INVESTIGATING THE MEDICAL EQUIPMENT MAINTENANCE PRACTICES IN SELECTED HOSPITALS IN ZAMBIA

BY

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A dissertation submitted to the University of Zambia in fulfilment of the requirements of the degree of Masters of Engineering in Engineering Management

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Declaration

I, **CHILUFYA QUEEN**, do hereby declare that the work presented in this study for the Degree of Masters of Engineering in Engineering Management, represents my own work and has not been presented either wholly or partially for any other degree at this or any other university.

Signature: ………………………………

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Certificate of Approval

This dissertation of **QUEEN CHILUFYA** has been approved as partial fulfillment of requirements for the award of the Degree of Master of Engineering in Engineering Management by the University of Zambia.

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ABSTRACT

The role of medical equipment is crucial for efficient healthcare delivery in any hospital. Physicians rely on equipment for the diagnosis and treatment of diseases. Therefore, the availability of medical equipment in good working condition and the optimal utilization of the equipment is important in improving the quality of health services. In Zambian hospitals, many pieces of medical equipment are unavailable because they are out of use due to many factors, the major one being poor maintenance. Even though the unavailability of medical equipment has dire consequences to the lives of many Zambians, investigations into its causes are uncommon. Using both qualitative and quantitative approaches, this study investigated the factors that affect medical equipment maintenance and maintenance practices in selected Zambian hospitals. Questionnaires and interviews were the main methods for data collection. Target population that consisted of Nurses and Medical equipment personnel. In total, there were Nurses (35) who only deal with the critical medical equipment at a particular time and Medical equipment personnel (25). The sample size was derived by calculating the sample from the target population. Sampling was done using stratified sampling method and applying Yamane (1967) formula. The study adopted proportionate stratified sampling where the general population was stratified into various groups. The study then distributed the sample size so determined based on the distribution of the population among the strata such that stratum with more elements in had more elements picked compared to stratum with smaller number of elements. The study was based on five major urban hospitals in Zambia are the University Teaching Hospital (UTH), Cancer Diseases Hospital (CDH), Levy Mwanawasa University Teaching Hospital (LMUTH), Kitwe Teaching Hospital (KTH), Ndola Teaching Hospital (NTH) and Livingstone Teaching Hospital (LTH). In this research we consider looking at critical medical equipment in improving the maintenance activities in hospitals.

Face validity and content validity were assessed by the experts in the field of medical equipment management. Pretest of all the study instruments were done at UTH. The results obtained were also compared to study that was done by Bahreini et al (2019). The methodology in the study of Bahreini (2019) consisted of the use of document review and interviews as tools for the collection of data and content analysis approach for results interpretation, therefore, the study by the researchers was used for validation of the results because of the similarities in the approach.

Data were analyzed using the content analysis approach to identify the underlying themes and subthemes. The themes identified included: resources, quality control, documentation, education, service and planning. The study established that among the factors affecting maintenance are lack of adequate space, computers, inadequate fund allocation, poor documentation of maintenance activities, and lack of training for medical equipment maintenance personnel and involvement of the medical equipment maintenance personnel in decision-making patterning to medical equipment. To address these factors, improvement in resources provision, quality control, documentation, education, service and medical equipment-related planning must be realized. In this paper, a multi-criteria decision-making analysis model (MCDMA) in solving existing maintenance practices that lead to equipment downtime was adopted. The MDCA approach was used to try and improve the maintenance practices that are wrongly done as found in the factors affecting maintenance. This approach will improve factors such as funding allocation towards spare parts and replacing medical equipment, maintenance prioritization whether PM or CM, training, quality assurance and planning.

Keywords: factors affecting maintenance, medical equipment maintenance; maintenance practices; Zambian hospitals, content analysis approach.

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ACRONYMS AND ABBREVIATIONS

WB- World Bank

WHO- World Health Organization

HCS- Health Care System

TPM- Total Productive Maintenance

RCM- Reliability Centered Maintenance

PM- Preventive

CM- Corrective Maintenance

CBM- Condition-based maintenance

PIR- Periodic inspection and replacement strategy

QIR- Quantile-based and replacement strategy

MEMS- Medical Equipment Management System

CE/MBE- Clinical and Biomedical Engineering

CMMS- Computerized Maintenance Management Systems

HC-UFMG- Hospital of Federal University of Minas Gerais

FDA- Food Drug Association

UTH- University Teaching Hospital

CDH- Cancer Diseases Hospital

LMUTH- Levy Mwanawasa University Teaching Hospital

KTH- Kitwe Teaching Hospital

LTH- Livingstone Teaching Hospital

CHAPTER ONE

1 INTRODUCTION

Zambia is a Southern African country with an estimated population of 18 million as reported by the World Bank (WB) (The World Bank, 2019). It is worth noting that the population of Zambia is young and fast-growing, its growth cannot be handled by the health facilities of the country due to various factors.

Health facility inability to handle the growing population is attributed to many things, one of the known causes is the medical equipment failure which can be prevented by proper maintenance and management. Medical equipment maintenance and management is one of the major activity considered in ensuring proper functioning of the health facility, safety of both the patient and the user and ensuring proper diagnosis and treatment of diseases is done.

A study carried out by the World Health Organization (WHO) has shown that nearly 50% of medical devices in developing countries are either under-functioning, subject to improper usage or not maintained properly due to the absence of effective maintenance management policies (Adnan et al 2017). Equipment prolonged downtime has resulted in many average Zambians waiting for days, weeks or even months before a diagnosis or treatment of an illness (The Association of Chartered Certified Accountants, 2013).

1.1 Background to the study

With breakdown of medical equipment, it is impossible for the Health Care System (HCS) to fully deliver its services. The role of medical equipment is crucial for efficient healthcare delivery in any country. In addition, physicians rely on equipment for diagnosis and treatment of diseases. Therefore, the availability and optimal utilization of medical equipment is important in improving the quality of health services.

According to statistics on medical equipment failures from WHO, about 80% of all medical equipment failure cases are caused by preventable factors and failures, due to inadequate maintenance alone account for about 60% of all the medical equipment performance cases. In addition to this, failures due to inappropriate handling, environmental stress and wear-out account for about 20% of all the failure cases (Adnan et al 2017).

The baseline study by the Government of the Republic of Zambia found that 30% of the medical equipment needs repair, are out of order, or is not commissioned, and will need immediate attention. It was commonly expressed that better equipment management would improve usage in developing countries (Government of the Republic of Zambia, 2012).

A study conducted by Oosting and the others (2018) titled “Equipment for essential surgical care in nine countries across Africa: availability, barriers and need for novel design” in which Zambia was one of the participative country showed that 20% of surgeries are delayed or canceled in the public hospitals and only 8% in the private sector due to equipment failure. In the same study, Oosting and the others reported that lack of maintenance was the most reason for failure with 47%, followed by failure due to old or overused equipment with 36%. Failure as a result of limited infrastructure facilities (mainly power outages) was reported to be 11% (Oosting et al 2018). A similar study conducted by Mbohwa and Mwanza (2015) showed that 69.4% of the respondents who participated in the study stated that the action on the equipment was only taken after failure had occurred. Preventive maintenance programs do exist in the maintenance department but they are not adhered to (Mwanza & Mbohwa 2015).

1.2 Statement of the problem

The growing sophistication of medical equipment has significantly improved the individual and society’s health. The advancement has improved survivability in the face of disease or injury and greatly enhanced patients’ life quality through an improved diagnosis and therapeutic results. Medical equipment is a crucial asset that substantially contributes to the effectiveness and healthcare services quality enhancement. As the medical equipment aids various services in the healthcare sector, the management representative, such as clinical engineers, must monitor and upkeep the assets by performing several maintenances works throughout the equipment life cycle (Zamzam et al 2021).

Zamzam et al. (2021) reported that equipment failures are commonly due to inappropriate carriage and storage, preliminary breakdown, mishandling, lack of maintenance, environmental stress, random breakdown, improper restoration methods, and wear-out failure. The authors added that

50–80% of malfunctioning equipment is due to weak maintenance and a deficiency of highly skilled technicians. Furthermore, the authors highlighted that the four leading causes of those failures are preventable incidence, insufficient technical personnel, data deficiency, and lack of predictive maintenance. Therefore, medical equipment maintenance and management can be progressively improved by identifying the influential factors (Zamzam et al 2021).

A study conducted by Arab-Zozani et al reported that the most common cause of medical equipment downtime is poor maintenance, planning, and management. He also reported that a study of world health organization (WHO) has shown that nearly half of medical devices in developing countries are operated incorrectly or are not maintained properly due to inappropriate management policy. He further reported that the potential to manage and maintain medical equipment in these countries remains rather weak (Arab-Zozani et al 2021).

A study conducted by Mullally (2017) in which he compared the diagnostic tests that were conducted between the years 2013 and 2015 in Ndola Teaching Hospital. In the study, he found that inadequate functional medical equipment is listed as one of the main challenges most health facilities face in Zambia. He reported that tests carried out at the facility in 2013 in medical examinations were 1755 and only 765 tests were done in 2015 due to breakdown of the X-ray equipment from January to December. Tests under special investigations were 1154 in 2013 but only 211 were done in 2015 as a result of the breakdown of the equipment and unavailability of the fluoroscopic unit. He further reported that the number of tests done under routine investigations were 28023 but only 12368 were observed in 2015 due to equipment breakdown, tests under emergency were seen to have reduced from 2312 in 2013 to 649 in 2015 as a result of equipment breakdown and ultrasound scan test reduced from 12640 in 2013 to 6930 in 2015 as a result of the ultrasound scanner breakdown (Mullally 2017) as summarized in **Error! Reference source not found.**

Table 1.2-1: Comparison between 2013 and 2015 diagnostic tests done by Ndola Teaching Hospital

Diagnostic tests	Done in 2013	Done in 2015	Reason
Medical examinations	1755/1755	765/1755	X-ray equipment breakdown

Tests under special investigations	1154/1154	211/1154	Equipment breakdown and unavailability of the fluoroscopic unit
Routine investigation	28023/28023	12368/28023	Equipment breakdown
Tests under emergency	2312/2312	649/2312	Equipment breakdown
Ultrasound scan test	12640/12640	6930/12640	Ultrasound scanner breakdown

1.3 Aim and objectives

1.3.1 Aim

To investigate the medical equipment maintenance practices conducted in selected hospitals in Zambia.

1.3.2 Objectives

The aim of the study were met by addressing the following specific objectives:

i. To determine the factors affecting medical equipment maintenance in hospitals.
ii. To assess factors affecting medical equipment maintenance in the hospitals.
iii. To determine possible solutions to improve maintenance.

1.4 Research questions

In order to effectively address the specific objectives, the following questions were answered:

i. What are the factors affecting maintenance in hospitals?
ii. How are the factors affecting maintenance?
iii. What possible solutions can be implemented in order to improve maintenance?

1.5 Significance of the study

Maintenance activities are a major contributor to the effective operation and uptime of medical equipment as well as that of the hospital at large. Achievement of this can be attributed to the execution of rightly maintenance practices. This research determined the factors affecting maintenance, and proposed an approach to maintenance activities such as CM, PM, quality assurance, budgeting etc. by using the Multi-Criteria Decision-Making analysis (MCDM).

1.6 Limitations of the study

Conducting research in some hospitals proved to very difficult as the participation of the participants in the study was that of unwillingness, this is seen in the absence of Ndola Teaching Hospital in the study. Data review on some policies could not be disclosed as the hospitals could not allow.

Data analysis in the literature reviewed was not disclosed fully to enable proper understanding and identify a better method to use. Literature on the maintenance of medical equipment in Zambia is not available, even if the information is found, it lacked peer reviewing.

1.7 Research ethics consideration

This research involved human subjects that are involved in the usage and maintenance and management of medical, therefore before conducting this study clearance certificate was obtained from the University of Zambia Ethics Committee. Participation by the personnel was voluntary, the respondents were informed on the research they are participating in, they were provided with sufficient information and assurances about taking part to allow them to understand the implications of their involvement. The use of offensive, discriminatory, or other unacceptable language was avoided in the formulation of questionnaire and interview. Privacy and anonymity of respondents remained secretive and acknowledgement of works of other authors used in any part of the dissertation with the use of referencing was observed.

1.8 Outline of the dissertation

This dissertation is organized in five (5) chapters. Chapter one introduces the study by providing a background to the medical equipment maintenance practices. This is followed by the statement of the problem, together with the description of the research aim, objectives and questions. The Significance of the study, limitations and research ethics considerations are also included. Finally, the chapter presents the outline of the entire dissertation and the summary.

Chapter two provides the exploration of maintenance practices. It specifically focuses on the following: definition of maintenance, history of maintenance, types of maintenance, maintenance strategies, maintenance effect, theoretical background, data collection and analysis from the literature review and knowledge gap.

Chapter three presents information on the methodological aspects of the study. It begins by giving a brief introduction, research design, target population sample size, sampling procedure, case study hospitals and medical equipment, research instrument, data analysis and results validation.

Chapter four focuses on the main findings and discussions of the study and is informed by an integration of both qualitative and quantitative findings. It starts with the presentation of factors affecting maintenance in the selected hospitals and how these factors are affecting maintenance and followed by an introduction of an approach to maintenance improvement.

Finally, chapter five provides the conclusion and recommendations. It starts by giving a quick summary of the whole research process; addressing key issues such as the research aim, methodology, findings and contributions of the study. The last part of the chapter suggests areas for further research.

1.9 Summary

This chapter presented the background to the problem. It highlighted the challenges in medical equipment maintenances. The chapter further presented the statement of the problem together with the research aim, objectives, questions and the significance of the study. The research ethics consideration, limitations of the study, the organization of the entire study has also been outlined. The next chapter provides a literature review in maintenance for the purpose of not only positioning the study in the context of current knowledge, but also identifying gaps in current knowledge; hence justifying the need for the study.

CHAPTER TWO

2 LITERATURE REVIEW

2.1 Definition of maintenance

Manufacturing companies, running a business nowadays, face higher and higher demands in the range of production infrastructure reliability and ensuring indefectible operations, which are deprived of unscheduled downtimes. It is not easy due to unanticipated events which might occur during equipment runtime. Disturbances in proper plant functioning, with high probability, lead to serious productivity losses, declines in quality and also noticeable deteriorations in overall performance. Preventing mentioned, undesirable machines defects and failures as well as reduction adverse effects caused by them are possible by means of ensuring correct maintenance actions in production management system (Gackowiec 2019). The research conducted by Carpitella et al defines maintenance as the combination of technical and organizational activities aimed at guaranteeing systems' functioning during their whole life cycle, in terms of retaining them in (or restoring them to) a state in which they can perform their required tasks (Carpitella et al 2021). Maintenance is a term related to all activities and procedures, planned and not, which are undertaken to ensure constant accessibility of operational equipment in production plant. Maintenance refers to all technologies and management carried out to ensure that equipment performs or that restores its specified functions. Maintenance plays an important role in the normal operation of industrial equipment, military equipment, transportation tools and other systems, as well as ensuring the safety and reliability of the system (Zhao, Gao & Tang 2022). Maintenance requires "technical skills, techniques, methods to properly utilize the assets like factories, power plants, vehicles, equipment and machines". Maintenance is said to be a critical element for production effectiveness (Gackowiec 2019).

Poor maintenance management contributes to financial drain to the organization as it can limit the real performance of the organization. Other than that, the organization is faces significant harms and very risky to its buildings and assets, people and the continuation of the organization performance. Therefore, effective maintenance management can contribute to an organization in achieving its strategic goals concerning efficient management, reputation and can satisfy the stakeholders. The maintenance organization must be able to understand the value of the maintenance management that can bring the best practice to the organization, as they can align their strategies and operations towards demonstrating and delivering the best maintenance management (FTMaintenance 2019).

Maintenance has no fundamental value as it is conducted to support the organizations' main objectives and strategic function of the building. The goals of maintaining the value of the maintenance of an organization need to be emphasized so that the organization can perform the maintenance management, support the core business and support the needs of the stakeholder. The effective maintenance management contributes to the sustainable and cost-effective maintenance to the organizations; The good practices encourage the productivity of the organization and facilities operation; Continual quality improvements in keeping the pace of the organizations to remain competitive and relevant; Enhancing the workplace and facilities safety, security and comfort to the stakeholders and users can lead to the reliability building services (Mohamed, Misnan & Mong 2018).

2.2 History of maintenance

The first industrial revolution is an idea everybody knows as the main industrial revolution and is now taught at schools. It could be compared with the Neolithic Revolution which caused the society to shift from hunters and collectors to agriculture. It was a giant leap towards today's form of society. It started in England and was characterized as a change in the use of energy sources, forms of transport, information transfer and industrialization of production. It was also a crucial period of social, cultural and political changes in individual countries. The symbol of the first industrial revolution was a steam engine invented by James Watt in 1765 (Poór et al 2019). Since the start of the first industrial revolution, there has been a massive increase in labor productivity through the introduction of new ways in agriculture, the introduction of machinery and alternate field cultivation.

