UNIVERSITY of RWANDA

COLLEGE OF SCIENCE AND TECHNOLOGY

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

INVESTIGATION OF PATIENT SAFETY AND THE USE OF MEDICAL EQUIPMENT: A CASE STUDY OF RWANDA HEALTHCARE

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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, MUSABWAMANA Viviane, declare that this dissertation entitled "**Investigation of patient safety and the use of medical equipment: a case study on Rwanda healthcare**" is my original work 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 "**Investigation of patient safety and the use of medical equipment case study on Rwandan healthcare**" is a record of original work done by MUSABWAMANA Viviane (Reference number: 220020549), an MSc. Degree student in Biomedical Engineering.

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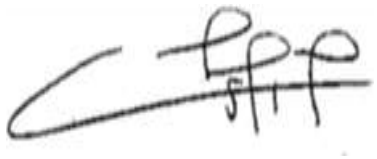

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ABSTRACT

This thesis deals with patient safety and the use of medical equipment in Rwanda healthcare. Medical equipment is a key contributor to patient safety. Clinicians rely on medical equipment to provide healthcare, they trust others, including Biomedical Engineers, to make sure measurements and calibration are accurate at all times to facilitate precision in diagnosis, rehabilitation, and treatment of patients. As any wrong measurement due to lack of calibration could lead to catastrophic consequences. This could include death, disability, inaccurate diagnosis, misprescribion of medication. Medical errors are one of the leading five causes of death. In the healthcare industry, establishing an effective patient safety program is crucial. The aim of this study is to investigate patient safety programs and illustrate ways to improve patient safety while using medical equipment with Rwanda healthcare as a case . This study looks at the benefits, efficacy, effectiveness, safety, appropriateness, and cost-effective analysis of patient safety in medical equipment use. The tool utilised to gather the data needed for the thesis' was a questionnaire. The collected data were analyzed using statistical analysis software SPSS version 21 and Microsoft Excel. Chi-square test analysis and Binary logistic regression analysis were used to test the correlation and significance between the dependent variable (availability of practices on the accuracy of medical equipment) and the independent variables (Parametric settings, testing of equipment, test of equipment after repairing, plan for test calibration, calibrated test cover all medical equipment). The alpha (α) level of 0.05 was used to determine the statistical significance of the data. More generally, the result showed that there is a significant, and correlation between the dependent and the independent variables. As an example, the Testing of equipment which is independent variable with p-values equal to 0.001 for testing the correlation and p-value of 0.008 for signicance test, the results showed that its p-values are less than alpha of 0.05, therefore there is correlation and significance between variables.Based on the existing of this correlation and significance, the study findings demonstrated the necessity of adopting patient safety programs related to medical equipment when adding new technology, repairing, troubleshooting, or moving the equipment before it goes back to services for a better output of the parameters.

Keywords: Patient safety, Medical equipment, Calibration, Effectiveness and Measurement

LIST OF ACRONYMS

Ho: Null Hypothesis

MOH: Ministry of Health/Rwanda

RBC: Rwanda Biomedical Center

DH: District Hospitals

BMET: Biomedical Technicians

BME: Biomedical Engineer

CL: Confidence Level

DF: degree of freedom

MDs: Medical devices

SDGs: Sustainable Development Goals

SMART: Specific Measurable, Affordable, Realistic and Time-bound

SPSS: Statistical Package for Social Sciences

WHO: World Health Organization

HICs: high-income countries

LICs: low-income countries

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CHAPTER 1. GENERAL INTRODUCTION

1.1 Introduction

Healthcare facilities must prioritize patient safety while using medical equipment, as it is an important key to the functionality of the hospital. Global atlas of medical devices, state that one of the top five causes of death involves medical errors [1]. The Universal Health Coverage mandate of the Sustainable Development Goals calls for safe, effective, and appropriate medical devices and states that there is a need to prevent diseases, diagnose early and treat them effectively [1]. Worldwide, patient safety is a public health problem, but the issues around patient safety differ depending on the setting, local culture, and available resources [2]. The factors that affect patient safety on medical equipment are improper maintenance, lack of knowledge on calibration, lack of testing tools, poor plan and budget for procurement. Calibration is key for the functionality of the medical equipment and if it is not done properly it can cause inaccurate diagnoses, medical misprescriptions, or even death [3].

In the African Region, awareness of patient safety has grown considerably in recent years as a result of several positive developments [4].

Over the last century, the medical device industry has expanded rapidly and inevitably. As the sophistication and complexity of designed instrumentation increases, there is a need to develop better, more effective, and more efficient maintenance processes as part of the safety and performance requirements [5]. Nothing is more important to the health industry, whether it is hospitals or medical device manufacturers, than patient safety [6]. As a result, all quality-conscious hospitals regard periodic testing and calibration of devices as a permanent feature of their quality control regimen, to which they strictly adhere. It demonstrates their dedication and commitment to quality and continuous improvement. Testing and calibration of devices ensures the accuracy, efficiency in diagnosis and treatment, and device durability.

However, medical errors are a well-known source of harm in healthcare system, but clinical measurement errors are rarely if ever, identified as the source of adverse events [7]. In recent years, an increasing number of patients have experienced adverse events as a result of medical device malfunction [8]. Diagnosis and treatment, as well as device longevity, allow one to achieve the highest level of quality control and patient safety.

Moreover, correct diagnosis and appropriate patient treatment rely heavily on the accuracy and functionality of medical devices, in addition to the knowledge and experience of medical doctors. In a wide range of serious medical situations, medical device functionality is critical for patients. As a result, it is critical to conduct rigorous and independent testing of medical device functionalities to obtain the most accurate and reliable diagnosis and patient treatment[9].Hence, to investigate the impact of calibration on the performance of medical devices and patient safety by comparing the performance of a selected sample of medical devices to international standard references or manufacturer recommendations [7].

Medical equipment management professionals ensure that the equipment used in patients' care is operational, safe, and properly configured to meet the mission of the medical treatment facility and that it continues to function effectively and in good working order. Proper maintenance, for example, can extend the life of equipment [10].

Patient outcomes are dependent on the creation, delivery, management, and use of safe and effective medical equipment, instruments, and related technology. The purpose of this research is to investigate patient safety programs and illustrate ways to improve patient safety while using medical equipment with Rwanda healthcare as a case study, to analyze the practice that influences patient safety related to medical equipment, to identify the factors that can help to improve patient safety in the hospital, and to point up ways of improving patient safety of medical equipment. Patient safety is a critical problem in healthcare, and the hospital's patient safety program has an impact on safety-related behaviors and minimizes medical errors [11].

1.2 Problem statement

Medical equipment plays a critical role in healthcare, they are used in hospitals, doctors' offices, and in the home to diagnose, treat and prevent illness. Lack of patient safety programs in place and the lack of calibration of those medical equipment can cause death, disability, inaccurate diagnosis, and misprescribing of medicine [12]. International standards and guidelines on patient safety advise that only equipment that is tested, calibrated, and fit for purpose is to be used for diagnosis, treatment, and rehabilitation of patients in clinical settings. Clinicians rely on medical equipment to provide healthcare, but there are not aware of the measurement and calibrations that are done in the background by biomedical engineers. One way of improving patient safety of medical equipment is to adhere to the biomedical engineering principles such as inventory of biomedical equipment, replacement plan, and comprehensive programs for inspecting, testing,

and maintaining biomedical equipment by qualified individuals are carried out which is still a challenge to accomplish without a calibration program. Moreover, poorly maintained equipment may not give accurate results if calibration is not considered, further compromising patient safety.

1.3. Research questions

The following few questions are the baselines, which guided this study

1. What is the practice to ensure the accuracy and precision of medical equipment that contribute to patient safety?
2. Do the parameters of medical equipment accurate at all times? Are there appropriate test equipment, standards operating procedures, regulations, and policies used to verify the accuracy of measurements on medical equipment?
3. Is there any data which shows that medical equipment used in Rwandan healthcare system is safe and contributes to patient positive outcomes?
4. Is there any national patient safety programs that includes medical devices, equipment, and technology?

1.4 Objectives

1.4.1 General objective

The main objective of this study is to investigate patient safety programs and illustrate ways to improve patient safety while using medical equipment in Rwanda healthcare settings.

1.4.2 Specific objectives

- To analyze the practice that influences patient safety related to medical equipment.
- To identify the factors that can help to improve patient safety in the hospital.
- To illustrate ways of improving patient safety of medical equipment.

1.5 Study Scope

This research study investigated and illustrated ways to improve patient safety while using medical equipment against a biomedical standard. Due to the impact of medical equipment's inaccurate performance on patient safety and the quality of health services provided to patients, the main target in this study is patient safety on medical device performance by bearing in mind

calibration where the questionnaire focused on equipment management especially measurement and calibration of them. Moreover, this will let the hospitals know where to correct and improve.

1.6 Significance of the Study

This research study seeks to contribute in improving patient safety programs and the quality of healthcare delivery in Rwanda. The information obtained from this research study will assist to assess the patient safety program for medical equipment in Rwandan healthcare, identify existing knowledge and resources, applied to the patient safety programs, and to propose new ways of improving patient safety of medical equipment as per international standard guidances.

1.7 Thesis organization

Chapter 1 covers the introduction information including background and motivation, the problem statement, the study objectives (both general and specific), the research questions, the scope of the study, the significance of the study, and the organization of the thesis. Chapter 2 presents the literature review about the patient safety-related literature, the legal and regulatory framework for safety standards, medical device hazards, medical equipment management strategies, the calibration of medical devices, and the impact of health information technology on patient safety and the identified gaps. Chapter three explains the methodology used in this study. Chapter four describes the results and discussion. Finally, in Chapter 5, there is conclusion and recommendations.

CHAPTER 2. LITERATURE REVIEW

2.1. Introduction

This Chapter presents different related literature about patient safety and the use of medical equipment. The Chapter also presented a theoretical and empirical review of medical equipment management such as doing the calibration, having analyzers or tools for that calibration, and training programs for the concerned people. This literature review is based on many different selected published papers, books, and other related documents.

2.2. Patient safety-related literature

Despite the acknowledged potential of modern medicine to cure and mitigate illness, one of the defining realizations of the 1990s was that hospitals were not safe places for recovery. According to M. Emanuel et al.(2009) there were dangerous environments for patients. Therefore, the growing interest in patient safety is a key response to this reality [13].

To maintain the equipment's effectiveness and decrease the risk of causing harm to a patient, periodic calibration is necessary [14]. The Global Atlas of Medical Devices is the outcome of the first Baseline Country Survey on Medical Devices. The project began in 2010 and has been updated regularly to provide information on the global situation regarding medical devices [15]. According to the ISO 13485 of Quality System Regulation, the medical equipment industry is regulated by strict standards, which are created to address the most recent trends in quality management system methods, as well as adjustments to regulatory standards and evolving technological needs for the safety of medical equipment. The updated edition places more focus on risk management and risk-based decision-making, and it makes adjustments to reflect the stricter regulatory constraints placed on medical device use [16].

When accuracy in diagnosis and treatment efficacy cannot be compromised, testing and calibration of biomedical equipment to assure quality control in equipment are becoming increasingly important [17]. A new health system for the twenty-first century was published by the Institute of Medicine in 2001 patient safety was discussed in the context of overall quality, and the study advocated for a healthcare delivery system that is safe, effective, patient-centered, timely, efficient, and equitable [18].

However, patient safety research and activity have traditionally been preoccupied with high-income countries (HICs) but recent years have seen a shift of focus to low-income countries (LICs), so that the training and action for patient safety used can be a method to improve patient safety wisdom, quality improvement wisdom, and wisdom from practice [19].

As with any machine, medical equipment is prone to wear and tear over time, which directly affects its accuracy and performance. A growing global policy emphasis is visible on the necessity of ensuring that care is of sufficient quality to be effective and does not hurt patients, in addition to enabling universal access to care. However, maintaining patient safety in practice is still a difficult task [20].

As a source of intelligence about the flaws that underlie risk in organizations and about the chances for improvement of patient safety, and as an indication of healthcare system the absence of patient safety supplies and equipment validation was noted as a significant risk which is either insufficient or unavailable of patient safety body for medical equipment [21].

A report published by the World Health Organization in 2005 states that more than half of medical devices in developing countries are not functioning properly [22]. The main purposes of not functioning which this study is focus on is calibration. Those medical devices need mostly calibration.

The main purposes of calibration in medical devices are:

- Ensuring complete work
- Extending life economically
- Reducing service costs
- Ensuring efficient use
- The efficient workforce in terms of staff
- Increasing patient satisfaction
- Increasing the quality of health services [23]

Medical device calibration is the determination and reporting of whether medical devices in health institutions function properly or not. The accuracy of measurements by a repaired or adjusted device can be determined by calibration [23].

2.3. Legal and regulatory framework for safety standards

A recent study proposed numerous approaches for improving medical device safety, including safety standards (DIN EN 60601-1) [24]. This improvement in medical device safety has also become an important research topic [25]. However, more research is essential to determine how to improve the identification and systematization of errors, and thus the analysis of real-world individual cases.

At the same time, the diversity and complexity of medical devices and their systems have grown significantly because safety of medical equipment without regulation cannot prevent all misuse, usability as a means of increasing operational safety. In addition, it is important to implement essential safety measures in the early stages of development and it is a critical activity in the design process [26]. The primary goal of Medical Device Regulations is to ensure their safety, quality, effectiveness, and performance as intended as well as patient safety [27].

