a lack

of English-language proficiency which limit the ability of BMET to join forums, attend conferences, and otherwise improve their ability to participate in the BMET community [27].

2.7. Summary

Numerous standards and best practices to optimize the management of medical equipment maintenance have been cited in the literature, however many hospitals and health care organizations in Rwanda do not benefit from them, one of the causes is the lack of specific tools to plan, implement and assess medical equipment maintenance in Rwandan healthcare organizations. Accordingly, the development of an evidence-based approach for medical equipment maintenance in Rwanda will help Rwandan healthcare organizations to benefit from maintenance excellence.

CHAPTER 3. METHODOLOGY

3.1. Introduction

This chapter provides the systematic method used in this study, it includes the processes and tools used in data collection, data management, and data analysis. It also includes the limitations encountered during this study. Methods of qualitative research were used in this research.

3.2. Research Process

In order to study current maintenance procedures in Rwanda, a questionnaire was used to gather data from study participants. Three data sources were used in this research. The first source was the hospital administration; Hospital administration was involved as they are in charge of ME procurement, research, and quality improvement as well as accreditation. The second source was the biomedical engineering department, a department that is directly involved in medical equipment maintenance. The third source was clinical staff; they were involved as users of medical equipment. The questionnaire was directed to these three data sources. The questionnaire was adapted from International Standards.

3.2.1. Data collection procedures

For the Biomedical engineering department staff, the researcher sought email contacts for biomedical engineers and biomedical technicians in Rwanda biomedical council. For Administration and clinical care staff, the researcher sought authorization from The University Teaching Hospital of Butare (CHUB) and Kigeme district hospital from the southern province; Gahini district hospital from the eastern province; Kibuye referral hospital from the western province and Ruhengeri referral hospital from Northern Province. Microsoft team forms were used to administer the survey and store collected data. All participants were contacted via e-mail. The email included the introduction of the researcher; explanations about the study and a link that contains the questionnaire.

3.2.2. Sampling

Purposive sampling was used to conduct this study and was continued until the saturation point was reached. Participants were selected from different hospitals. The inclusion criteria were:

1. All Biomedical Engineer and Technician for biomedical department staff

2. Nurses, anesthesiologists, lab technicians and scientists, radiologists, general practitioners, and specialists who use different medical equipment and are in charge of unit or head of department for clinical care staff
3. Service providers who work in the Quality department, research and education department, Procurement department, and unit Directors for administration staff.

3.2.3. Data collection tools

The questionnaire was developed with two main sections. The first inquired about information related to how the ME maintenance program is done and its fulfillment of international standards and the second section explored the opinions of the respondents on solutions to enhance the medical equipment maintenance program. The questionnaire was pretested with 2 colleagues who are also biomedical staff and 2 supervisors and was piloted with 2 clinical care staff and 1 administration staff who did not participate in the study. Further modifications were made based on the feedback from piloting. Moreover, the researcher received assistance from research supervisors to ensure adequate study design and data quality.

3.2.4. Measures

Six (6) measures were included in this study

1. Resources: The availability of physical resources (workshops, tools, etc.) and human resources
2. Quality control: safety and performance testing; adjustment and calibration
3. Documentation: Recording processes and providing user manual and service manuals
4. Quality management: the availability of policy; Planning; implementation management and the assessment
5. Education services: Training

3.3. Data management

Data was collected using a survey through Microsoft Forms. Data collected was downloaded in excel format and only the research and research advisors had access to the data. After downloading raw data on excel, a clean-up process followed, after which data was uploaded to SPSS for analysis.

3.4. Data Analysis

SPSS version 21.0 was used to summarize key measures and for better analysis cross-tabulation data analysis was used. Furthermore, PESTLE analysis (Political Economic Social Technological Legal Environment) was used to study the environment under which medical equipment maintenance in Rwanda is. SWOT analysis (Strengths, Weaknesses, Opportunities, and Threats) was used to assess the performance, risk, and potential of the medical equipment maintenance program in Rwanda. Opportunities and strengths were explored; it also helped to explore weaknesses and threats to identify potential detractors and other factors that harm medical equipment maintenance in Rwanda.

For visually brainstorm, organization, and presentation of all ideas during this study, Xmind mind mapping software was used.

3.4. Research design Method

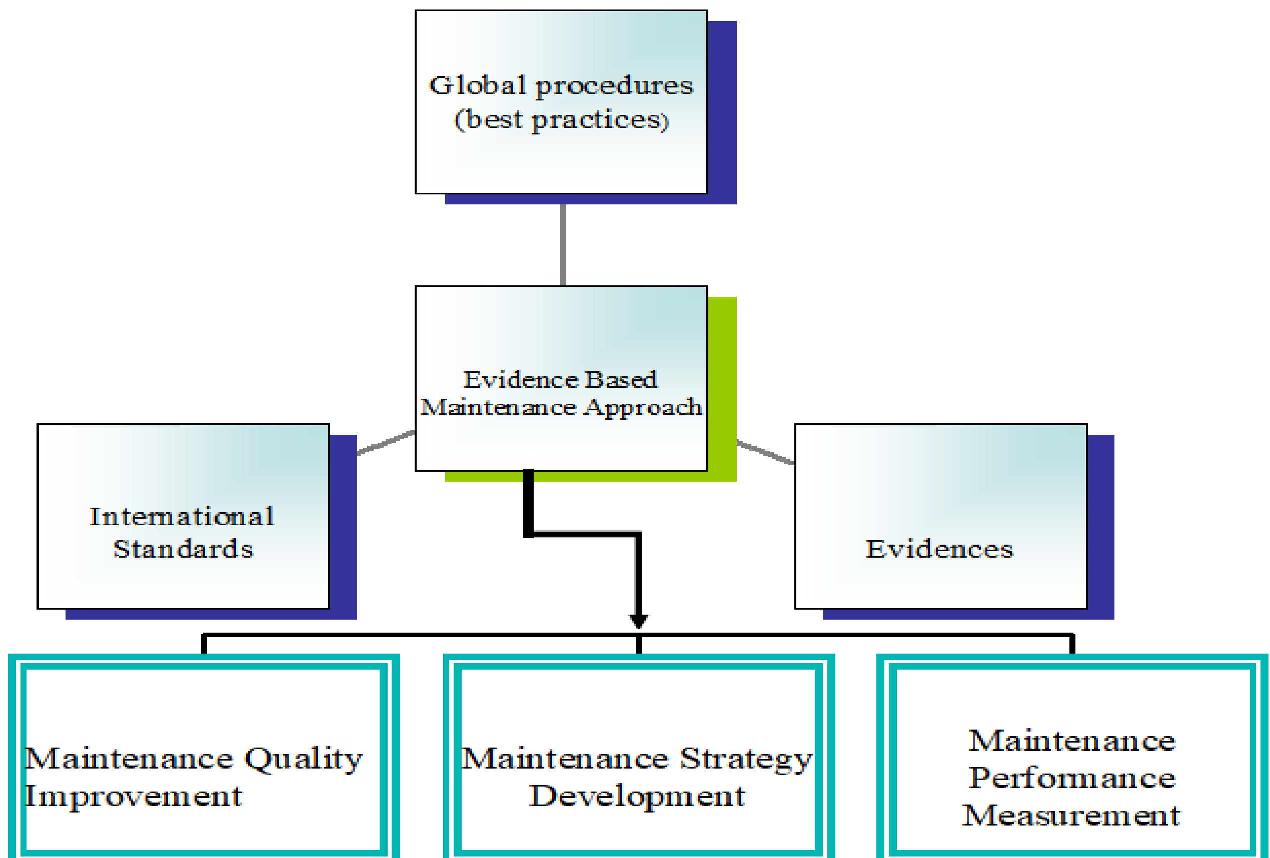

Figure3.1. Maintenance approach block diagram

Figure3.1. is a block diagram showing the design of the study it shows that the evidence-based approach maintenance uses the collected evidence, international standards, and best practices as inputs and from them, it suggests maintenance quality improvement and maintenance strategy development as well as maintenance performance as outputs of the approach.

3.5. Limitations of the study

- The data in this study come from different stakeholders in the management of medical equipment from geographically diverse hospitals and different hospital levels that add validity to its conclusions. However, it is highly dependent on hospitals' staff opinions. The participation from policy maker's institutions was very low.
- Some of the designated hospitals did not participate in this study due to delay in obtaining ethical clearance.

