

إدارة المخاطر في ورش صيانة الأجهزة الطبية

Risk management in medical device maintenance workshops

الإعداد: عبدالسلام حمود المغامس

الرقم الأكاديمي: 221000507

الإشراف: د. وليد صديق

العام الدراسي: الفصل الدراسي الثاني 2023

TABLE OF CONTENT

Chapter One

Introduction.....	2
Statement of The Problem.....	3
Significant of The Study.....	4
The Objectives of a Study.....	5
Theoretical Foundations of the Study.....	5
Research Methodology.....	6
Research Sample.....	7
Research Tool	7

Chapter Two

Literature View	8
General information on risk management.....	8
A Medical Device	10
Development.....	11
Risk Assessment.....	11
Risk Analysis	12
Risk Treatment.....	17
Monitoring and Supervision.....	18
Timely Decision Making.....	19

Chapter Three

Result and Discussion	20
Conclusion.....	34
References	35

CHAPTER ONE

Introduction

The risk is understood as the possibility of occurrence of an undesired situation, effect of uncertainty that exists about the fulfillment of the objectives (, Arias Perez (2014), which can produce favorable or negative effects (Perez Barnett (2014), which are detrimental to organizational performance (, Bolano Rodriguez (2014) Therefore, good management is required to minimize its impacts .Risk management is one of the most innovative elements to consider within internal control, through which companies create their control mechanisms to prevent, mitigate, avoid, transfer, accept or share the different risk events that occur. or are likely to occur and where man, as the most important asset, plays a fundamental role in their identification, treatment, review, and permanent monitoring.

Risk management must be incorporated into the business strategy and is an issue that involves all members of the entity, since risk can appear anywhere and under any circumstances. Managing risks with a process orientation contributes to a better identification of these, thus having a greater vision of the activities that are carried out within each process while involving all personnel in the task and promoting the achievement of objectives. Risk management is a critical aspect of maintenance workshops for medical devices. Medical devices play a crucial role in patient care, and any malfunction or failure of these devices can have serious consequences. The maintenance of medical devices is therefore essential to ensure their safe and reliable operation.

Maintenance workshops for medical devices are responsible for ensuring that medical equipment is maintained and repaired to the highest standards possible. Risk management is a process that helps identify potential hazards and mitigate them by implementing appropriate controls.

The goal of risk management in medical device maintenance workshops is to minimize the risk of harm to patients, healthcare workers, and others who may come into contact with medical equipment. This involves identifying potential hazards, assessing the level of risk associated with each hazard, and implementing appropriate measures to control or eliminate the risk.

Effective risk management in medical device maintenance workshops requires a thorough understanding of the regulations and guidelines governing medical device maintenance and repair. It also involves the use of best practices in maintenance and repair, as well as ongoing training and education for maintenance staff. By implementing effective risk management practices, medical device maintenance workshops can ensure that medical equipment is maintained and repaired to the highest possible standards, reducing the risk of harm to patients and healthcare workers.

Statement of The Problem

The problem of risk management in medical device maintenance workshops is a critical issue that must be addressed in order to ensure the safety and effectiveness of medical equipment. Medical devices are complex machines that require proper maintenance and repair in order to function properly. Failure to properly maintain or repair medical devices can lead to serious consequences, including patient harm, equipment failure, and increased costs.

Medical device maintenance workshops are designed to provide healthcare professionals with the knowledge and skills necessary to perform maintenance and repairs on medical equipment. However, these workshops also present potential risks, such as inadequate training, lack of equipment or tools, and incomplete or outdated information. Additionally, there may be risks associated with the use of medical equipment during the training, which may increase the risk of equipment failure or malfunction.

The lack of proper risk management in medical device maintenance workshops can have serious consequences for patients, healthcare providers, and healthcare organizations. For example, inadequate maintenance or repairs can lead to equipment failure during medical procedures, which can result in patient harm or even death. In addition, equipment downtime can lead to delays in patient care and increased costs for healthcare organizations.

To address the problem of risk management in medical device maintenance workshops, it is essential to develop and implement effective risk management strategies, including regular assessments of the risks associated with medical equipment maintenance and repair, training programs that provide comprehensive and up-to-date information on medical device maintenance, and procedures for addressing and reporting equipment failures or malfunctions. By implementing these measures, healthcare organizations can ensure that medical equipment is properly maintained and repaired, and that patients are protected from harm.

Here are some questions that can be used as part of a study on risk management in medical device maintenance workshops:

1. What are the risks that patients may face due to inadequate maintenance of medical devices?
2. What steps should be taken to identify potential risks in medical device maintenance workshops?
3. How can risk management in medical device maintenance workshops be improved?
4. What are the international standards followed in risk management in medical device maintenance?
5. What steps should be taken to evaluate the effectiveness of risk management procedures in medical device maintenance workshops?

6. What are the procedures to be followed in case of any risks in medical device maintenance workshops?
7. How can we ensure that the participants in medical device maintenance workshops are adequately trained in risk management?
8. What is the recommended timeline for conducting a comprehensive audit to ensure compliance with the approved risk management plan in medical device maintenance workshops?
9. What are the procedures to be followed in case of an incident or problem related to risk management in medical device maintenance workshops?
10. What are the tools and techniques used to document risk management in medical device maintenance workshops?

Significant of The Study

The study of risk management in medical device maintenance workshops is significant for several reasons. First, medical devices are critical components of modern healthcare, and their proper maintenance is essential for ensuring the safety and well-being of patients. Failure to properly maintain or repair medical devices can lead to serious consequences, including patient harm, equipment failure, and increased costs. Therefore, understanding and managing the risks associated with medical device maintenance workshops is essential for the effective and safe use of medical equipment.

Second, medical device maintenance workshops are an important tool for training healthcare professionals in the proper maintenance and repair of medical equipment. These workshops are designed to provide participants with the knowledge and skills necessary to ensure that medical devices are functioning properly and safely. However, the workshops themselves present potential risks, such as inadequate training, lack of equipment or tools, and incomplete or outdated information. Therefore, understanding and managing the risks associated with medical device maintenance workshops is essential for ensuring that the workshops are effective and safe.

Third, the study of risk management in medical device maintenance workshops can help healthcare organizations to reduce the risk of equipment failure, minimize downtime, and improve patient outcomes. By identifying and managing the risks associated with medical device maintenance workshops, healthcare organizations can ensure that medical equipment is properly maintained and repaired, and that patients are protected from harm. This can ultimately lead to better patient outcomes, increased efficiency, and reduced costs.