As a result, a medical device is classified based on the risk it poses to the patient and/or the user. Therefore, an initial regulatory classification system is to determine the level of control required for a medical device [28]. Moreover, post-market surveillance is a broad term that encompasses all medical device-monitoring activities. Post-market surveillance is divided into proactive and reactive activities. Proactive activities covering, testing, and establishment inspection on the medical device's safeness while reactive problem management considers all contributory causes, including causes that contributed to the duration and impact of incidents. This surveillance data help with patient injury prevention, medical device improvement, standard development, and regulatory refinement[29]. The requirements that must be met to guarantee the protection of people and the environment, for now and in the future, are established by an integrated and consistent set of safety requirements. The format and style of the requirements facilitate their use for the harmonized establishment of a legal and national regulatory framework [30].

2.4. Medical Device Hazards

A hazard is a potential source of harm that occurs due to the inherent risk of medical treatment, device failure, device malfunction, and device use [31]. It is caused by, how a device is used and the knowledge of the user. It has been suggested that the frequency and severity of hazards associated with medical device use may far outweigh those associated with device failure. According to reports presented by the Committee on Quality of Health Care in America at the institute of medicine, 98000 people die in hospitals each year because of medical errors [32]. Consequently, medical device hazards have potential negative impacts. Use-related hazards can

occur for a variety of reasons, including using the device in unexpected ways, device use that is inconsistent with the user's expectations about the device's operation, and the use environment, such as work load and mental load [31]. A renowned expert, James Reason, asserts that errors are dependent on two different types of failures: either the correct action does not proceed as intended (an error of execution) or the original intended action is not correct (an error of planning. Errors can occur at any stage of the healthcare process, including during diagnosis, treatment, and preventative care. Device failure hazards include inadequate reprocessing of medical devices and patient handling of the device [33].

2.5. Medical Equipment Management Strategies

Over the last 20 years, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) medical equipment management standards have been a major driving force in the practice of clinical engineering (CE) in the United States [34]. JCAHO has continuously revised and improved these standards over the years as health care and technology have evolved. Some of the changes will allow us to refocus our resources on areas with the greatest potential for improving patient care and organizational success [35].

In 2004, " JCAHO identifies appropriate inspection and maintenance strategies for all medical equipment on the inventory for achieving effective, safe, and reliable operation of all equipment," following EC.6.10 and EP4. Following, JCAHO, hospitals may use different strategies for different items as appropriate. As a result, hospitals are permitted to avoid scheduling inspection or maintenance tasks for specific pieces or types of medical equipment [36]. Furthermore, different maintenance and/or inspection procedures or schedules for identical devices used in different areas or on different patient populations are acceptable. The schedules may differ depending on factors such as frequency of use and the severity of failure on patient safety. A second opportunity for improvement is to use a grace period (or slippage) to determine when a piece of equipment is overdue for a scheduled inspection or maintenance event [34].

2.6. Calibration of medical devices

The calibration of medical equipment is important in terms of patient care. The performance of life-saving medical equipment must be strictly monitored. The various processes associated with a calibration activity can be potential sources of risk. Many hospitals have their clinical

engineering professionals (CEP) for maintenance and calibration, while the rest rely on outside vendors. Both internal and external calibration pose risks associated with healthcare equipment failure. Modern medical equipment, unlike industrial gauges and transmitters, has a highly complex architecture due to the synthesis of multiple sensor networks and processor boards. [37][38]. Medical care has significantly improved with the progress in instrumentation technology. However, the safety and reliability of a complex circuit tend to deteriorate significantly with aging and rigorous usage [37]. Internal-calibration hospitals have technicians who are trained to handle maintenance tasks but lack the insight of a metrologist. Similarly, using non-accredited external calibration is risky because there is no guarantee that appropriate standards will be maintained[39]. The risks of medical errors in health care are well understood. However, risk assessments are scarce for clinical measurement errors [38][39]. To avoid patient suffering caused by equipment malfunction, medical device accuracy must be ensured [8]. As a result, strict and impartial calibration should be performed for independent evaluation of functionalities in medical equipment [7].

Mainly, the risks associated with medical equipment calibration have to be identified, as a way to mitigate them. The Failure Modes and Effects Analysis (FMEA) based risk assessment which is a methodical, proactive strategy for reviewing a process to identify potential failure points and estimate the relative impact of various failures to determine the process elements that require the most improvement performed as based on expert opinion to rank the various failure modes based on priority, to demonstrate its effectiveness, the proposed framework which was applied to such complex systems, however, are frequently prone to errors which result to an irregular failure of any component that can endanger a patient. The poor performance of these composite systems is attributed to incorrect calibration, in an independent assessment of the impact of calibration, 58% of the medical equipment was found to deviate from their tolerance [7].

According to Nememew et al., (2020) who describes that the failure events caused by clinical measurement error can be prevented if calibration of medical equipment are considered [40]. However, to overcome the issues raised Multi-Criteria Decision-Making (MCDM) and FMEA techniques have been widely used in the risk assessment of medical equipment design, maintenance, and hospital administration[41]. FMEA together with quality function deployment (QFD), and lean were used to develop hospital risk management [42]. The calibration of a device measures its performance in terms of response to a reference piece of equipment[43]. Improper

calibration causes clinical measurement errors and reduces diagnostic confidence, which affects patient safety. Nonetheless, risk assessment in calibration has remained largely unexplored [44].

2.7 Health Information Technology on patient safety

2.7.1 The impact of health information technology on patient safety

Since the original Institute of Medicine (IOM) report, there has been a rapid advancement and adoption of health information technology, with varying degrees of evidence about the impact of health information technology on patient safety [45].

Health information technology (HIT) improves patient safety by decreasing medication errors, decreasing adverse drug reactions, and increasing adherence to practice guidelines. Without a doubt, health information technology is a valuable tool for improving healthcare quality and safety. For this reason, healthcare organizations must exercise caution when deciding which technologies to invest in, as research shows that some technologies have limited evidence of improving patient safety outcomes [45].

In addition, patient safety is a subset of healthcare that is considered as the avoidance, prevention, and amelioration of adverse outcomes or injuries caused by health-care processes [46]. The Institute of Medicine's (IOM) report "To err is human" called for the development and testing of new technologies to reduce medical errors and stated that the use of information technology as a critical first step in transforming and changing the healthcare environment to achieve better and safer care [47].

Health information technology encompasses a wide range of technologies, from simple charting to advanced decision support and integration with medical technology. HIT provides numerous opportunities for improving and transforming healthcare, such as lowering human errors, improving clinical outcomes, facilitating care coordination, increasing practice efficiencies, and tracking data over time [45]. Since the publication of the original IOM report, there has been an acceleration in the development and adoption of health information technology, with varying degrees of evidence about the impact of health information technology on patient safety [48].

2.7.2 Benefits of health information technology

The advantages of health information technology (HIT) include the ability to store and retrieve data; the ability to rapidly communicate patient information in a legible format; improved

medical equipment safety through increased legibility, potentially lowering the risk of medical errors; and the ease of retrieval of patient information HIT is increasing patient engagement as health-care consumers. It gives patients access to their medical records, making them feel more informed about their conditions and encouraging them to actively participate in shared decision-making and it improves medical equipment safety [49]. Medical alerts clinical flags and reminders, better tracking and reporting of consultations and diagnostic testing, clinical decision support, and the availability of complete patient data all have the potential to improve patient safety. Data collected through the use of HIT can be used to assess the improvement of medical practice [50].

2.7.3 Patient Safety Concerns with HealthInformation Technology

Technology-related adverse events can be associated with all components of a comprehensive technology system and may involve errors of either commission or omission. These unintended consequences are typically caused by human-machine interfaces or organizational/system design" [51]. Medical errors can be caused by fragmented displays, rigid ordering formats, incompatible orders, and functional separations that prevent full comprehension of a patient's health-care needs [49].

With electronic charting, the risk of patient data mismatch, inserting data into the wrong patient's chart or documenting patient information under the wrong visit increases. Mismatches can also occur when using paper charts. However, as the amount of data transferred between different systems grows, the possibility of mass mismatch exists and must be considered [52].

Although robust interoperability would enable the exchange of patient information and the availability of a comprehensive picture of the patient's care, achieving such a goal has proven difficult, data exchange between all health care settings and providers would reduce errors and improve patient safety. However, Products that use proprietary technology and are therefore challenging to integrate with other systems for data exchange are nevertheless available on the market [52].

2.10. Summary

It is irrefutable that preventing and reducing risks, errors, and harm that occur to patients while using medical devices is possible. A cornerstone of the discipline is a continuous improvement based on learning from errors and adverse events. Patient safety is fundamental to delivering

quality essential health services. This Chapter pinpoints that the use of technology in medical device manufacturing reduces patient risk while enhancing their safety. In addition, continuous testing and calibration of medical equipment should contribute much to patient safety in case of follow-up is done in a good information.

CHAPTER 3. RESEARCH METHODOLOGY

3.1 Introduction

A comprehensive investigation led to ensuring that the used medical equipment is safe. Qualitative data was collected through online questionnaire and physical observation. This Chapter discusses on research design, research procedures, observations and discussion, study area, sample size determination, data collection and data analysis method.

3.2 Research design

The study is composed of qualitative data collected using the questionnaire tool to get the primary data. The secondary data was obtained through a search on the internet for the literature of books, articles, and discussions from biomedical engineers and technicians. The information gathered assisted the researcher to get the findings to draw the conclusion, recommendations, and suggestions for further research.

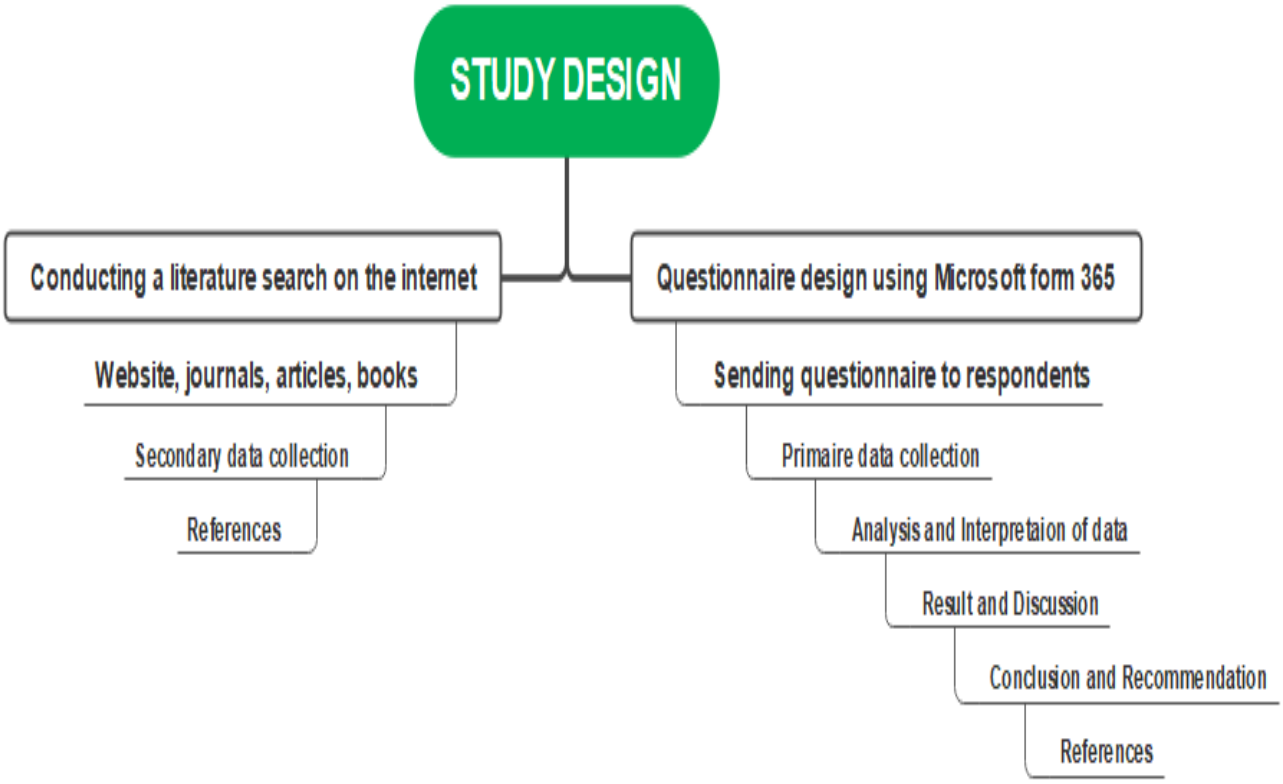


Figure 3.1: Research design

3.3. Research Procedure

In order to learn more about the patient safety of medical equipment in a local and global context, many literatures were examined during the study. The coordinator of the MSc program in Biomedical Engineering gave the introduction letter that was to be given to the institutions in order to gain permission for data collection and obtain the data that were required for this thesis. Questionnaires were sent to the chosen respondents (including Biomedical Engineers, Biomedical Technician, and Nurses) who could respond to the questions in the provided questionnaire during the data collection during a period of 3 months, in the field. SPSS (Version 21.0. Armonk, NY: IBM Corp.) which was used to analyze the data that was obtained. Results from questionnaire was complied into Excel and precessed into SPSS, the chi-square test and logistic linear regression analysis were used to test the relationship and the significance between the dependent and independent variables. Consequently, the findings and suggestion were provided.

3.4 Study Area

This study were done in different area with different instutitions such as Ministry of Health (MoH), Rwanda Biomedical Centre (RBC), District Hospitals (DH), referral hospitals, provincial hospitals, and teaching hospitals.

3.5 Sample size determination

Several factors, including the purpose of the study, the risk of selecting a bad sample, and the allowable sampling error, usually influence the sample size. In addition, three criteria need to be specified to determine the appropriate sample size, namely, (1) the level of precision, (2) the level of confidence, and (3) the degree of variability in the attributes.