3.6. Summary

During this research qualitative methods were used because they offer a comprehensive and complete picture of different aspects of maintenance, here the selection of respondents was done in a way of not just finding people willing to participate in the research but finding people who are most informed on medical equipment management and whose responses are more useful to this research, it focuses on relevant information rather than focusing on numbers and equations.

CHAPTER 4. RESULTS AND DISCUSSION

4.1. Introduction

This chapter contains three (3) sections. The first section is a description of the main findings of this study; it includes variables and statistical analyses. The second section is a discussion that interprets the results and relates them to the research questions. The last section is the suggested approach delivered according to the findings of the research.

4.2. Qualitative results

The findings are presented in the form of texts to explain research data, in form of tables to represent exact values of data, and in form of figures to display relationships between variables. Findings are grouped according to the measures including quality management; resources, quality control, documentation, and education.

Information from 81 participants was collected from different departments in different hospitals over the course of one month. The participants were biomedical technicians (25.9%, n=21); biomedical engineers (2.5%, n=2); Clinician care staff (51.9%, n=42); Hospital Administrators (16%, n=13), and others like ICT staff; internal auditors and professional interns (3%, n=3). Individuals in the district, provincial, referral hospitals, and RBC represented 45.7% (n=37), 1.2% (n=1), 51.9% (n=42), and 1.2 %(n=1) respectively.

4.2.1. Quality management

The majority of respondents confirmed following a maintenance policy/guideline (93.8%); the majority also confirmed that the guidelines are institutional policies (55.6%, n=45). The majority of participants confirmed having the maintenance plan for all equipment (67.9%, n=55) but only 60.5% confirmed that the plan is communicated to all it may concern; the others revealed that it is not communicated or they don't know. The majority of participants conformity that preventive maintenance is a priority 74.1 %(n=60) but also the majority revealed that preventive maintenance is developed but not implemented correctly 51.9% (n=42). In quality management improvement the availability of a good development maintenance program assessment form was analyzed and 43.2% (n=35) reported having a maintenance program assessment form.

The majority of respondents scored the level of the required estimated budget and the calculations of cost-benefit of medical equipment maintenance are performed within hospitals at a medium level (35.8%, n=29) and other several respondents scored it at a low level.

Table 4.1. Descriptive statistics for quality management

SN	Variables	Frequency	Percent	Cumulative Percent
Following a policy				
1	Yes	76	93.8	93.8
2	No	2	2.5	96.3
3	I don't know	3	3.7	100
Policy owner				
1	Institutional Policy /guideline	45	55.6	60.8
2	National Policy/guideline	23	28.4	91.9
3	International Policy/guideline	6	7.4	100
Having maintenance plan				
1	No plans for any medical equipment maintenance activities	3	3.7	3.7
2	There are plans for some medical equipment maintenance activities	23	28.4	32.1
3	There are plans for all medical equipment maintenance activities	55	67.9	100
Confirming the priority of preventive maintenance				
1	Yes	60	74.1	74.1
2	No	11	13.6	87.7
3	I don't know	10	12.3	100
Preventive maintenance implementation				
1	The preventive maintenance plan is not developed	5	6.2	6.2
2	Preventive maintenance is developed but not implemented correctly	42	51.9	58

3	The preventive maintenance plan is developed and implemented correctly	34	42	100
Having maintenance program assessment form				
1	Yes	35	43.2	56.5
2	No	32	39.5	77.4
3	I don't know	14	17.3	100
Maintenance Budget and benefit calculations				
1	1 for lowest	8	9.9	10.3
2	2 for low	18	22.2	33.3
3	3 for medium	29	35.8	70.5
4	4 for high	14	17.3	88.5
5	5 for highest	9	11.1	100

4.2.2. Physical and Human resources

The availability of human resources and physical resources of maintenance such as workshops and the levels of commonly needed spare parts and maintenance tools for both preventive and corrective maintenance, safety and performance testing tools, and other facilities such as computers, software, etc. were analyzed. The majority of respondents 66.7% (n=54) reported that the dedicated area for maintenance (workshops) was not standardized and according to the results few respondents are comfortable with the availability of maintenance and testing tools as well as spare parts and other accessories.

Table 4.2. Descriptive statistics for resources

SN	Variables	Frequency	Percent	Cumulative Percent
Availability of standardized maintenance workshop				
1	Yes	27	33.3	33.3
2	No	54	66.7	100
Levels of availability of maintenance tools and testing tools				
1	1 for lowest	17	21	21.8
2	2 for low	11	13.6	35.9
3	3 for medium	28	34.6	71.8
4	4 for high	16	19.8	92.3
5	5 for highest	6	7.4	100
Levels of availability of common needed spare parts and accessories				
1	1 for lowest	15	18.5	19
2	2 for low	13	16	35.4
3	3 for medium	25	30.9	67.1
4	4 for high	16	19.8	87.3
5	5 for highest	10	12.3	100
Availability of qualified personnel for ME equipment maintenance management				
1	1 for lowest	6	7.4	7.6
2	2 for low	9	11.1	19
3	3 for medium	42	51.9	72.2
4	4 for high	16	19.8	92.4
5	5 for highest	6	7.4	100

Table 4.3. Cross-tabulation analysis on the availability of workshop

SN	Professional of respondent	Choices		Total
		Yes	No	
1	Hospital Administrator (Director of unit, Procurement, quality management etc.)	8	5	13
2	Biomedical Engineer	1	1	2
3	Biomedical Technician	5	16	21
4	Clinician care staff (general practitioners, specialists, nurse, radiologist, lab technician and scientist, etc.)	12	30	42
5	Other	1	2	3
		27	54	81

Table 4.4. Cross-tabulation analysis on availability of maintenance and testing tools

SN	Professional of respondents	Levels				
		1 for lowest	**2 for low**	**3 for medium**	**4 for high**	**5 for highest**
1	Hospital Administrator (Director of the unit, Procurement, quality management, etc.)	0	1	8	4	0
2	Biomedical Engineer	0	0	2	0	0
3	Biomedical Technician	6	1	4	5	3
4	Clinician care staff (general practitioners, specialists, nurses, radiologists, lab technicians, scientists, etc.)	10	9	14	6	2
5	Other	1	0	0	1	1
		17	**11**	**28**	**16**	**6**

Table 4.3 summarizes the distribution of responses of respondents' professional roles and the availability of standardized maintenance workshops. According to the results, 8 out of 13

hospital administrator respondents confirmed that the workshop is standardized but on the other side, 16 out of 21 biomedical technicians, 1 out of 2 biomedical engineers, and 30 out of 42 clinician care staff biomedical engineers reported that the workshop was not standardized.

Table4.4. summarize the distribution of responses of respondents' professional roles and the availability of maintenance and testing tools. The results show that the big number of respondents who think that the level of availability of maintenance and testing tools is low is under medical equipment users and biomedical technicians.

Table 4.5. Cross-tabulation analysis on availability of common needed spare parts and accessories

SN		Levels				
		1 for lowest	**2 for low**	**3 for medium**	**4 for high**	**5 for highest**
1	Hospital Administrator (Director of unit, Procurement, quality management etc.)	1	2	6	3	1
2	Biomedical Engineer	0	0	0	2	0
3	Biomedical Technician	4	5	4	3	5
4	Clinician care staff (general practitioners, specialists, nurse, radiologist, lab technician and scientist, etc.)	9	6	14	7	4
5	Other	1	0	1	1	0
		15	**13**	**25**	**16**	**10**

Table4.5. summarize the distribution of responses of respondents' professional roles and the availability of maintenance and testing tools. The results show that the big number of respondents who think that the level of availability of commonly needed spare parts and accessories is low is under medical equipment users and biomedical technicians.