The most characteristic maintenance form during this period was the breakdown maintenance (also known as "reactive maintenance" or "corrective maintenance"). Break down maintenance is a form of maintenance, where repairs are done only after the breakdown. The aim of it is to put the broken machine back to the regular operational conditions. The breakdown maintenance has its advantages and disadvantages. The advantages includes usage of less time and money to do nothing, there is no initial cost, and it requires far less planning. On the other hand, the unpredictable nature of breakdowns leads to shorter asset life, safety issues, inefficient use of time, and can get a lot more expensive. (Poór et al, 2019)The strategy of "letting the device work until it goes wrong" was the first that humankind naturally applied. On first sight it is the easiest and natural way of maintenance. Machines were rather simple and therefore there was no need for a specialist that would know how to repair it at the beginning. Even nowadays, reactive maintenance is the most widely used maintenance activity with over 55%. Never the less with the increasing complexity of machines, especially after the beginning of the first industrial revolution a new trend started appearing among the industries (Poór, et al 2019).

The Second Industrial Revolution began about one hundred years later in 1870 and was connected to electrification and assembly lines. It resulted in mass production based on division work and electrically powered lines. In 1870 the first large scale assembly line was built up in a slaughterhouse in Cincinnati. Later, the assembly line idea was adopted by Henry Ford for his Model T automobiles factories. Another extraordinary innovation was the light bulb by T. A. Edison in 1879 and transformer, designed by Nicole Tesla (Poór et al 2019). Work organization was improved by Frederick Taylor, who came up with ways to boost factory profitability up by to a hundred times. His principles of work organization aimed for precise determination of the work process and performance-based wage (Poór et al 2019). Other inventions of the second industrial revolution were dynamite, phone, aircraft and many others. Due to these new inventions, the way of life has changed. Science was suddenly connected to the technology, research results from natural sciences were being applied in industry. Sometimes the Second Industrial Revolution is known as the Revolution of the Technical Science. (Poór et al 2019).

With the peak of the second industrial revolution the machines became more complex and production grew rapidly. Breakdowns caused higher and higher expenses and therefore first attempts of preventive maintenance (also known as planned maintenance) appeared. Even Henry Ford recommended preventive maintenance in his FORD MANUAL from 1919. Preventive maintenance can be characterized as: Action based on a specific timetable that identifies, avoids or mitigates the decay of component or framework state so in order to maintain or expand its life by means of controlled corruption to an adequate level (Poór et al 2019). There are two essential kinds of preventive maintenance - maintenance in periodic cycles or maintenance dependent on equipment status. Maintenance in periodic cycles anyway seems to be unreasonably costly for about 92% of machine parts. Device-based (proactive) maintenance exchanges parts and interferes with the machine only when deviations begin to show up in its procedure, making it more efficient (Poór et al 2019). Preventive maintenance brings less likelihood of breakdowns, fewer downtimes and might be more savvy than reactive. Then again, it builds costs with customary substitutions, there is a requirement for extra parts and planned downtime increases (Poór et al 2016).

As indicated by Poór et al (2019) by simply spending the necessary resources to carry out the maintenance activities of the designer, the facility's life is extended, and its reliability is increased. In addition to increase reliability, savings are also being made. This savings can be up to 12% on average to 18% of saved costs. Depending on the current state of maintenance, device reliability and downtimes, many companies dependent on purely reactive maintenance and can save much more than 18% by starting the right preventive maintenance program. Although preventive maintenance is not an optimal machine maintenance program, it has several advantages over purely reactive maintenance (Poór et al 2019). Performing preventive maintenance on the device as designed by the designer will prolong the life of the device. This means saving money. Preventive maintenance (lubrication, filter replacement, etc.) will usually result in higher device efficiency, which will be reflected in savings. Even if the catastrophic scenario is not prevented, the number of disorders will go down.

The beginning of the third Industrial Revolution dates back to not much of a milestone in human history, the drop of atomic bombs on the Japanese cities of Hiroshima and Nagasaki in August 1945. The use of technology controlled thermonuclear reaction of atomic bombs started a third industrial revolution. Its termination dates back to the early 1990s, by the time of the decentralized merger of thousands, then by millions of people through the Internet using personal computers and mobile phones. The beginning of the third Industrial revolution goes back to 1969, when the first programmable logic controller, e.g. PLC, was made (Poór et al 2019). It is a small industrial computer, a control unit, for real-time automation of processes. The key characteristics of this period were automation, the boom in electronics and information technology. These features were subsequently introduced into production in order to drive machines and automate them (Poór et al 2019).

The Third Industrial revolution is often referred to as a period of scientific and technological revolution and, as has already been said, the arrival of computers. Productive Maintenance (also referred to as PM started appearing after the Second World War. This new approach towards maintenance combines Corrective Maintenance and Preventive Maintenance with a data-driven, analytical approach, and is performed to increase the broadly economic efficiency of production (Poór et al 2019). It strives to identify and address the problems that can lead to breakdowns in the first place, such as improper machinery lubrication, misalignment, contamination and other suboptimal conditions. Productive maintenance brings longer lifespan of equipment, decreased downtime (both planned and unplanned), lower spare parts inventory and is more cost-effective. The big challenge, however is, that it requires, unlike previous maintenance approaches, a large shift of paradigms and organizational changes. Maintenance is integrated into the company strategy and is recognized as improvement worthy. Data starts being collected and, in some cases, real-time monitoring is enabled. Statistical models are applied and new discoveries concerning fatigue are made.

Perhaps the two best-known methods which developed during the period of the third industrial revolution were Total Productive Maintenance (TPM) with origin in Japan and Reliability Centered Maintenance (RCM) with origin in the USA. Reliability Centered Maintenance is "a procedure to establish maintenance requirements for any physical asset in its operational context." (Poór et al 2019). It guarantees that systems keep on doing what their user requires in their present working setting. The reliability-oriented maintenance strategy addresses fundamental issues not secured by other maintenance programs. Perceives that not all machinery in a company has a similar significance that the construction and operation of the equipment are different, and that is more likely to cause a fault for various reasons. It also considers the way that the company does not have a boundless budget and personal assets and should be optimized. The RCM technique screens the activity of every component and characterizes the outcomes of its failures. While deciding the outcomes, every one of the activities of the elements of the monitored device must be determined (Poór et al 2019). If the level of risk due to failure cannot be can't be decreased by the chosen maintenance mode, then it is necessary to reconstruct the element. Thus, RCM also deals with the assessment of possible causes of device failures (e.g. neglected maintenance, wear, etc.). RCM prompts an expansion in cost-effectiveness, reliability, machine uptime, and a greater comprehension of the dimension of risk.

Total Productive Maintenance (TPM) TPM was presented by Seichi Nakajima, who during the 60s studied Preventive Maintenance systems in the US and Europe. He worked out his knowledge in a complex system that was given a working name Total Productive Maintenance. In 1971, he brought the framework into Japanese organizations (Poór et al 2019). Total productive maintenance is equipped to connecting all staff in the workshop to exercises that minimize downtime, limit accidents and occurrences. The TPM is about beating the conventional division of people into workers working on the machine, and "workers who fix it". It depends on the way that the worker who deals with the machine gets the opportunity to initially catch the anomalies in his work and sources of future equipment failure. Motto of TPM is: "Protect your machine and take care of it with your own hands" (Poór et al 2019). Thus, the greatest diagnostic and maintenance activities in TPM are exchanged from the traditional support straightforwardly to the production workers - the production sections (Poór et al 2019). It usually starts with enhancing the work environment, cleaning machines and checking their condition (Poór et al 2019) besides, the operator figures out how to "understand his machine", to figure out how to carry on as his "very own. The TPM depends on the help of item maintenance by little gathering activities (production groups). The TPM is applicable wherever where production (operation, equipment) is based on technological service (operators). TPM objectives are: zero downtime; zero errors; and zero disturbances (Poór et al 2019).

Predictive maintenance (nowadays also called PdM) is now the highest form of maintenance as of today. It is a method of preventing asset failure by analyzing production data to identify patterns and predict issues before they happen (Poór et al 2019). The key to this is a combination of big data analytics and artificial intelligence in order to create insights and detect patterns and anomalies. It includes continuous real-time monitoring of assets in combination with external data (e.g. environmental data, usage, etc.) with alerts based on predictive techniques such as regression analysis, for at least one important asset (Poór et al 2019).

The basic components of predictive maintenance in the context of industry are: Sensors, Cyber-Physical Systems, Internet of Things, Big Data, Cloud computing, Networks and Artificial Intelligence, Mobile networks, WIFI. Instead of experienced craftsmen and drained inspectors, businesses must employ reliability engineers and data scientists (Poór et al 2019). The data used for predictive maintenance are growing in count, as the companies collect data about the condition of assets, usage of assets, maintenance history, data from other assets that are relative to the work of monitored machine, both from inside and outside of the company (e.g. assets of our suppliers), environmental data and others. Some of the key critical success factors for the predictive maintenance implementation are budget, culture, technological solutions, availability of data, data security and others. A well-functioning predictive maintenance program can mean savings of 8% to 12%. Depending on the equipment and material conditions, it is possible to save 30% to 40% (Poór et al 2019).

2.3 Types of maintenance

The effectiveness of a maintenance strategy will depend on the type of maintenance service used by the healthcare organization. Maintenance services can be classified into three types: using an in-house biomedical engineering service department, outsourcing all the maintenance services to independent companies and mixing in-house with outsourced services. The in-house biomedical engineering service is used in order to ensure patient safety and quality control of medical equipment. In-house maintenance services can offer several benefits for healthcare organizations including greater economy, an increase in the skills of technical staff and engineers, the ability to compile service manuals and ensure the timely availability of spare parts (Mkalaf 2015).

Outsourced services tend to involve negotiated contracts with the Original Equipment Manufacturers (OEM) who take responsibility for the medical equipment they have provided and employ contractors, distributors and consultants who provide competence, knowledge and manpower in maintaining the equipment. This kind of outsourced service is a popular approach to maintenance and support requirements. Over the past decade, several manufacturers and suppliers have offered a total performance guarantee of their products or have supplied a functional product and are taking full responsibility for the equipment maintenance and provision of spare parts. Many organizations depend on this type of maintenance service in order to achieve minimum operating costs including labor. However, the equipment may be individually designed, with few, if any standby facilities, limited spares and a shortage of skilled and experienced maintenance engineers. In spite of this, a significant issue is that long-term contract maintenance service may not be useful for healthcare organizations for many reasons: it is difficult for top management to monitor maintenance procedures; the fixed costs of the contract cannot be changed; there may be difficulty in cancelling the contract and in the long term these types of contractual services can result in poor administrative control and financial problems for the health care organizations (Mkalaf 2015).

Outsourcing is a concept utilized by enterprises to streamline their activities. External service providers specializing in particular tasks and processes are given responsibility for these areas. In recent times the frequency of outsourcing has increased in providing ‘technical infrastructure management’ (Mkalaf 2015).

The decision whether to select an in- house or outsourced maintenance service is affected by the maintenance cost of each type of critical medical equipment. The cost of maintenance service depends on all maintenance activities necessary. In order to reduce the significant costs related to service contracts, some of healthcare organizations have attempted to change their maintenance service from outsourced to in-house (Mkalaf 2015).

2.4 Maintenance strategies

The European committee for standardization defines maintenance strategy as “management method used in order to achieve the maintenance objective” with examples of outsourcing of maintenance activities and the allocation of resources (Sielaff et al 2021). The basic idea of a maintenance strategy is to achieve the optimization objectives of improving component reliability, increasing availability and reducing maintenance cost by reasonably planning maintenance under the condition of limited maintenance resources (such as spare parts, maintenance tools, maintenance personnel, etc.) (Zhao, Gao, & Tang 2022).

Carpitella et al (2021) groups maintenance strategies into the following main categories:

Reactive (or corrective) maintenance: This maintenance policy assumes that interventions are accomplished after failure occurrence, to restore an item into a functioning state. Corrective maintenance can be further distinguished into immediate and deferred corrective maintenance, depending on the readiness in carrying out interventions upon failures. In the first case, maintenance interventions are executed immediately after those failures directly influencing production and/or core services by the deputed maintenance crew which is immediately available in site. In the second case, interventions are not immediately carried out after fault detection but delayed in time according to rules established by the management. This case regards those maintenance activities that are not so urgent or require longer execution times (due, for instance, to their sudden or complex nature or to the need of involving an external maintenance crew) (Carpitella et al 2021). According to Zhao, Gao, & Tang (2022), Corrective maintenance also known as post failure maintenance was mainly used in the 1940s. They further reported that this strategy is driven by failure events. Only after component failure, are repair activities arranged. Therefore, the normal working plan of components will be interrupted and some losses will be incurred. In addition, because failure events usually occur suddenly, this strategy is prone to untimely maintenance caused by the untimely preparation of maintenance resources. This situation increases the failure loss of components, to a certain extent. The many disadvantages of corrective maintenance stimulated the emergence and development of other maintenance strategies. However, due to the uncertainty of component failure, subsequent maintenance strategies are often considered together with corrective maintenance (Zhao, Gao, & Tang 2022).

Preventive maintenance: Interventions belonging to this category are based on such criteria as time, age, usage or condition information and take place prior to the occurrence of failures with the aim of keeping equipment in specified conditions through organized check-up, detection and prevention of potential failure. This strategy can also be referred to as “time-based maintenance”, and can be further grouped into maintenance scheduled at planned intervals. Interventions in maintenance scheduled at planned intervals are carried out according to an established schedule, as in the case of age-based and clock-based maintenance (respectively referring to the time that a system achieves a certain age and a particular calendar time (Carpitella et al 2021).

According Zhao, Gao, & Tang (2022), preventive maintenance strategies arrange maintenance activities according to the relationship between failure rate, failure time distribution, life distribution and their respective thresholds obtained from a large number of failure statistical data of similar components. According to the types of information, preventive maintenance can be further divided into age dependent maintenance strategies, periodic maintenance strategies, sequential maintenance strategies and failure limited maintenance strategies (Zhao, Gao, & Tang 2022).

Age-dependent preventive maintenance strategies refer to when the status value of the component reaches a preset value at which replacement activity happens. If the component fails before reaching the preset age value, the replacement happens immediately. This introduces three maintenance effects, i.e., minor maintenance, imperfect maintenance and perfect maintenance, into the age dependent maintenance strategy. Through this, the optimal maintenance age, optimal detection interval and detection times are obtained by minimizing the maintenance loss per unit of time (Zhao, Gao, & Tang 2022).

Periodic preventive maintenance strategy refers to when maintenance activities are carried out at regular intervals. This maintenance strategy does not need to consider the age of components, and the formulation process is simple and flexible. However, it does not consider the difference in degradation rate at different stages of components, so it cannot decrease the risk of failure caused by the aggravation of component degradation rate in the later stages of service.

A sequential preventive maintenance strategy is an improvement of the periodic maintenance strategy. It considers the increase in equipment degradation rate and failure frequency during service through successively reducing the maintenance time interval and increasing the maintenance frequency. A sequential maintenance strategy can make planned maintenance time more suitable for the actual situation by introducing various factors into the maintenance decision model. These factors, such as the decreasing age factor and the increasing failure rate factor, can characterize the different performance degradations of components at different service stages, to some extent. However, these factors are usually difficult to determine in engineering. Therefore, when factors have some deviation, mismatch between maintenance demand and maintenance operation can easily occur (Zhao, Gao, & Tang 2022).

According Zhao, Gao, & Tang (2022), failure limit preventive maintenance strategy refers to setting the maintenance opportunity according to the relationship between the failure rate, other reliability indexes of components and the threshold. Repair shall be carried out when the component failure rate reaches its threshold. If the component fails during operation, it shall be corrected through minor repair. They cited Maillart et al. (2002) who divided the performance degradation process of components into two stages: the normal service stage with cycle T1 and performance degradation stage with cycle T2. No maintenance operation is carried out in the time period of (0, T1). Under (T1, T1 + T2] maintenance is carried out within the time period. When the time is greater than T1 + T2, the components are replaced. As the failure limited maintenance strategy controls the reliability indexes, such as failure efficiency and failure rate, it is more suitable for components with high reliability requirements. The key to this strategy is to set a reasonable failure rate threshold in advance. In engineering, the failure rate threshold is difficult to ascertain (Zhao, Gao, & Tang 2022).

Condition-based maintenance: It belongs to the preventive maintenance category, but includes a combination amongst condition monitoring, investigation and testing, by performing analyses on results of maintenance actions. Interventions are scheduled not at established intervals but as needed on the basis of asset conditions. Predictive maintenance is a type of condition-based maintenance carried out based on predictions derived by collecting results from repeated analyses on significant parameters related to the wearing process of items (Carpitella et al 2021).

Opportunistic maintenance: This strategy aims to combine preventive and corrective maintenance strategies. In other words, when a component of a system fails, not only is the action of corrective maintenance performed, but also interventions of preventive maintenance are carried out on other units not yet failed in order to prevent future failures (Carpitella et al 2021).