1. **The Level of precision:** The level of precision, sometimes called sampling error, is the range in which the true value of the population is estimated to be. This is often expressed in percentages. In the present study, a high precision of results was preffered (i.e., **10%)**
2. **The confidence level:** In the present study, the population size implies that the assumption of normal populations (normal distribution) is straightforward for both strata and therefore, value was equal to **86%**

3. **Degree of variability:** It refers to the variation of the distribution of attributes of interest in the population. The more heterogeneous a population is, the larger the sample size required to obtain a given level of precision. A proportion of 50% indicates a greater level of variability than either 20% or 80%. 20% and 80% indicate that a large majority do not or do have the attributes of interest. The previous studies' indicator values will allow the present study to choose an appropriate degree of variability. Therefore, the degree of variability provisionally adopted in this study was **60%.**

Based on the above factors, the sample size that is accepted statistically for the study will be determined using the following formula as it is shown in equation 1:

$n = \frac{z^2 pq}{e^2}$ (1)

Where:

p : is the proportion of people satisfied with the desired characteristics.

$q = (1 - p)$: is the proportion of people not satisfied with the desired characteristic.

e : is the acceptable margin of error or the level of precision required.

n: sample size

For this particular study, z is the value of the standard normal random variable at an 86% level of confidence and it was found with alpha which is equal to **1-86%= 14%** and it helps to get z-value on the distribution table[53].

This formula is used when the total population is not known, in this study the sample size is equal to 51 respondents and it is determined in the following way:

$n = \frac{1.46^2(0.6)(0.4)}{0.1^2}$= **51 respondents;** the value of z was found from area of distribution table

3.6 Data collection and analysis method

The definition of data is the information gathered during the investigation that can be used to create conclusions [54]**.** To answer specific research questions, test hypotheses, and evaluate results, data collection is the act of gathering and evaluating the information on pertinent variables in a planned, systematic way[55].

In this study, the questionnaire tool was built by using Microsoft form 365 and then, used for the data collection process. The questionnaire was simple, clear, and straightforward to the targeted respondents.and it was prepared for easy understanding and interpretation by the respondents. The questionnaire was specific, measurable, affordable, realistic, and time-bound (SMART). The questionnaire consisted of fifteen questions including both open and closed questions that were built based on the objectives of the good study. The observation and discussion with the biomedical engineers/technicians were also used to assess their attitudes, knowledge, and skills, including patient safety practice with medical equipment's everyday life. Data analysis covers a wide range of distinct processes and techniques. It involves dealing with the data itself as well as objectives, connections, choices, and ideas. The data used in this study included qualitative data. The data that was collected during the research was saved as an Excel sheet, and the excel sheet containing the collected data was imported into SPSS software for descriptive analysis. The binary logistic regression model and Chi-square test were used to test the relationship and significance between independent and dependent variables. The statistically significant p-value, which is less than 0.05 were used. The results were later presented in form of pie charts, tables, and graphs for easy interpretation.

3.7 Summary

The questionnaire was used in this study to collect data. Through using Microsoft form 365, a questionnaire tool was created and utilized to collect data the questionnaire met the SMART criteria of being specific, measurable, affordable, realistic, and time-bound.

Fifteen questions, both open-ended and closed-ended, made up the questionnaire, which was organized depending on the study's goals. For descriptive analysis, the gathered data was examined using SPSS software version 21. To examine the significance of the association between the independent and dependent variables, the binary logistic regression model and the chi-square test analysis were utilized.

CHAPTER 4. RESULTS AND DISCUSSION

4.1. Introduction

This chapter provides a thorough summary of the analyzed data. Together with their interpretation and discussion in light of the study's goals are investigate patient safety programs and illustrate ways to improve patient safety while using medical equipment with Rwanda healthcare as a case study, to analyze the practice that influences patient safety related to medical equipment, to identify the factors that can help to improve patient safety in the hospital, to illustrate ways of improving patient safety of medical equipment. To analyze the gathered data following the study's objectives, SPSS were used.

4.1.1. Qualitative results

This study has 51 respondents in total. The questions asked to the respondents during the data collection focused on the professional background of the respondents and to the institutions have a systematic formal process that gathers information to support healthcare decision-making. In addition to this, other questions related to healthcare technology management to know how they can improve or create patient safety programs and the quality of healthcare delivery. The following describes each qualitative outcome that the respondents supplied:

- **The professional background of the respondents**

Regarding the respondents' professional backgrounds, the study revealed that many participants were made of Biomedical Engineers (BME) and Biomedical Technicians(BMET). The number of respondents and their corresponding percentages are the following: Allied professional (n=3, 5.9%), Nurses (n=2, 3.9%), biomedical engineer (n=23, 45.1%), biomedical technician (n=22, 43.1%) and others such as hospital administrator with n=1, 2.0%. The percentage of participants according to their professional background is shown in the Figure 4.1.

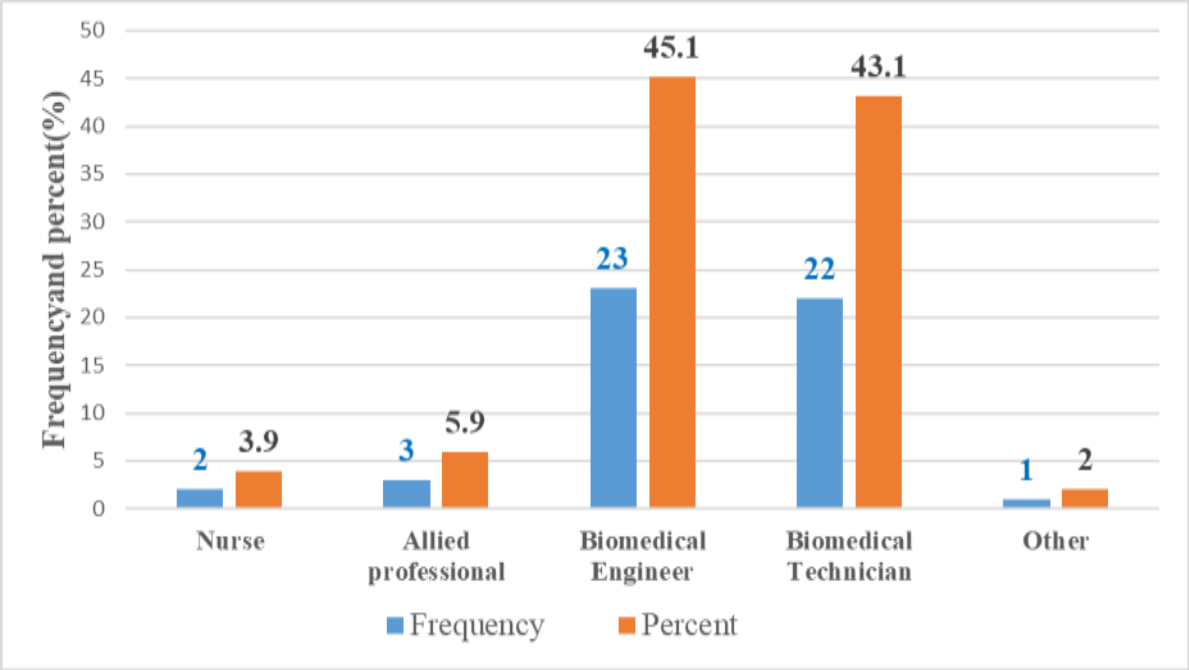


Figure 4.1 : Histogram of the Professional background of respondents

The questionnaire was composed by 15 questions. The answers to those questions were obtained from the above Professional background of respondents. Table 4.1 presents questions and answers obtained from the respondents.

- **Practices for medical equipment**

Patient safety as a healthcare displine that emerge with the developing of complexity in healthcare system that may increasing the patient harm. This study primarily investigate, the availability of practices that lead to ensure the accuracy of medical equipment with the materials that contribute to the patient safety , about 78.4% of respondent showed that there are availability of the practices done for maintaining patient safety practices (Table 4.1)

TABLE 4.1: Practice to ensure the accuracy of medical equipment that contribute to patient safety.

Possible answers	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	40	78.4	78.4	78.4
No	4	7.8	7.8	86.3
Maybe	2	3.9	3.9	90.2
No idea	5	9.8	9.8	100.0

Total	51	100.0	100.0	

- **Parameter setting for medical equipment accuracy assessment**

Medical equipment accuracy assessment as an important tool used in quality improvement process in order to avoid the negative impact that can be encountered by patient. The present study use different parameters such as (checking Biomed report and checking service provider report) that ensures which extent the medical equipment are accurate. As showed in figure 4.2 76.5% of respondents depicted that the proposed paramenter are mostly applied in different hospital.

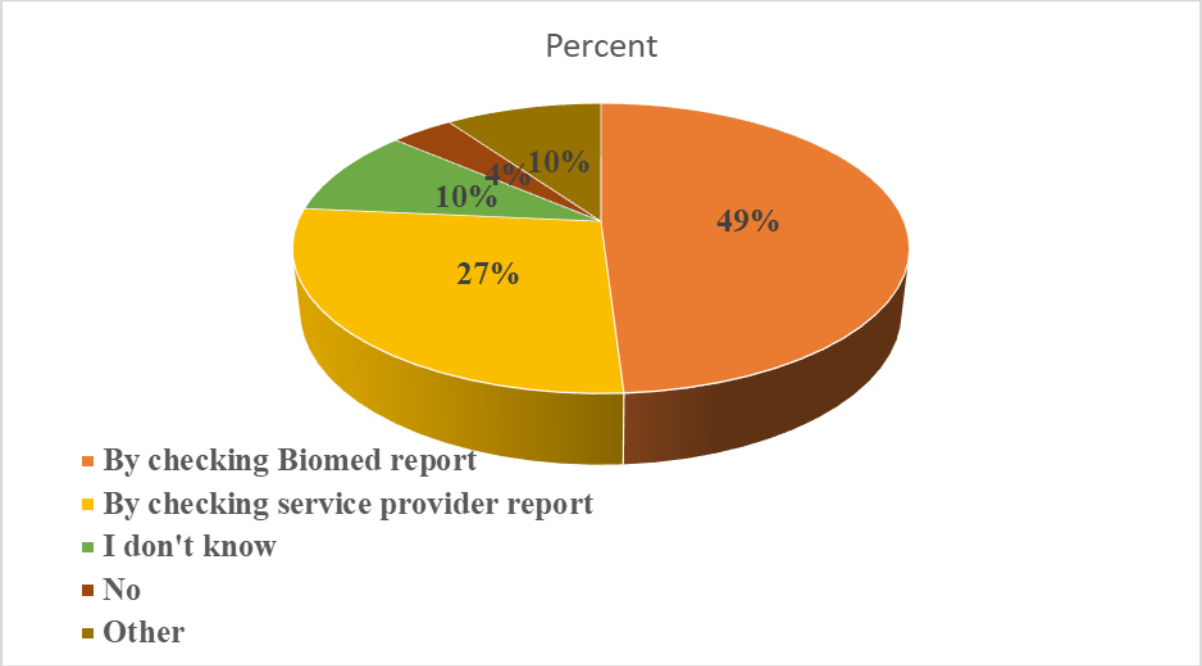


Figure 4.2: parameters of medical equipment accuracy assessment

- **Medical equipment testing and calibration**

Medical testing considered as the process of demonstrating that the medical device are reliable and safety to performing while being used. This may lead to the safety of patient because the performance medical equipment is well tested before use. The current study carried out in different hospitals also showed that, about 67% of respondents comfirmed that the medical devices tested before use (Figure 4.3).

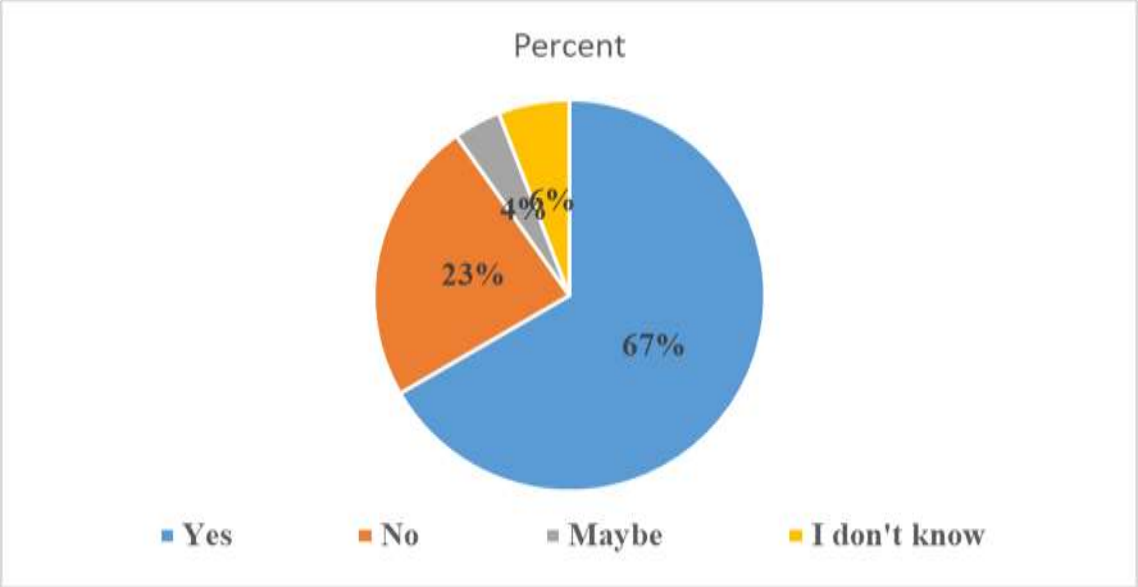


Figure 4.3: Availability of testing equipment, analyzers and simulators

Not only for new medical equipment but also the present study intend to recogonize if the old equipment tested after repairing them and it found that 41% agreed that is is sometimes tested while 53% 0f respondend comirmed that the repaired devices tested every time, and 6% declared that no testing performed those medical equipment (Figure 4.4)