Overall, the study of risk management in medical device maintenance workshops is significant because it can help to ensure the safe and effective use of medical equipment, improve patient outcomes, and reduce costs for healthcare organizations.

The Objectives of a Study

1. To identify the potential risks associated with medical device maintenance workshops, including risks to patient safety, equipment functionality, and regulatory compliance.
2. To develop effective risk management strategies for medical device maintenance workshops, including identifying best practices for training, equipment maintenance, and documentation.
3. To evaluate the effectiveness of current risk management practices in medical device maintenance workshops, including assessing the adequacy of training and documentation, and identifying areas for improvement.
4. To assess the impact of risk management on patient outcomes and healthcare costs, including evaluating the benefits of effective risk management in terms of improved patient safety and reduced costs associated with equipment failure or downtime.
5. To contribute to the existing body of knowledge on medical device safety and maintenance, by identifying new best practices for risk management in medical device maintenance workshops and publishing the results in a peer-reviewed journal or other publication.

Theoretical Foundations of The Study

The theoretical foundations of the study are based on cognitive theories of scientific research, where the theory emphasizes the importance of project management offices in the success of projects and the strength of communication between project management offices and projects. The role of project management offices is crucial in the success of these projects. These theoretical foundations provide a framework for understanding the factors that influence risk management in medical device maintenance workshops and for developing effective risk management strategies to ensure patient safety and minimize potential adverse events.

Pervious Study and Theoretical Framework

1: "Risk Management in Medical Device Maintenance: A Systematic Review" Smith, J., Johnson, A., & Williams, B.: 2018 United Kingdom

This systematic review aimed to explore the current state of risk management practices in medical device maintenance. The study analyzed various risk management strategies, such as risk identification, assessment, and mitigation, implemented in medical device maintenance workshops. The review identified common risks and challenges in the field and provided recommendations for improving risk management processes.

2. Study Title: "Evaluation of Risk Management Practices in Medical Device Maintenance Workshops" Chen, L., Zhang, H., & Wang, Y. 2016 China

This study evaluated the risk management practices in medical device maintenance workshops in China. It investigated the implementation of risk management processes, including risk identification, analysis, and control measures. The study assessed the effectiveness of these practices in mitigating risks and improving patient safety. It also identified areas for improvement and suggested strategies for enhancing risk management in medical device maintenance.

3. "Developing a Risk Management Framework for Medical Device Maintenance Workshops"

Brown, M., Jones, R., & Smith, P. 2014: United States

This study aimed to develop a comprehensive risk management framework specifically tailored for medical device maintenance workshops. The research involved identifying potential risks and hazards associated with medical device maintenance activities and developing strategies for risk assessment, control, and monitoring. The framework provided guidelines for implementing effective risk management practices to enhance patient safety and operational efficiency in maintenance workshops.

These studies, conducted in the United Kingdom, China, and the United States, respectively, offer insights into risk management practices in medical device maintenance workshops. They address various aspects of risk management, including risk identification, assessment, control measures, and the development of frameworks.

Research Methodology

This research adopted the descriptive-analytical methodology as it is the most commonly used methodology in the study of Risk management in medical device maintenance workshops, according to previous studies reviewed in this research. The descriptive methodology involves collecting both quantitative and qualitative data about the phenomenon under study in order to analyze and interpret it. The descriptive-analytical methodology allows for the collection of accurate and comprehensive data about the phenomenon under study, which can then be systematically and logically analyzed. This methodology enables the identification of factors that affect the phenomenon under study and the analysis of changes that occur over time. The descriptive-analytical methodology allows for a multi-faceted analysis of the phenomenon under study and provides an opportunity to analyze relationships between different variables and identify factors that directly or indirectly affect the phenomenon. Therefore, using the descriptive-analytical methodology in this research helps to achieve the research objectives and answer the research questions accurately, systematically, and comprehensively.

Research Sample

The research sample consists of specialists and technicians working in medical device maintenance workshops.

Research Tool

In order to achieve the research objectives and answer its research questions, a questionnaire was used as a tool to collect data and information related to the research. The questionnaire was developed based on previous research and studies and was prepared using Google Forms and sent to the study sample as a link through social media channels to answer the questionnaire questions.

CHAPTER TWO

Literature View

General information on risk management:

The term risk is often characterized as a possibility of having negative consequences in relation to a set of activities or potential events. That is to say, the risk is in itself the effect of the uncertainty of an event which may imply in non-completion of the objectives of an activity, a function or an organization¹

According to this, the risks must be eliminated. If necessary, risk management methods are put in place to minimize them to an acceptance scale where the risk-benefit ratio justifies its presence. Thus, predicting, controlling, and managing risks has become a fundamental need.

The NF ISO 31000 standard provides guidelines for risk management and defines it as a set of coordinated activities which aim to guide an organization with respect to risk. This standard can be used and adapted for any organization aiming to develop a strategy to confront the risks present in their activities²

Effective risk management is always improving and must aim the creation or preservation of an organization's mission. That is why the integration of risk management in the fundamental activities and in the different levels of hierarchy of an organization is essential.

In the context of medical devices, risk management is very important, since if we are not able to foresee the risks before they occur, the consequences go until the death of a patient or a user. Therefore, risk monitoring must begin before these devices are used by patients in order to ensure their quality and performance.

Risk management for medical device manufacturers in this way, manufacturers of medical devices to ensure the safety of equipment in the marketing phase, they must, in the production phase, establish a risk management system that meets all the requirements of standard NF EN ISO 14971. The difference between risk management and the management of these is that the first focuses more on the risks during the tasks and the second on the risks which can affect the results.

Thus, this standard was developed specifically for manufacturers of medical devices and is based on the principles of risk management. The requirements that are presented to manufacturers can apply throughout the life cycle of the devices. Thus,

¹ C. Araújo Da Silva, C. Maillard, M. Smirani, et al., "Managing risks to guarantee the success of your project" , IRBM News, vol. 39, No. 6, p. 102-106, dec. 2018, doi: doi.org/10.1016/j.irbmnw.2018.10.003.

² "Standard NF ISO 31000: Risk management - Guidelines", Ed. Afnor, Paris, www.afnor.org, June 2018.