4.2.3. Quality control

Figure4.1. summarizes the performance of medical equipment testing and calibration. The majority of respondents (43%, n=35) reported that it was not performed according to regulations,

16% (n=13) of respondents didn't know if it was performed and 41 %(n=33) of respondents confirmed that it was performed according to regulations

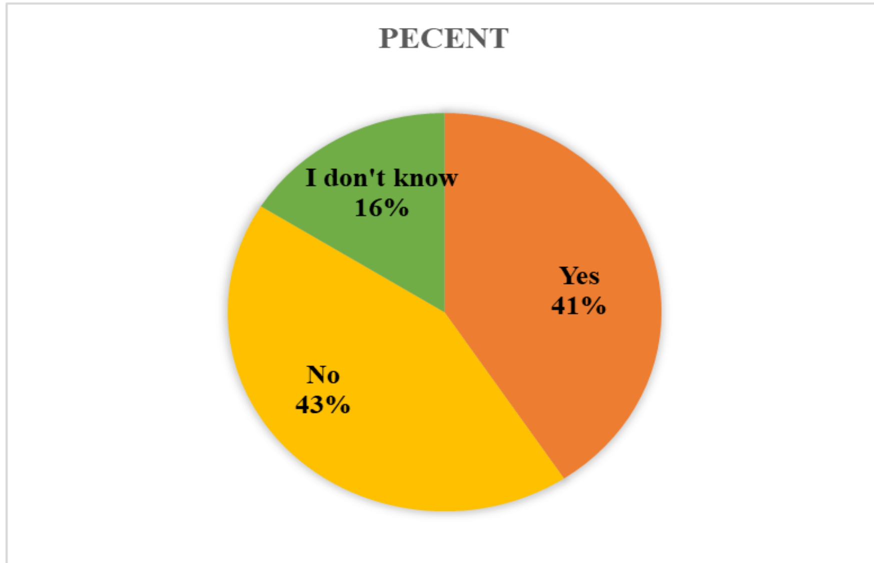

Figure4.1. Performance of quality control

4.2.4. Outsourcing management (private management)

The management of outsourcing performance on behalf of the hospital and central level was analyzed.

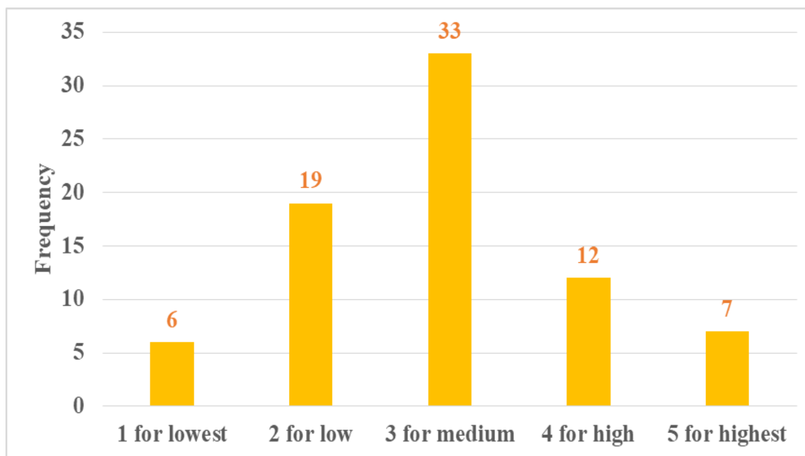

Figure 4.2. Hospital's management levels

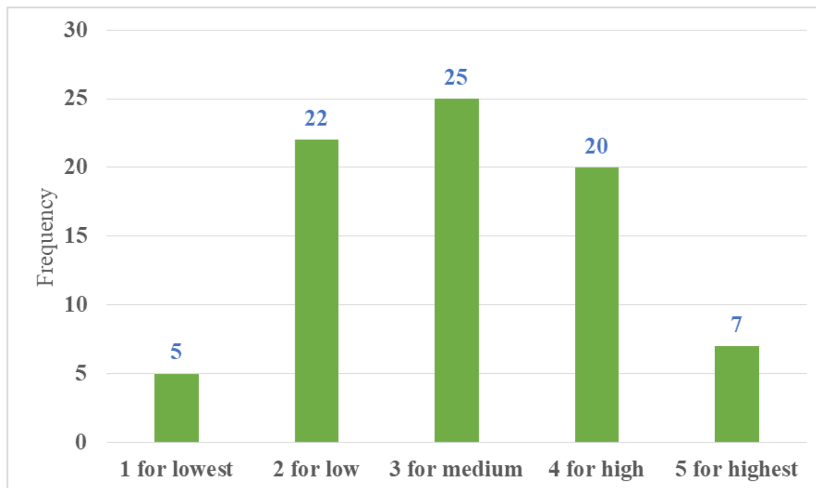

Figure 4.3. Central management level

7.4% (n=6) of respondents scored the level of monitoring private companies within the hospital at the lowest level; 23.5% (n=19) scored it at the low level; 40.7% (n=33) scored it at medium level; 14.8%(n=12) scored it at a high level and 8.6%(n=7) scored it at the highest level.

The majority of respondents scored the level of corporating and monitoring equipment maintenance private companies at a low level which includes 6.2% (n=5) of participants scored it at the lowest level and 27.2%(n=22) scored it at a low level; 30.9% (n=25)of participants scored it at medium level; 24.7%(n=20) scored it at a high level and 8.6%(n=7) scored it at the highest level.

4.2.5. Documentation

Within the scope of documentation assessment, an analysis was conducted to assess the availability of manuals and process documentation.

Table 4.6. Descriptive statistics for documentation

SN	Variables	Frequency	Percent	Cumulative Percent
Availability of quick user labels and manuals				
1	Yes	53	65.4	65.4
2	No	21	25.9	91.4
3	I don't know	7	8.6	100
Process documentation				
1	There is no documented process for investigation and repairing reporting	7	8.6	8.6
2	There is a documented process for investigation and repairing reporting but it is not done regularly	47	58	66.7
3	There is a documented process for investigation and repairing reporting and it is done regularly and compiled	27	33.3	100

Table 4.6. summarize the documentation process in hospitals. 65.4% (n=53) of respondents confirmed that the hospital prepares and delivers quick user labels and manuals, 25% (n=21) didn’t confirm and 8.6 %(n=7) didn’t know if manuals and labels are available. The majority of respondents 66.7% (n=58) reported that there is a documented process for investigating and repairing reporting in their institution but that is not done regularly. 8.6% reported that there is no documented process and 33.3% confirmed the availability of a documented process for investigation and repairing reporting and it is done regularly and compiled

The availability of an electroni**c** application or database to keep information about medical equipment maintenance was also analyzed. Only 47% confirmed having an electronic way of keeping information as shown in figure 4.4

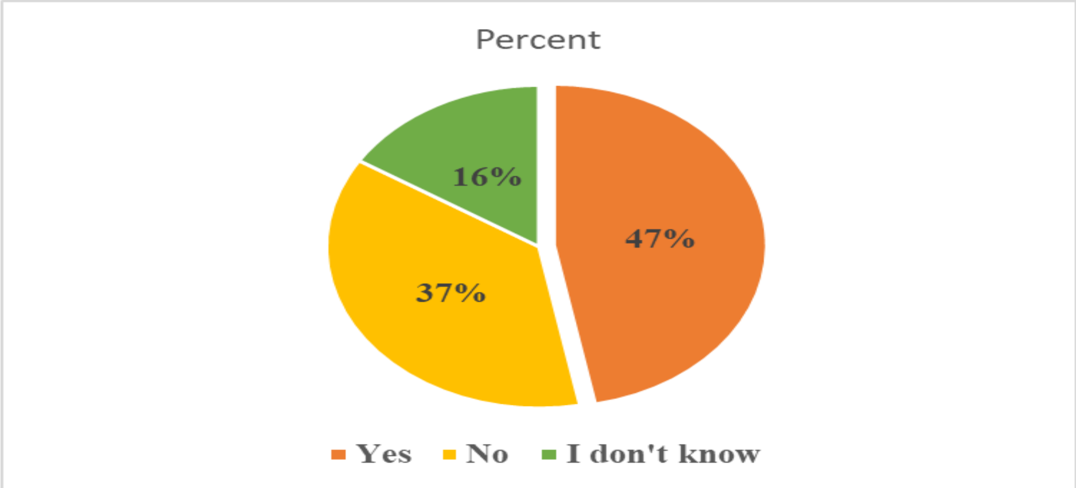

Figure4.4. Availability of an electronic way of keeping maintenance information

Among those who have the electronic way for keeping maintenance information, biomedical staff was reported as the most that have access to the electronic way as shown in figure 4.5
56.5% of the respondents who reported having the electronic way for maintenance management reported that it is accessed by biomedical technicians; 21% reported the accessibility of medical equipment users; 16.1% reported the accessibility of hospital management team and 6.5% reported the accessibility of policymakers.