Predictive maintenance: Predictive maintenance monitors the performance degradation process of components by using condition monitoring technology, predicting their status in the future, and constantly updating the maintenance scheme according to the prediction results. In addition, the maintenance threshold in predictive maintenance can be updated immediately, according to the degradation degree of components. Predictive maintenance strategies can formulate immediate maintenance measures for equipment whose status can be monitored, and the maintenance operation can be dynamically updated with the change in equipment monitoring signals until the update stop conditions are met. Due to this feature, predictive maintenance strategies are only applicable to equipment whose condition can be monitored (Zhao, Gao, & Tang 2022).

Batch Maintenance Strategies: Batch maintenance refers to the simultaneous preventive maintenance of multiple components in equipment according to the same maintenance cycle. The maintenance is carried out only when the fault number reaches the threshold. Batch maintenance strategies are simple and easy, and have been widely used in industrial practice. However, these strategies will also repair the components in good condition in a maintenance cycle, which will inevitably lead to excessive maintenance and waste of maintenance resources (Zhao, Gao, & Tang 2022).

Opportunistic maintenance: Opportunistic maintenance means that, when a component of the equipment needs to be repaired, other components that need to soon be repaired are repaired in advance. This strategy can reduce the incidence of equipment shutdown and maintenance and reduce the equipment maintenance cost. The opportunity maintenance decision optimization model at the equipment level was also established with the expected maintenance cost rate as the optimization objective and the opportunity maintenance service age as the optimization variable. The occurrence of preventive maintenance or post fault maintenance of some components in the equipment was used to carry out opportunistic maintenance on other components. The opportunistic maintenance strategy has strong practicability in engineering applications by repairing other components at the same time with the help of the maintenance opportunity of some components. However, this maintenance strategy will affect planned preventive maintenance plans, which may increase the average maintenance cost of components in the long run and reduce the effective service time of components in the life cycle. Therefore, opportunity maintenance can be adopted only when the cost of opportunity maintenance in advance is greater than the cost of any preventive maintenance originally planned.

Group Maintenance Strategies: Group maintenance is based on the idea that sharing the maintenance resources of the same type of components can save maintenance costs. It can reduce maintenance costs by combining multiple components of the same type. Compared with batch maintenance, group maintenance can repair multiple components according to different maintenance cycles. According to different decision-making methods, a group maintenance strategy can be divided into static group maintenance and dynamic group maintenance (Zhao, Gao, & Tang 2022).

Static group maintenance strategy: The static group maintenance strategy assumes that the equipment operates in a long term and stable working condition environment, and obtains the maintenance plan according to the static rules according to the long term historical operation state data of multiple components. This plan does not make any adjustments during equipment operation. This strategy is mostly used in multicomponent equipment with low reliability and high economic requirements, and all maintenance intervals are fixed. According to the timing of maintenance, static group maintenance can be further divided into corrective group maintenance and preventive group maintenance (Zhao, Gao, & Tang 2022).

Corrective group maintenance strategy is mainly for multicomponent equipment with a redundant design, and the components in such equipment can only be repaired by the corrective maintenance method. When the failure of a single component does not affect the equipment operation, it can wait for the failure of multiple components for group maintenance (Zhao, Gao, & Tang (2022).

Preventive group maintenance is to set a benchmark maintenance interval that makes the preventive maintenance interval of multiple components an integral multiple, so as to increase the probability of the coincidence of maintenance times of various components. When the preventive maintenance time of two or more components coincides with the reference maintenance time interval, preventive group maintenance can be carried out for multiple components (Zhao, Gao, & Tang (2022).

2.5 Maintenance Effect

Maintenance mainly includes servicing and repair. Among them, servicing is the activity that maintains the stability of the equipment working state and prevents state degradation. Actions such as cleaning, dust removal and lubrication are all servicing actions. Repair is an activity undertaken after system failure. These failures can only be recovered by repair actions, such as replacing parts (Zhao, Gao &Tang 2022).

Each maintenance action has an impact on equipment degradation to certain degrees. In order to accurately describe these impacts, scholars have proffered the concepts of perfect maintenance, imperfect maintenance and minor maintenance. Among them, perfect maintenance refers to restoring equipment to its initial operation state. For example, replacement is a kind of perfect maintenance and can make the repaired equipment as new, in a timely manner (Zhao, Gao &Tang 2022).

In practice, equipment maintenance methods vary greatly. The maintenance process may be affected by human error, poor quality of spare parts, insufficient maintenance time and other factors, so that the equipment cannot be restored to a new state. Based on this, researchers proposed maintenance concepts other than perfect maintenance, such as imperfect maintenance and minor maintenance. Among them, the effect of imperfect maintenance lies between minor maintenance and perfect maintenance. The failure rate of equipment after maintenance is reduced, but it is still higher than that of equipment in a new state. The condition of the equipment is also worse than new but better than the failed equipment. The common imperfect maintenance forms in the literature includes medium maintenance, overhaul, etc. Minor repair refers to equipment being restored to the state before the fault, after maintenance, without being changed. It is generally considered that a minor repair does not change the fault rate of the system (Zhao, Gao &Tang 2022).

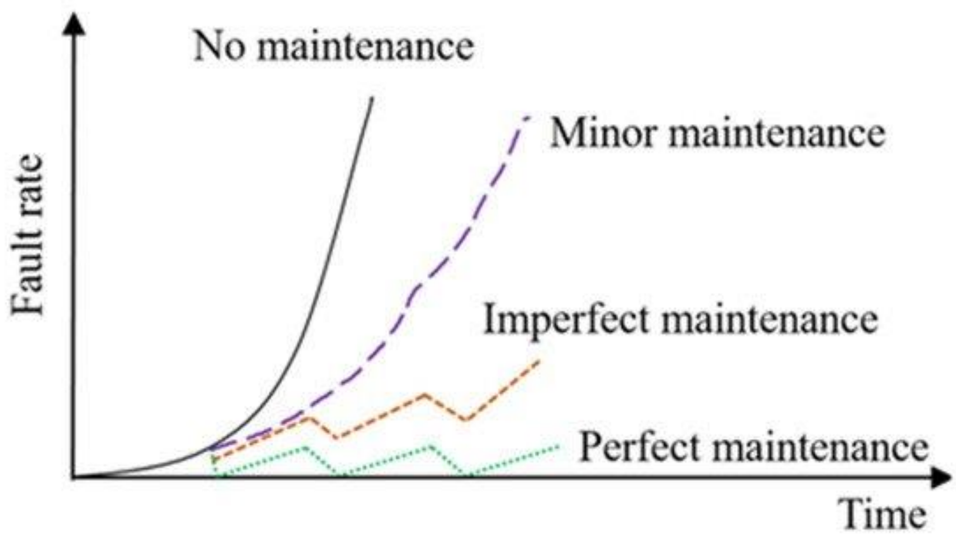

Figure 2.5-1: Maintenance effects by (Zhao, Gao &Tang 2022)

2.6 Concepts of maintenance

Medical equipment requiring calibration, maintenance, repair, user training and decommissioning activities are usually managed by clinical engineers. Who ensures that medical equipment is kept in working condition, and is safe, accurate, and reliable and operates at the required level of performance effectively? Lack of proper maintenance of medical equipment leads to equipment downtime, reduces the level of device performance, and wastes costs and resources (Bahreini et al 2018).

Planning plays a major in role maintenance and requires the assessment of a number of parameters, including how a piece of equipment is used, how often it is used, its intended use, risk associated with its usage and its failure rates (Iadanza et al 2019).

Medical Equipment Management System (MEMS) includes the equipment inventory, a work order system, the preventive maintenance schedules/procedures, outsourcing contract management and all service history records. Today, the Clinical and Biomedical Engineering (CE/BME) is responsible for the healthcare asset management and healthcare technology assessment, clinical staff safety, repair and maintenance, risk and safety management, and also contrast monitoring and quality improvement. In addition, Computerized Maintenance Management Systems (CMMS) is a fundamental information resource in most healthcare systems to track each piece of equipment and maintain accurate records of inventory and data for medical equipment. (Bahreini et al 2018).

Other researchers have indicated that maintenance planning starts from a clear understanding and review of the company's corporate policy, strategies and service delivery plans to develop effective equipment and building plans to ensure maintenance priorities and strategies are relevant and in align with business directions. Maintenance planning provides appropriate maintenance programme and procedures for execution of tasks based on frequent basis (daily, weekly, monthly, yearly etc.), depending on available maintenance policy, whereas, planning standard and procedures shall also be laid down. Strategic maintenance plans affects the implementation of maintenance planning practices and equipment condition assessment. Maintenance budget is a significant tool as in all maintenance operations and should not be neglected by any means. Spares of good quality and high skilled manpower are obtained from the available budget. Mkilania (2016) cited Bowers (2005) who commented that maintenance planning should reflect and identify needs, establish goals and allocate fund to meet goals, scheduling maintenance and allocating funds for implementation, the act which is of great importance towards best maintenance practices. Documentation, information processing and handling are very important tools in the maintenance planning and implementation. Equipment data need to be captured stored, processed, shared and updated accordingly to match with technology and business demands (Mkilania 2016).

Planning and scheduling maintenance activities is a very difficult issue for a public sector, as it is done and stored manually. Processing and keeping data manually doesn't provide an effective maintenance planning and scheduling, for that it becomes very difficult to achieve best maintenance practice. Mkilania (2016) cited Lukacs (2003) who through his research, argues that organizations with proactive attitudes to planning represent the world top organizations in terms of profits margin and return on equity. Mkilania (2016) cited Qiping (1997) who through his research in Hong Kong and UK revealed that public sectors in many countries have been experiencing a problem of not prioritizing maintenance issues, such as budgeting and resource allocation (Mkilania 2016).

Best maintenance practices are achieved by having maintenance policy and strategy in place whereas rules and standards are set, however, the development of strategic maintenance plans and implementations are of significant importance and meanwhile the review or benchmarking the execution of maintenance activities provide the room for determining the actual maintenance performance of a certain organization. Over again, based on the policy, an improvement action may be developed as required. Effective maintenance policy and strategy implementation is influenced by various factors such as position of maintenance department in the organization structure, budgetary allocation, contract management, resources planning, communication, data recording and handling, motivation issues, training and development ((Mkilania 2016. Successful policy and strategy implementation depends on the effectiveness of an organization and maintenance management (Mkilania 2016).

2.7 Theoretical background

2.7.1 Maintenance in medical equipment

Today’s modern hospital is highly dependent on various types of medical equipment to assist in the diagnosis, monitoring and treatment of patients. It is impractical to provide health services without them. Medical equipment deals with patient care ranging from small and simple devices to complex and big. This ranking can be found in different types of hospitals and primary care settings. According to the studies conducted in Iran, about one-third of the costs of setting up and equipping the hospital is allocated for purchasing medical equipment. Therefore, medical equipment should be maintained to good working condition and higher safety level to prevent injuries occurring in patients as well as in users (Arab-Zozani et al 2021).

The maintenance of medical equipment is important for reducing dispatch costs, reducing patient dissatisfaction, timely patient treatment, and reducing mortality and risks during patients care. It is an integral part of the life cycle of the device. Usually, much more money is spent on maintaining equipment over than on its procurement. Maintenance is defined as any action which helps hospitals to provide an adequate level of service and to protect or promote the performance of their equipment to operate regularly and efficiently. Therefore, maintenance management is a fundamental aspect of hospital management (Arab-Zozani et al 2021).

Good maintenance management must have well planned and implement programs that can minimize breakdowns or failures of the medical device. This is particularly critical in developing countries for providing good healthcare services and saving scarce resources and alternatives. The equipment maintenance management of the hospital not only makes them easily accessible when needed but also increases their reliability and reduces their failure rate (Arab-Zozani, al. 2021).

Medical equipment plays a significant role in the hospital system hence, the purchase, maintenance and replacement of medical equipment are key factors in hospitals to implement medical care service. Thus, to assure the quality of healthcare delivery medical devices, use-safety assessment of the maintenance management in hospitals is imperative. To achieve these objectives, hospitals must develop assessment checklists which identify the performance status of medical equipment maintenance. It is essential for managers and engineers, not only to enhance hospital capability but also to predict the risks related to sudden failure (Arab-Zozani et al. 2021).

Maintenance management consists of the activity-based work planning and budgeting that includes planning, scheduling, assigning, implementing and evaluating the strategies. The maintenance management creates the cost for the works and specifies the performance standards that need to be achieved by the organization. The maintenance management comprises of the four stages: Planning, Organizing, Directing and Controlling. The administration provides a systematic approach that establishes what types of works that need to be done, when it should be done, what resources is necessary for every kind of jobs, and what are the related cost required. Therefore, the organization is able to determine the commitments and accountability of their roles in the providing best quality of the facilities and services (Mong et al 2018).

2.7.2 Factors affecting maintenance

Studies have indicated that the most common cause of medical equipment downtime is poor maintenance, planning, and management. (Bahreini et al 2019). According to Bahreini et al (2019), There are several factors that affect maintenance management and one of them is physical resources. These include workspace, tools and test equipment, supplies, replacement parts, and operation and service manuals needed to perform maintenance mechanisms. Financial resources for maintenance primarily focus on two tasks: monitoring costs and managing the budget. A study conducted by Arab-Zozani et al (2021), physical resources is a factor affecting maintenance and is attributed to human resources which refer to the provision and allocation of experienced and skilled manpower based on need, financial resources which include the allocation of sufficient and necessary funds and budgets based on the goal and be allocated to priority goals according to the operational plan of the medical engineer unit (Arab-Zozani et al 2021). Maintenance programme is another factor according to Bahreini (2019) that is required for financial planning where the costs and benefits of the current situation and the new proposal can be compared, this means that each medical device in the hospital must have a history of all time and expenses associated with maintaining that device. Quality control tests is also another factor which include tests of safety, performance and calibration which refer to all technical tests that require special equipment and are of special importance for the health of the patient and staff (Bahreini et al 2019 & Arab-Zozani 2021). Documentation of the maintenance processes and activities is another factor, which when not implemented, maintenance and management of equipment will simply lead to inconsistent implementation and unpredictable outcomes (Bahreini et al 2019 & Arab-Zozani 2021).

Bahreini et al (2019) reported that another factor is lack of corresponding maintenance personnel composition. Maintenance personnel placement is done most often casually, personnel division of labor is not clear, and the maintenance caters to some surface problems and fails to do finishing repair (Bahreini et al 2019). In many situations, calibration, modification or repair of medical equipment by an incompetent personnel can result in injury to the patient or loss of medical record.

Another factor affecting maintenance according to the studies conducted by Rona (2018) is maintenance cost. Lack of considering the maintenance cost implications when procuring a medical equipment can affect the maintenance programme, as maintenance cost includes costs such as cost of spare parts used during corrective and preventive maintenance, cost of accessories replaced, Biomedical Engineers' labor (work + transportation) cost, all administrative and logistic cost to allocate parts and services, upgrading and modification costs and training costs.

Lack of inspection and Preventive Maintenance is another factor affecting maintenance, periodic inspections, development of maintenance standards, the existence of external supervisors, and the existence of written and comprehensive guidelines (Arab-Zozani et al 2021).

Training is also another factor affecting maintenance, which includes training for both technical and user training for medical engineers and users are. In the category of the service, after-sales service, repair and maintenance contracts, outsourcing of the decommissioning process are factors affecting maintenance. The last dimension is design and implementation, which refers to issues such as defining the level of user access, organizing joint committees, establishing inter-sectorial communication, policy development and purchasing medical equipment based on needs (Arab-Zozani et al 2021).