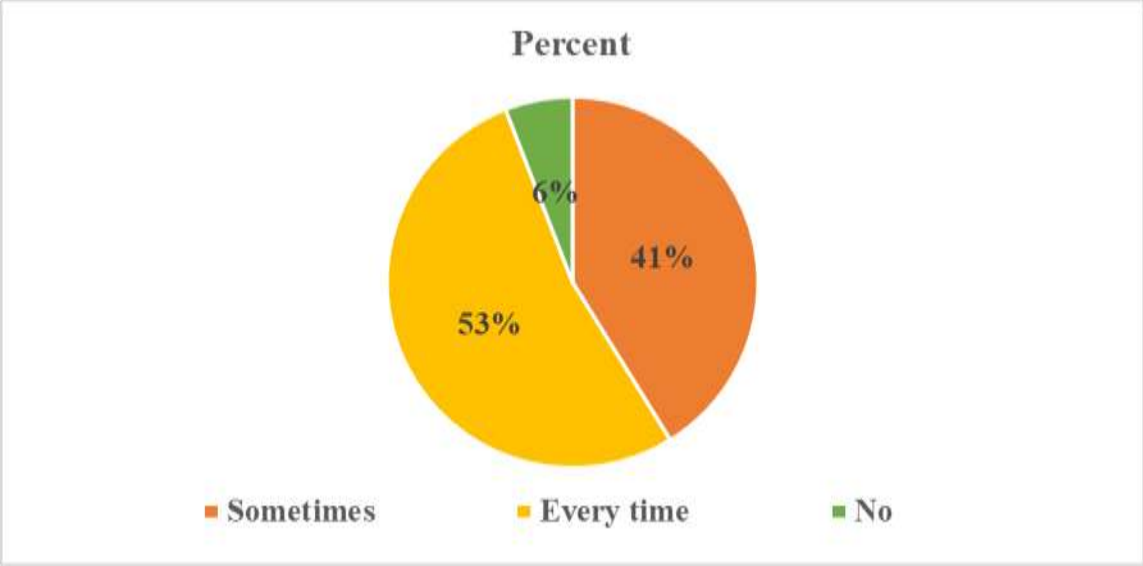


Figure 4.4: Test the equipment after repairing it, troubleshooting it, or just moving it before it goes back to services.

Calibration as a good measurement and procedure for fixing and detecting uncerntanties in measurement so that to bring them to an acceptable level. This is very crucial for the accuracy of medical equipment, as it can seriously affect the diagnostic procedure and endanger patient safety. The figure 4.5 indicated that 67.% of respondents comfirm there is an existing plan for calibration for a tested equipment (Figure 4.6). But, unfortunately 61% of respondents depicted tthat it is not done to all medical devices and this may lead to endanger the patients safety (Figure 4.6).

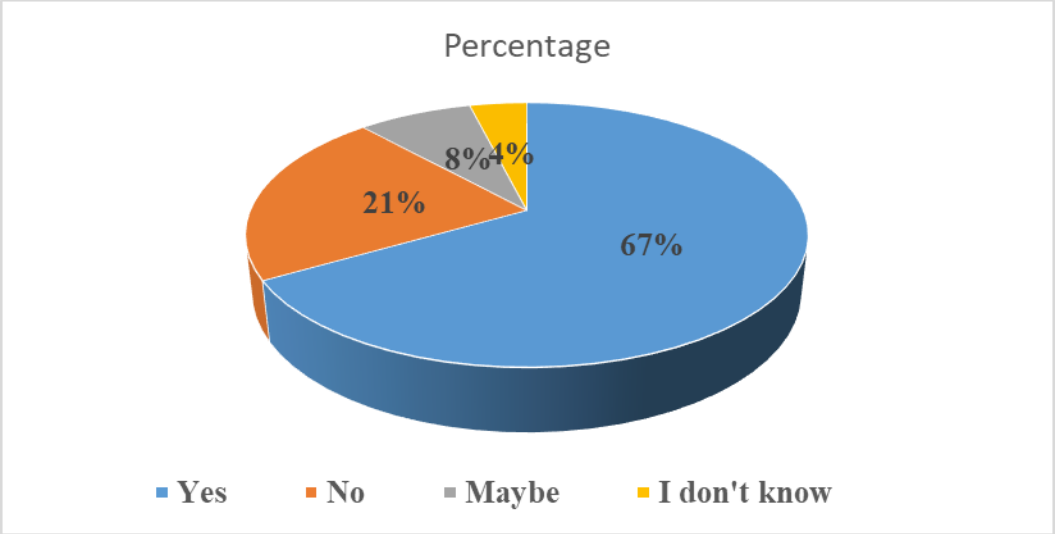


Figure 4.5: Plan of calibration of your test equipment, simulators and analyzers

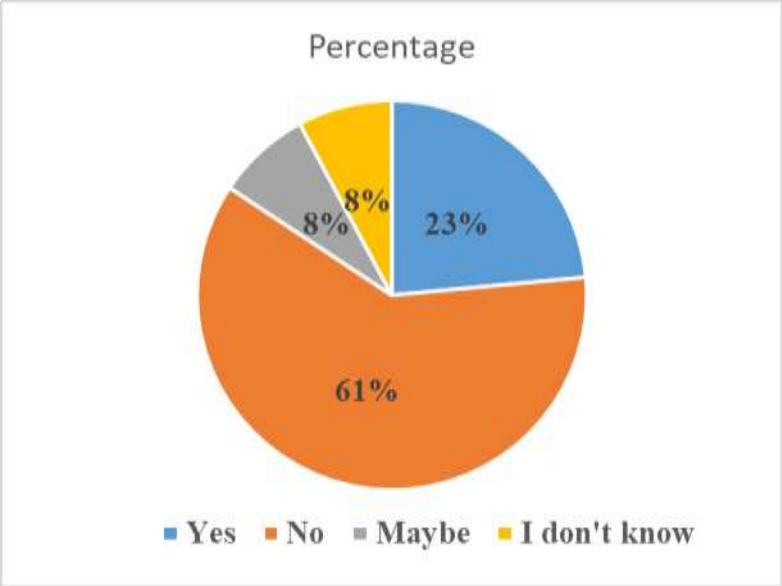


Figure 4. 6: If yes, is it for all the medical equipment

Regular calibration require to follow any reguration and policies to ensure that are well performing correctly and using accurate measurement. This study showed that about 67% of respondents comfirmed there are a set of regulations and policies followed for medical equipment calibration and accuracy measuremt (Figure 4.7).

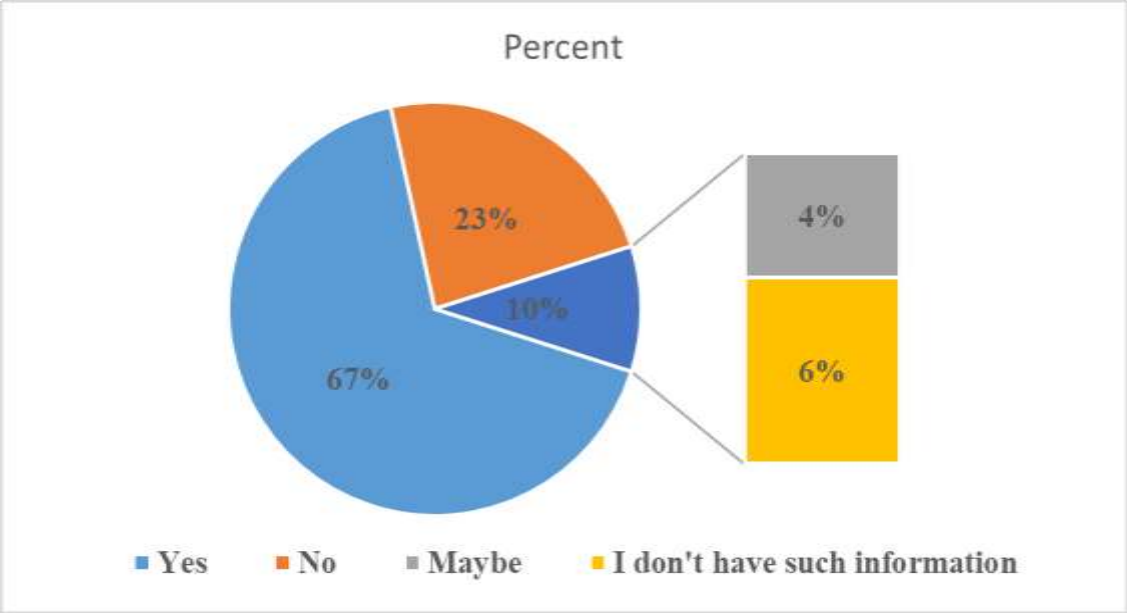


Figure4.7: Availability of regulations and polices followed to verify the accuracy of measurements

- **Standard Opereting Procedure on medical equipment accuracy verification**

Standard Operating Procedure(SOP) describes the process, procedure and the the responsibilities for the use and maintenance of medical equipment and instruments during the equipment test. This is very important aspect which helps to achieve the patient safety, during this study high number of respondnts (69%) agreed that there is an SOP used to ensure the accuracy of medical equipment (Figure 4.8).

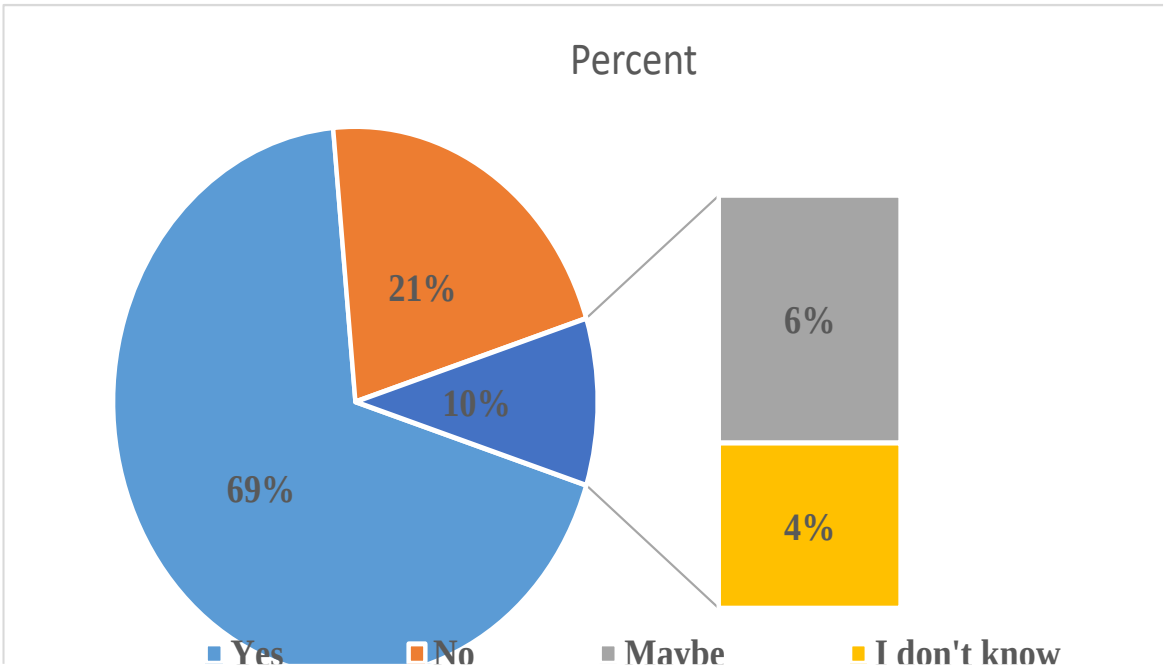


Figure 4.8: Standards operating procedures used to verify the accuracy of measurements.

- **Database and healthcare system**

This study also investigate on the availability of database and system where medical equipment informations is stored and ensure it is used correctly, purposively for maintaining the patient safety. Unfortunately, 49% of respondent reported that there are database of medical equipment in the healthcare system (Figure 4.9) which is still under maintenance, but the high percentage of respondents showed that there is no reporting system related to medical equipment incident (Table 4.2) to this emphasize 35.3% of medical related incident have been reported by different hospital through a reporting system (Figure 4.10).