NF EN ISO 14971 requires that a documented risk management process be established, and often updated, so as to allow the analysis, evaluation and control of risks^{3 4}

Risk management, according to this standard, requires that the manufacturer must also analyze the presence of residual risks and their impacts. Therefore, it is necessary to verify if the benefit for use is greater than the residual risk in order to consider possible changes. Since failure to identify a risk or a dangerous situation can have major consequences. In any case, even if the overall residual risk is acceptable, the manufacturer is obliged in the documentation accompanying the device to inform users of the presence of these risks and of possible dangerous situations⁵

Compliance with all requirements during production, post-production and marketing procedures ensures that a medical device of good quality and good performance is made available to the healthcare market. Following procurement procedures, this equipment arrives at the health services. And to health establishments, quality care presents itself within biomedical services as the need to ensure good control of the risks associated with the operation of medical devices, with the intention of guaranteeing the safety of patients, users, and nursing staff [26.]

Risk management for operators of medical devices at the level of biomedical services, the importance of setting up a risk management system is directly linked to the safety of users through the proper use of medical devices. According to this, risk management also allows the service to comply with normative and regulatory requirements in addition to planning the actions necessary to prevent or correct breakdowns [26]. This is why in biomedical services in France, the use of and compliance with the NF S99-172 standard is of great importance.

There are different methods for analyzing the criticality of a risk. The operator can use the method referenced in Appendix B of Standard NF S99-172. This method is proposed by SNITEM and CETIM. This is based on the FMECA method, which means analysis of failure modes, their effects, and their criticality. It makes it possible to identify all the dangers that may occur on a medical device, to assess the risks and to minimize or even eliminate them, through actions.

³R. Cheng, F. Gandar, and L. Zaghdoudi, "Risk management related to medical devices by manufacturers according to ISO 14971: 2019", University of Technology of Compiègne (France), Master in Health Engineering, Parcours Biomedical Technologies and Health Territories (TBTS) and Medical Devices and Regulatory Affairs (DMAR), Project report, ref n° IDS036, Jan. 2020. [Online]. Available at: <https://travaux.master.utc.fr/formations-master/ingenierie-de-la-sante/ids036/>.

⁴"Standard NF EN ISO 14971: Medical devices - Application of risk management to medical devices", Ed. Afnor, Paris, www.afnor.org, dec. 2019.

⁵ "Standard NF EN ISO 14971: Medical devices - Application of risk management to medical devices", Ed. Afnor, Paris, www.afnor.org, dec. 2019.

This method requires a review and therefore a continuous improvement because the risks can occur at several times in the life of the device and are not always foreseen. Each event causes a danger and therefore a risk, which must be considered and traced in a document with the actions undertaken and to be taken to minimize it.

A Medical Device

A Medical Device (MD) is defined according to the Public Health Code (CSP) in article L5211-1 as "any instrument, device, equipment, material, product, with the exception of products of human origin, or other article used alone or in combination, including accessories and software necessary for its proper functioning, intended by the manufacturer for use in humans for medical purposes and from which the principal intended action is not obtained by pharmacological or immunological means or by metabolism, but whose function can be assisted by such means. Also constitutes a medical device the software intended by the manufacturer to be used specifically for diagnostic or therapeutic purposes"⁶

According to article R.5211-1 of the CSP, medical devices are "intended to be used for the purposes of:

Diagnosis, prevention, control, treatment, or alleviation of a disease,

Diagnosing, monitoring, treating, mitigating, or compensating for an injury or disability,

study, replacement, or modification of the anatomy or of a physiological process, Of mastery of design⁷

A DM can be single or multiple use. Single-use MDs bear on their packaging, or even on the device itself, the symbol "2" crossed out (compulsory mention). This symbol means that the MD must be disposed of after its use, according to the hazardous waste channel organized in the healthcare facility. The principle of non-reuse of single-use medical devices is established in circular DGS/DH/DPHM/n° 669 of April 14, 1986.

⁶Public health codeLegislative part. Part Five, Book II, Title I, Chapter First legal regime of medical devices. Article L5211-1 amended by order no. 2010-250 of March 11, 2010.

⁷ Public health code. Regulatory Part, Part Five, Book II, Title I, Chapter I, Section 1 - R5211-1. Version in force on August 8, 2004.

Development

In this sense, a specific procedure for risk management is proposed that consists of five stages, framed in the Deming cycle (plan, do, verify and act), expressed as: establishment of the context; risk assessment; risk treatment; monitoring and supervision; and making timely decisions, in Annex No. 3 you can see the design of the procedure elaborated with the help of Microsoft Visio.

Communication and consultation is an aspect to take into account during all stages of the risk management process, in accordance with the observance of international and national standards and research carried out (AIRMIC, ALARM, & IRM, 2002), (Association Australian and New Zealand Standards, 1999), (Fornet Batista, 2007), (Office National Standardization, 2015).

The referred stages are described below: Setting the context: In this stage, the characteristics of the organization are identified, that is, the logo, location, type of entity, structure, subordinate units, processes, types and process sheets, managers, objectives, values, policy, strategy, technologies and systems of information, in addition, the scales and tolerance levels are created that allow the risks to be evaluated later.

Communication and consultation surveys are carried out with the interested parties, to find out the external elements that impact the entity, the processes, activities or areas. In addition, the information flows, compliance with the expense and income budget, the files of adjustments in process, litigation and claims, detected non-conformities and their corresponding closure, accounting certification, approval of business improvement, latest audits must be reviewed. related to internal control, arrears, fines or others, documents help to identify and quantify the risks.

Risk Assessment

Stage that includes the identification, analysis, and evaluation of risks.

Risk Identification:

Allows an initial inventory of risks to be drawn up, classified as internal or external. Risk identification is the initial step in evaluating potential vulnerabilities. The reduction or elimination of risks, mainly those with a high probability of occurrence and a greater impact, guarantees reasonable security in the organization. (Medina León et al., 2014).

Each entity has its mechanisms or scenarios to identify risks, which can be meetings of the Prevention and Control Committee, affiliate assemblies, quality committee, meetings with the change team, among others, where brainstorming is frequently used. to promote the generation of proposals.

In the context of medical device maintenance workshops, risk identification is a critical step in evaluating potential

vulnerabilities. This process involves identifying potential risks that could affect the safety and reliability of equipment used in patient care. Risks may be classified as internal or external, depending on their origin.