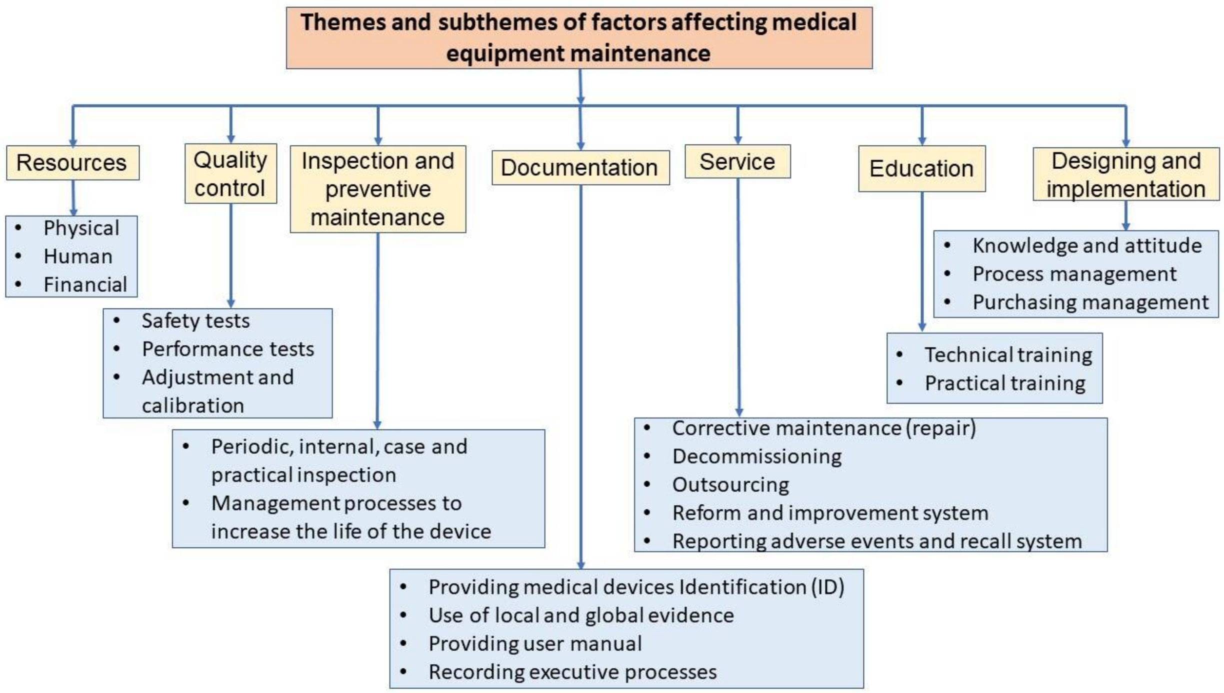

Figure 2.7-1: Themes and subthemes for factors affecting medical equipment maintenance (Adapted from: Bahreini et al. 2019)

Medical equipment management

Study conducted by Ssekitoleko et al (2021) categorized the factors affecting maintenance into four (4) major categories which includes medical equipment management, technical human resource, Administrative support, and Procurement guidelines. The researchers found that under medical equipment management, hospitals did not have manuals which makes equipment maintenance very difficult. They further reported that a survey conducted by the ministry of health in 2015 found that only 13.4% of the health facilities in Uganda had scheduled medical equipment maintenance and that only 37% of the health facilities in Uganda have a budget for routine maintenance and repair of medical equipment. This failure to follow routine maintenance procedures results in the escalation of equipment faults (Ssekitoleko et al 2021). Technical human resource involves lack of adequate staff, the available maintenance personnel worked on atleast 167 equipment on average. Administrative support looks at the support the maintenance personnel receive from the hospital administrators. The lack of support is characterized by public hospitals having long bureaucracies in the procurement process of spare parts and consumables and minimal funding to support medical equipment maintenance (Ssekitoleko et al (2021).

Procurement guidelines as of the factors affecting maintenance involves the lack of procurement process to follow guidelines when procuring equipment or accepting a donated equipment. The lack to follow the laid down guidelines resulted in hospitals having atleast 7% of medical equipment being purchased or received as donation but never put to use due to lack of installation space, lack of consumables, or incompatibility with existing infrastructure and resources (Ssekitoleko et al (2021).

2.7.3 Techniques designed in improving the maintenance practices in hospitals

A study conducted by Bahreini et al (2019) in which they were investigating the factors affecting maintenance, to try and improve on the factors affecting maintenance, they decided to design a checklist for uniformity and accurate and comprehensive assessment. This checklist varied from hospital to hospital. For example, the maintenance management evaluation checklist of Tabriz Medical Equipment Office includes 15 indicators (technical force, medical engineering unit, medical equipment ID, quality control tests, PM, training, medical equipment and spare parts storage, service and maintenance contract, the existence of purchase process, the existence of decommissioning process, the existence of recall system and reporting of adverse events, ensuring sound electricity, implementing a continuous maintenance improvement process, familiarizing with the general administration’s rules and website, management and allocating a separate budget for maintenance) (Bahreini et al 2019).

Another study conducted by Vala et al (2018), to ensure availability of the equipment is by developing operation and maintenance protocols targeting important focal root causes of equipment failure earlier identified. The operator protocols are modelled such that they guide operators prudently operate the equipment, thus reduce operation related failures. The maintenance protocols were expected to guide biomedical engineers optimally maintain the equipment efficiently by increasing opportunities for maintenance, i.e. daily, weekly and monthly basis. The enhanced interventions are expected to assist the engineers identify early onset of failures, hence intervene more promptly prior to equipment outage Vala et al (2018).

In the study conducted by Chaudhary and Kaul (2015) in factors affecting utilization of medical diagnostic equipment, they proposed every health care organization to develop a strategic framework to manage medical equipment and adopt a more pro-active role in the procurement of right medical equipment at the right time, equipped with the right technology at the right place of working. They also proposed that care must be taken at the time of procurement to ensure there is provision for the up-gradation of technology after some years of use of that equipment They also suggested to have a periodic evaluation of the quality of performance of equipment in the hospital which will be advantageous to all concerned, namely hospital, professional, government, and the management so that better utilization of the resources is ensured (Chaudhary and Kaul 2015).

A study conducted by Aliow et al (2021) concludes that human resource capacity development is a significant predictor of medical equipment utilization. The positive effect of human resource capacity development on medical equipment utilization implies that improving the human resources in terms of training, involvement in decision making, motivation and remuneration leads to enhanced utilization of medical equipment. The study also concludes that the existence and use of medical equipment management policy is associated with improved utilization of medical equipment at Mandera referral hospital. The research concluded that medical equipment procurement policy was a significant predictor of medical equipment utilization. Finally, study also concludes that adherence to service charter has a significant effect on medical equipment utilization (Aliow et al 2021).

A study conducted by Thapa et al (2018) in which they were looking at “application of lean six-sigma approach to reduce biomedical equipment breakdown time and associated defects”, they proposed the use of daily routine maintenance into the existing biomedical maintenance system, wherein the biomedical engineer had to conduct daily routine inspection of all the equipment, as most of the equipment are critical, whenever equipment’s failed measures were taken immediately. This had led to a significant positive impact in reduction of breakdown time and the number of associated defects. The existing process of biomedical equipment maintenance system where complaints regarding the equipment were registered via phone call was replaced by registering the complaints through Hospital Management Information System (HMIS) software. With this new process, the complaints were being addressed rapidly, which is documented in HMIS for future references. PPM (Planned Preventive Maintenance) schedule was followed strictly in a timely manner. This had a positive impact on this study as any minor preventive maintenance of modifications done in the equipment will reduce major defects later. This will not only reduce the breakdown time and number of defects, but also reduce the financial burden of equipment's failure. The equipment Failure Analysis Worksheet was introduced for critical equipment. After this the factors contributing to the equipment's failure were found and the corrective measures were taken to prevent such failure in future, which was done in the form of appropriate checks when equipment failed which was well documented in Equipment's Failure Analysis Sheet for future reference. A monthly breakdown time of biomedical equipment were analyzed and documented with the unique equipment's identification number which played a crucial role in assessing the specific cause of failure in each equipment and if repeated issues were occurring in the same equipment, by which such specific equipment can be focused and preventive measures can be implemented in future to reduce the breakdown time and also the number of defects in such equipment. Problem frequency analysis was introduced with specific categorization like physical, technical, accessories, electrical and unspecified for the failed equipment, which was followed accordingly and documented after the repair. This was done to keep a track on the specific type of causes of equipment's failure, by which the frequent type of defects involved are known so that the preparation of the inventory of specific spare parts is done well in advance and hence reduce the breakdown time of equipment. 5-whys analysis was also adopted to know the root cause of specific types of defects that could lead towards the clue for preventive measures, which could reduce the number of defects and eventually breakdown time (Thapa et al 2018).

A protocol for biomedical equipment handling during hopper cleaning was introduced, which includes periodic training of biomedical equipment handling for hopper cleaners and the compulsion of presence of a biomedical engineer during fumigation and pest control whose responsibility is to make sure that the biomedical equipment is covered appropriately during fumigation which prevents the corrosion of the expensive biomedical equipment and thereby reduces the number of defects and improves the lifespan of the biomedical equipment which will have significant long-term positive financial implication for the hospital. The delay in delivery of spare parts of failed equipment was reduced by addition of a process, wherein emails and reminder calls are made regularly to the concerned company of the equipment at regular intervals of time until the spare parts are procured which has reduced the breakdown time of equipment significantly. The unorganized workplace for maintenance and storage of equipment in biomedical engineering department was improved by enforcing precisely planned 5S technique. 5S techniques refers to Seiri (Sort), Seiton (set in order), Seiso (Shine), Seiketsu (Standardize) and Shietsuke (Sustain). In biomedical engineering department where equipment and spare parts and various repairing tools were sorted according to their frequency of usage and red tagging of the unused equipment was done with reasons and actions to be taken clearly and were set in organized way with appropriate labelling. 5S implementation played a pivotal role in this study in decreasing the breakdown time by improving the work efficiency in the biomedical engineering department (workshop area, equipment and spare parts store room and office). After 5S implementation, the needed spare parts and needed repairing tools were readily available, which subsequently lead to reduction in breakdown time (Thapa et al 2018).

2.8 Data collection and analysis tools in literature

Researchers such as Rona et al (2018) used documents review and interviews as the main methods for data collection. Semi structured interviews were conducted with a purposive sample of 14 clinical engineers with different degree of education and job levels. Interviews were voice recorded and transcribed verbatim. Qualitative data were analyzed using a content analysis approach (inductive and deductive) to identify the underlying themes and sub-themes.

Other studies conducted by Estevão et al (2017), which aimed to identify and analyze the factors that contribute to the effectiveness of the management of medical-care equipment at the Hospital of Federal University of Minas Gerais (HC-UFMG) in Belo Horizonte, Minas Gerais, a case study was performed along with a field research at HC-UFMG, through interviews using a semi-structured questionnaire to professionals who handle and operate medical-care equipment; professionals who provide maintenance on equipment, and professionals who manage the operation and maintenance of equipment.

Another study conduct by Mwanza and Mbohwa (2015), a descriptive research design was used in order to trace the relationship among the facts obtained and observed in order to gain a deeper understanding of the patterns regarding the maintenance practices. Purposive sampling was used in the distribution of questionnaires at three hospitals; Kitwe Central Hospital, Nchanga North Hospital and Ronald Ross Hospital. The data obtained from the questionnaires, structured interviews and direct observations was analyzed quantitatively and qualitatively. Under quantitative analysis, SPSS and Microsoft excel were used (Bupe & Mbohwa 2015).

2.9 Knowledge gap in the literature review

The studies carried out of developing world hospitals (e.g. Asia, Africa, Middle East etc.) focus on reasons for poor performance due to lack of planning, organization, finances and resources. These factors are so much applicable to Zambian public hospitals and these are the findings from the current study. In the Zambian context other issues surrounding the quality of health-care maintenance often relates to the types of maintenance services and the systems used in managing the processes. Furthermore, most study reviews focus on two types of maintenance strategies: preventive or corrective. However, neither of these strategies avoid the sudden failure of medical equipment or increase reliability. This is because the focus is on routine inspection without analyzing the different types of medical equipment and their associated risks. The Food Drug Association (FDA) have classified medical equipment into three classes, Class I medical devices are defined as those that are not intended for use in supporting or sustaining life or of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury. Class II are devices for which general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device and Class III contains devices that are usually for sustaining and or supporting life, are implanted or present a potential unreasonable risk of illness or injury (Frolovs 2021). The maintenance strategies that have been proposed by the various researchers such as Sielaff et al (2021), Carpitella et al (2021) and Zhao, Gao, and Tang (2022) have not been realigned to suit the classification of medical equipment proposed by the FDA.

2.10 Conclusion

In chapter two of the literature review, we looked at what maintenance is, its importance to industries especially with the rise of more sophisticated technologies. Also looked at how maintenance has evolved from the first industrial revolution to present day. We also looked at the various maintenance strategies from the different scholars. Maintenance effects and concepts of maintenance were also reviewed. Under theoretical background, we looked at maintenance in medical equipment, factors effecting maintenance and techniques designed by researchers to solve the found problems in the existing maintenance practices in the various hospitals. Knowledge gap in the literature was also analysed.

CHAPTER THREE

3 METHODOLOGY

3.1 Introduction

The chapter elaborated on the methods used to collect and analyze relevant data for the study. The elements covered included research design, target population, sampling procedures, sample and sampling techniques, research instruments, data collection procedure and data analysis and presentation.

3.2 Research design

The research adopted qualitative and quantitative approach aimed at examining the factors affecting maintenance in the selected hospitals in Zambia. According to Rutberg and Bouikidi (2018) quantitative research employs the use of numbers and accuracy, while qualitative research focuses on lived experiences and human perceptions (Rutberg and Bouikidi 2018). The design concerning qualitative design was chosen because the researcher was interested in factors after the interaction between maintenance personnel with medical equipment after maintenance has occurred without having to control the environment in which the factors interact with medical equipment maintenance. The quantitative was also chosen because for results analysis.

3.3 Target population

Target population is a complete enumeration of all the elements that the researcher is interested in studying and to which generalization is made after data analysis and interpretation (Cohen et al., 2007). Table 3.3-1 presents the target population that consisted of Nurses and Medical equipment personnel. In total, there are Nurses (35) who only deal with the critical medical equipment at a particular time and Medical equipment personnel (25).

Table 3.3-1: Population sample size

Sn	Category	Number of staff
1	Nurses	35
2	Medical equipment maintenance personnel	25

Source: Ministry of Health

3.4 Sample size

The sample size was derived by calculating the sample from the target population by applying (Yamane, 1967) Formula.

$$n = \frac{N}{1+N(e)^2}$$

Where: n= Sample size, N= Population size e= Level of Precision.

At 95% level of confidence and P=5

$n = 60/1+60\ (0.05)^2$

n=52

3.5 Sampling Procedure

Sampling is a process of picking elements from the population that is representative of the population (Kothari 2012). This research involved staffs from five different public hospitals across the country who directly interact with medical equipment on daily basis. Sampling was done using stratified sampling method and applying Yamane (1967) formula. The study adopted proportionate stratified sampling where the general population was stratified into various groups. The study then distributed the sample size so determined based on the distribution of the population among the strata such that stratum with more elements in had more elements picked compared to stratum with smaller number of elements. The proportionate sampling is presented in Table 3.5-1

Table 3.5-1: Sample Distribution

Sn	Category	No. of Staff	percentage	Sample
1	Nurses	35	58.3	30
2	Medical Equipment maintenance personnel	25	41.7	22
	Total	**60**	**100**	**52**

3.6 Case study hospitals and medical equipment

The study was based on five major urban hospitals in Zambia (*Table 3.6-1*). These are the University Teaching Hospital (UTH), Cancer Diseases Hospital (CDH), Levy Mwanawasa University Teaching Hospital (LMUTH), Kitwe Teaching Hospital (KTH), Ndola Teaching Hospital (NTH) and Livingstone Teaching Hospital (LTH). These hospitals were selected because they classified as level 2 and level 3 hospitals with medical equipment ranging from simple to sophisticate. The hospitals are also referrals for the level 1 hospitals and are considered specialized health facilities. The basic description of the hospitals is shown in *Table 3.6-1*.

Table 3.6-1: Basic description of the case study hospitals

Hospital Name	**Bed capacity**	**Province**	**Facility type**
CDH	252	Lusaka	Specialized
LMUTH	730	Lusaka	Tertiary
UTH	1215	Lusaka	Tertiary
KTH	624	Copper Belt	Tertiary
LTH	325	Livingstone	Tertiary

All medical equipment large, small, or complex are essential in the treatment and diagnosis of patients. In this research we consider looking at critical medical equipment in improving the maintenance activities in hospitals. A critical equipment according to Wang (2012) is one that must be maintained at least as often as the manufacturer recommends, such critical equipment includes, but is not limited to, life-support devices, key resuscitation devices, critical monitoring devices, equipment used for radiologic imaging, and other devices whose failure may result in serious injury or death of patients or staff" Wang (2012). According to Mwanza, and Mbohwa (2015), critical equipment are special kind of equipment used to attend to patients with special and rare medical cases. Examples of critical equipment includes incubators, resuscitators, auto clef, suction machines, oxygen concentrators and cylinders, boilers, cold rooms etc. (2015), In this study, the critical medical equipment is as highlighted in Table 3.6-2Table 3.6-2: Selected Critical equipment shows the 15 selected critical medical equipment in relation to the identified criterion proposed by Wang (2012).

Table 3.6-2: Selected Critical equipment

Sn.	Medical equipment
1	Kidney dialysis machine
2	Cardiac catheterization
3	Anesthesia machine
4	Defibrillator (Manual)
5	Diathermy
6	Ventilator
7	Infusion Pump
8	Electrocardiograph
9	Electro surgical unit
10	Defibrillator (Automated)
11	Nebulizer
12	Oxygen concentrator
13	Suction machine
14	Mechanical ventilator
15	Patient monitor

3.7 Research Instruments

Primary data was collected using structured questionnaires and interviews. Structured questionnaires adopted consisted of open ended questions in order to allow the respondents to give a more detailed information. Albudaiwi (n.d) defines open-ended questions as questions that do not provide participants with a predetermined set of answer choices, instead allowing the participants to provide responses in their own words. Qualitative studies that utilize open-ended questions allow researchers to take a holistic and comprehensive look at the issues being studied because open-ended responses permit respondents to provide more options and opinions, giving the data more diversity than would be possible with a closed-question or forced-choice survey measure (Albudaiwi n.d). The questionnaire method was preferred given the large sample size and inadequacy of financial resources as well as time constraint. The questionnaire was divided into parts with the first part covering descriptive information and the later part covering variable specific information. The study also adopted semi structure interview that was used on nurses. This type of interview was used in the study in order to allow the interviewer ask questions even beyond what has been structured.