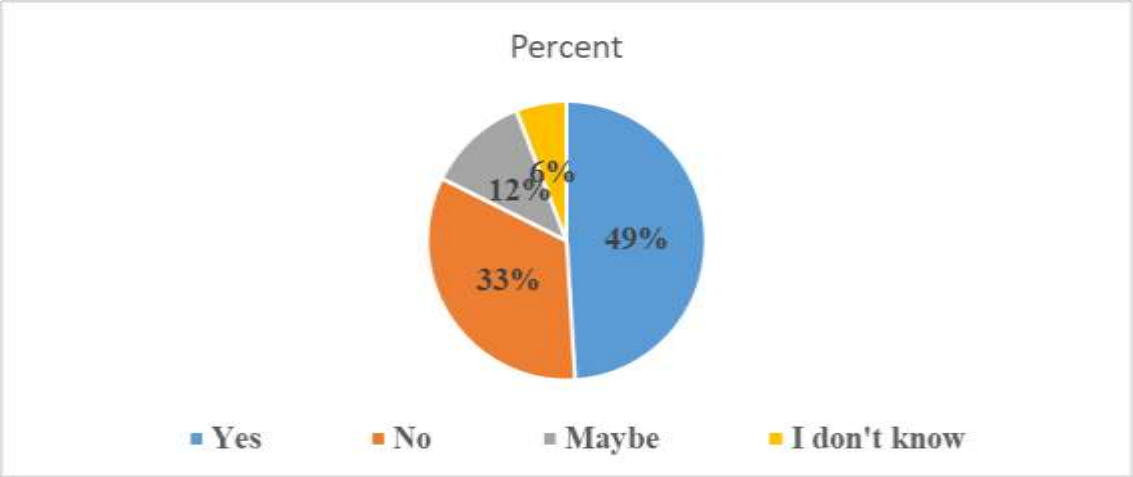


Figure 4.9: Is there any data base that shows that medical equipment used in our healthcare system is safe and contribute to patient positive outcomes

Table 4.2: Reporting system related to medical equipment incident

Possible answers	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	32	62.7	62.7	62.7
No	14	27.5	27.5	90.2
No idea	5	9.8	9.8	100.0
Total	51	100.0	100.0	

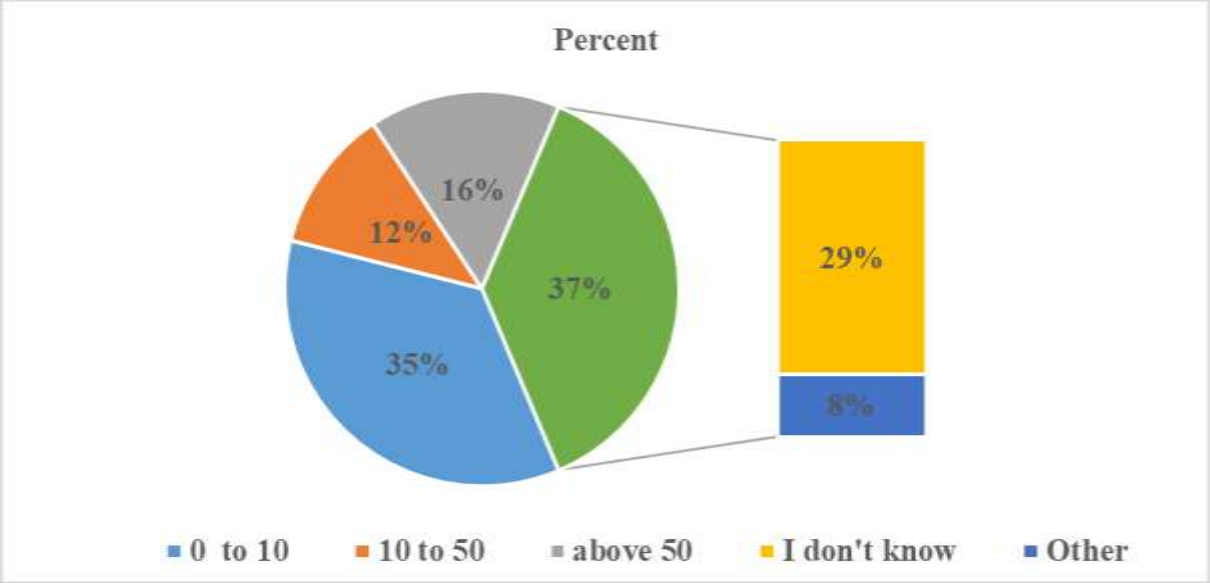


Figure 4.10: In the last two years, how many incident related to medical equipment are reported in your hospital.

More generally, this study intended to know if there are a national patient safety program which consider medical devices, based on the respondent percentages is found to deficit where only 27.5% confirmed that they are available and 66.7% confirmed negative (Table 4.3)

Table 4.3: Is there any national patient safety program that include medical devices, equipment and technology

Possible answers	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	14	27.5	27.5	27.5
No	20	39.2	39.2	66.7
No idea	17	33.3	33.3	100.0
Total	51	100.0	100.0	

92.2% of respondents depicted that patient safety related medical devices is needed because, if medical equipment is well tested it's brings positive impact to the patient (Figure 4.11).

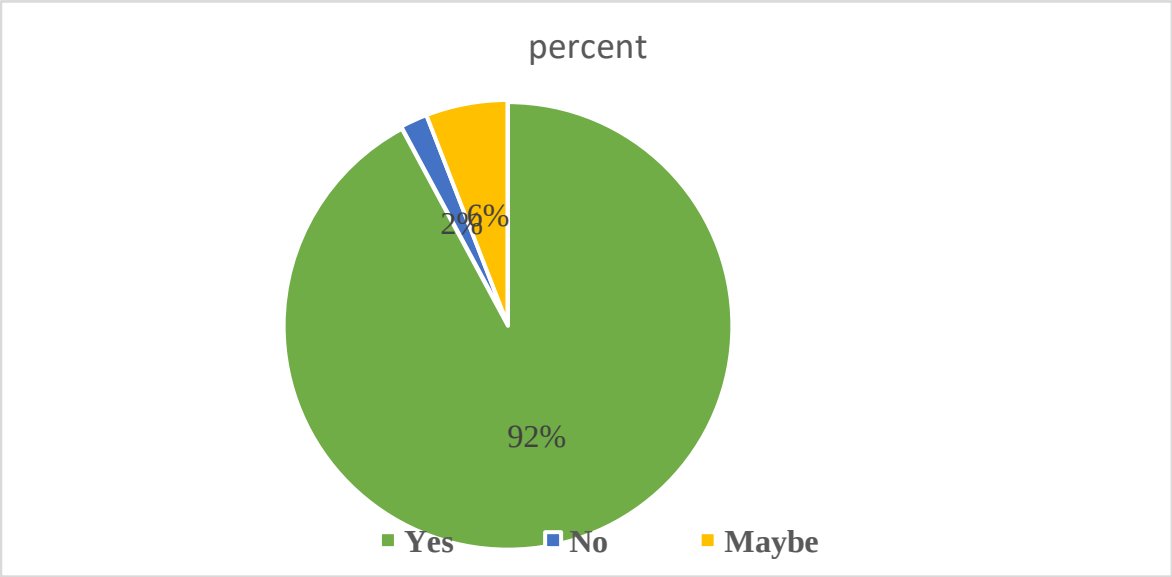


Figure 4.11: Do you think patient safety related to medical equipment is needed

4.1.2. Test of Correlation and Significance of Variables

In order to test the relationship between variables (independent and dependent variables) and their significance, binary logistic regression analysis and chi square test were used. The measure of a variable known as correlation demonstrates the simultaneous association or strength of a link between two variables [56]. The purpose of the statistical test of significance is to determine if an observed difference suggests that the characteristics of two or more groups are the same or different, or whether there is a relationship between two or more variables.

Table 4. 4 Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	30.449[a]	.524	.710
	Estimation terminated at iteration number 7 because parameter estimates changed by less than .001		

The model summary table (Table 4.4) reports the strength of the relationship between the model and the dependent variable. The multiple correlation coefficient (R) is the linear correlation between the observed and model-predicted values of the dependent variable. Its large value indicates a strong relationship. According to Cox & Snell [57] R Square Nagelkerke R Square,

the R square value for binary logistic regression model range between 0-1, the more the R square-value tends to be 1, this indicates the stronger significance between independent and dependent variables [58]. Based on the analysis, the results for Cox & Snell R Square and Nagelkerke R Square are 0.524 and 0.710 correspondingly.

Binary logistic results

This study also used the Binary Logistic Regression Model to investigate if there is a statistical significance between selected variables (independent variables) and the availability of practices on the accuracy of medical equipment. The eleven variables commonly associated with those willingness are listed below.

Table 4.5: Shows the significance of variables

SN	**Variables(selected factors)**	**B**	**S.E.**	**Wald**	**df**	**Sig.**	**Exp(B)**
1	Professional background	4.488	1.575	8.125	1	0.004	0.011
2	Parametric settings	0.044	0.549	0.006	1	0.937	0.957
3	Testing of equipment	6.285	2.386	6.935	1	0.008	0.002
4	Test of equipment after repairing	5.05	1.85	7.452	1	0.006	156.009
5	Plan for test calibration	5.792	2.501	5.365	1	0.021	327.737
6	Calibrated test cover all medical equipment	3.012	1.247	5.833	1	0.016	20.324
7	Systematic methodology(SOP)	2.9	1.881	2.377	1	0.123	18.179
8	Regulation and policies for accuracy	6.137	2.359	6.77	1	0.009	0.002
9	Database of medical equipment(system)	1.817	0.768	5.603	1	0.018	0.162
10	Safety program for medical devices and test	2.28	1.099	4.308	1	0.038	9.78
11	Need for medical equipment safety	6.354	2.612	5.916	1	0.015	574.554
	Constant	7.973	5.522	2.085	1	0.149	2902.794

While assessing the contribution of the nine variables (selected factors) on availability of practices on the accuracy of medical equipment, the following notations and meanings were used [59]: B: Regression coefficient in the binary logistic regression model. S.E: Standard error. Exp (B): Odds ratio. Sig.: p-values (in the column of Sig.). Wald: A Wald chi-square test was used to

determine whether the coefficients within the model are statistically significant. df: Degree of freedom (for the Wald chi-square test).

Factor is said to be significance if p is less than 0.05 and if wald is grater that critical value at 1 degree of freedom also indicate the significant between variable.

- **Chi-square test results**

The chi-square test is a statistical measure used in sampling analysis to assess the relationship between two attributes (variables) [60]. It is symbolized as χ^2. In this study, the significance of the chi-square value [χ^2 (calculated)] was determined by using the suitable degree of freedom [df = (r − 1)*(c − 1)] and the degree of significance ($\alpha = 0.05$) in comparison with the chi-square value from a table [χ^2 (critical)][58]. Table 4.18 indicates the chi-square test results to find relationships between variables (selected factors) and Availability of practices on the accuracy of medical equipment.

Table 4.6: Correlation of variables (selected factors) to the Availability of practices on the accuracy of medical equipment

S.N	Variables(selected factors)	Df(r-1)(c-1)	χ^2(Calculated)	χ^2(Critical)	p-value	χ^2 test (Ho)*
1	Professional background	4	15.95157	9.488	0.0030848	SR
2	Parametric settings	0.1	15.43531	9.488	0.0038785	SR
3	Testing of equipment	3	16.22421	7.815	0.0010201	SR
4	Test of equipment after repairing	2	7.675485	5.991	0.0215422	SR
5	Plan for test calibration	3	19.92532	7.815	0.0001759	SR
6	Calibrated test cover all medical equipment	3	20.88658	7.815	0.0001111	SR
7	Systematic	3	22.21319	7.815	0.000058	SR

	methodology(SOP)				8	
8	Regulation and policies for accuracy	3	16.22421	7.815	0.0010201	SR
9	Database of medical equipment(system)	3	12.48556	7.815	0.0058921	SR
10	Safety program for medical devices and test	2	6.739286	5.991	0.0344019	SR
11	Need for medical equipment safety	2	9.853295	5.991	0.0072507	SR

*****Ho: There is no relationship between the selected independent variable (selected factors) and the dependent variable (Availability of practices on the accuracy of medical equipment). SR= the selected factors is statistically related to the Availability of practices on the accuracy of medical equipment. r = number of rows. c = number of columns.

Since the chi-square test result calculated is greater than critical values (values obtained by considering values of degree of freedom at the level of α=0.05 found in χ^2 table. There is a stronger evidence of rejecting null hypothesis means that there a strong relationship between variables and the availability of practices on the accuracy of medical equipment. Finally, this study depicts that there are a strong correlation between dependent variable and a selected variables (factors).

Determination of expected values

$$E_i = \frac{Row\ total * Column\ total}{n}$$

E_i= Expected value

Chi-square calculation

$$\chi^2 = \Sigma \frac{(O_i - E_i)^2}{E_i}$$

χ^2= chi-square

O_i= Observed value

E_i= Expected value

4.2 Findings

4.2.1 Current situation

The current situation from observation and discussion with the Biomedical Engineer/Technician is that the BMET/BME knows that Patient safety related to medical equipment is needed but because of not having a clear policy on that, it puts them not in a good position to request that practice.

4.2.2 Proposed Solution

- Ministry of Health and Rwanda Biomedical Centre could establish a new patient safety program for medical equipment.
- The setting of SOPs, patient safety procedures, and policies for medical equipment.
- Every hospital could have testing and calibration tools and a trained biomedical engineer/technician to ensure the safety of patients and users.
- Medical equipment must be well maintained and the people in charge have to be well trained.
- To ensure patients understand their treatment, verify all medical procedures, and seek to ensure standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations.
- Developing patient safety policies on medical equipment and acquiring the appropriate tools and training on them.
- Increase biomedical technicians in hospitals, purchase quality medical equipment, continue to learn, and do more research in the biomedical field this is higly recommended to MoH and to the biomedical students.

4.3 Discussion

This thesis intended to stimulate interest and action to improve patient safety programs and the quality of health care delivery in Rwanda healthcare settings. Research questions were aimed at ascertaining the clinical implication of incorrectly calibrated medical equipment in healthcare

settings. Additionally, the research also looked at and assessed how well medical devices work in Rwanda in comparison to the accepted international standard.

4.3.1 What is the practice to ensure the accuracy and precision that contribute to patient safety?

As we know, all equipment degrades over time due to continuous use. According to a survey on medical devices that was done by the WHO for the global atlas of medicine in 2022, a healthy healthcare system depends on technology, particularly for patient monitoring, disease prevention, diagnosis, and treatment, medical devices are crucial the World Health Assembly issued resolution WHA60.29 in recognition of the considerable influence that technology has on medical device to wards the measurement which reads to accuracy and precision [61]. Moreover considering the specific objective which says to assess patient safety programs for medical equipment in Rwandan healthcare with the response got from the answer of survey it was clear that the research question is answered by founding that the practice is not fully developed nor considered. The use of a qualified source who complies with a national standard is crucial when developing and conducting a calibration program. The best option is to choose a company that has ISO 17025 accreditation. Specific to testing and calibration laboratories, ISO/IEC 17025: 2005 outlines their needs and sets very high standards for those who use it. Through their accrediting body, accredited calibration suppliers have certain supervisory protection, including frequent audits and reviews and particular Quality Management System criteria this meets the specific objective which is to analyze the practice that influences patient safety related to medical equipment.