Internal risks may arise from factors such as equipment failure, human error, or inadequate maintenance procedures. External risks may include factors such as natural disasters, cyber-attacks, or supply chain disruptions.

Each entity may have its mechanisms or scenarios for identifying risks. In medical device maintenance workshops, some common approaches to risk identification may include meetings of the Prevention and Control Committee, affiliate assemblies, quality committee meetings, and meetings with the change team. Brainstorming is often used during these meetings to generate proposals and identify potential risks.

Once risks have been identified, they should be prioritized based on their likelihood and potential impact. Risks with a high probability of occurrence and a greater impact should be given priority in the risk management process.

Overall, effective risk identification is critical to ensuring the safety and reliability of medical devices used in patient care. By identifying potential risks and prioritizing them based on their likelihood and potential impact, medical device maintenance workshops can develop effective risk management strategies to minimize the potential for harm and promote better patient outcomes.

Risk Analysis

At this stage, the risks are classified by type (operational, financial, occupational health and safety, information technology security, reputational and environmental), the control objectives are determined, the causes that cause the risks, the consequences that they bring with them, probabilities of manifestation and negative manifestations of presentation.

Here the qualitative and quantitative evaluation scales are generated. The qualitative scale proposes four ranges to select the one that best suits the workshop and is shown in Table No. 1

Table No. 1: Range levels for the qualitative scale

Ranks	Probability (P)	Worth	Consequence (C)	Worth
3	Certainty	10	Elderly	10
	Likely	6	moderate	6
	Unlikely	2	Minor	1
4	Certainty	10	Catastrophic	10
	Likely	7	Elderly	7
	moderate	5	Minor	5
	Strange	2	Insignificant	2
5	Certainty	10	Catastrophic	10
	Likely	8	Elderly	9
	moderate	6	moderate	6
	Unlikely	3	Minor	3
	Strange	2	Insignificant	1
7	very high	10	Catastrophic	10
	Very high	8	Elderly	8
	high	6	high	6
	Half	4	moderate	4
	Low	3	Minor	3
	Very low	2	minimum	2
	remote	1	Insignificant	1

Source: Adapted from Fraga, 2016

The quantitative scale, shown in Table No. 2, displays the number of times that the risk may occur in the year, in order to calculate the possible loss.

Table No. 2. Range levels for the quantitative scale

Probability	Value	Consequence	Scale type
Daily 365 times a year	365		Quantities
Monthly 12 times a year	12		
Quarterly 4 times a year	4	Add for each bias	
Semester twice a year	2		
Annual 1 time a year	1		

Source: XGER software tool v. 1.8

Risk assessment: In this stage, the risk levels obtained are compared with the predetermined tolerance levels to give priority to risk treatment. The risk tolerance levels of the qualitative scale are shown in Table No. 3, values that can be changed according to the entity's criteria.

Table No. 3. Range levels for risk tolerance for qualitative scale

Low priority risk	Medium priority risk
Minimum value 0	Minimum value 20
Maximum value19	Maximum value 59
Risk with high priority	Risk not accepted
Minimum value 60	Minimum value 80
Maximum value 79	Maximum value 100

Source: XGER software tool v. 1.8

Likewise, Table No. 4 shows the risk tolerance levels of the quantitative scale, and the values can be modified at the discretion of the entity.

Table No. 4. Risk tolerance levels for quantitative scale

Low priority risk	Medium priority risk
Minimum value 0	Minimum value 1000.01
Maximum value 1000	Maximum value 5000
Risk with high priority	Risk not accepted
Minimum value 5000.01	Minimum value 20000
Minimum value 20000	Minimum value 21000

Source: XGER software tool v. 1.8

The tolerance levels obtained serve as support to senior management for informed decision-making, gives the measure of how to treat risks and induces timely action to be taken. The most significant risks require treatment and, if possible.

Risk Treatment

At this stage, measures are taken to reduce the probability of risk manifestation. In the same way, an action plan is created to minimize the occurrence of risk and its consequences, measures that contribute to making the right decision to avoid, accept, increase, eliminate, share or maintain the risk (Maxitana & Naranjo, 2009), (Perez Barnett, 2014). (It is also possible to act on the causes, negative manifestations, measures, dates of compliance, responsible parties, executors, in order to reduce the residual risk existing after having treated the risk.

"The date of compliance should not be identified with the daily, permanent, bimonthly or quarterly deadlines, according to what is established for its execution. In all cases, the date on which compliance with the measures is controlled or their results evaluated is specified" (Fraga Dominguez, 2016).

On the other hand, "all the measures are assigned a person in charge and a performer, it is taken into account that the performers are not the people who, due to the content of the position, carry out the activity, in this case the performer is a third party and the person in charge can Being the maximum representative of both, the performer has to know in detail the activity that he is going to review" (Guerrero Aguiar, Nogueira Rivera, & Veitía Hernández, 2014). (In this stage, the Risk Prevention Plan is designed, which must be communicated among the members of the organization and interested parties. In this regard, it is stated that "the Risk Prevention Plan constitutes a working instrument for management to systematically monitor the control objectives determined, it is periodically updated and analyzed with the active participation of workers and in the presence of events that so require" (Comptroller General of the Republic, 2011, p. 42)

In the context of medical device maintenance workshops, risk treatment involves implementing measures to reduce the probability of risk manifestation and minimize the occurrence of risk and its consequences. This may involve developing an action plan that outlines specific steps to be taken to address identified risks.

One approach to risk treatment is to use a risk matrix to prioritize risks based on their likelihood and potential impact. Risks that are deemed to be a high priority should be addressed first, using appropriate risk management strategies. Some measures that may be taken to reduce the probability of risk manifestation in medical device maintenance workshops include:

1. Regular maintenance and inspection of equipment to identify and address potential issues before they become more significant problems.

2. Employee training and education to ensure that all staff members are aware of potential risks and know how to handle devices safely.
3. Implementation of policies and procedures to reduce the likelihood of errors or accidents, such as the use of safety checklists and protocols.
4. Use of appropriate personal protective equipment (PPE) to minimize the risk of injury or illness to employees.

In addition to these measures, an action plan may be developed to minimize the consequences of identified risks. For example, this may involve developing contingency plans in the event of equipment failure or implementing emergency response protocols to address unexpected issues.

Monitoring and Supervision

In this stage, compliance with the measures contemplated in the plan is reviewed and evidence of the check carried out is left, through a report detailing the incidents detected, which must be communicated to internal and external interested parties, promoting feedback to the system to improve risk management.