3.8 Data analysis

The data collected were analyzed using both qualitative and quantitative approaches. For qualitative analysis, the content analysis method was used. The content analysis used involved the use both the deductive and inductive approaches. According to Streefkerk (2019), inductive reasoning aims at developing a theory while deductive reasoning aims at testing an existing theory (Streefkerk 2019), this means the deductive approach involved the use of themes that have already been identified in the literature reviewed, while the inductive approach involved developing new themes from the results obtained.

The procedure for data analysis was as outlined in Figure 3.8-1. The initial part of the analysis was based on the deductive approach. First, factors that affect medical equipment maintenance as identified together with the subthemes and themes developed from them in the literature (*Figure 2.7-1*). Then, the collected data was analyzed to determine factors, subthemes and themes based on the information given by the respondents from the hospitals. The developed themes were then compared with those found in the literature. If the themes were found to match with those in the literature, then the names of the themes as they are in the literature were adopted. However, if the themes did not match, then, a comparison at subtheme level was done. Two options were expected. The first possibility was for some subthemes for the themes from the data analysis matching with those in the literature. In this case, if all the subthemes in the theme from data analysis were part of those for a single theme in the literature, then the data analysis theme was deemed to be a subset of the existing theme and the name of the literature-based theme was adopted. If the subthemes in the data analysis-based theme matched with subthemes in different literature-based themes, then the theme was deemed to be the union of those literature-based themes and in this case, the name of the new theme was to be adopted.

In the case where the subthemes in the data analysis-based themes do not match with those in the literature-based themes, new themes were developed using the inductive approach. For this approach, first the themes were analyzed further to check if there is a possibility of generalizing them into a higher them. If generalization into a higher theme could not be achieved, then the themes were considered as new themes. If generalization to higher themes was achievable, the themes were grouped as subthemes of the higher themes until generalization was not achievable, then the final higher themes became new themes. The new theme identified and adopted under inductive analysis is planning with the following subthemes: (1) Medical equipment and spare part budgeting; (2)) Equipment procurement; (3) Accepting a medical equipment donation; (4) Any meetings related to medical equipment.

For quantitative analysis basic chats were developed to show the maintenance practices in the five selected Zambian hospitals regarding some selected critical medical equipment.

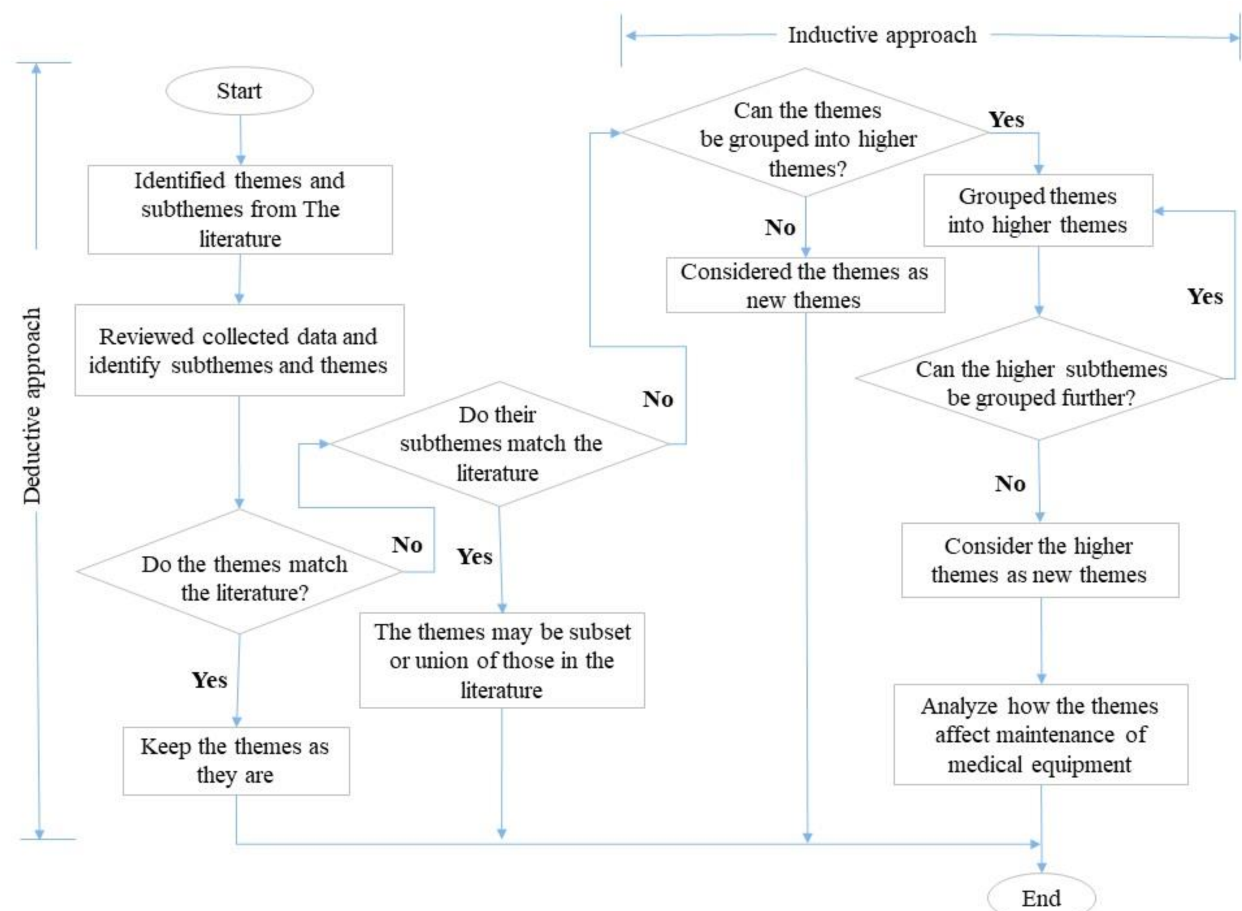

Figure 3.8-1: Data analysis procedure

The quantitative analysis which involved the use of excel as a tool to solve existing maintenance practices in the hospitals was used.

3.9 Results validation

Face validity and content validity were assessed by the experts in the field of medical equipment management. Pretest of all the study instruments were done at a selected UTH. Identified problems with pretest were corrected and necessary modifications were made accordingly. The results obtained were also compared to study that was done by Bahreini et al (2019). The methodology in the study of Bahreini (2019) consisted of the use of document review and interviews as tools for the collection of data and content analysis approach for results interpretation, therefore, the study by the researchers was used for validation of the results because of the similarities in the approach.

CHAPTER FOUR

4 RESULTS AND DISCUSSIONS

4.1 Introduction

The chapter presents the research findings and discussion. The study sought to investigate the maintenance practices in the selected hospitals in Zambia. The data collected was analyzed using content analysis and charts were developed for the quantitative analysis. The data was presented in the form of tables, charts and associated explanations.

4.2 Factors affecting maintenance in the hospitals and how they are affecting maintenance

The research sought to establish the factors affecting maintenance in the hospital. Data analysis resulted in the identification factors that affect medical equipment maintenance in the selected hospitals. These factors affecting maintenance were grouped into subthemes and themes using the content analysis method which involve the use of inductive and deductive approaches. The identified factors under deductive approach were resources, quality control, documentation, education, service and planning and were termed as themes as they were the umbrella for the other factors. These themes originated from themes as highlighted in *Figure 2.7-1* a study conducted by Bahreini et al. (2019). Using the inductive approach, factors determined were inspection and preventive maintenance, and design and implementation and were termed as new themes because they were not seen in the literature. A summary of themes and subthemes are illustrated in *Figure 4.2-1*.

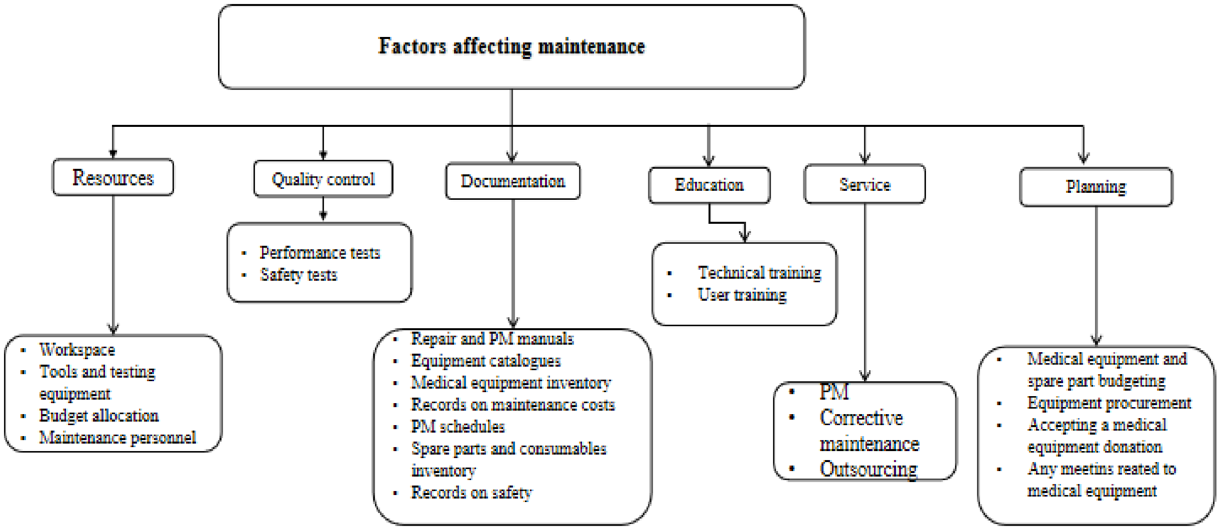

Figure 4.2-1: Factors affecting maintenance

4.2.1 Resources

All maintenance activities depend on resources. And the assessment of the effectiveness of any maintenance program basically refers to the optimal use of the available limited resources (Iadanza et al. 2019). Bahreini et al. (2019) listed physical, human and finances as subthemes of the resources theme (*Figure 2.7-1*), and showed that factors under physical resources include workspace, tools and test equipment, consumables, replacement parts, and operation and service manuals needed to guide maintenance procedures. In agreement with Bahreini et al. (2019), data analysis from this study showed that the subthemes under resources theme include workspace (workshop), maintenance tools and testing equipment, budget allocation and maintenance personnel as shown in Table 4.2-1 and Figure 4.2-1 respectively.

To have an insight into how these factors affect maintenance effectiveness in the Zambian hospitals, analysis of the data from the interview conducted with the medical equipment maintenance personnel of the medical equipment maintenance department for each hospital highlights the availability of resources for each hospital (Table 4.2-1). The table shows that only the CDH has no workspace for conducting maintenance services. For the other four hospitals, the workspaces they have were said to be inadequate for the number of people in their maintenance departments and to fully meet the works involved. However, the availability, adequacy, or non-availability of workspace should be understood in the context of where medical equipment should be maintained.

According to WHO (2016), there are two options of where medical equipment maintenance can be done. The first option is where the equipment is maintained in the room where it resides. In this case, essential tools and testing equipment must be taken to the worksite. The second option is where the medical equipment is taken to the designated workspace (workshop) where maintenance works (PM or CM) are done. While some equipment fit only in the first option, others fit only in the second option and yet others can be maintained using either option. Since the personnel involved in the survey should be fully aware of these options for the medical equipment maintenance their assertions were assumed to have considered the options. Thus, the absence of workspace or its inadequacy has negative effects on the efficiency of maintenance operations in the five hospitals. This is because a good workspace provides good lighting and access to utility systems required by the equipment, storage space for tools and testing equipment and provides space for documentation (WHO, 2016).

Table 4.2-1: Availability of resources

Resources	Hospitals				
	UTH	**CDH**	**LMUTH**	**KTH**	**LTH**
Workspace	Available but inadequate	Not available	Available but Inadequate	Available but inadequate	Available but inadequate
Tools and testing equipment	Available	Available	Available	Not adequate	Available
Budget allocation	Not adequate	Not adequate	Not adequate	Not available	Not adequate
Maintenance personnel	8 against 1215 bed capacity	5 against 252 bed capacity	5 against 730 bed capacity	6 against 624 bed capacity	6 against 325 bed capacity

Tools and testing equipment include computers, multimeters, safety analyzers, ECG simulators, patient simulator laparoscope, defibrillator analyzer and various workshop tools. One or more of these is required for any maintenance activity. However, hospital at least the minimum requirement for tools and testing equipment. For one hospital, it was found that it had only one multimeter as a testing equipment for the whole hospital. Computers, as part of the tools and test equipment, are vital for the implementation of CMMS. Of the five hospitals, four had computers with only one having internet connectivity. However, none of the hospitals was using any computerized maintenance management system.

According to Bahreini et al. (2019), the financial subtheme involves the monitoring of costs and management of the budget. An adequate budget allocation is needed for the procurement of spare parts (for PM and CM) and consumables. Availability of spare parts is very critical for both PM and CM. Persistent lack of spare parts due to low budget or no budget allocation for maintenance of the equipment may lead to the decommissioning of the equipment. For equipment for which spare parts can be procured, among the problems that affect the availability of spare parts in stock is usually the limited budget and the low priority on consumables and spare parts (Government of the Republic of Zambia 2012).

The data analysis results on when the spare parts are ordered show that in most cases, spare parts are ordered after a medical equipment breaks down (Figure 4.2-2). This results in disturbances in medical equipment maintenance schedules, and this may greatly contribute to the long non availability durations of the affected equipment due to the procurement process that can sometimes be lengthy (Government of the Republic of Zambia 2012). Table 4.2-1 shows that all the five hospitals do not have adequate budget allocation which has the likelihood of negatively affecting the efficiency of the maintenance activities because of challenges with procurements and meeting other maintenance costs (WHO, 2016).

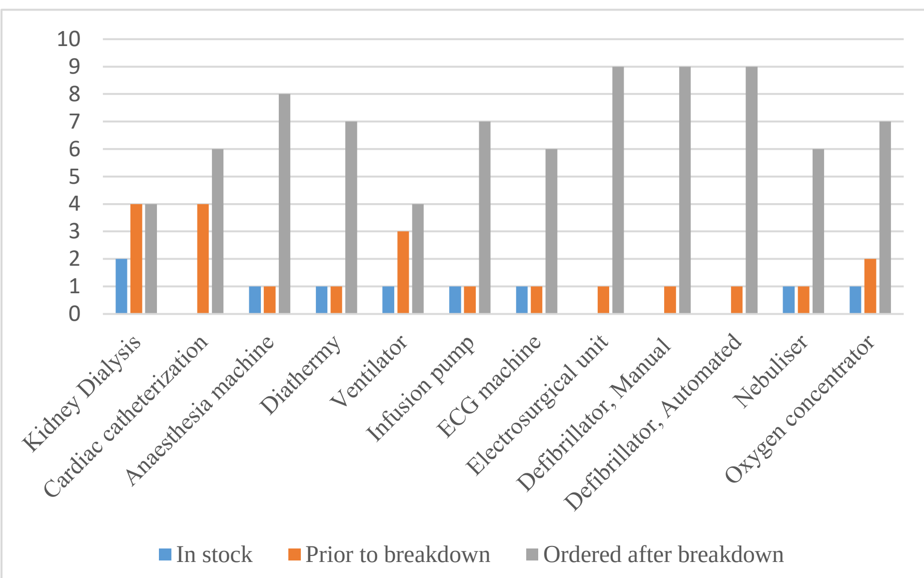

Figure 4.2-2: Periods when spare parts are ordered

The human resources subtheme involves the provision of trained and skilled maintenance and operation personnel (Bahreini et al. 2019). Maintenance personnel are needed for the execution of the maintenance works on medical equipment. The availability of adequate skilled personnel is needed for effective maintenance and determines the extent to which maintenance is done under in-house, outsourced or mixed systems (Government of the Republic of Zambia, 2012; WHO, 2016). Table 4.2-1 shows the number of maintenance personnel against the hospital bed capacity. From the literature reviewed no standard ratios of maintenance personnel to hospital size were found which could be used to determine whether the numbers of maintenance personnel in Table 4.2-1 were adequate or not. However, considering that the numbers of medical equipment maintenance personnel included general hospital maintenance staff, the medical equipment maintenance personnel were found to be inadequate.

4.2.2 Quality control

Quality control of medical equipment is cardinal because of human or animal subjects being treated or diagnosed with them. In the literature, quality control constitutes performance tests, safety test, and adjustment and calibration of the equipment (Bahreini et al. 2019).

In this study, quality control was broken down into performance tests and safety tests of medical equipment.

Table *4.2-2* highlights the results obtained from the analysis of the data from the interviews conducted with the the medical equipment maintenance personnel of each of the five hospitals.

Table 4.2-2: Quality control

Safety	**Hospitals**				
	UTH	**CDH**	**LMUTH**	**KTH**	**LTH**
Performance tests	Conducted after repair of an equipment				
Safety tests	Conducted when needed	Not conducted	Conducted when needed	Not conducted	Not conducted

Performance tests of medical equipment must be conducted after any medical equipment maintenance works to ensure the equipment is performing according to specifications. There are different safety aspects to be considered when implementing a maintenance program. These include safety of the technical staff during the maintenance period, safety of users and the safety of patients (WHO, 2016). Safety tests must be conducted after maintenance works and whenever an equipment arrives in the hospital. Safety tests must also be conducted on medical equipment utilities such as power systems, gas and water supplies and infection control.