4.3.2 Do the parameters of medical equipment accurate at all times? Are there appropriate test equipment, standards operating procedures, regulations, and policies used to verify the accuracy of measurements?

There is a requirement to only use equipment that is tested, calibrated, and fit for purpose. Over the past 20 years, Rwanda's health sector has made significant improvements to the population's health. Within a given industry, calibration intervals can vary significantly. The equipment and the type of application have an impact on frequency. Calibration should typically be done once a year at the very least and as suggested by the manufacturer. The frequency will be significantly higher in more crucial applications. This comes to meet the specific objective which is to identify

the factors that can help to improve patient safety in the hospital, related to the survey to answer to the knowledge and the will of doing calibration but the resources are the issue for the engineers.

4.3.3 Is there any data which shows that medical equipment used in our healthcare system is safe and contributes to patient positive outcomes?

Every calibration must be done following a traceable, national, or international standards. By ensuring that the test standards used are routinely calibrated by higher level reference standards, traceability is achieved. When performing calibration with instrument, the technician's job is to make sure that the results are standardized within its calibration interval and the unique identifier is entered on the relevant calibration data sheet to maintain traceability. International standards recommend having a recording system for the specific objective which tends to advice and illustrate ways of improving patient safety of medical equipment. This study founds that the data to show the patient safety of medical equipment are not available.

4.3.4 Is there any national patient safety program that includes medical devices, equipment, and technology?

Almost all equipment ages and deteriorates in some way. Components fail stability test and deviate from their listed specification, as they get older. Even routine handling can harm calibration, and even if an item of equipment seems to be in good physical condition, rough treatment can entirely throw it out of calibration. Equipment continues to fulfill specifications thanks to routine calibration. Having a well-organized calibration program can frequently improve quality, production, and profitability. This study founds that there is no national safety program, however, having a national safety program can help in reducing malfunction of medical equipment.

4.4 Summary

To achieve the objectives of this study, 51 respondents were interviewed on the safety and use of medical equipment with emphasis on calibration practice in ensuring equipment accuracy and safety, it was clear that about 78.4% respondents confirmed the availability of practices to ensure the accuracy of medical equipment contributes more to patient safety. This study also assessed the relationship between the independence and dependence variables. Various factors influencing

the availability of practice that ensure the accuracy of medical equipment for patient safety were analyzed using descriptive statistics and statistical analysis including chi-square tests, and a binary logistic regression model.

Chi-square test results indicated that professional background, parametric settings, testing of equipment, the test of equipment after repairing, plan for test calibration, calibrated test cover all medical equipment, systematic methodology (SOP), regulation and policies for accuracy, database of medical equipment (system), safety program for medical devices and test need for medical equipment safety were strongly associated ($p< 0.05$) with the availability of medical equipment practice(Professional background, Parametric settings, Testing of equipment, Test of equipment after repairing, Plan for test calibration, Calibrated test cover all medical equipment, Systematic methodology (SOP), Regulation and policies for accuracy, Database of medical equipment(system), Safety program for medical devices and test and Need for medical equipment safety) In addition, a binary logistic regression model showed that of the 11 selected variables 5 were positively correlated; while four (4) were negatively correlated ($p< 0.05$) with the available practice on the medical equipment.

CHAPTER 5. CONCLUSION AND RECOMMENDATION

5.1 Conclusion

For healthcare settings, the health and safety of patients remain the top priority. With this, healthcare givers rely on the accuracy and precision of the instruments that they are using to diagnose, treat and monitor patients. Many of the obstacles to patient satisfaction and safety identified by staff can not be overcomed without the right structures of governance, management, and accountability in place, yet it was clear from the interview conducted that all of these need substantial improvement. For example, optimizing patient safety within the available resources will require engagement and leadership from policy makers such government institutions at all levels.

With the advancement of technology, the use of medical equipment is increasing. These devices require quick and accurate calibration to perform accurate and precise measurements in various applications. The results from this study are relevant for the quality of patients' care because the healthcare giver's sensitivity to the medical device's calibration is important in terms of ensuring the coutcome of the medical device. Incorporating the patient safety programs into healthcare worker applicants' curricula and ensuring that staff members receive ongoing in-service training can thereby improve safety of patients and indirectly improve the quality of medical equipment. Therefore, the precision and accuracy of a device are of utmost importance.

To serve the users and ensure that public health and safety are not compromised, the medical device industry is regulated by strict standards, moreover, it is necessary to encourage the hospitals to put more effort into strategic planning for patient safety as well as medical equipment safety 'if not to create them' and encourage supporting staff and implementing effective training programs in hospitals because periodic calibration will maintain the equipment's effectiveness and decrease the risk of causing harm to a patient.

5.2 Recommendations

These days, information technology has become a vital and integral part to improve and to provide solutions to many critical problems in institutions. In addition to that, this study recommends MoH, RBC, and all hospitals to have: (a) a committee that looks at patient safety, (b) dissemination of all incidents alerts so that people will be aware of them and try to avoid

them, (c) available information regarding patient safety and regular tests and their reports could be done and communicated.

The practice of patient safety related to medical equipment as standards recommends MoH to have the needs to validate the patient safety programs through engagement with experts and policy makers for greater development of quality of life. Because of this, a broader application of patient safety practices could be used in making decisions about buying or improving health technology that can be used.

5.3 Future study

For future study, it is highly recommended that the researchers dig deep into this subject of patient safety related to medical equipment and develop an SOPs for each medical equipment on patient safety because as the years go on, medical equipment needs to be checked and be put to international standard and for effeicient use in Rwanda. In order to continue to grow, we need to understand that the better medical equipment is treated the better it works, so this study also recommends Rwandan researchers to study on functionality of medical equipment towards patients safety. As a result, if the equipment works well, the medical doctor will have good results from them, and this will keep promoting the healthcare standard of our country.

REFERENCES

[1] M. U. Lucian L. leape Lucian L. Leape Harvard T. H. Chan School of Public Health Boston, *Making Healthcare Safe The story of the Patient Safety Movement*. 2021.

[2] S. World Health Organization 2012 WHO document Production Services, Geneva, "Patient Safety Research A guide for development training programmes," 2012.

[3] L. R. M. Michael P. Gallaher, "The Impact of Calibration Error in Medical Decision Making," no. January, 2015.

[4] S. Cluster, "Guide for Developing National Patient Safety Policy and Guide for Developing National Patient Safety Policy and," no. December, 2014.

[5] A. Badnjevic, L. Gurbeta, E. R. Jimenez, and E. Iadanza, "Testing of mechanical ventilators and infant incubators in healthcare institutions," *Technol. Heal. Care*, vol. 25, no. 2, pp. 237–250, 2017, doi: 10.3233/THC-161269.

[6] S. A. Saleh S Altayyar Department of Biomedical Technology,King Saund University, "Medical Equipment and Patient Safety," *J. Anal. Pharm. Res.*, vol. 2, no. 5, 2016, doi: 10.15406/japlr.2016.02.00034.

[7] A. Saleh, M. Ma, A. Am, N. Ae, and A. Mo, "2 Healthcare Technology Management Administration, King Fahad Medical City, Ministry of Health," vol. 29, no. 12, pp. 2553–2560, 2018.

[8] 2011 FDA Oct. 31, "Understanding Barriers to Medical Device Quality," *FDA Rev. Doc.*, p. 45, 2011.

[9] S. Centre International de Conférences Genève (CICG) Geneva, "Third WHO Global Forum on Medical Devices," no. May 2017, 2017.

[10] D. Mutia, J. Kihiu, and S. Maranga, "Maintenance Management of Medical Equipment in Hospitals," *Ind. Eng. Lett.*, vol. 2, no. 3, pp. 9–19, 2012.

[11] I. Mohammadfam, M. Kamalinia, M. Momeni, R. Golmohammadi, Y. Hamidi, and A. Soltanian, "Evaluation of the Quality of Occupational Health and Safety Management Systems Based on Key Performance Indicators in Certified Organizations," *Saf. Health Work*, vol. 8, no. 2, pp. 156–161, 2017, doi: 10.1016/j.shaw.2016.09.001.

[12] Y.-L. Cheng *et al.*, "Patient Safety: Preventing Patient Harm and Building Capacity for Patient Safety," *Intech*, vol. 11, no. tourism, p. 13, 2016.

[13] M. Emanuel, Linda Berwick, Don Conway, James Combes, John Hatlie, Martin Leape,

Lucian Reason, James Schyve, Paul Vincent, Charles Walton, “What Exactly Is Patient Safety?,” *J. Med. Regul.*, vol. 95, no. 1, pp. 13–24, 2009, doi: 10.30770/2572-1852-95.1.13.

[14] K. A. Keeley, “Equipment Safety, Maintenance and Inspection: What the Oral Surgeon Needs to Know,” *Oral Maxillofac. Surg. Clin. North Am.*, vol. 29, no. 2, pp. 209–221, 2017, doi: 10.1016/j.coms.2016.12.012.

[15] W. H. Organisation, *World Health Assembly issued resolution WHA60.29*, no. Licence: CC BY-NC-SA 3.0 IGO. 2007.

[16] World Health Organization (WHO), *Human Resources for Medical Devices: The role of biomedical engineers*. 2017.

[17] P. Oxymeters, P. Simulators, and F. Monitors, “Testing and Calibration of Bio-Medical Equipment.”

[18] J. Corrigan, “Crossing the quality chasm,” *Build. a Better Deliv. Syst. A New Eng. Care Partnersh.*, no. March, pp. 95–98, 2005, doi: 10.17226/11378.

[19] E. Mattox, “Medical devices and patient safety,” *Crit. Care Nurse*, vol. 32, no. 4, pp. 60–68, 2012, doi: 10.4037/ccn2012925.

[20] V. K. Rathi and S. T. Gray, “Medical Device and Device Safety,” *Otolaryngol. Clin. North Am.*, vol. 52, no. 1, pp. 103–114, 2019, doi: 10.1016/j.otc.2018.08.013.

[21] E. Aveling, Y. Kayonga, A. Nega, and M. Dixon-woods, “Why is patient safety so hard in low-income countries ? A qualitative study of healthcare workers ’ views in two African hospitals,” pp. 4–11, 2015, doi: 10.1186/s12992-015-0096-x.

[22] J. H. with editing by R. MacDonald, “Methodology briefing paper summarizes the methodology used by the Priority Medical Devices (PMD) project team for the research and subsequent content published in the report, Medical Devices,” 2010.

[23] S. A. GULEC, *PHYSIOLOGICAL ROLE OF INTESTINAL COPPER TRANSPORTER ATP7A IN*. 2013.

[24] S. Weininger, M. B. Jaffe, and J. M. Goldman, “The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems,” *Anesth. Analg.*, vol. 124, no. 1, pp. 127–135, 2017, doi: 10.1213/ANE.0000000000001386.

[25] M. Der Anwendung and V. Medizinprodukten, “Defizite in der Patientensicherheit,” *Dtsch. Zeitschrift für Klin. Forsch.*, vol. 16, no. 3/4, pp. 102–105, 2012.

[26] N. Geissler *et al.*, “Patient safety related to the use of medical devices: A review and investigation of the current status in the medical device industry,” *Biomed. Tech.*, vol. 58, no. 1, pp. 67–78, 2013, doi: 10.1515/bmt-2012-0040.

[27] R. Spotlight, “[Medical Device]medical device errors,” vol. 5, no. July 2013, pp. 12–17, 2015.

[28] A. Arnould, R. Hendricusdottir, and J. Bergmann, “The Complexity of Medical Device Regulations Has Increased, as Assessed through Data-Driven Techniques,” *Prosthesis*, vol. 3, no. 4, pp. 314–330, 2021, doi: 10.3390/prosthesis3040029.

[29] T. G. H. T. F. Lalis Georgette , GHTF Chair Study Group 2 Endorsed, “Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form,” 2006.

[30] International Atomic Energy Agency (IAEA), “Governmental, Legal and Regulatory Framework for Safety,” *IAEA GSR Part 1(Rev.1)*, vol. 1, p. 42, 2016.

[31] Cdrh, “Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management,” *Guid. Ind. FDA Premarket Des. Control Rev.*, pp. 2–33, 2000.

[32] and M. S. D. Linda T. Kohn, Janet M. Corrigan, *To Err Is Human: Building a Safer Health System*, vol. 52, no. 1 SUPPL. 2018.

[33] H. Devices, “Top 10 health technology hazards for 2015 are named,” *OR Manager*, vol. 31, no. 2, pp. 15–17, 2015.

[34] K. Willson, K. Ison, and S. Tabakov, *Medical Equipment Management*. 2013.

[35] S. A. Ibrahim, K. A. Reynolds, E. Poon, and M. Alam, “The evidence base for US joint commission hospital accreditation standards: Cross sectional study,” *BMJ*, 2022, doi: 10.1136/bmj-2020-063064.

[36] Joint Commission on Accreditation of Healthcare Organizations., “Accreditation Program: Hospital,” p. 290, 2009.

[37] J. Yoshioka, M. Nakane, and K. Kawamae, “Healthcare Technology Management (HTM) of mechanical ventilators by clinical engineers,” *J. Intensive Care*, vol. 2, no. 1, pp. 1–2, 2014, doi: 10.1186/2052-0492-2-27.