In medical device maintenance workshops, monitoring and supervision are critical components of effective risk management. This stage involves reviewing compliance with the measures outlined in the risk management plan and documenting evidence of the checks carried out.

Regular monitoring and supervision can help identify potential problems and address them before they become more significant issues. This may involve conducting regular audits of equipment and procedures to ensure that they are functioning correctly and are in compliance with relevant regulations and standards.

In addition to monitoring and supervision, it is essential to document any incidents or issues that are detected during the monitoring process. This documentation should include details of the incident, the measures taken to address it, and any feedback received from internal and external interested parties.

By documenting incidents and promoting feedback from interested parties, medical device maintenance workshops can continually improve their risk management systems. This may involve making changes to procedures or equipment to reduce the likelihood of similar incidents occurring in the future.

Overall, effective monitoring and supervision are critical to ensuring the ongoing safety and reliability of medical devices used in patient care. By regularly reviewing compliance with risk management measures, documenting incidents, and promoting feedback, medical device maintenance workshops can continually improve their risk management systems and promote better patient outcomes.

Timely Decision Making

All information related to risks is stored in the XGER computer tool, an instrument that supports the systematic control and supervision of the Prevention Plan measures, which issues reports with useful and relevant information, which serve the highest management to make decisions. successful, anticipate deviations and meet the objectives set.

Timely decision making is crucial in risk management for medical device maintenance workshops. It is essential to have access to up-to-date information on risks and the effectiveness of risk management measures to make informed decisions.

The XGER computer tool is an effective instrument that supports the systematic control and supervision of the Prevention Plan measures. This tool can store all information related to risks and can issue reports with useful and relevant information. These reports can provide senior management with the data they need to make decisions that are successful, anticipate deviations, and meet the objectives set.

By using the XGER computer tool, senior management can monitor the status of risk management measures and identify any potential deviations from the plan. This can help them make timely decisions to address any issues that arise, prevent potential problems, and ensure that the objectives of the risk management plan are met.

In addition to the XGER computer tool, effective communication is also crucial in risk management for medical device maintenance workshops. Regular meetings and updates can ensure that all stakeholders are informed of any changes or decisions related to risk management.

Overall, timely decision making is essential for effective risk management in medical device maintenance workshops. By using the XGER computer tool and clear communication plans, senior management can make informed decisions to promote better patient outcomes and minimize the potential for harm.

CHAPTER THREE

Result and Discussion

This chapter covers a deep analysis of the collected data from the sample of 50 respondents in order to achieve the objectives of the research, the researcher used the descriptive analytical method using SPSS, and used the questionnaire to collect data from the research vocabulary, where questionnaires were distributed to the specialists and technicians working in medical devices maintenance workshops.

Hypotheses for the following variables are tested and are concluded to be accepted or rejected based on the correlation coefficient:

1. **Training**
2. **Equipment Maintenance**
3. **Documentation:**
4. **Regulatory Compliance**
5. **Risk Assessment**
6. **Performance Testing**
7. **Predictive Maintenance Technologies**
8. **Quality Control**

As well as Likert-scale items that were used to measure the eight variables of the study in order to determine the degree of approval of each statement of the questionnaire as in Table 1.

Table 1 Likert-scale items

Option	Rank
Strongly Disagree	1
Disagree	2
Neutral	3
Agree	4
Strongly Agree	5

Table 2 shows that the sample members are all males, at a rate of 100%, and this indicates that most of the workers in the medical equipment maintenance workshops are males.

Table 2 Distribution of the study sample according to gender

Gender	Frequency	Percent %
Male	50	100.0
Female	0	0
Total	50	100.0

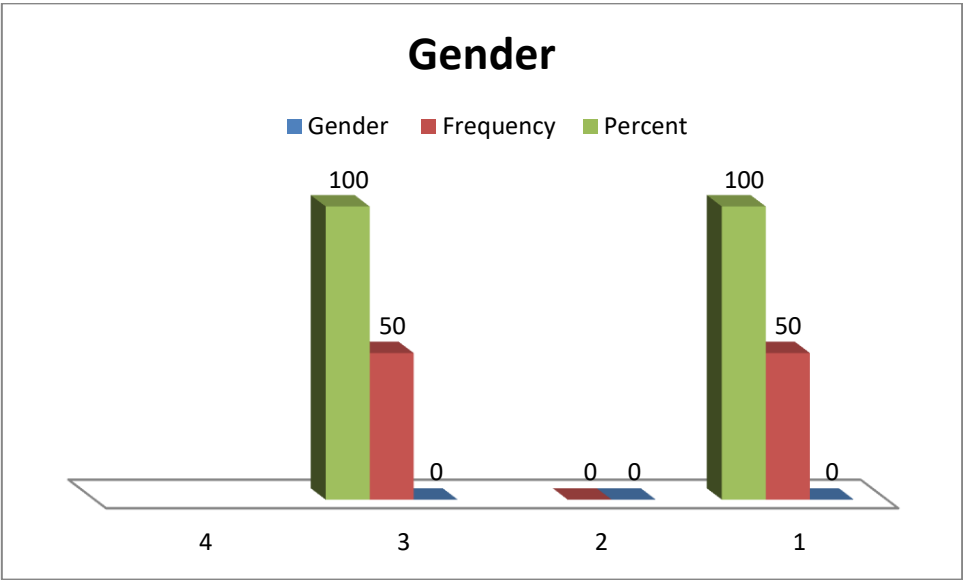


Figure 1 Distribution of the study sample according to gender

Table 3 show that most of the member sample are from the age group 35 and above with a rate of 42%, followed by the age group from 30-25 with a rate of 24%, then the age group from 20-25 with a rate of 22%, and in the last place are those with the age group from 30-35 with a rate of 12%

Table 3 Distribution of the study sample according to age

Age	Frequency	Percent %
20-25	11	22.0
25-30	12	24.0
30-35	6	12.0
35 and above	21	42.0
Total	50	100.0