4.2.3 Documentation

One of the fundamental responsibilities of a clinical engineering manager is the documentation of the maintenance processes and activities. Without proper documentation, maintenance and management of equipment will simply lead to inconsistent implementation and unpredictable outcomes. These data provide the inventory database of every maintenance task performed on the device (Bahreini 2019). Documentation regarding the maintenance of medical equipment includes having records on all maintenance activities such as CM, PM, equipment catalogues, a detailed inventory of all medical equipment, records on maintenance costs, installations costs, spare parts and their costs. Documentation also includes records on performance and safety tests conducted and all training done on medical equipment. Keeping records of medical equipment pertaining to maintenance enables the smooth planning and operation of maintenance activities. It provides reference points regarding any decision making towards maintenance. It also enables maintenance tracking when a service of either PM or CM is outsourced. *Table 4.2-3* highlights the results obtained from the interviews conducted with the senior most members of medical equipment maintenance personnel on documentation. The table shows that LTH has the best documentation practices while KTH has the worst. This shows the likelihood of poor maintenance management with KTH.

Table 4.2-3: Documentation

Documentation	**Hospitals**				
	UTH	**CDH**	**LMUTH**	**KTH**	**LTH**
Repair and PM manuals	Available	Available	Not available	Not available	Available
Equipment catalogues	Not available	Available	Not available	Not available	Available
Medical equipment inventory	Available	Available	Available	Not available	Available
Records on maintenance costs	Not available	Not available	Not available	Not available	Available
PM schedules	Available	Not available	Available	Not available	Available
Spare parts and consumables inventory	Available	Not available	Available	Not available	Available
Records on safety	Available	Not available	Available	Not available	Not available

4.2.4 Education

According to the findings in the research conducted by Imani et al. (2018), training is one of the main components of medical equipment maintenance management and there is great importance attached to the existence of trained force and having a training program for medical equipment users. From Table 4.2-4**Error! Reference source not found.**, all hospitals do not conduct in-house technical training of members of staff.

Data analysis results show that with an exception of LTH, user training is conducted when the need for training arises. A report by Tropical Health and Education Trust (THET) (2015) have identified the life cycle of medical equipment, in the cycle is training of medical equipment for both the users (medical personnel) and the maintenance personnel, therefore, to improve the maintenance practices in the hospitals, training is needed frequent for both the users and the maintenance personnel.

Table 4.2-4: Education

Education	**Hospitals**				
	UTH	**CDH**	**LMUTH**	**KTH**	**LTH**
Technical training	Not conducted	Not conducted	Not conducted	Not conducted	Not conducted
User training	Conducted when a need arises	Conducted when a need arises	Conducted when a need arises	Conducted when a need arises	Conducted

4.2.5 Service

Regarding the maintenance system employed in the hospitals, the results showed that for many critical equipment, most of the maintenance is done under the in-house system *Figure 4.2-3*. The results show that most of these major hospitals have skilled personnel to maintain the critical equipment in *Figure 4.2-3*.

Concerning the maintenance type used in the hospitals, from the results obtained, the prominent type of maintenance practiced is CM (*Table 4.2-5***Error! Reference source not found.**).

However, in some instances CM also suffers due to inadequate financial resources (*Table 4.2-1*) to procure spare parts when a certain part fails. Delayed procurement of spare parts translates in delayed equipment maintenance because orders for spare parts are made after equipment failure as shown in Figure 4.2-2. *Table 4.2-5* shows that CDH and KTH do not conduct PM while it UTH LMUTH and LTH conduct it when need arises. Though the three hospitals conduct PM, reports from the medical equipment maintenance personnel showed that the maintenance being conducted constituted routine checks every morning to get reports on equipment that might have malfunctioned during the night. This shows that for all the hospitals, no PM is conducted.

Once a complete and accurate inventory of biomedical equipment has been assembled, a report that lists all outsourced equipment service should be produced (Laktash 2015). Outsourcing of either PM or CM is observed in all hospitals. However, challenges exist with the keeping of proper records of the outsourced services and maintenance schedules that show when each equipment under outsourced services will go for maintenance.

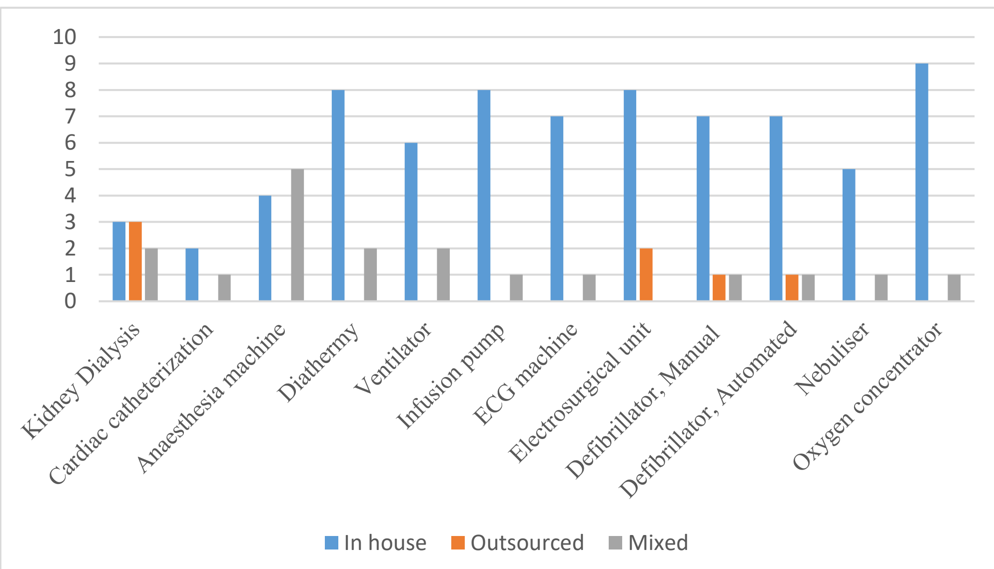

Figure 4.2-3: Approaches to maintenance for critical equipment

Table 4.2-5: Maintenance practices

Service	Hospitals				
	UTH	**CDH**	**LMUTH**	**KTH**	**LTH**

Preventive maintenance	Conducted sometimes	Not conducted	Conducted sometimes	Not conducted	Conducted sometimes
Corrective maintenance	Conduct	Conducts	Conducts	Conducts	Conducts
Outsourcing	Conducts	Conducts	Conducts	Conducts	Conducts

4.2.6 Planning

Planning in relation to medical equipment involved four activities in this research, this is included medical equipment and spare part budgeting, equipment procurement, accepting a medical equipment donation, and meetings related to medical equipment as highlighted in Table 4.2-6

Table 4.2-6: Planning

Service	**Hospitals**				
	UTH	**CDH**	**LMUTH**	**KTH**	**LTH**
Medical equipment and spare part budgeting	Involved	Not involved	Involved	Not involved	Involved
Medical equipment procurement	Involved	Not involved	Involved	Not involved	Involved
Providing guidance on accepting a medical equipment donation	Sometimes	Not involved	Sometimes	Not involved	Sometimes
Medical equipment related meetings	Involved	Not involved	Involved	Not involved	Involved

The results obtained showed that CDH, and KTH are entirely not involved in any planning activities relating to medical equipment. While the rest showed involvement, though not all suggestions brought forth by the medical equipment maintenance department in these planning meetings are accepted by hospital management.

4.3 Improving medical equipment through prioritization of medical equipment in maintenance decisions

4.3.1 Introduction

The ever-increasing number and complexity of medical devices demands that hospitals establish and regulate a Medical Equipment Management Program (MEMP) to ensure that critical devices are safe and reliable and that they operate at the required level of performance. A study by Taghipour et al (2011) reported that clinical engineering departments in hospitals are responsible for establishing and regulating a Medical Equipment Management Program to ensure that medical devices are safe and reliable. In order to mitigate functional failures, significant and critical devices should be identified and prioritized *(Taghipour, Banjevic & Jardine 2011).* In this paper, we presented a multi-criteria decision-making analysis model (MCDMA) in solving existing maintenance practices that lead to equipment downtime. Multi-criteria decision analysis (MCDA) is a decision-making tool that can take into account multidimensional factors and enables comparison of (medical) technologies by combining individual criteria into one overall appraisal. This approach has slowly gained traction within Health Technology Assessment (HTA) and its elements are gradually being incorporated into HTA across Europe (Baran-Kooiker, Czech & Kooiker 2018). Using this model required first the classification of medical equipment according their criticality as proposed by the researchers. Though there are various ways in which the criticality of a medical equipment is classified, in this research we adopted the classification by Wang (2012). A critical equipment according to Wang (2012) is one that must be maintained at least as often as the manufacturer recommends, such critical equipment includes, but is not limited to, life-support devices, key resuscitation devices, critical monitoring devices, equipment used for radiologic imaging, and other devices whose failure may result in serious injury or death of patients or staff' Wang (2012). Based on Wang's (2012), critical medical equipment were identified as shown in *Table 3.6-2*. The identified critical medical equipment does not imply that these are the only ones but these were selected because they are found in almost all Level 1, Level 2 and Level 3 Zambian hospitals and the ones that have were used in this study.

The MDCA approach was used to try and improve the maintenance practices that are wrongly done as found in the factors affecting maintenance. This approach will improve factors such as funding allocation towards spare parts and replacing medical equipment, maintenance prioritization whether PM or CM, training, quality assurance and planning.

4.3.2 Prioritizing equipment for corrective maintenance

We identified criteria under corrective maintenance and weighting was given to each criteria using percentages as shown in Table 4.3-1

Table 4.3-1: Prioritizing equipment for corrective maintenance

Criteria	**Weighting**
Equipment function	0.1
Load on hospital as a result of the failed equipment	0.2
The presence of an alternative	0.2
Equipment status	0.1
Maintenance Complexity	0.1
Average time of repair	0.1
Number of failures	0.1
maintenance cost	0.1
Total Weighting	**1**

The equipment were then given a rating scale which ranged from 1 to 10. The “1” means lowest, worst, complicated or expensive while “5” means average, and “10” means excellent, highest, not complicated or cheap. The rating for each equipment is highlighted in *Table 4.3-2*.

The priority number of each request is then calculated as a weighted sum of six different numeric values developed by each criteria, and the device with the highest priority number is serviced first. Table 4.3-3 shows that the infusion pump followed by the ventilator should be prioritized first in terms of corrective maintenance. Therefore, if failure was to occur in these equipment, priority number one should be given the utmost attention.

Table 4.3-2: Scaling the equipment

Criteria	**Weighting**	Kidney dialysis Machine	Cardiac catheterization	Anethesia Machine	Defibrillator	Diethermy	Ventilator	Infusion pump	Electrosurgical Unit	Nebulizer	Oxygen concentrator	Patient Monitor
Equipment function	0.1	5	5	4	5	5	6	7	4	2	4	5
Load on hospital as a result of the failed equipment	0.2	9	5	6	7	4	8	8	6	3	5	4
The presence of an alternative	0.2	1	3	5	5	6	4	7	4	8	7	5
Equipment status	0.1	6	4	5	5	7	6	7	7	5	5	6
Maintenance Complexity	0.1	7	8	6	6	5	5	4	6	4	4	6
Average time of repair	0.1	3	3	5	3	5	6	5	6	3	3	4
Number of failures	0.1	7	7	6	5	6	6	5	5	4	3	3
maintenance cost	0.1	2	2	5	5	5	3	8	5	3	3	3
Total Weighting	**1**											

Table 4.3-3: calculating the priority equipment

Criteria	Weighting	Kidney dialysis Machine	Cardiac catheterization	Anethesia Machine	Defibrillator	Diethermy	Ventilator	Infusion pump	Electrosurgical Unit	Nebulizer	Oxygen concentrator	Patient Monitor
Equipment function	0.1	0.5	0.5	0.4	0.5	0.5	0.6	0.7	0.4	0.2	0.4	0.5
Load on hospital as a result of the failed equipment	0.2	1.8	1	1.2	1.4	0.8	1.6	1.6	1.2	0.6	1	0.8
The presence of an alternative	0.2	0.2	0.6	1	1	1.2	0.8	1.4	0.8	1.6	1.4	1
Equipment status	0.1	0.6	0.4	0.5	0.5	0.7	0.6	0.7	0.7	0.5	0.5	0.6
Maintenance Complexity	0.1	0.7	0.8	0.6	0.6	0.5	0.5	0.4	0.6	0.4	0.4	0.6
Average time of repair	0.1	0.3	0.3	0.5	0.3	0.5	0.6	0.5	0.6	0.3	0.3	0.4
Number of failures	0.1	0.7	0.7	0.6	0.5	0.6	0.6	0.5	0.5	0.4	0.3	0.3
maintenance cost	0.1	0.2	0.2	0.5	0.5	0.5	0.3	0.8	0.5	0.3	0.3	0.3
Total Weighting	**1**	5	4.5	5.3	5.3	5.3	5.6	6.6	5.3	4.3	4.6	4.5

The very method can be used to identify the prioritization criteria for preventive maintenance, quality assurance, in terms of budgeting, replacing a medical equipment with a new equipment or procuring medical equipment, what is critical is identifying the criteria that the prioritizing model will depend on.

4.3.3 Summary

From the results received and analyzed, factors affecting maintenance were determined by usually using the content analysis using the inductive and the deductive approach. The main factors affecting maintenance were identified and this includes resources, quality control, documentation, education and planning. The assessment on how the factors found affect maintenance was done by looking at the status at which factors affecting maintenance where at the hospitals. From the findings, most factors are in bad state. In improving the maintenance practices, we proposed a model called MDCA approach which is simply prioritizing maintenance activities.

CHAPTER FIVE

5 CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

5.1 Conclusions

Medical equipment maintenance plays a major role in the health care system. It is critical in ensuring user and patient safety. Moreover, it is among the major determinants of the effectiveness and efficiency of patients' diagnosis and treatment. Consequently, medical equipment breakdowns have been a major contributing factor to the ineffective performance of medical equipment and all the activities and procedures dependent on it.

Factors that contribute to the poor maintenance of medical equipment have not been extensively investigated in the literature especially regarding developing countries. This study used both qualitative and quantitative approaches to investigate the causes of poor medical equipment maintenance in five major urban hospitals in Zambia. The study used a questionnaire and interviews to gather data on factors that affect the maintenance of medical equipment in the selected hospitals. Both deductive and inductive content analysis approached were used for data analysis. The results showed that the factors affecting the maintenance of medical equipment in the five major urban hospitals in Zambia fall under five major themes which are resources, quality control, documentation, education and service. These themes compare well with those found by Bahreini et al. (2019). The study further investigated how the factors under the themes affect medical equipment in the five selected hospitals. The following were the major conclusions on each theme and general recommendations:

i. The five major hospitals have inadequate resources in terms of workspace and budget allocation. With the limited budget, procurement of maintenance services, spare parts and consumables is negatively affected thereby reducing the effectiveness of maintenance activities.
ii. Quality control is not adequate because performance tests are carried out after repair works are done rather than implementing a drawn schedule. Regarding safety tests, the two hospitals that perform them, do so only when the need arises not as scheduled. For three hospitals, safety tests are not even done at all. This lapse in the performance of quality control measures endangers both users and patients.
iii. Other than the LTH which lacks only in keeping of safety records, the four major hospitals need much more improvements regarding documentation. Of these, the

hospital with the worst documentation practice is the KTH. This situation should raise great concern because proper documentation is cardinal. It provides reference information for costings, frequency of a medical equipment breakdowns, spare parts usage, and reliable companies supplying either medical equipment or spare parts. In case of arrival of a new medical maintenance personnel to the hospital, documentation enables quick adaptation to the environment. Documentation also enables proper monitoring of service contracts in situation where an equipment is serviced by a contracted company.

iv. Concerning service, all the hospitals do not conduct PM. This means they depend on CM which has major drawbacks especially under situations of limited financial resources.

v. Regarding education, all the hospitals except LTH, do not conduct in-house members of staff technical training. Technical staff training is usually conducted outside the country with the help of outside organizations' sponsorships. User training is done when a need arises for all hospitals other than the LTH which does it regularly.

vi. Most of these major hospitals have skilled personnel to maintain the critical equipment because most of the critical equipment involved in this study is maintained using the in-house maintenance system. However, the number of maintenance personnel is not adequate because some of the few available personnel are also involved in the general hospital maintenance works.

vii. In most of these hospitals, spare parts are ordered after equipment breakdown. This practice implies equipment remains out of use till the spare parts are procured. Since the procurement process can be lengthy in some instances, broken-down equipment might remain out of use for long periods.

viii. Despite most of these major hospitals having computers, they do not use any CMMS for comprehensive and effective documentation of maintenance activities. This means there are challenges of implementing maintenance management programs.

ix. From the analysis of the way various hospitals handle different medical equipment maintenance factors, it is shown that KTH and LTH have the worst and best maintenance regimes respectively. Therefore, this shows that KTH would be a priority hospital for medical equipment maintenance practices improvement.