[38] J. C. M. Richard and R. M. Kacmarek, “ICU mechanical ventilators, technological advances vs. user friendliness: The right picture is worth a thousand numbers,” *Intensive Care Med.*, vol. 35, no. 10, pp. 1662–1663, 2009, doi: 10.1007/s00134-009-1581-6.

[39] M. J. T. P. D, “Medical Metrology in Australia . Lack of quality control of physical medical measurements in Australia,” pp. 1–23, 2011.

[40] M. A. Hossain, M. Ahmad, M. R. Islam, and Y. David, “Mathematical modeling of clinical engineering approach to evaluate the quality of patient care,” *Health Technol. (Berl).*, vol. 10, no. 2, pp. 547–561, 2020, doi: 10.1007/s12553-019-00390-9.

[41] F. A. Alzahrani, M. Ahmad, and T. J. Ansari, “applied sciences Towards Design and Development of Security Assessment Framework for Internet of Medical Things,” no. August, 2022, doi: 10.3390/app12168148.

[42] P. Harikumar and P. G. Saleeshya, “Integrating FMEA, QFD and Lean for Risk management in hospitals,” *IOP Conf. Ser. Mater. Sci. Eng.*, vol. 577, no. 1, 2019, doi: 10.1088/1757-899X/577/1/012040.

[43] M. Sezdi, “Two Different Maintenance Strategies in the Hospital Environment : Preventive Maintenance for Older Technology Devices and Predictive Maintenance for Newer High-Tech Devices,” vol. 2016, 2016.

[44] S. Das, S. Roychowdhury, and J. Maiti, “Risk Assessment in the Calibration of Medical Equipment,” *2021 Int. Conf. Maint. Intell. Asset Manag. ICMIAM 2021*, no. Mcdm, 2021, doi: 10.1109/ICMIAM54662.2021.9715197.

[45] Y. K. Alotaibi and F. Federico, “The impact of health information technology on patient safety,” *Saudi Med. J.*, vol. 38, no. 12, pp. 1173–1180, 2017, doi: 10.15537/smj.2017.12.20631.

[46] The Leapfrog Group, “What is patient safety? [Video file],” 2016.

[47] Institute of Medicine, *Shaping the Future; Crossing the quality chasm: a new health system for the 21th century*, no. March. National Academies Press, 2001.

[48] S. N. Tadiboina, “The importance and leverage of modern information technology infrastructure in the healthcare industry,” no. December, 2022, doi: 10.6084/m9.doione.IJRTI2212044.

[49] American College of Obstetricians and Gynecologists, “Patient Safety and Information Technology,” *Commitee Opin.*, vol. 125, no. 618, pp. 268–273, 2015.

[50] K. Adane, M. Gizachew, and S. Kendie, “The role of medical data in efficient patient care delivery: A review,” *Risk Manag. Healthc. Policy*, vol. 12, pp. 67–73, 2019, doi: 10.2147/RMHP.S179259.

[51] E. Coiera, J. Ash, and M. Berg, “The Unintended Consequences of Health Information Technology Revisited,” *Yearb. Med. Inform.*, no. 1, pp. 163–169, 2016, doi: 10.15265/iy-2016-014.

[52] A. Sopan, C. Plaisant, S. Powsner, and B. Shneiderman, “Reducing wrong patient selection errors: exploring the design space of user interface techniques,” *AMIA Annu. Symp. Proc.*, vol. 2014, pp. 1056–1065, 2014.

[53] S. landau and B. S. Everitt, *HandBook of statical analuses using SPPS*, vol. 4, no. 1. 2557.

[54] B. Kabir, Syed Muhammad Sajjad Curtin Universityy Publication, Chittagong-4203, “Basic Guidelines for Research: An Introductory Approach for All Disciplines Methods of data collection (pp.201-275)Edition,” no. July 2016, 2018.

[55] C. U. Stephen A Sweet,Cornell University and Karen Grace Martin, *Stephen C. U. A Sweet,Cornell University and Karen Grace Martin, Data_analysis with SPSS A First Course in Applied Statistics. Second Edition*. .

[56] Daniel Arkkelin, “Using SPSS to Understand Research and Data Analysis,” *Psychol. Curric. Mater.*, vol. 1, p. 194, 2014.

[57] E. R. Ugba and J. Gertheiss, “A Modification of McFadden’s R^2 for Binary and Ordinal Response Models,” pp. 1–18, 2022.

[58] J. KOTHARI C.R Former Principal, College of Commerce University of Rajasthan, *the accuracy of medical equipment*. .

[59] H. A. Park, “An introduction to logistic regression: From basic concepts to interpretation with particular attention to nursing domain,” *J. Korean Acad. Nurs.*, vol. 43, no. 2, pp. 154–164, 2013, doi: 10.4040/jkan.2013.43.2.154.

[60] R. S. Rakesh Rana and I. A. Statistical Section, Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, GOI, New Delhi, “Chi - square Test and its Application in Hypothesis Testing,” vol. 1, no. 1, pp. 69–71, 2015, doi: 10.4103/2395-5414.157577.

[61] W. H. Organization, *Global atlas of medical devices*. 2022.

APPENDICE

Appendix 1: Mode of Data Collection (Questionnaire)

Investigation of patient safety and the use of medical equipment: Rwandan health

Hello,
My name is Viviane MUSABWAMANA, Masters of Biomedical Engineering, Center of Excellence in Biomedical Engineering and e-Health, University of Rwanda.

you have been identified as key person to participate in the research project with the title: **"Investigation of patient safety and the use of medical equipment: case study on Rwandan healthcare. "** This research is being conducted as part of a core requirement of the Masters completion in Biomedical Engineering at the University of Rwanda. questionnaire is to fulfil the requirement of Msc project in Biomedical Engineering, form the university of Rwanda. **It is 15 question that will take 5 min of your time to answer**. This questionnaire will allow to collect data that will help me to gain an understanding of current status of patient safety related to medical equipment in Rwandan hospitals. The purpose of this research is to assess the level of patient safety related to the use of medical device in Rwandan healthcare, to identify the existing knowledge and resources, which is applied to patient safety of medical equipment, to compare with related international standards, regulations and guidelines.
Microsoft form is used to allow an automatic return of the questionnaire to me once completed. **This questionnaire will expire in 2 weeks' time**. Thank you in advance for your help. **Viviane/Msc student)**

1. What is your professional background? *

- ◯ Nurse
- ◯ Allied professional
- ◯ Biomedical Engineer
- ◯ Biomedical Technician
- ◯ Others(Hospital Design)

2. Are there any practices to ensure the accuracy of medical equipment that contribute to patient safety? *

- ◯ Yes
- ◯ No
- ◯ Maybe
- ◯ I don't have such information

3. How do you ensure that the parameters of medical equipment are accurate ? *

- ◯ By checking Biomed report
- ◯ By checking service provider report
- ◯ I don't know
- ◯ No
- ◯ Other

4. Are there appropriate testing equipment, analyzers and simulators? *

- ◯ Yes
- ◯ No
- ◯ Maybe
- ◯ I don't know

5. Do you test the equipment after repairing it, troubleshooting it, or just moving it before it goes back to services? *

- ◯ Sometimes
- ◯ Every time
- ◯ No

6. Is there any plan of calibration of your test equipment, simulators and analyzers? *

- ◯ Yes
- ◯ No
- ◯ Maybe
- ◯ I don't know

7. If yes, is it for all the medical equipment? *

- ◯ Yes
- ◯ No
- ◯ Maybe
- ◯ I don't know

8. Are there any standards operating procedures used to verify the accuracy of measurements? *

- ◯ Yes
- ◯ No
- ◯ Maybe
- ◯ I don't know

9. Are there any regulation and polices followed to verify the accuracy of measurements? *

- ◯ Yes
- ◯ No
- ◯ Maybe
- ◯ I don't have such information

10. Is there any data base that shows that medical equipment used in our healthcare system is safe and contribute to patient positive outcomes? *

- ◯ Yes
- ◯ No
- ◯ Maybe
- ◯ I don't know

11. Is there any reporting system related to medical equipment incident? *

- ◯ Yes
- ◯ No
- ◯ I don't have such information

12. In the last two years, how many incident related to medical equipment are reported in your hospital? *

- ◯ 0 to 10
- ◯ 10 to 50
- ◯ above 50
- ◯ I don't know
- ◯ Other

13. Is there any national patient safety program that include medical devices, equipment and technology? *

- ◯ Yes
- ◯ No
- ◯ I don't have such information

14. Do you think patient safety related to medical equipment is needed? *

- ◯ Yes
- ◯ No
- ◯ Maybe

15. What can you recommend on the improvement of patient safety related to medical equipment in Rwandan hospitals? *

Appendix 2: The respondent's suggestion

Q15) what can you recommend on the improvement of patient safety related to medical equipment in Rwandan hospitals?

Rwanda ministry of health and Rwanda Biomedical Centre should establish a new patient safety program related to medical equipment, as it plays a vital role and promotes a good health care delivery.
Setting of SOPs
I would recommend all hospitals to take account on the patient safety of the equipment as serious as they can just for the sake of the good functioning of the equipment that insures us that we are safe and the environment is safe also, Thank you
Every hospital shall develop the patient safety procedures , buy the appropriate testing tools and train the technician and end users of the machine how to use them.
The safety testing of medical equipment should be done regularly
I think there should be tests and policy related to medical equipment safety. Also a well elaborated reporting systems may be of great advantage
calibration is needed for medical equipment because we are applied them on patient
To provide testing tools, analyzers, simulators and calibration systems.
Make sure patients understand their treatment, verify all medical procedures and seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations
check life time and do calibration regularly
Developing the patient safety policies on medical equipment and acquire the appropriate tools and training on them .
What I would recommend as a Biomedical technician is to introduce more simulators in health facilities to ensure medical equipment parameters accuracy
Medical equipment must be well maintained and the people in charge have to be well trained
I recommend to avail a specific biomedical team for calibrating medical equipment in hospital

Centrale level can help to improve the patient safety
I would recommend to make the competence of personnel and to increase the number of biomedical engineers
To continue improving patient safety according to the new standard
I would like to recommend to give training for the engineers
It's better to care to standard of medical equipment's and to train the -end users of equipment for to use it in good quality.
I recommend to do 3 months preventive and curative maintenance of devices
Routine training to biomedical technicians
I recommend that as such as possible every health care facility must take care of patient safety related to medical equipment
Every hospital should have testing & calibration tools and trained Biomed to ensure safety of patients and users.
I think every end user in the hospital should take a medical equipment as their own responsibility to protect a patient not only a responsibility of a Biomedical Engineer.
Ensure regular calibration, maintenance and repair, correct use of all medical equipment all times
Improvement is of spare part in biomedical equipment
I would like to let you know that the technical trainings on equipment is more important, I would recommend to offer training opportunity to hospital Biomedical engineers so that they can maintain well equipment to its lifetime.
Increase biomedical technician in hospitals, buy quality medical equipments, continue to learn and do more researches.
To be careful on calibration of medical equipment to avoid accidents
Based on my experience in Biomedical Engineering. I recommend that there should be an established firm to train BMET to calibrate medical equipment. Also I recommend the hospital to invest in Equipment calibration, simulator and analyzer for BME for them to carry out the testing and calibration of medical equipment. In additional to that the government regulatory agencies should establish the policies and regulations governing equipment testing and calibration

Increase the number of Biomedical technician in hospital, increase training of sophisticated equipment
It is better to put effort on Verification of universal protocol, use of monitoring technology and make sure that all patients are familiar with medical equipment so that they can also prevent errors in their own care.
To provide calibration tools.
I can recommend providing a lot of medical equipment mostly in district hospitals and health centers, ensure that these hospitals have sufficient biomedical technicians to perform well these duties and provide as much as possible trainings for them about those medical equipment may help.
Thank you, I can recommend this; to improve medical equipment and more trainings
To perform preventive maintenance on time to be sure if any equipment in service is functioning properly
Medical equipment users, engineers training
Only the known quality equipment should be allowed to enter the country , second hand equipment should not be allowed to enter the country as their life time expired or is bear , testing equipment & tools should be available and only used by appropriate person well trained. Equipment life time should be respected where sensitive equipment can cause harm to patient and or even to the other personal & environment, guideline & police for proper disposal followed, develop SOPs for each equipment to guide the user as well as availability of service manual to guide their maintenance personal, only the equipment should be used be appropriate person . Every incident, report , maintenance records should be evaluated and monitored properly.. avail more trainings for each type required .
Most of all Rwandan hospitals do not have testing equipment, analyzers and simulators, patient safety and the safety use of medical equipment must be taken into consideration for patient welfare and better Health technology outcome.
Every hospital need to have biomedical technician all shift and they must have platform that they can share the ideas and access information like newest technology are coming on market and must have some training and that platform must have recertification system related to daily job moreover the hospital managers need to be

aware about biomedical engineering....
To make sure every BMET technician is well trained and ready to fulfill equipment manufacturer's safety procedures, and end users too
We need more testing tools and training to know how to use them. Thank you
We request help for our biomedical so that we can be sure of the equipment we are using
For us to be sure of the result engineers need equipment and training for better output
To facilitate all hospitals to have analyzers and simulators and then to help hospital technicians to increase their skills on advanced equipment technology.
I am recommending the hospital managers or a regulating body that overlooks medical equipment to provide biomedical engineers/ technicians in healthcare facilities with testing tools, simulators and analyzers as well as standard operating procedures and protocols of how testing and simulation should be conducted to ensure patients are safe.
They must develop policy and procedures regarding to the manufacture recommendation
Avail information regarding patient safety and regular tests and their reports should be done and communicated
By improve the why the use using medical equipment
Clear policies, leadership capacity, skilled healthcare professionals
Calibration equipment is needed

Appendix 3: Letters of approval

3.1 Approval Letter of Gatunda District Hospital

REPUBLIC OF RWANDA

Gatunda, On 10/01/2023
No.663/GDH/B.A/2023

EASTERN PROVINCE
NYAGATARE DISTRICT
GATUNDA HOSPITAL
E-mail:gatunda.hospital@moh.gov.rw

To: Ms. MUSABWAMANA Viviane
Email: musaviviane@gmail.com
Phone: +0788703353
KIGALI

Re: Response to your letter.