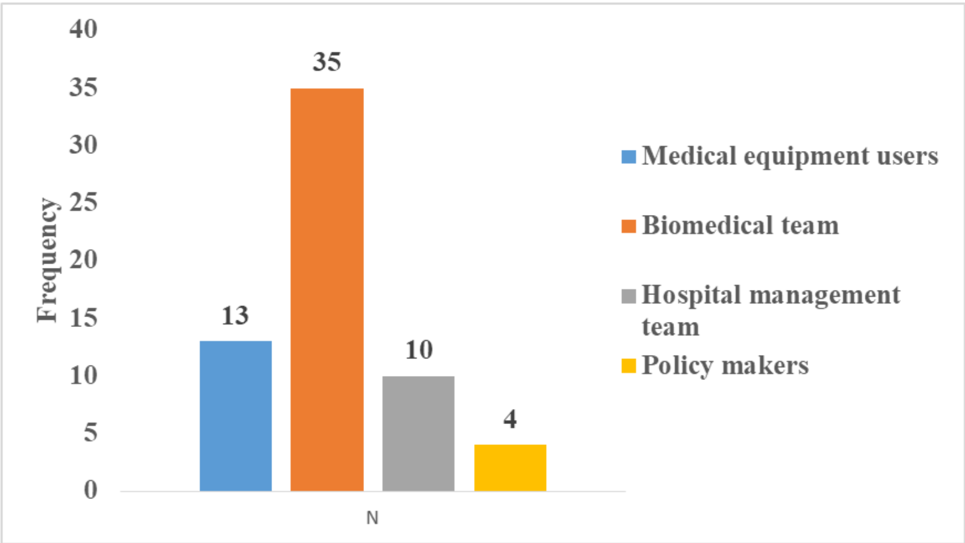

Figure 4.5. Accessibility of electronic application or database for maintenance information

4.2.6. Education

The levels of developing training programs based on the training needs of medical equipment users and engineers in hospitals were analyzed. The majority of respondents scored the level of developing training program based on the needs of stockholders in the management of medical equipment maintenance at a low level this includes 21% (n=17) who scored it and the lowest level 23.5%(n=19) at a low level; 29.6 %(n=24) scored it at medium level; 18.5%(n=15) scored it at a high level and 6.2% (n=5) score it at the highest level.

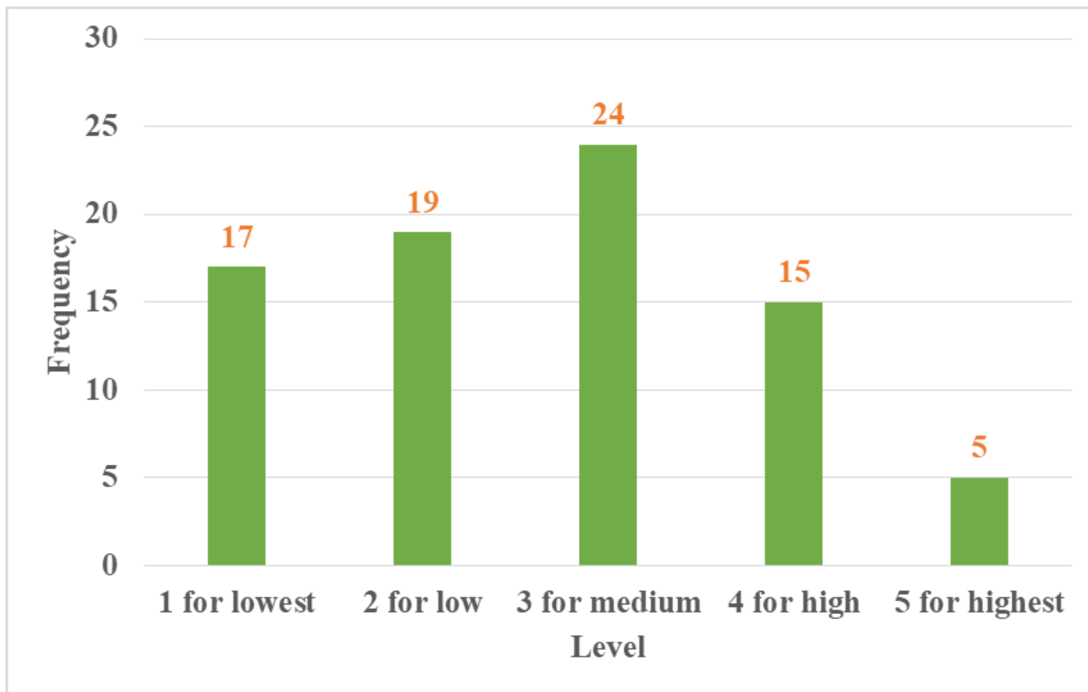

Figure 4.6 Training based on users' and biomedical technicians' needs

4.2.7. Themes from respondents

During this research, the participants responded two questions about the underlying reasons that cause the increase in downtime as well as the perceived solutions to minimize the reasons.

Lack of spare parts and accessories (24.2%, n=53) and the overloaded work of biomedical technicians (23.7%, n=52) were repeatedly reported as the most common reasons that cause the increase in downtime. Other reasons were contractors' services (15.5%, n=34); budget issues (14.2%, n=31); lack of tools (13.7%, n= 30); lack of skills (6.8%, n=15) and other reasons (1.8%, n=4).

Solutions regarding the reasons that cause the increase of downtime from respondents were analyzed and six (6) major themes that emerged were: 1) Increasing the number of biomedical

teams in hospitals 2) Accountability of policymakers 3) Availing spare parts and accessories 4) Enhance training programs on medical equipment 5) Increase resources for medical equipment maintenance and 6) Involving end users in maintenance planning and implementation.

4.2.7.1. Increasing the number of biomedical teams

The majority of respondents suggested increasing the number of biomedical technicians. Particularly, a recurring complaint was that one biomedical technician is not enough for a hospital.

"I would suggest RBC and Ministry of Health to Increase Biomedical Technicians at the Hospitals because there is the big gap which leads to poor service in Maintenance department" (biomedical technician)

*"Enough Biomedical teams are needed" (*Clinician care staff)

4.2.7.2. Accountability of policymakers

As solutions, respondents suggested the accountability of policymakers (MOH and RBC) in terms of developing national policies regarding medical equipment management; regular assessment of maintenance programs; providing training and resources, and managing outsourcing services

"Irresponsibility of RBC/MoH / Districts Hospitals biomedical technicians on strict follow up to contract Managers" *(*Clinician care staff)

4.2.7.3. Availing spare parts and accessories

Several respondents suggested availing most common spare parts and accessories as a solution for reducing downtime.

"Avail maintenance spare parts for each type of medical equipment at Central level RBC and hospital request it" (biomedical technician)

"For fruitful management of Medical equipment, the Ministry of Health must enhance Biomedical Engineers training program and enough spare parts budget for reducing maintenance cost and equipment downtime" (biomedical engineer)

4.2.7.4. Enhancing training program on medical equipment

Increasing the number of specific trainings on medical equipment was repeatedly suggested as a solution to enhancing the maintenance program.