5.2 Recommendations

Currently, comprehensive policies and guidelines on the maintenance of medical equipment are still lacking in Zambia. To ensure medical equipment is always properly maintained and calibrated for excellent performance, comprehensive medical equipment management policies and guidelines should not only be developed but also effectively enforced. There is also a need to ensure that all the hospitals have adequate workspace coupled with adequate tools and testing equipment.

The major constraint in implementing current existing policies in the five selected hospitals involved in this study is poor budget allocation and funding. There is need for improved budget allocation and funding if medical equipment must be well maintained. Under the current situation of deficient financing, CM coupled with the practice of ordering spare parts after equipment breakdown is not only more costly but also makes equipment out of use for a long time. Therefore, to mitigate the effects of CM under these conditions of inadequate budget funding, hospitals should shift from practicing more of the reactive CM to the proactive PM. Moreover, with respect to quality control, rather than the current where quality control tests are done when need arises in some hospitals and not done at all in others, all hospitals should do periodical quality control tests to guarantee medical equipment safety regarding both users and patients. For this, proper schedules must be drawn and implemented.

Constant training of the users and technical personnel is something that is not observed or give much attention in the five hospitals. These trainings are vital to the improvement of medical equipment maintenance effectiveness and use correctness both leading to improved health care services delivery.

Improving medical equipment requires a maintenance approach that is able to overshadow the challenges in maintenance practices such as lack of funding, implement the PM or CM and any other activities therefore, MDCA will be best suited looking at inadequacies that is faced by the maintenance personnel.

More research work is needed to establish mechanisms through which the challenges relating to factors impairing medical equipment maintenance can be overcome thereby meeting the above stated policy and hospital-based recommendations. Also, research should be done to establish the ideal ratio of technical staff to hospital bed capacity which is not known for Zambian hospitals as observed in the current study.

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6 APPENDICES

6.1 Sample of results obtained

6.2 Appendix 1: Interview guide questions - Head of Biomedical Engineering Unit/ Head of Clinical Engineering

Personal information (Tick where appropriate and applicable)

Age

21-30 years

31-40 years

41-50 years

51-60 years

Gender

Male

Female

Education Level

Diploma

Bachelor’s degree

Master’s degree

Higher Master’s degree

Qualification (please state)

____

Work experience

Less than 2 years

2- 5 years

5- 10 years

10- 15 years

More than 15 years

State name of the hospital

____

.

1. Physical resources

1.1 Workspace

1.1.1 Availability of workspace **(state whether available or not)** ___________________________________

1.1.2 Number of people operating in the workspace **(state number)**

____

1.1.3 State whether the space is adequate or inadequate ___________________________

1.1.4 State the safety and healthiness of the area **(state whether excellent, good, poor)**

____

1.2 Tools and test equipment

1.2.1 Availability of tools and test equipment **(state whether available or not)**

____

1.2.2 State the number of tools and test equipment against the number of people **(state whether adequate or not adequate)**

____

1.2.3 State the types of testing equipment available in the workshop and state whether adequate or not adequate.

1.2.3.1 Type and number 1 ___________________ **adequate or not adequate** ________________

1.2.3.2 Type and number 2 ___________________ **adequate or not adequate** ________________

1.2.3.3 Type and number 3 ___________________ **adequate or not adequate** ________________

1.2.3.4 Type and number 4 ___________________ **adequate or not adequate** ________________

1.2.3.5 Type and number 5 ___________________ **adequate or not adequate** ________________

1.2.4 Availability of internet, computers, printers, softwares for specific machines **(state whether available or not)**

____

1.2.5 Number of computers, printers against the number of Biomedical Engineers **(state whether adequate or not)**

____

1.3 Financial resources

1.3.1 Availability of hospital policy on the allocation of funds for preventive maintenance costs **(state whether available or not and provide evidence)** ____

1.1.1 Availability of hospital policy on the allocation of funds for corrective maintenance costs **(state whether available or not and provide evidence)** ____

1.1.2 Availability of hospital policy on the allocation of funds for spare parts and consumables **(state whether available or not and provide evidence)** ____

1.1.3 If the hospital policy on the allocation of funds for the maintenance programme is available **(state whether the funds are adequate or not)** ____

1.1.4 State the amount of funds in kwacha budgeted for towards maintenance every year **(state the amount)**

____

2. Human resources

2.1 Total number of available medical equipment maintenance personnel **(state the number and whether adequate or inadequate)**

____

2.2 Trained Biomedical Engineers and Biomedical engineer technologist **(state the number)** ___________________________

2.3 State the minimum years of experience of biomedical engineers/technologist available in your hospital **(state the years)**

____

2.4 Other maintenance personnel **(state their qualifications and their years of experience)**

2.4.1 Maintenance personnel 1 ____

2.4.2 Maintenance personnel 2 ____

2.4.3 Maintenance personnel 3 ____

2.4.4 Maintenance personnel 4 ____

2.4.5 Maintenance personnel 5 ____

2.4.6 Maintenance personnel 6 ____

2.5 Availability of specialization among maintenance personnel (Biomedical Engineers/ technologists) **(state whether available or not)**

____

2.6 If specialization is available in **2.4** state the specialization

____

2.7 Availability of continuous development programme policy among medical equipment maintenance personnel **(state whether available or not and provide evidence)** ____

3. Safety tests

3.1 Availability of performance test and safety training policy on medical equipment. **(state whether available or not)**

____

3.2 Frequency of performance test and safety training **(state whether the training is often done, sometimes or never done)**

____

3.3 State how often electrical safety checks on medical equipment is done and provide eveidence **(very often, sometimes, never done)**

____

4. Documentation

4.1 Availability of service, preventive maintenance, and user manual **(state whether available or not and provide evidence)**

____

4.2 Availability of information such as equipment catalogues on medical equipment in the department **(state whether available or not)**

____

4.3 Availability of information on equipment such as device specifications, warranty status, service installations, acceptance tests, preventive maintenance, calibration, etc. **(State whether available or not and provide evidence)**

____

4.4 State how this information is stored **(state whether hard, soft copy or others and provide evidence)**

____

4.5 Availability of medical equipment tracking system on repair, maintenance, service **(state whether available or not and provide evidence)** ____

4.6 Availability of records on costs associated with repairs, installation, and calibration **(state whether available or not and provide evidence)** ____

4.7 Availability of information on job requests, internal and external service records, PM schedules, warranty periods, spareparts and consumables inventory, service contract and purchasing information, quality assurance, reporting, cost control, and alerts and hazards **(state whether available or not and provide evidence)**

____

4.8 How is quality assurance in question **4.7** done and by whom (explain)

____

____

____

____

4.9 Availability of documentation for tests such as performance tests, electrical safety tests etc. **(state whether available or not and provide evidence)**

4.10 Availability of vendor business cards **(state whether available or not and provide evidence if available)**

____

5. Training

5.1 Availability of user training schedule **(state whether available or not and provide evidence)**

____

5.2 How often are the user training **(state the number of times in a year)**

____

5.3 Availability of technical training schedule **(state whether available or not and provide evidence)**

____

5.4 How often are the technical training **(state the number of times in a year)**

____

6. Outsourcing of service contracts on sophisticated equipment

6.1 State availability of service contracts on sophisticated equipment **(state whether available or not and provide evidence)**

____

6.2 State effectiveness of the service contracts **(state whether very effective, partially effective or not effective)**

____

7. Reporting adverse events and recall system

7.1 Availability of the criteria for reporting incidents and recalling medical equipment **(state whether available or not and provide evidence)** ____

7.2 Availability of a written format for reporting adverse events **(state whether available or not and provide evidence)**

____

7.3 Availability of records on how often the adverse events occurs **(state whether available or not and provide evidence)**

6.3 Appendix 2: Questionnaire - Medical equipment maintenance personnel

Personal information (Tick where appropriate and applicable)

Age

21-30 years

31-40 years

41-50 years

51-60 years

Gender

Male

Female

Education Level

Diploma

Bachelor's degree

Master's degree

Higher Master's degree

Qualification (please state)

____

Work experience

Less than 2 years

2- 5 years

5- 10 years

10- 15 years

More than 15 years

State name of the hospital

____

1. Do you have any or all of the following critical medical equipment if Yes, Circle the critical medical equipment items.

	Yes	No
Kidney dialysis machine	☐	☐
Cardiac catheterization machine	☐	☐
Anaesthesia machine	☐	☐
Defibrillator	☐	☐
Diathermy	☐	☐
Ventilator	☐	☐
Infusion pump	☐	☐
ECG Machine	☐	☐
Electrosurgical Unit	☐	☐
Defibrillator, Automated, Transport	☐	☐
Defibrillator, Manual	☐	☐
Nebuliser	☐	☐
Oxygen concentrator	☐	☐

2. **Do you have any other critical medical equipment that are not listed in question 1, please give title of equipment.**____

3. The total number of units of this device currently in use.

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Ventilator

Infusion pump

ECG Machine

Electrosurgical +Unit+ Mechanical Vibration

Defibrillator, Automated, Transport

Defibrillator, Manual

Nebuliser

OXYGEN CONCENTRATOR

Other critical equipment

4. How long this device has been in service for?

	Up to one year	1-4 years	5 years and over
Kidney dialysis machines	☐	☐	☐
Cardiac catheterization	☐	☐	☐
Anaesthesia machines	☐	☐	☐
Defibrillator	☐	☐	☐
Diathermy	☐	☐	☐
Ventilator	☐	☐	☐
Infusion pump	☐	☐	☐
ECG Machine	☐	☐	☐
Electrosurgical Unit	☐	☐	☐
Defibrillator, Automated, Transport	☐	☐	☐
Defibrillator, Manual	☐	☐	☐
Nebuliser	☐	☐	☐
Oxygen concentrator	☐ ar	☐	☐
Other critical equipment	☐	☐	☐

5. Average number of patients who are serviced by this device per month.

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Ventilator

Infusion pump

ECG Machine

Electrosurgical Unit

Defibrillator, Automated, Transport

Defibrillator, Manual

Nebuliser

Oxygen concentrator

Other critical equipment

6. Average usage time per patient.

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Ventilator

Infusion pump

ECG Machine

Electrosurgical Unit

Defibrillator, Automated, Transport

Defibrillator, Manual

Nebuliser

Oxygen concentrator

Other critical equipment

7. IF these devices break down, are there any alternatives that can do the same work and provide the required health services to patients.

	Yes	No
Kidney dialysis machines	☐	☐
Cardiac catheterization	☐	☐
Anaesthesia machines	☐	☐
Defibrillator	☐	☐
Diathermy	☐	☐
Ventilator	☐	☐
Infusion pump	☐	☐
ECG Machine	☐	☐
Electrosurgical Unit	☐	☐
Defibrillator, Automated, Transport	☐	☐
Defibrillator, Manual	☐	☐
Nebuliser	☐	☐
Oxygen concentrator	☐	☐
Other critical equipment	☐	☐

Other (please specify)

8. How often are these alternatives used?

	Very often	Often	Occasionally	Seldom	Never
Kidney dialysis machines	☐	☐	☐	☐	☐
Cardiac catheterization	☐	☐	☐	☐	☐
Anaesthesia machines	☐		☐		☐
Defibrillator	☐	☐	☐	☐	☐
Diathermy	☐	☐	☐	☐	☐
Ventilator	☐	☐	☐	☐	☐
Infusion pump	☐	☐	☐	☐	☐
ECG Machine	☐	☐	☐	☐	☐
Electrosurgical Unit	☐	☐	☐	☐	☐
Defibrillator, Automated, Transport	☐	☐	☐	☐	☐
Defibrillator, Manual	☐	☐	☐	☐	☐
Nebuliser	☐	☐	☐	☐	☐
Oxygen concentrator	☐	☐	☐	☐	☐
Other critical equipment	☐	☐	☐	☐	

9. Is the maintenance for this equipment carried out [largely]

	In house	Outsourced	Mixed
Kidney dialysis machines	☐	☐	☐
Cardiac catheterization	☐	☐	☐
Anaesthesia machines	☐	☐	☐
Defibrillator	☐	☐	☐
Diathermy	☐	☐	☐
Ventilator	☐	☐	☐
Infusion pump	☐	☐	☐
ECG Machine	☐	☐	☐
Electrosurgical Unit	☐	☐	☐
Defibrillator, Automated, Transport	☐	☐	☐
Defibrillator, Manual	☐	☐	☐
Nebuliser	☐	☐	☐
Oxygen concentrator	☐	☐	☐
Other critical equipment	☐	☐	☐

Other (please specify)

10. Are you involved in decision making regarding maintenance policy for critical medical equipment?Tick the appropriate circle.

Yes ◯

No ◯

11. How often are the critical spare parts readily available?

	Very often	Often	Occasionally	Seldom	Never
Kidney dialysis machines	☐	☐	☐	☐	☐
Cardiac catheterization	☐	☐	☐	☐	☐
Anaesthesia machines	☐	☐	☐	☐	☐
Defibrillator		☐	☐	☐	☐
Diathermy	☐	☐	☐	☐	☐
Ventilator	☐	☐	☐	☐	☐
Infusion pump	☐	☐	☐	☐	☐
ECG Machine	☐	☐	☐	☐	☐
Electrosurgical Unit	☐	☐	☐	☐	☐
Defibrillator, Automated, Transport	☐	☐	☐	☐	☐
Defibrillator, Manual	☐	☐	☐	☐	☐
Nebuliser	☐	☐	☐	☐	☐
Oxygen concentrator	☐	☐	☐	☐	☐
Other critical equipment	☐		☐	☐	☐

12. if the answer in 11 is occasionally, seldom, or never, please explain why its difficulty in obtaining parts.

___

13. Are the critical spare parts kept in stock by you or your maintenance supplier or do they have to be ordered prior to or after a breakdown?

	In stock	Prior to breakdown	Ordered after breakdown
Kidney dialysis machines	☐	☐	☐
Cardiac catheterization	☐		☐
Anaesthesia machines	☐	☐	☐
Defibrillator	☐	☐	☐
Diathermy	☐	☐	☐
Ventilator	☐	☐	☐
Infusion pump	☐	☐	☐
ECG Machine		☐	☐
Electrosurgical Unit	☐	☐	☐
Defibrillator, Automated, Transport	☐	☐	☐
Defibrillator, Manual	☐	☐	☐
Nebuliser	☐	☐	☐
Oxygen concentrator	☐	☐	☐
Other critical equipment	☐	☐	☐

14. If this equipment ever fails, please indicate how many times per year in your experience?

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Ventilator

infusion pump

ECG Machine

Electrosurgical Unit

Defibrillator, Automated, Transport

Defibrillator, Manual

Nebuliser

Oxygen concentrator

Other critical equipment

15. What are the common reasons for the failure (Breakdown) of this device?

	Technical	Human	Over-use
Kidney dialysis machines	☐	☐	☐
Cardiac catheterization	☐	☐	☐
Anaesthesia machines	☐	☐	☐
Defibrillator	☐	☐	☐
Diathermy	☐	☐	☐
Ventilator	☐	☐	☐
Infusion pump	☐	☐	☐
ECG Machine	☐	☐	☐
Electrosurgical Unit	☐	☐	☐
Defibrillator, Automated, Transport	☐	☐	☐
Defibrillator, Manual	☐	☐	☐
Nebuliser	☐	☐	☐
Oxygen concentrator	☐	☐	☐
Other critical equipment	☐	☐	☐

16. Has this device ever failed while providing health care services to patients?

	Yes	No
Kidney dialysis machines	☐	☐
Cardiac catheterization		☐
Anaesthesia machines	☐	☐
Defibrillator	☐	☐
Diathermy	☐	☐
Ventilator	☐	☐
Infusion pump	☐	☐
ECG Machine	☐	☐
Electrosurgical Unit	☐	☐
Defibrillator, Automated, Transport	☐	☐
Defibrillator, Manual	☐	☐
Nebuliser	☐	☐
Oxygen concentrator	☐	☐
Other critical equipment	☐	☐

17. If your answer is (Yes) to Q25, how many times has it broken down in the last 5 years?

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Ventilator

Infusion pump

ECG Machine

Electrosurgical Unit

Defibrillator, Automated, Transport

Defibrillator, Manual

Nebuliser

Oxygen concentrator

Other critical equipment

18. How often do you keep records of maintenance costs?

Very often ◯

Often ◯

Ocasionally ◯

Seldom ◯

Never ◯

19. How detailed are your records?

20. How often is the data used for maintenance decisions?

Very often ◯

Often ◯

Ocasionally ◯

Seldom ◯

Never ◯

21. Please estimate the total maintenance cost (in terms either or both of $ or downtime) when it is carried out in- hospital, for the following equipment per month.

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Respironics, BIPAP

Ventilator

Infusion pump

ECG Machine

Electrosurgical Unit

Defibrillator, Automated, Transport

Defibrillator, Manual

Nebuliser

Oxygen concentrator

Other critical equipment

22. Please estimate the total maintenance cost (in terms either or both of $ or downtime) when it is carried out outsourced, for the following equipment per month.