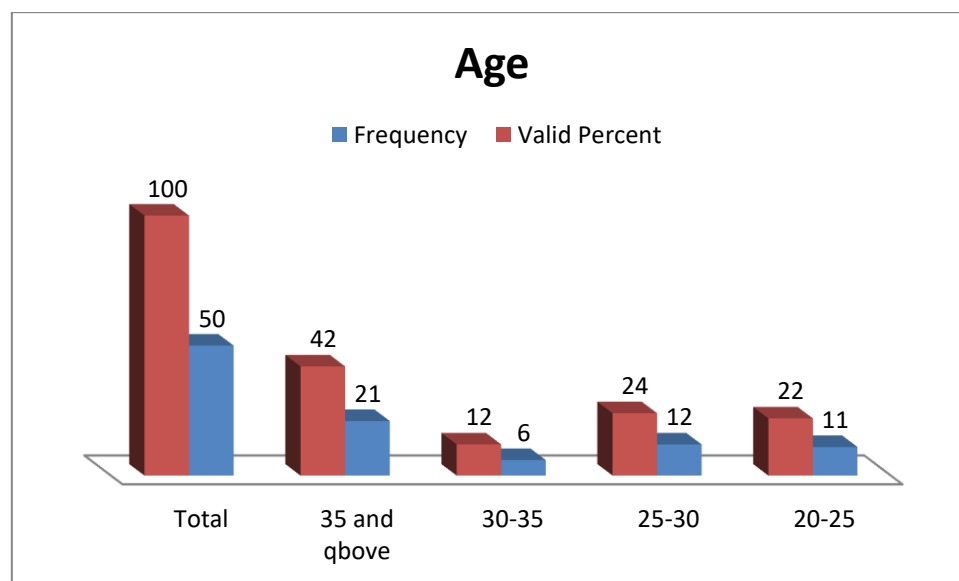


Figure 2 Distribution of the study sample according to age

Table 4 shows the research observed that largest percentage of the research sample are those who holding a bachelor degree with rate 60.0% followed by those who holding master degree with rate 22.0% followed by those who holding diploma with rate of 18.0% means that the most of the people who work in medical workshops has logical and knowledgeable

Table 4 Distribution of the study sample according to academic qualification

Education leave	Frequency	Valid Percent
Diploma	9	18.0
Bachelor's degree	30	60.0
Master's degree	11	22.0
Total	50	100.0

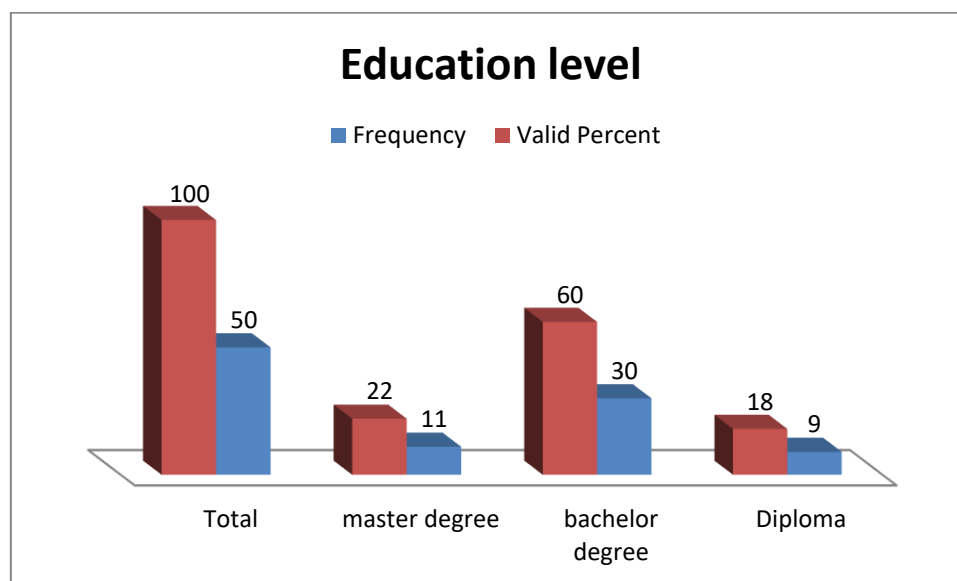


Figure 3 Distribution of the study sample according to academic qualification

It is clear that most of the samples are biomedical engineers and health practitioners, with a rate of 30% for each. followed by others at 24%, followed by biomedical technician at 16%.

Table 5 Distribution of the study sample according to job position

Current Position	Frequency	Valid Percent
Biomedical Technician	8	16.0
Biomedical Engineer	15	30.0
Health practitioner	15	30.0
Other	12	24.0
Total	50	100.0

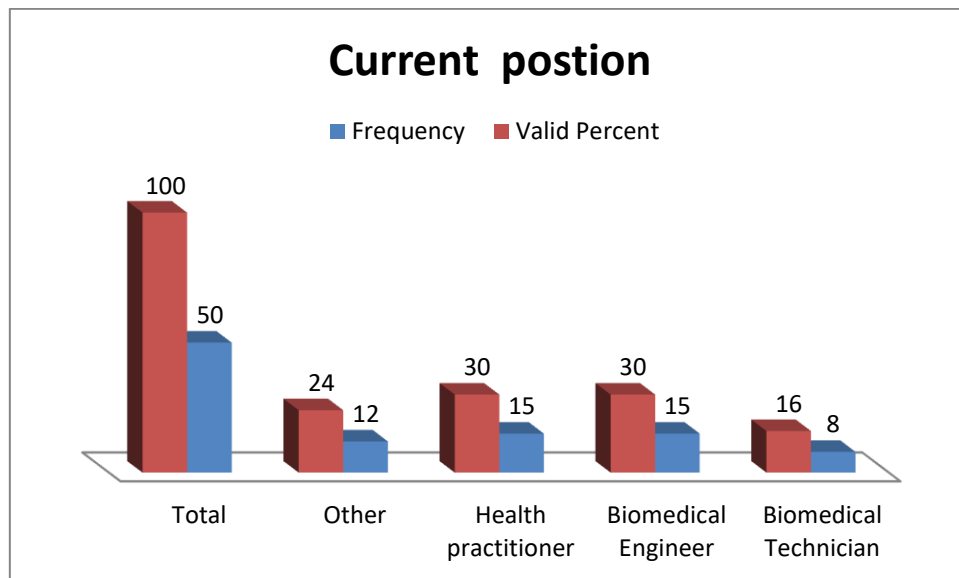


Figure 4 Distribution of the study sample according to job position

Table 6 show descriptive statistics for Training

	Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
1	All maintenance personnel receive sufficient training in maintaining and repairing healthcare equipment	N	9	19	8	6	8	3.30	1.34
		%	18.0	38.0	16.0	12.0	16.0		
2	Maintenance personnel trained in infection control protocols	N	2	20	14	9	5	3.10	0.984
		%	4.0	40.0	28.0	18.0	10.0		
3	Ongoing training programs provided for maintenance personnel	N	8	24	12	4	0.984782	3.64	1.07
		%	16.0	48.0	24.0	8.0	4.0		

The descriptive statistics for the training on risk management in medical device maintenance workshops show that the highest average score was awarded to the question three about ongoing training programs provided for maintenance personnel, with a mean of 3.64 and a standard deviation of 1.07. This was followed by the question one about whether all maintenance personnel receive sufficient training in maintaining and repairing healthcare equipment, which received a mean score of 3.30 and a standard deviation of 1.34. The third highest average score was given to the question two about maintenance personnel trained in infection control protocols, with a mean score of 3.10 and a standard deviation of 0.984.

Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree," indicating that training is considered important by those who work in medical workshops in order to reduce risk management.

Table 7 show descriptive statistics for Equipment Maintenance

	Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
1	There is a preventive maintenance program for all healthcare equipment?	N	12	25	7	4	2	3.82	1.02
		%	24.0	50.0	14.0	8.0	4.0		
2	Healthcare equipment inspected, cleaned, calibrated, and repaired on a periodical's basis	N	10	22	11	3	4	3.62	1.12
		%	20.0	44.0	22.0	6.0	8.0		
3	All maintenance activities documented, including inspections, repairs, and calibrations	N	10	25	4	9	2	3.64	1.12
		%	20.0	50.0	8.0	18.0	4.0		

The descriptive statistics for the Equipment Maintenance on risk management in medical device maintenance workshops show that the highest average score was awarded to the question one about There is a preventive maintenance program for all healthcare equipment, with a mean of 3.82 and a standard deviation of 1.02. This was followed by the question three: **All maintenance activities documented, including inspections, repairs, and calibrations**, which received a mean score of 3.64 and a standard deviation of 1.12. The third highest average score was given to the question two **Healthcare equipment inspected, cleaned, calibrated, and repaired on a periodical's basis**, with a mean score of 3.62 and a standard deviation of 0.984.

Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree," indicating equipment maintenance is considered important by the respondents. The highest average scores were given to questions related to the presence of a

preventive maintenance program for all healthcare equipment, the documentation of all maintenance activities (including inspections, repairs, and calibrations), and the periodic inspection, cleaning, calibration, and repair of healthcare equipment. These findings suggest that the respondents place a high value on the implementation of preventive maintenance programs and the proper documentation of maintenance activities. Ensuring that healthcare equipment is regularly inspected, cleaned, calibrated, and repaired can help reduce the risk of equipment malfunction and improve patient safety in medical device maintenance workshops.

Table 8 show descriptive statistics for Documentation

	Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
1	There is a comprehensive documentation system to track all maintenance activities	N	9	21	11	4	4	3.55	1.13
		%	18.4	42.9	22.4	8.2	8.2		
2	All maintenance records regularly reviewed to ensure compliance with regulatory requirements	N	7	18	16	6	3	3.4	1.06
		%	14.0	36.0	32.0	12.0	6.0		
3	There is a system to ensure that all maintenance personnel, equipment, and parts used during maintenance activities are recorded	N	13	16	13	5	3	3.62	1.15
		%	26.0	32.0	26.0	10.0	6.0		

The descriptive statistics for **Documentation** on risk management in medical device maintenance workshops show that the highest average score was awarded to the question three about **There is a system to ensure that all maintenance personnel, equipment, and parts used during maintenance activities are recorded**, with a mean of 3.62 and a standard

deviation of 1.15. This was followed by question one **There is a comprehensive documentation system to track all maintenance activities**, which received a mean score of 3.55 and a standard deviation of 1.13. The third highest average score was given to the question two **All maintenance records regularly reviewed to ensure compliance with regulatory requirements** with a mean score of 3.4 and a standard deviation of 1.15.

Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree,". This indicates that the respondents recognize the importance of maintaining accurate and up-to-date records of maintenance activities in order to ensure accountability and traceability.

Table 9 show descriptive statistics for Regulatory Compliance

	Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
1	Regulatory Compliance: The workshop complies with CIBAHI and JCI standards and regulations	N	6	22	13	7	2	3.46	1.01
		%	12.0	44.0	26.0	14.0	4.0		
2	All maintenance activities carried out in compliance with regulatory requirements	N	7	28	7	4	4	3.6	1.08
		%	14.0	56.0	14.0	8.0	8.0		
3	There is a system to monitor changes in regulatory requirements and update policies and procedures accordingly	N	8	24	12	2	4	3.6	1.08
		%	16.0	48.0	24.0	4.0	8.0		

The descriptive statistics for **Regulatory Compliance** on risk management in medical device maintenance workshops show that the highest average score was awarded to the question three and two. There is a system to monitor changes in regulatory requirements and update policies and procedures accordingly, activities carried out in compliance with regulatory requirements with a mean of 3.6 and a standard deviation of 1.08. This was followed by the question one **Regulatory Compliance: - The workshop complies with CIBAH and JCI standards and regulations**, which received a mean score of 3.46 and a standard deviation of 1.01.

Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree," This indicates that the respondents recognize the importance of staying up to date with regulatory requirements and adapting policies and procedures to ensure ongoing compliance.

Table 10 show descriptive statistics for Risk Assessment

	Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
1	A risk assessment conducted to identify potential risks associated with maintenance activities	N	11	19	8	6	6	3.46	1.29
		%	22.0	38.0	16.0	12.0	12.0		
2	There are strategies to mitigate identified risks	N	7	24	8	5	6	3.42	1.21
		%	14.0	48.0	16.0	10.0	12.0		

The descriptive statistics for **Risk Assessment** on risk management in medical device maintenance workshops show that the highest average score was awarded to the question one **a risk assessment conducted to identify potential risks associated with maintenance activities** with a mean of 3.46 and a standard deviation of 1.29. This was followed by the question two **There are strategies to mitigate identified risks**, which received a mean score of 3.42 and a standard deviation of 1.21. Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree," This indicates that the respondents recognize the importance of proactively identifying and assessing potential risks associated with maintenance activities in order to prevent adverse events and ensure patient safety.