"*Train sufficient biomedical engineers at a higher level*" (Hospital Administrator)

"*Plan for regular training for clinicians about medical equipment's maintenance*" (Clinician care staff)

"*Lack of skills about medical equipment's maintenance and missing training on medical equipment*" (biomedical technician)

4.2.7.5. Increasing financial resources for medical equipment maintenance

Some respondents suggested finding different strategies for getting enough money for supporting medical equipment maintenance

"*All institutions must work hand in hand with the maintenance team to solve some financial issues not only deepening to the RBC"* (biomedical technician)

4.2.7.6. Involving end users in maintenance planning and implementation

Involving end users in maintenance planning and implementation for better management was suggested as a solution for reducing downtime

"*Prepare and implement the preventive maintenance plan, training of technicians and engineers, involving the end users in developing and implementing the preventive and curative maintenance plans and provide feedback on timely manner when there is a problem in maintenance of Equipment's"* (Clinician care staff)

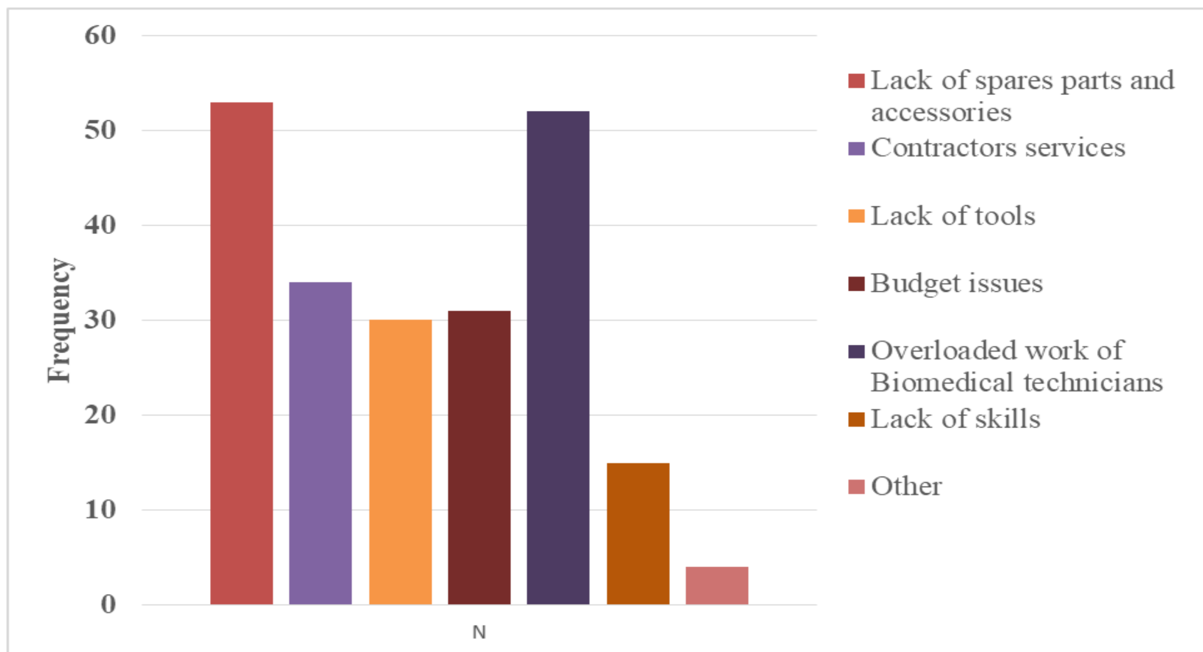

Figure 4.7. Level of underlying reasons that cause the increase in downtime

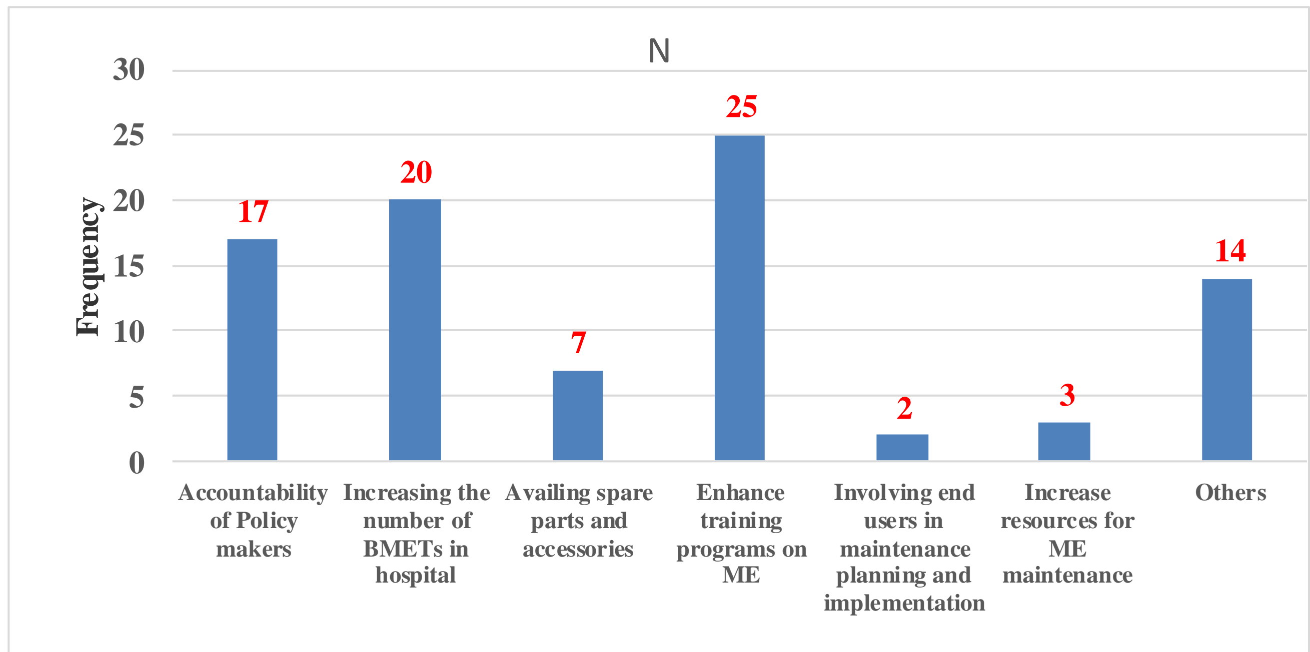

Figure 4.8. Perceived solutions

4.3. Discussion

The hypothesis question of this research focused on studying the current ME maintenance program within Rwandan hospitals, identifying if the program complies with international standards, identifying the factors affecting ME maintenance in Rwandan hospitals, and identifying strategies for optimizing ME maintenance planning, implementation, and monitoring. This section relates the results to the research questions.

4.3.1. Current ME maintenance program and its compliance with international standards

The results of this research show that the level of compliance of medical equipment maintenance programs with international standards within Rwandan hospitals in different aspects:

1. According to ISO 13485 for quality management, it is recommended to have a policy, and the policy should be communicated[15]. The research findings show that the most used policies are institutional policies (55.6%) this reveals that there is no explicit national policy regarding medical equipment maintenance in Rwanda.
2. Although, there are plans for medical equipment within hospitals the results show that there is poor implementation of the plan. The majority of respondents revealed that all equipment are included in the maintenance plan, studies have shown that not all

equipment needs to be added to the maintenance program because very few hospitals have the biomedical team to accomplish this level of effort[10].

3. According to the WHO, medical equipment maintenance relies on several physical resources. These include standardized workshops, tools and test equipment, spare parts, and accessories needed for maintenance performance. All these resources should be taken into consideration during maintenance program planning[10]. The findings of this research show that most hospitals do not have adequate physical resources. Lack of spare parts is one of the largest barriers to medical equipment maintenance programs. According to the results this was more reported by biomedical technicians and end users rather than hospital administrators, hospital administrators need to understand that the productivity biomedical department will be limited without appropriate workshops, tools, and testing equipment. Investment in physical resources will leads to an effective maintenance program as well as reduce maintenance costs.
4. Maintenance processes that include quality control, preventive maintenance, and corrective should be performed and documented following standards[10][17] According to the findings preventive maintenance and procedures such as calibration, safety checks, and performance assurance testing are not implemented effectively. On the other hand, corrective maintenance has documented processes for investigation, repairing, and reporting, but these are not done regularly. 66.7% of participants reported that the processes were not followed
5. The majority of hospitals do not have a well-developed assessment form for monitoring maintenance programs this means there is no real performance measure such as downtime, mean time to failure, and mean time between failures as well as services provided by the biomedical department
6. The level of training based on the needs of medical equipment users and technicians was mostly reported at a low level. The participants suggested enhancing training and implementing more continuing education.
7. There is a shortage of biomedical technicians and engineers in Rwandan hospitals and this generates overloaded work of biomedical equipment. The results show that the overloaded work of a biomedical technician is one of the major causes of the increase in downtime.