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Ventilator

Infusion pump

ECG Machine

Electrosurgical Unit

Defibrillator, Automated, Transport

Defibrillator, Manual

Nebuliser

Oxygen concentrator

Other critical equipment

23. In your experience, do you know of cases in hospitals, where patient outcomes have been affected by the break down of critical medical equipment?

Yes ◯

No ◯

24. Indicate the level of risk in relation to a patient's life, if this medical device fails (breaks down) while it is in service.

Very risk ◯ Risk ◯ Less risk ◯

25. When critical medical equipment does fail (break down), how is that failure usually managed?

	Duplicate equipment	Call supplier	In-house maintenance	Borrow equipment	Other
Kidney dialysis machine	☐	☐	☐	☐	☐
Cardiac catheterization machine	☐	☐	☐	☐	☐
Anaesthesia machine	☐	☐	☐	☐	☐
Defibrillator	☐	☐	☐	☐	☐
Diathermy	☐	☐	☐	☐	☐
Ventilator	☐	☐	☐	☐	☐
Infusion pump	☐	☐	☐	☐	☐
ECG Machine	☐	☐	☐	☐	☐
Electrosurgical Unit	☐	☐	☐	☐	☐
Defibrillator, Automated, Transport	☐	☐	☐	☐	☐
Defibrillator, Manual	☐	☐	☐	☐	☐
Nebuliser	☐	☐	☐	☐	☐
Oxygen concentrator	☐	☐	☐	☐	☐
Other critical equipment		☐	☐	☐	☐

Other (please specify)

26. If maintenance is carried out in- house, how long is the device unavailable (on average per days/months)?

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Ventilator

Infusion pump

ECG Machine

Electrosurgical Unit

Defibrillator, Automated, Transport

Defibrillator, Manual

Nebuliser

Oxygen concentrator

Other critical equipment

27. How often is the medical device become unavailable to treat patients who require its service?(Times per month)

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Ventilator

Infusion pump

ECG Machine

Electrosurgical Unit

Defibrillator, Automated, Transport

Defibrillator, Manual

Nebuliser

Oxygen concentrator

Other critical equipment

28. How is the health care service of this device provided to patients?

	On demand	Patient has to be placed on waiting list	Priority list
Kidney dialysis machines	☐		☐
Cardiac catheterization	☐	☐	☐
Anaesthesia machines	☐	☐	☐
Defibrillator	☐	☐	☐
Diathermy	☐	☐	☐
Ventilator	☐	☐	☐
Infusion pump	☐	☐	☐
ECG Machine	☐	☐	☐
Electrosurgical Unit	☐	☐	☐
Defibrillator, Automated, Transport	☐	☐	☐
Defibrillator, Manual	☐	☐	☐
Nebuliser	☐		☐
Oxygen concentrator	☐	☐	☐
Other critical equipment	☐	☐	☐

29. What are the reasons for the unavailability of this device for providing healthcare to patients?

	Limited number of this device available	Device out of service/ breakdown
Kidney dialysis machines	☐	☐
Cardiac catheterization	☐	☐
Anaesthesia machines	☐	☐
Defibrillator	☐	☐
Diathermy	☐	☐
Ventilator	☐	☐
Infusion pump	☐	☐
ECG Machine	☐	☐
Electrosurgical Unit	☐	☐
Defibrillator, Automated, Transport	☐	☐
Defibrillator, Manual	☐	☐
Nebuliser	☐	☐
Oxygen concentrator	☐	☐
Other critical equipment	☐	☐

30. Do you think the current maintenance strategy helps increase the availability of this medical device to provide health care to patients in time?

	Agree	Strongly agree	Agree	Indifferent	Disagree	Strongly Disagree
Kidney dialysis machines	☐	☐	☐	☐	☐	☐
Cardiac catheterization	☐	☐	☐	☐	☐	☐
Anaesthesia machines	☐	☐	☐	☐	☐	☐
Defibrillator	☐	☐	☐	☐	☐	☐
Diathermy	☐	☐	☐	☐	☐	☐
Ventilator	☐	☐	☐	☐	☐	☐
Infusion pump	☐	☐	☐	☐	☐	☐
ECG Machine	☐	☐	☐	☐	☐	☐
Electrosurgical Unit	☐	☐	☐	☐	☐	☐
Defibrillator, Automated, Transport	☐	☐	☐	☐	☐	☐
Defibrillator, Manual	☐	☐	☐	☐	☐	☐
Nebuliser	☐	☐	☐	☐	☐	☐
Oxygen concentrator	☐	☐	☐	☐	☐	☐
Other critical equipment	☐	☐	☐	☐	☐	☐

31. Do you use measures of critical medical device reliability to evaluate your maintenance policy? Please answer Yes or No.

Yes ◯ No ◯

32. Do you think the current maintenance strategy helps optimise the failure rates (breakdown) of this critical medical device?

	Strongly agree	Agree	Indifferent	Disagree	Strongly disagree
Kidney dialysis machines	☐	☐	☐	☐	☐
Cardiac catheterization	☐	☐	☐	☐	☐
Anaesthesia machines	☐	☐	☐	☐	☐
Defibrillator	☐	☐	☐	☐	☐
Diathermy	☐	☐	☐	☐	☐
Ventilator	☐	☐	☐	☐	☐
Infusion pump	☐	☐	☐	☐	☐
ECG Machine	☐	☐	☐	☐	☐
Electrosurgical Unit	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
Defibrillator, Manual	☐	☐	☐	☐	☐
Nebuliser	☐	☐	☐	☐	☐
Oxygen concentrator	☐	☐	☐	☐	☐
Other critical equipment	☐	☐	☐	☐	☐

33. Do you think the current maintenance strategy is one of the reasons for unavailability of this critical medical device?

Strongly agree	Agree	Indifferent	Disagree	Strongly disagree
☐	☐	☐	☐	☐

34. Do you think the current maintenance strategy helps reduce the sudden breakdown of this critical device while providing medical service?

Strongly agree	Agree	Indifferent	Disagree	Strongly disagree
☐	☐	☐	☐	☐

35. Do you use any maintenance management software programs in order to predict the occurrence of sudden failure of these devices?

Yes ◯ No ◯

36. If your answer is Yes to Q35, What program is used?

---

37. Do you have any general suggestion to improve current maintenance management strategies in the hospital?

6.4 Appendix 3: Interview guide - Medical personnel

Personal information (Tick where appropriate and applicable)

Age

21-30 years

31-40 years

41-50 years

51-60 years

Gender

Male

Female

Education Level

Diploma

Bachelor's degree

Master's degree

Higher Master's degree

Qualification (please state)

____

Work experience

Less than 2 years

2- 5 years

5- 10 years

10- 15 years

More than 15 years

State name of the hospital

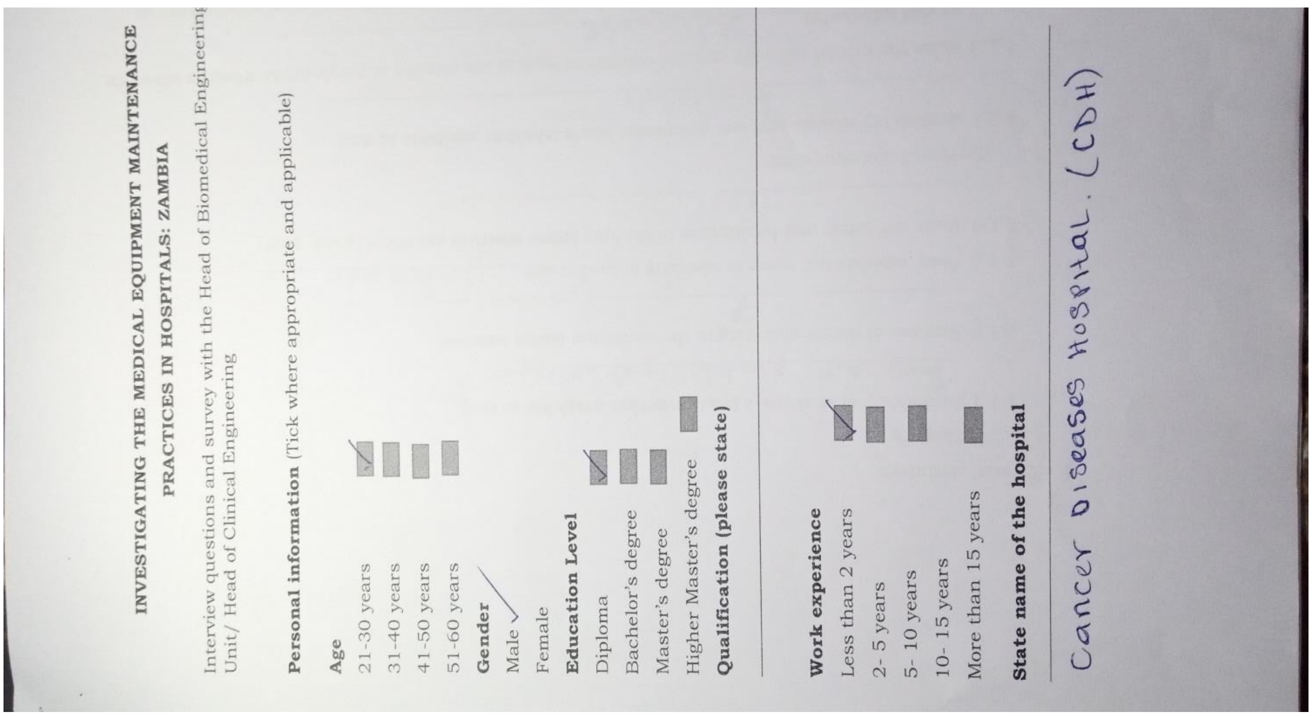
____

What are your experiences regarding critical shortage of medical equipment in this hospital?"

1. Has there been a moment of shortage of critical medical equipment in this hospital?"
2. Which equipment are prone to shortages?
3. Causes of equipment shortage or unavailability?

4. To your experience, what kinds of equipment are available in your hospital in terms of quality?
5. How is the maintenance of medical equipment done by maintenance personnel and are you involved in any maintenance?
6. Consequence of the shortages of critical medical equipment
7. Impact on patient care and service delivery
8. Impact on nurses/doctors and professions
9. Any legal implications for the hospital as a result of equipment shortage?
10. Impact on training of medical personnel (doctors and nurses)

6.5 **Appendix 4:** sample of response from the participant



INVESTIGATING THE MEDICAL EQUIPMENT MAINTENANCE PRACTICES IN HOSPITALS: ZAMBIA

Interview questions and survey with the Head of Biomedical Engineering Unit/ Head of Clinical Engineering

Personal information (Tick where appropriate and applicable)

Age

21-30 years ✓

31-40 years

41-50 years

51-60 years

Gender

Male ✓

Female

Education Level

Diploma ✓

Bachelor's degree

Master's degree

Higher Master's degree

Qualification (please state)

Work experience

Less than 2 years ✓

2- 5 years

5- 10 years

10- 15 years

More than 15 years

State name of the hospital

Cancer Diseases Hospital. (CDH)

1. Physical resources
   1.1 Workspace
      1.1.1 Availability of workspace **(state whether available or not)**
      There is no availability of workspace
      1.1.2 Number of people operating in the workspace **(state number)**
      7
      1.1.3 State whether the space is adequate or inadequate Inadequate
      1.1.4 State the safety and healthiness of the area **(state whether excellent, good, poor)**
      Poor
   1.2 Tools and test equipment
      1.2.1 Availability of tools and test equipment **(state whether available or not)**
      Available
      1.2.2 State the number of tools and test equipment against the number of people **(state whether adequate or not adequate)** Adequate
      1.2.3 State the types of testing equipment available in the workshop and state whether adequate or not adequate.

1.1.2 Availability of hospital policy on the allocation of funds for spare parts and consumables **(state whether available or not and provide evidence)**
Not available to some extent
1.1.3 If the hospital policy on the allocation of funds for the maintenance programme is available **(state whether the funds are adequate or not)**
Not adequate
1.1.4 State the amount of funds in kwacha budgeted for towards maintenance every year **(state the amount)** Unknown

2. Human resources
   2.1 Total number of available medical equipment maintenance personnel **(state the number and whether adequate or inadequate)** 5, ~~IN~~ Adequate
   2.2 Trained Biomedical Engineers and Biomedical engineer technologist **(state the number)**
   3
   2.3 State the minimum years of experience of biomedical engineers/technologist available in your hospital **(state the years)** 2 years
   2.4 Other maintenance personnel **(state their qualifications and their years of experience)**
      2.4.1 Maintenance personnel 1 Electrician, Diploma, over 5 years.
      2.4.2 Maintenance personnel 2 Refrigeration Technician, over 8 years.
      2.4.3 Maintenance personnel 3 ________
      2.4.4 Maintenance personnel 4 ________
      2.4.5 Maintenance personnel 5 ________
      2.4.6 Maintenance personnel 6 ________

2.5 Availability of specialization among maintenance personnel (Biomedical Engineers/ technologists) **(state whether available or not)** ___Not Available___

2.6 If specialization is available in **2.4** state the specialization

___None___

2.7 Availability of continuous development programme policy among medical equipment maintenance personnel **(state whether available or not and provide evidence)**

___Not available.___

3. Safety tests

3.1 Availability of performance test and safety training policy on medical equipment. **(state whether available or not)** ___Available___

3.2 Frequency of performance test and safety training **(state whether the training is often done, sometimes or never done)**

___often done.___

3.3 State how often electrical safety checks on medical equipment is done and provide eveidence **(very often, sometimes, never done)**

___Monthly___

4. Documentation

4.1 Availability of service, preventive maintenance, and user manual **(state whether available or not and**

4.2 Availability of information such as equipment catalogues on medical equipment in the department **(state whether available or not)** ___Available___

4.3 Availability of information on equipment such as device specifications, warranty status, service installations, acceptance tests, preventive maintenance, calibration, etc. **(State whether available or not and provide evidence)** ___Available___

4.4 State how this information is stored **(state whether hard, soft copy or others and provide evidence)**

___Soft copy___

4.5 Availability of medical equipment tracking system on repair, maintenance, service **(state whether available or not and provide evidence)** ___Available___

4.6 Availability of records on costs associated with repairs, installation, and calibration **(state whether available or not and provide evidence)**

___Not Available to some extent.___

4.7 Availability of information on job requests, internal and external service records, PM schedules, warranty periods, spareparts and consumables inventory, service contract and purchasing information, quality assurance, reporting, cost control, and alerts and hazards **(state whether available or not and provide evidence)** ___Not Available to some & extent.___

4.8 How is quality assurance in question **4.7** done and by whom (explain)

___It is done by the medical Equipment Technologist following the laid quality assurance procedures.___

4.9 Availability of documentation for tests such as performance tests, electrical safety tests etc. **(state whether available or not and provide evidence)**

4.10 Availability of vendor business cards **(state whether available or not and provide evidence if available)** Available

5. Training

5.1 Availability of user training schedule **(state whether available or not and provide evidence)** Available

5.2 How often are the user training **(state the number of times in a year)** Whenever need arise.

5.3 Availability of technical training schedule **(state whether available or not and provide evidence)** Not Available to some extent

5.4 How often are the technical training **(state the number of times in a year)** Very rare.

6. Outsourcing of service contracts on sophisticated equipment

6.1 State availability of service contracts on sophisticated equipment **(state whether available or not and provide evidence)** Available

6.2 State effectiveness of the service contracts **(state whether very effective, partially effective or not effective)** Partially Effective

7. Reporting adverse events and recall system

7.1 Availability of the criteria for reporting incidents and recalling medical equipment **(state whether available or not and provide evidence)** Available

7.2 Availability of a written format for reporting adverse events **(state whether available or not and provide evidence)** Available

7.3 Availability of records on how often the adverse events occurs **(state whether available or not and provide evidence)** Available.

6.6 **Appendix:** Submission of article for possible publication

THE UNIVERSITY OF ZAMBIA
DIRECTORATE OF RESEARCH AND GRADUATE STUDIES

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P O Box 32379
Lusaka
ZAMBIA

23rd December, 2021

Ms. Queen C. Muma
C/o The University of Zambia
School of Engineering
P.O. Box 32379
LUSAKA

Dear Ms. Muma,

RE: SUBMISSION OF ARTICLE FOR POSSIBLE PUBLICATION IN THE JOURNAL OF NATURAL AND APPLIED SCIENCES

On behalf of the Editorial Board of the Journal of Natural and Applied Sciences, I wish to acknowledge receipt of your manuscript1 entitled:-

"Determine the Factors Affecting Medical Equipment Maintenance in Hospitals: Zambia."

As per requirement, the article will be reviewed and the outcome communicated to you as soon as possible. I wish to thank you most sincerely for your interest in publishing with the Journal of Natural and Applied Sciences.

Yours sincerely,

P.P. Prof. L. Siaminwe
CHIEF EDITOR, JOURNAL OF NATURAL AND APPLIED SCIENCES

cc: Director, Directorate of Research and Graduate Studies
Assistant Director (Research), Directorate of Research and Graduate Studies
Assistant Registrar, Directorate of Research and Graduate Studies