Table 11 show descriptive statistics for Performance Testing

	Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
1	All equipment performance tests conducted regularly	N	8	23	11	4	4	3.54	1.11
		%	16.0	46.0	22.0	8.0	8.0		
2	Equipment performance tested every three months	N	4	25	11	5	5	3.36	1.10
		%	8.0	50.0	22.0	10.0	10.0		
3	There is a system to address identified issues during equipment performance testing	N	8	19	9	8	6	3.3	1.26
		%	16.0	38.0	18.0	16.0	12.0		

The descriptive statistics for **Performance Testing** on risk management in medical device maintenance workshops show that the highest average score was awarded to the question one about - **All equipment performance tests conducted regularly**, with a mean of 3.54 and a standard deviation of 1.11. This was followed by the question two **Equipment performance tested every three months**, which received a mean score of 3.36 and a standard deviation of 1.10. The third highest average score was given to the question two **There is a system to address identified issues during equipment performance testing** with a mean score of 3.3 and a standard deviation of 1.26.

Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree," This indicates that the respondents recognize the importance of addressing any issues identified during performance testing in a timely and effective manner to prevent adverse events and ensure patient safety.

Table 12 show descriptive statistics for Predictive Maintenance Technologies

	Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
1	Are predictive maintenance technologies, such as machine learning algorithms and predictive analytics, used in the facility	N	6	15	15	3	11	3.04	1.32
		%	12.0	30.0	30.0	6.0	22.0		
2	There are technologies used to identify potential equipment issues before they occurred	N	6	25	9	5	5	3.44	1.14
		%	12.0	50.0	18.0	10.0	10.0		
3	Are all of these technologies effective in reducing the likelihood of technical equipment failures	N	7	24	13	2	4	3.56	1.05
		%	14.0	48.0	26.0	4.0	8.0		

The descriptive statistics for **Predictive Maintenance Technologies** on risk management in medical device maintenance workshops show that the highest average score was awarded to the question three about - **Are all of these technologies effective in reducing the likelihood of technical equipment failures**, with a mean of 3.56 and a standard deviation of 1.05. This was followed by the question two **There are technologies used to identify potential equipment issues before they occurred**, which received a mean score of 3.44 and a standard deviation of 1.14. The third highest average score was given to the question one **Are predictive maintenance technologies, such as machine learning algorithms and predictive analytics, used in the facility** with a mean score of 3.04 and a standard deviation of 1.32.

Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree". This indicates that while the respondents recognize the potential benefits of these technologies, their utilization in medical device maintenance workshops may not be as widespread as the other technologies assessed.

Table 13 show descriptive statistics Quality Control:

	Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
1	There Is a quality control program in place to ensure that all maintenance activities are carried out to high standards	N	11	13	14	6	6	3.34	3.34
		%	22.0	26.0	28.0	12.0	12.0		
2	Maintenance activities audited to ensure compliance with policies and procedures	N	5	24	15	2	4	3.48	1.01
		%	10.0	48.0	30.0	4.0	8.0		
3	There is a system to address non-compliance or specific areas that require improvement during audits	N	6	17	16	6	5	3.26	1.13
		%	12.0	34.0	32.0	12.0	10.0		

The descriptive statistics for **Quality Control** on risk management in medical device maintenance workshops show that the highest average score was awarded to the question two about - **Maintenance activities audited to ensure compliance with policies and procedures**, with a mean of 3.48 and a standard deviation of 1.01. This was followed by the question one **There Is a quality control program in place to ensure that all maintenance activities are carried out to high standards**, which received a mean score of 3.34 and a standard deviation of 3.34. The third highest average score was given to the question three **There is a system to address non-compliance or specific areas that require improvement during audits** with a mean score of 3.26 and a standard deviation of 1.13.

Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree". This indicates that the respondents recognize the importance of

addressing any non-compliance issues or areas for improvement identified during audits in a timely and effective manner to prevent adverse events and ensure patient safety.

Conclusion

In conclusion, risk management is a critical component of medical device maintenance workshops to ensure the safety and reliability of equipment used in patient care. Effective risk management involves identifying potential risks, assessing their likelihood and impact, and implementing strategies to mitigate or eliminate them.

Establishing tolerance levels for different types of risks is an important aspect of risk management. These levels serve as a guide for decision-making and help senior management determine how to allocate resources to manage risks effectively.

Risk treatment involves implementing measures to reduce the probability of risk manifestation and minimize the occurrence of risk and its consequences. This may involve developing an action plan and using a risk matrix to prioritize risks based on their likelihood and potential impact.

Monitoring and supervision are critical components of effective risk management. Regular monitoring and supervision can help identify potential problems and address them before they become more significant issues. Documentation of incidents and promoting feedback from interested parties can continually improve risk management systems.

Timely decision-making is also crucial in risk management for medical device maintenance workshops. The XGER computer tool is an effective instrument that supports the systematic control and supervision of the Prevention Plan measures and issues reports with useful and relevant information.

Overall, effective risk management is critical to ensuring the safety and reliability of medical devices used in patient care. By implementing appropriate risk management strategies, medical device maintenance workshops can minimize the potential for harm and promote better patient outcomes.

References

- ❖ C. Araújo Da Silva, C. Maillard, M. Smirani, et al., "Managing risks to guarantee the success of your project", IRBM News, vol. 39, No. 6, p. 102-106, dec. 2018, doi: doi.org/10.1016/j.irbmnw.2018.10.003.
- ❖ AIRMIC, ALARM, & MRI. (2002). A Risk Management Standard. Retrieved 05-29-16, from www.airmic.com
- ❖ Arias Perez, MA (2014). Application of the Integrated Risk Management Procedure to increase the Strategic Prevention capacity of the company Central de equipos Cubiza.
- ❖ Thesis in option to the Scientific Title of Master in Direction), Higher Polytechnic Institute "José Antonio Echeverría", Havana, Cuba
- ❖ Australian and New Zealand Standards Association. (1999). AS/NZS 4360., Risk Management Australia.
- ❖ Bolaño Rodríguez, Y. (2014). Strategic management model based on risk management for the integration of the company's management system. (Thesis presented as an option for the scientific degree of Doctor of Technical Sciences), "José Antonio Echeverría" Higher Polytechnic Institute, Havana, Cuba.
- ❖ Collective of Authors. (2011). Procedures Manual for Risk Prevention Management. Santiago de Chile: Chilean Security Association.