8. The results show that the performance of outsourced contractors is not well monitored at the hospital level and central level. According to standards outsourcing services need to be qualified, monitored, and supervised to ensure satisfactory quality and cost-effectiveness.
9. Regarding documentation, the usage of an electronic method for keeping maintenance information is at a low level within Rwandan hospitals and the result shows that for hospitals that use an electronic method, its accessibility is limited to biomedical technicians. This means the usage of CMMS cited in the literature is at a low level within Rwanda hospitals and this creates a gap in complying with international standards
10. Regarding cost, the calculations of the maintenance program budget and benefits are not at a satisfactory level within Rwandan hospitals.

4.3.2. Factors affecting medical equipment maintenance in Rwandan Hospitals

The findings highlight a lack of spare parts and accessories and the overloaded work of biomedical technicians due to understaffing of biomedical staff. In addition to this, respondents reported contactors' services, lack of tools, budget issues, and lack of skills as factors that affect the medical equipment maintenance program. These issues emphasize a larger problem of limited resources, which is commonly seen even in larger LMICs according to the literature.

4.3.3. Strategies for optimizing ME maintenance planning, implementation, and monitoring

From the systematic review of international standards and best practices related to international ME maintenance as well as the findings from qualitative research, an evidence-based approach for medical equipment maintenance in Rwanda was suggested

4.3.4. Evidence-based maintenance approach

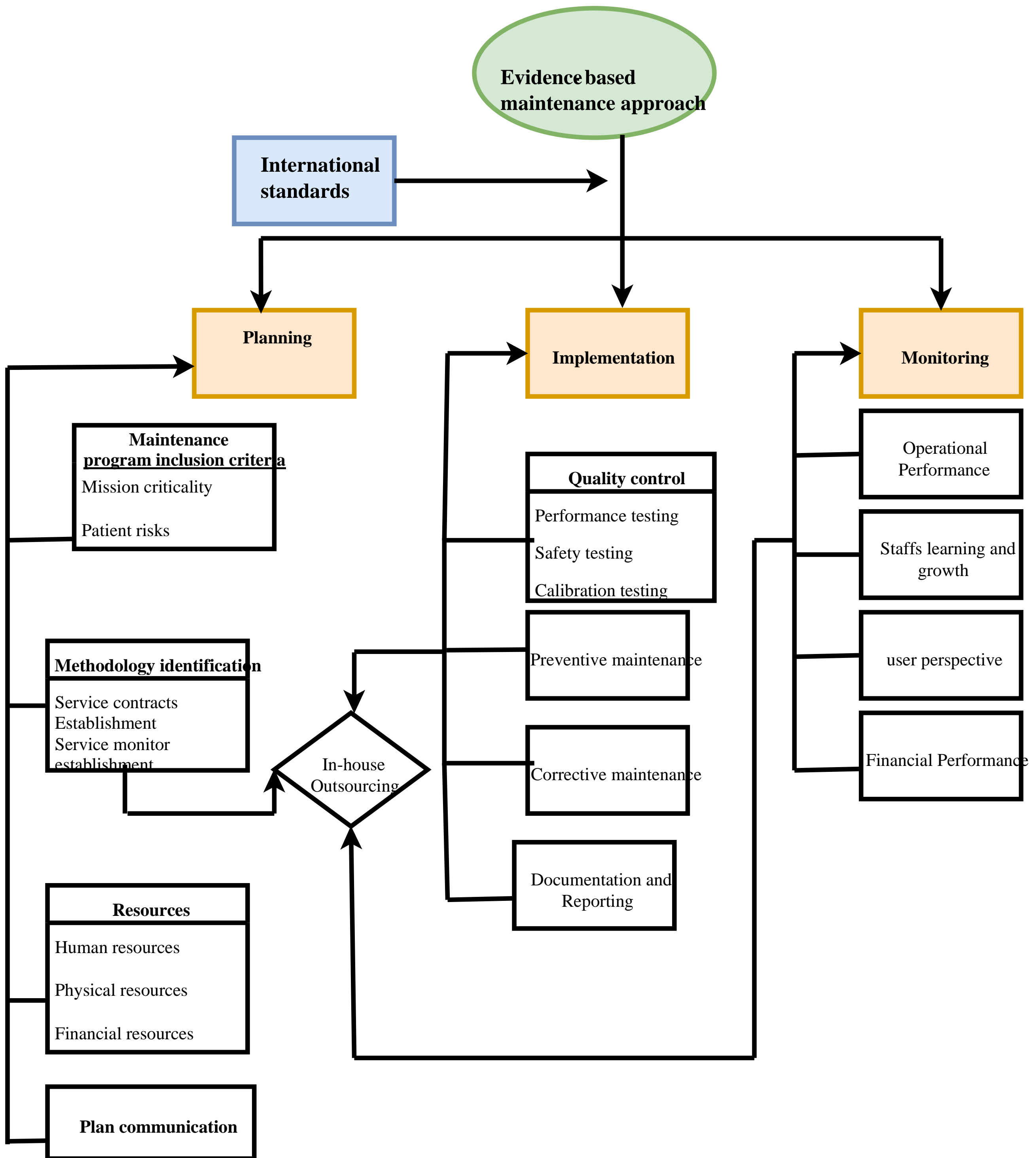

Figure4.9. Evidence-based maintenance approach

4.3.5. Evidence-based maintenance approach overview

- **Requirement specification of the proposed ME planning approach**

To achieve the most appropriate and cost-effective ME maintenance planning should consider four (4) critical elements.

1. The first element is the list of hospital ME to be included in the maintenance program. According to qualitative research findings Rwandan hospitals are still challenged with the shortage of biomedical engineers and technicians, and insufficient resources as a result the implementation of planned maintenance program which includes all ME in inventory is not implemented. Therefore, the method of mission and criticality as maintenance inclusion criteria discussed in chapter 2 is suggested by the new approach for quality improvement.
2. The second element is identifying how maintenance will be delivered to the ME included in the maintenance program. Here service contracts and service monitoring for both in-house and outsourcing services should be established.
3. The third element is the identification of all needed resources. Human resources should be well planned, here the number calculation of the required number of staff and the identification of their skills; education, and experiences. Human resources include technical personnel (Technicians, engineers, and service providers), As the availability of physical and financial resources are limitations in Rwandan public hospitals, therefore, the approach highlights considering them in advance for properly executing the intended activities. The
4. The last element to consider is the communication of the plan to all it may concern to insure the implementation.

- **Requirement specification of the proposed ME implementation approach**

Performance and safety testing, calibration, preventive maintenance, and corrective maintenance should be implemented using the correct and appropriate procedures. Quality control and preventive maintenance procedures should be defined by reviewing each model. For corrective maintenance, the equipment failure should be mentioned, maintained, and returned to service as quickly as possible. An investigation should be done. Effective implementation is done based on documentation and should be delivered and accessible. All implemented activities should be

appropriately reported. It should be done in both in-house and outsourced services. According to a systematic review, CMMS is a critical tool for optimizing the maintenance implementation of ME.

- **Requirement specification of the proposed ME monitoring approach**

Considering the current ME maintenance program within Rwandan hospitals, a balanced performance measurement system is needed that reflects the maintenance performance is needed. The proposed approach suggests defining performance indicators for operational performance; staff learning and growth; user perspective and financial performance discussed in chapter 2 should be established. Assessment checklists form used to evaluate services provided by both in-house and outsourced service providers should be developed.

4.4. Summary

The data collected this study contains useful information that answered the research questions. The analysis of collected data through different techniques contributed to the achievement of the main objective of this research of designing an evidence-based maintenance approach for medical equipment in Rwanda.

CHAPTER 5. CONCLUSION AND RECOMMENDATION

5.1. Conclusion

Medical equipment maintenance program management effectiveness increases the efficiency and productivity of health technology resources; which is particularly important when resources are limited. This allows healthcare organizations to provide an accurate diagnosis, effective treatment, or appropriate rehabilitation.

This study aimed to provide an evidence-based approach that will support and enhance the planning, implementation, and monitoring of medical equipment maintenance in Rwanda. This objective was achieved in three stages. In the first stage, a systematic review of international standards and best practices related to ME maintenance was conducted.