Reference is made to your letter of January 5th,2023 requesting for an approval to conduct data collection for the study entitled **<Investigation of patient safety and the use of medical equipment: case study on Rwandan healthcare>** in our institution.

I am pleased to inform you that your request has been approved with immediate effect. You will be working under supervision of Director General of **GATUNDA DISTRICT HOSPITAL.**

You are advised to present yourself to the administration of Gatunda District hospital before you start your data collection.

Sincerely,

Dr.NIYONKURU Aline Ernest
Director General of Gatunda Hospital

C.C:

- Director of finance and Administration Unit of Gatunda District Hospital
- Director of Medical and Allied Health Sciences Services Unit of Gatunda District Hospital

3.2 Approval letter of Munini District Hospital

REPUBULIC OF RWANDA

Munini on 23/04/2023
Ref.049/DRHOPMNNI/2023

SOUTHERN PROVINCE
NYARUGURU DISTRICT
MUNINI HOSPITAL
P.O Box 668 MUNINI
E-mail: Muninihospital@moh.gov.rw

To : Ms MUSABWAMANA Viviane
E-mail : musaviviane@gmail.com
Phone : +250788703353
KIGALI

Re: Response to your letter.

Reference is made to your letter of January 6th, 2023 requesting for data collection for the purpose of MSc thesis in Munini District Hospital;

I am delighted to inform you that your request has been approved with immediate effect. You will be working under supervision of **Director General of Munini District Hospital.**

You are advised to present yourself to the Administration of Munini District Hospital before you start your data collection.

Sincerely,

Dr. UWAMAHORO Evelyne
Director General of Munini Hospital.

C.C:
- Director of Finance and Administration Unit of Munini District Hospital.
- Ag. Director of Medical and Allied Health Sciences Services Unit of Munini District Hospital.

NYARUGURU

3.3 Approval letter of Kibagabaga Level 2 Teaching Hospital

REPUBLIC OF RWANDA

Kibagabaga ,17/01/2023

N°85./HOP. KIBAG/2023

MINISTRY OF HEALTH

KIBAGABAGA LEVEL2 TEACHING HOSPITAL

Po. Box: 6062, KIGALI

Email: kibagabaga.hospital@moh.gov.rw

To: Ms MUSABWAMANA Viviane

Phone: 0788703353

University of Rwanda

Dear applicant,

RE: Your request for Data Collection

Reference made to your letter requesting permission to collect the data within Kibagabaga District Hospital for your Research Proposal entitled **"Investigation of patient safety and the use of medical equipment: a case study on Rwandan health"** Based on the approval No: 113. **/KBGH_EC/2023** from the research Ethic committee, we are pleased to inform you that you are accepted to collect data within Kibagabaga Hospital. Please note that your study findings must be shared/presented to the research committee of the hospital before its dissemination.

Sincerely,

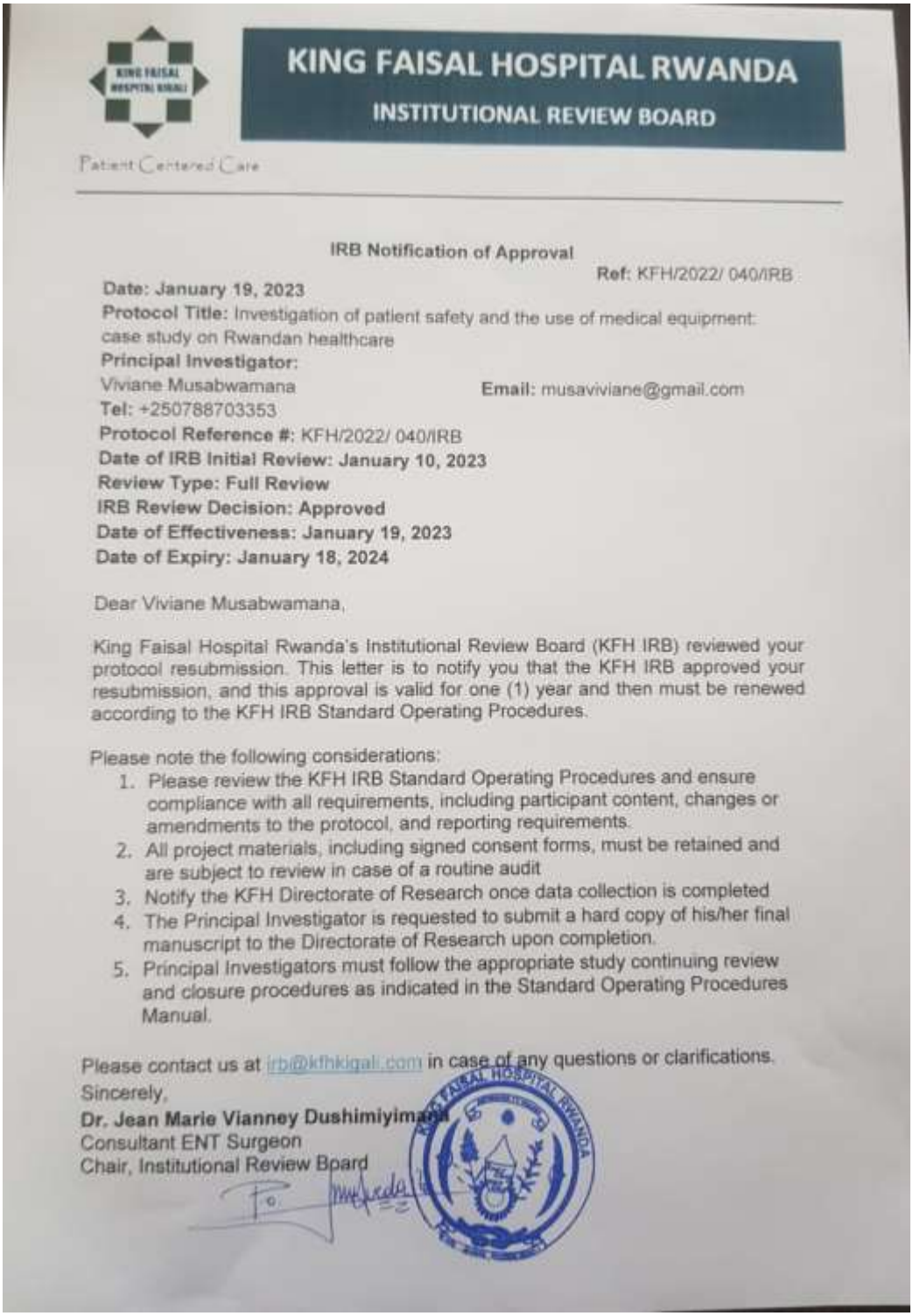
Dr. Ernest MUNYEMANA

Lt. Col

Director General of Kibagabaga Level2 Teaching Hospital

HOPITAL DE KIBAGABAGA

3.4 Approval letter of King Faisal Hospital



KING FAISAL HOSPITAL RWANDA

INSTITUTIONAL REVIEW BOARD

Patient Centered Care

IRB Notification of Approval

Ref: KFH/2022/ 040/IRB

Date: January 19, 2023
Protocol Title: Investigation of patient safety and the use of medical equipment: case study on Rwandan healthcare
Principal Investigator:
Viviane Musabwamana **Email:** musaviviane@gmail.com
Tel: +250788703353
Protocol Reference #: KFH/2022/ 040/IRB
Date of IRB Initial Review: January 10, 2023
Review Type: Full Review
IRB Review Decision: Approved
Date of Effectiveness: January 19, 2023
Date of Expiry: January 18, 2024

Dear Viviane Musabwamana,

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

Please note the following considerations:

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

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

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

KING FAISAL HOSPITAL RWANDA

3.5 Approval letter of Kibuye Referral Hospital

REPUBLIC OF RWANDA

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

To: Mrs. MUSABWAMANA Viviane

Dear Emile,

RE: Approval to conduct project work at Kibuye referral hospital

Reference is made to your letter dated on 4th January 2023 requesting the authorization to collect data as a part of your research project entitled **"INVESTIGATION OF PATIENT SAFETY AND THE USE OF MEDICAL EQUIPMENT: CASE STUDY ON RWANDAN HEALTHCARE."** and referencing to our accreditation procedures, after reviewing your pledge to ensure that all provided information will be used in the strict to ethical principles and 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 10th January 2023

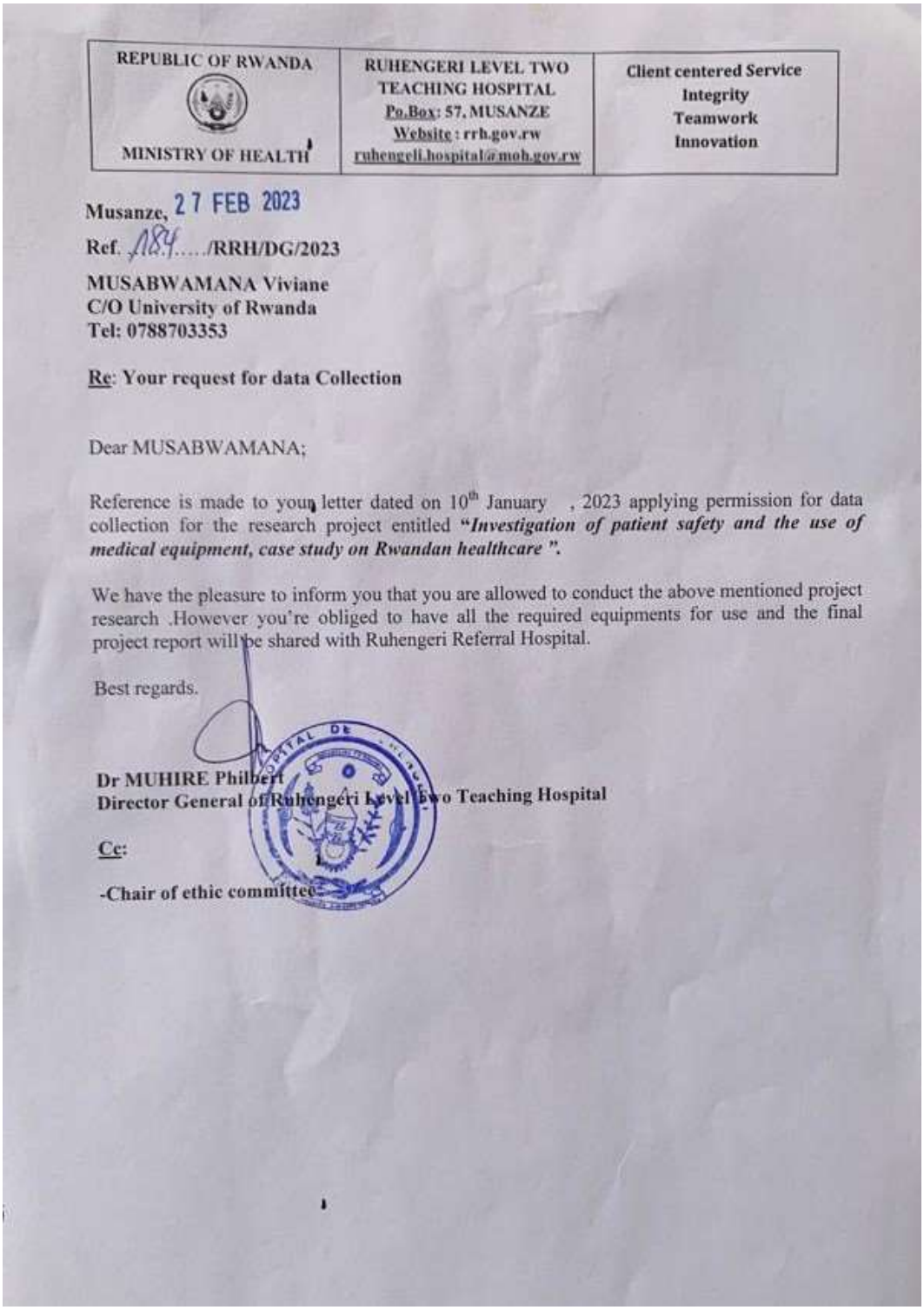
Jean Népo TWIZERIMANA

Chairperson, ethic committee

CC

- Director General, Kibuye referral hospital
- Clinical Director, Kibuye Referral Hospital
- Director of Nursing and Midwifery, Kibuye referral hospital
- Chairperson of Health and Safety committee, Kibuye referral hospital
- Head of Bio-medical Department, Kibuye Referral Hospital

3.6 Approval letter of Ruhengeri Level rwoo Teaching Hospital



REPUBLIC OF RWANDA MINISTRY OF HEALTH	RUHENGERI LEVEL TWO TEACHING HOSPITAL Po.Box: 57, MUSANZE Website : rrh.gov.rw ruhengeli.hospital@moh.gov.rw	Client centered Service Integrity Teamwork Innovation

Musanze, 27 FEB 2023

Ref. 184...../RRH/DG/2023

MUSABWAMANA Viviane
C/O University of Rwanda
Tel: 0788703353

Re: Your request for data Collection

Dear MUSABWAMANA;

Reference is made to your letter dated on 10th January , 2023 applying permission for data collection for the research project entitled ***"Investigation of patient safety and the use of medical equipment, case study on Rwandan healthcare ".***

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 Level two Teaching Hospital

Cc:

-Chair of ethic committee-