In the second stage, a qualitative study was used to collect data. The collected data consisted of the perspectives of the Clinical Engineering (CE) department administration, doctors, nurses, and procurement departments' staff concerning the efficiency factors of biomedical department maintenance services and potential areas for improvement. The increase of human resources, the availability of physical resources, training of human resources safety and performance testing, calibration, contracts management, documentation, and CMMS were identified as critical factors for maintenance program effectiveness. Related documents were international standards on medical equipment maintenance and other related guidelines and reports.

In the third stage, data extracted from the systematic review and the qualitative study were combined to provide an approach that can enhance the planning, implementation, and monitoring of maintenance programs within hospitals.

This study is the first to demonstrate the status of medical equipment maintenance programs in Rwandan public hospitals regarding international standards and has the potential to failure risk reduction of medical equipment, and maintenance cost reduction thereby the optimization of healthcare service in Rwandan healthcare organizations. It also contributes to the accreditation of Rwandan hospitals because it identified areas where there are gaps in compliance with standards and regulations and changes to meet standards and regulations,

Its findings could guide hospitals and policymakers towards a wiser investment of resources in healthcare technology management, particularly medical equipment maintenance programs that empower Rwandan Hospitals, this would facilitate high quality care for Rwandans and could

also enhances medical tourism in Rwanda, potential engines of Rwanda's economy. Thus, implementing such a plan is an important step in bettering the quality of life of all Rwandans.

5.2. Recommendations

For policymakers:

- MOH is recommended to develop and implement National policies for maintenance management. This can be done by setting and reinforcing the National HTM team/committee whose responsibilities include defining the standards for the maintenance process, and maintenance resources management, ensuring proper implementation, supporting and supervising the training programs, etc.
- Biomedical engineering professionals are critical to the implementation of the medical equipment maintenance program as well as healthcare technology management. It is recommended to the MOH introduce skilled biomedical engineers in healthcare facilities. This can be achieved through collaboration with universities that can help in designing programs related to medical equipment management and maintenance and offer the basic degree.
- It is recommended to the MOH, and RBC Provide critical needed physical resources. This can be achieved by conducting surveys to identify the critical needs in physical resources including standardized workshops, maintenance tools, and spare parts stocks to have a strategic plan related to consider them in the new hospital's plan and upgrading the existing one
- CMMS is an important tool in management maintenance that can assist the planning, implementation, and monitoring of equipment performance and personnel performance and generate reports and appropriate documents for accreditation. It is recommended to the MOH and RBC to reinforce the usage of CMMS for maintenance program management. The CMMS should be standardized; it should include an equipment inventory module, spare parts inventory, management module, maintenance module, and contract management module.
- Maintenance program assessment and training programs should be reviewed and enhanced at the hospital level and central level to be more productive. This should be done through the development of an assessment checklist for assessing the validity and

reliability of the maintenance program. Policymakers are recommended to develop an assessment checklist that includes all dimensions related to the practical and technical needs of all personnel involved in medical equipment management.

For hospital Management:

- Hospital administrators are recommended to increase their accountability toward medical equipment maintenance. This can be done by including biomedical staff in the senior management committee within the hospital and building their capacity towards HTM, especially maintenance
- Think about creative approaches for increasing hospital revenue to support medical equipment maintenance-related costs

For the Biomedical department team and ME users:

- BMET and ME users are recommended to maximize the utilization of medical equipment. This includes effective maintenance activities, effective usage of medical equipment, and effective reporting. this can be achieved by good collaboration between the biomedical department team and ME users and by training users

5.3. Future research work

The current study is an initial exploration of the current maintenance program within Rwandan public hospital. I was only able to collect information on the compliance of international and to identify some of the factors affecting maintenance program management. More research on factors affecting the compliance of maintenance programs with international standards and the relationship between those factors is required.

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APPENDICES

Data collection tools

Evidence-based maintenance Approach for medical equipment in Rwanda

Hello,
My name is Raissa GATANGANWA ,Master of Biomedical Engineering in Center of excellence in biomedical engineering and E-health candidate, University of Rwanda.

You have been identified as key person to participate in the research project with the title: "**Evidence-based maintenance Approach for medical equipment in Rwanda**". This research is being conducted as part of a core requirement for the Master completion in Biomedical engineering at the University of Rwanda. Medical Equipment maintenance approach comprises three major strategies : 1)Inspection which includes procedures for ensuring that equipment is working properly and is safe for both patients and users; 2) Preventive Maintenance (PM) which targets to extend the life of the equipment and reduce failure rates; 3) Corrective Maintenance (CM) which restores the function of a failed device and allows it to be put back into service. The Proper management of maintenance is a well-planned and implemented program that hospitals can minimize medical equipment 's breakdowns and incidents. This is specifically very important in developing countries for providing quality healthcare services as well managing resources.

The purpose of this research is to identify factors associated with medical equipment maintenance and its level of compliance with international standards within Rwandan public Hospitals. Furthermore, provide an evidence based approach that will support and enhance the planning, implementation and monitoring of medical equipment maintenance in Rwanda.
Filling out the questionnaire will take about **5 to10 minutes.** The information collected will be kept anonymous and confidential. It will not include any of your names and will only be accessed by the project team. The results will be used for research purposes only, not for your professional or your institution evaluation as well as comparing the performance of institutions. Your individual responses will not be shared with anyone outside the research team at any time.

1. Can you tell me your Professional Role ? *

- ◯ Hospital Administrator (Director of unit, Procurement, quality management etc.)
- ◯ Biomedical Engineer
- ◯ Biomedical Technician
- ◯ Clinician care staff(general practitioners, specialists, nurse , radiologist, lab technician and scientist, etc.)
- ◯ Other

2. what is your primary Institution *

- ◯ District Hospital
- ◯ Provincial Hospital
- ◯ Referral Hospital
- ◯ RBC
- ◯ Ministry of health

3. Does your institution follow any guideline about medical equipment maintenance? *

- ◯ Yes
- ◯ No
- ◯ I don't know

4. if yes , who's that Policy or guideline?

◯ Institutional Policy /guideline

◯ National Policy / guideline

◯ International Policy / guideline

5. Does your institution/ Organization have plans for medical equipment maintenance activities? *

◯ No plans for any medical equipment maintenance activities

◯ There are plans for some medical equipment maintenance activities

◯ There are plans for all medical equipment maintenance activities

6. Are the maintenance plans communicated to all it may concern? (including medical equipment users,) *

◯ Yes

◯ No

◯ I don't know

7. In your institution do you have Standard Operating Procedures (SOPs) and forms for every maintenance process of medical equipment? *

- ◯ No
- ◯ A. Yes, Only for preventive maintenance
- ◯ B. Yes, Only for corrective maintenance
- ◯ C. Both A&B

8. Is Preventive maintenance Planned and performed timely and regularly in your Hospital/Institution? *

- ◯ Preventive maintenance plan is not developed
- ◯ Preventive maintenance is developed but not implemented correctly
- ◯ Preventive maintenance plan is developed and implemented correctly

9. Is preventive maintenance a priority in hospital's activities and action plan? *

- ◯ yes
- ◯ No
- ◯ I don't know

10. Is safety test, calibration and performance tests performed based on regulations in hospital? *

- ◯ Yes
- ◯ No
- ◯ I don't know

11. What average time it takes the repairing ?

- ◯ 1-6 hours
- ◯ 6-12 hours
- ◯ 12-24 hours
- ◯ 24-48 hours
- ◯ Above 48 hours

12. Can you tell me the reasons that causes the increase of downtime (or the time of repairing). select all that apply *

- ☐ Lack of spares parts and accessories
- ☐ Contractors services
- ☐ Lack of tools
- ☐ Budget issues
- ☐ Overloaded work of Biomedical technicians
- ☐ Lack of skills
- ☐ Other

13. At which level does your hospital/ institution have qualified and well trained Personnel in charge of medical equipment management (1 is lowest level and 5 is the highest level) ?

1	2	3	4	5

14. At which level does your institution have a developed training program based on the training needs of medical equipment users and engineers(1 is lowest level and 5 is the highest level)?

1	2	3	4	5

15. Does hospital prepare and deliver quick user labels and manuals for each medical equipment *

◯ Yes

◯ No

◯ I don't know

16. When there is medical equipment failure can you tell me about the repairing process? *

◯ There is no documented process for investigation and repairing reporting

◯ There is a documented process for investigation and repairing reporting but it is not done regularly

◯ There is a documented process for investigation and repairing reporting and it is done regularly and compiled

17. Does hospital have a standardized dedicated area for medical equipment maintenance(workshop) which includes separate areas for tools and personnel and equipped with washing rooms, toilet and other facilities such as air conditioning, recommended voltage, tables ? *

◯ Yes

◯ No

18. At which level your institution have maintenance tools for both preventive and corrective maintenance, safety and performance testing tools and other facilities such as computer, software etc.(1 is lowest level and 5 is the highest level)

1	2	3	4	5

19. Does your institution have a well developed assessment form for medical equipment maintenance *

- Yes
- No
- I don't know

20. At which level does Hospital have most common needed and necessary spare parts and accessories (1 is lowest level and 5 is the highest level)?

1	2	3	4	5

21. Do you have an electronic way to keep the information about medical equipment maintenance *

- Yes
- No
- I don't know

22. If yes , is it easy for users , engineers and the management to access it. (select the group which access it easily)

- [ ] Medical equipment users
- [ ] Biomedical team
- [ ] Hospital management team
- [ ] Policy makers

23. At which level does the performance of private companies(outsourcing) is monitored by medical equipment management department? (1 is lowest level and 5 is the highest level)

1	2	3	4	5

24. At which level does the required estimated budget and the calculations of cost benefit of medical equipment maintenance are performed in your institution /Hospital?(1 is lowest level and 5 is the highest level)

1	2	3	4	5

25. At which level policy makers (Ministry of health and RBC) corporate and monitor medical equipment maintenance private companies ?

1	2	3	4	5

26. Are there any solutions that you have in mind with regards to the factors affecting medical equipment maintenance?

Regional Centre of Excellence in Biomedical Engineering and E-Health (CEBE)

To: The Director General/ CEO

Kigali-Rwanda

Dear Director General

Subject: **Data Collection's Introductory Letter for Biomedical Engineering Master's Degree Student, Ms. Raissa GATANGANWA**

CEBE is referring to the MoU between the Centre (CEBE) and the Ministry of Health; we are also referring to the operation of CEBE which is based on innovation, consultancy, and service ecosystem to achieve high-impact results in support of key health sector initiatives.

Therefore, this is to introduce Ms. Raissa GATANGANWA,

A Master's Degree Student with reference number 220020564

Who is doing the master's degree research works under the East African Regional Center of Excellence in Biomedical Engineering and E-Health (CEBE), Biomedical Engineering program.

Her research topic is: **Evidence-based maintenance approach for medical equipment in Rwanda**

She, therefore, needs to collect data for the related Master's degree dissertation; however, the management of CEBE declares that no publications of the data can be made without an ethical clearance to do so.

Your support in this regard will be highly appreciated

Prof. Celestin Twizere

Director of CEBE

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

CENTRE HOSPITALIER UNIVERSITAIRE
DE BUTARE(CHUB)
OFFICE OF DIRECTOR GENERAL

Huye, 31/10/2022
Ref: CHUB/DG/NS/10/1964/2022

GATANGANWA Raissa,
Email: gatanganwaraissa147@gmail.com
Tel. +250 785184236

Dear Raissa Gatanganwa

Re: Your request for data collection

Reference made to your letter requesting for permission to collect the data within University Teaching Hospital of Butare for your research project entitled ***"Evidence-based maintenance Approach for medical equipment in Rwanda"***, based to the approval **N° EC/UTHB/ 146/2022** from our Ethics Committee, we are pleased to inform you that you are accepted to collect data within University Teaching Hospital of Butare. Please note that your final document will be submitted in our research office.

You are requested to avail a signed list of data collectors, if applicable and COVID 19 vaccination card.

Sincerely,

For

Dr. Sabin NSANZIMANA
Director General of CHUB

Cc:

- Head of Clinical Education and Research Division
- Director of Research
- Chairperson of Ethics Committee
- Research officer
- Director of Medical and non-medical maintenance equipment

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REPUBLIC OF RWANDA
MINISTRY OF HEALTH
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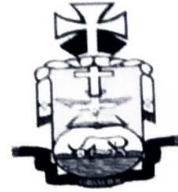


Date: 7/11/2022
N0: 318/Hop.Gah/D.A.Kay/Pce de l'Est/2022

GATANGANWA Raissa,
E-mail:gatanganwaraissa147@gmail.com
Tel: +250785184236

Dear Raissa Gatanganwa

Re: Your request for data collection

Dear Madam,

Reference made to your letter requesting for permission to collect the data within Gahini District Hospital for your research project entitled **"Evidence-based maintenane approach for medical equipment in Rwanda"** We are pleased to inform you that your request is approved.

Thanks,

Dr NGABIRE NKUNDA Philippe
Director General Gahini Hospital

REPUBLIC OF RWANDA MINISTRY OF HEALTH	RUHENGERI REFERRAL HOSPITAL *NR 4, RD 45* Po. Box: 57, MUSANZE Ruhengeli.Hospital@moh.gov.rw	Client centered Service Integrity Teamwork Innovation

Musanze, 05 JAN 2023

Ref. M85...../RRH/DG/2023

Raissa GATANGANWA
Tel: 0785184236

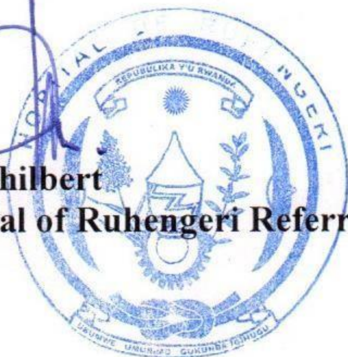
Re: Your request for data Collection

Dear GATANGANWA;

Reference is made to your letter dated on 07th November, 2022 applying permission of data collection for the research project entitled ***"Evidence-based maintenance approach for medical equipment in Rwanda"***

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

Best regards.



Dr MUHIRE Philbert
Director General of Ruhengeri Referral Hospital

Cc:

-Chair of Ethic committee

REPUBLIC OF RWANDA

SOUTHERN PROVINCE
NYAMAGABE DISTRICT
KIGEME HOSPITAL
Tel. : 0788823228 (Director General)
B.P. 43 NYAMAGABE
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ANGLICAN CHURCH OF RWANDA

KIGEME DIOCESE
Legal Personality Nº 318/05 of 10/11/1992
PO Box 67 NYAMAGABE
E-mail: dkigemeear@yahoo.fr

Kigeme, 05/11/2022
Ref. No: 783/07.02.05/20/HOPKG/2022

To: Raissa GATANGANWA

Re: Approval to conduct data collection at Kigeme District Hospital

Dear Madam,

Reference made to your letter requesting permission for collecting data within Kigeme District Hospital for your research project entitled **"Evidence Based Maintenance Approach for Medical Equipment in Rwanda"** We are pleased to inform you that your request is approved.

Sincerely,

Done at Kigeme on 5th /11/2022

Dr Ephraim NZABONIMANA

Director General of Kigeme Hospital

REPUBLIC OF RWANDA

KARONGI DISTRICT
KIBUYE REFERRAL HOSPITAL
PHONE 0780442626
P.O Box 44 KIBUYE
Email: kibuyereferralhospital53@gmail.com

To: Raissa GATANGAWA

Dear Madam,

RE: Approval to conduct project work at Kibuye referral hospital

Reference is made to the introductory letter with your letter dated on 16th November 2022 requesting the authorization to collect data as a part of your research project entitled **"EVIDENCE-BASED MAINTENANCE APPROACH FOR MEDICAL EQUIPMENT IN RWANDA AT KIBUYE REFERRAL HOSPITAL, RWANDA."** and referencing to our accreditation procedures, after reviewing your pledge to ensure that all provided information will be used in the strict academic purpose and that ethical principles will be full respected , **approval has been granted to your project work.**

Please note that the approval is valid for 12 months after receiving this letter. In addition, at the end the hospital shall need to be given the final report of your study.

Sincerely,

Done at Kibuye on 18th November 2022

Jean Népo TWIZERIMANA

Chairperson, ethic committee

CC

- Director General, Kibuye referral hospital
- Clinical Director, Kibuye Referral Hospital
- Head of Biomedical Department, Kibuye Referral Hospital