STUDY TOPIC

COST EFFECTIVE MAINTENANCE OF DIAGNOSTIC ELECTRO MEDICAL EQUIPMENT IN MILITARY HOSPITALS

A CRITICAL ANAYLSIS

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SUPERVISOR CERTIFICATE

This is to certify that this thesis titled "**Cost Effective Maintenance of Diagnostic Electro-Medical Equipment in Military Hospitals – A Critical Analysis'** is a bona fide research project done by the candidate, Lt Col Muhammad Kamran, under my supervision, in partial fulfillment of the requirement for the award of Masters in Medical Administration degree by Quaid-e-Azam University, Islamabad.

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DECLARATION

I, Lt Col Muhammad Kamran hereby declare that I have presented my original research work in this thesis titled, "**Cost Effective Maintenance of Diagnostic Electro-Medical Equipment in Military Hospitals – A Critical Analysis'**" and I take the responsibility of rendering it free of any plagiarism, grammar, spelling or typing mistakes as far as humanly possible.

This thesis is a presentation of my original work. It has been made sure that clear reference to the literature and acknowledgement of other's research is indicated when such material is referred to in this thesis.

Date: Sep, 2021

Lt Col Muhammad Kamran
M.Sc (Medical Administration) Ser 39

DEDICATION

My thesis is dedicated to my mother, who has been a constant source of support and encouragement during all challenges of my life and who gave joy and courage to me to complete this thesis.

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ABSTRACT

Background. Maintenance is a crucial component in terms of the life cycle management of medical equipment. It is essential to improve the utilization and distribution of resources, which are restricted in quantity and scope, for clinical engineering departments. Medical equipment maintenance is separated into two categories: scheduled and corrective maintenance. Scheduled maintenance is regularly carried out.

Objectives. The objective of this study was to analyse the existing Diagnostic Electro Medical Eqpt maintenance system and to determine its cost effectiveness using a structured questionnaire distributed to specialists and health care administrators in selected hospital settings

Methods. The study was mixed cross-sectional one. It was conducted at 3 x military hospitals (Qta / Hyd / Sibi). In-depth interviews by policy makers, Comdts of hosps and wksps and EME personnel using interview method incorporated descriptive study part. A total of 56 sample size including specs, Policy makers, EME Staff and administrators were included utilizing the easy sample technique in the quantitative analysis. Universal sampling for the collection of samples was employed. For the collection of data, semi-structured questionnaires were employed. The data gathered by the questionnaire were then examined by SPSS.

Results. Study showed that there is dft of EME echs with capacity issues and dependence on vendors. These hospitals were shown to employ conventional maintenance methods with focus on preventative maintenance and corrective maintenance.

Conclusion. The findings and results of study suggest that there should be training of EME staff with cap enhancement. Recommendations were provided to enhance the maintenance approach employed by these military hospitals according to data gathered and evaluated via SPSS.

Keywords. Maintenance, diagnostic Electro-medical eqpt, EME Offrs / Staff, cost effective, Military hospitals

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CHAPTER – 1

INTRODUCTION

1. Medical devices have a huge influence on the lives of society as whole. The significant contribution in healthcare service delivery in contemporary time is of equipment based besides drugs or other services. They consist of mostly high maintenance costs and massive initial investments. Therefore, it is imperative to sort out an orderly, well planned and oversee maintenance program that extends the duration of its useful life and cut back on the cost of ownership of equipment. This is important for keeping a healthcare organization safe for carrying out procedures, therapies and treatment. A maintenance strategy includes procedures for preventive maintenance, inspection and corrective maintenance to make sure that the medical equipment is working safely and effectively for which it is designed. The proper execution of the maintenance program is essential for ensuring optimum equipment functionality. The effective solution to the maintenance problem is very complicated. Study shows that in some developing countries more than 60% of medical equipment is not used due to poor facilities for maintenance and repair.[1]

2. Role of Electro medical equipment (EME) is critical for effective and efficient healthcare service delivery. Quality of Medical devices is highly essential in improving patients treatment and personnel's health. Hence, the accessibility and favourable utilization of medical equipment is imperative in refining the quality of health devices and services. In general, studies have been carried out at global level to evaluate and assess the maintenance management of medical devices.[2]

3. The medical equipment's maintenance is critical for attaining objective and goal of health care providers. Owing to the fact, it is mainly responsible for keeping medical equipment functional, decreasing failures rate, ensuring the safety and protection requirements and enhancing the quality of the healthcare service. It is the responsibility of maintenance department in a hospital to ensure the protection of medical devices, their accessibility and availability while

maintaining the operation costs nominal. The choice of the best maintenance strategy is a pivotal decision to decline the medical device downtime, enhance the availability and reduce the up-keeping costs.[3]

4. Medical equipment maintenance is as essential as its design and development. Generally, cost of up-keeping a piece of equipment over its life cycle is much higher than on its acquisition. In last few decades, complexity and cost of medical equipment has sharply increased. Reliability engineering techniques and maintenance strategies have been remarkably upgraded in the last two decades which have been successfully applied in many industries to enhance the functionality of equipment maintenance management.[4]

5. Maintenance management of medical equipment becomes significantly essential in the world because of the excess demand for hospital services to the high price of technology and its consistent growth and evolution for the improvement of quality processes of high, medium and low technological equipment; besides to enhance the protection of the patient and the user of the equipment.[5]

6. Electro medical equipment must be maintained in working order and periodically calibrated for effectiveness and accuracy. There should be a proper management for maintenance of electro medical equipment. With the rapid advancement of technologies, electro medical devices are one of the fastest growing industries, whereas our professionals are not precisely compatible to the current equipment. Suppose, if damaged device is getting used for a detection of disease and the results are inappropriate then it can lead to a loss of a precious life. An equipment can be manufactured separately or in combination with other. Simple device is easy to repair than a complexed one but in today's big data era, sophisticated medical devices are more abundant and expensive.[6]

7. There are regulations for maintenance of medical equipment, first is when an equipment is arrived it should be monitored properly either it is working or not. Secondly, it should be placed in a clean area and need to get cleaned regularly.[6] The dust can damage the particles inside the equipment. Medical devices

require proper repair/maintenance to obtain some benefits and conserve large amount of money otherwise negligence regarding equipment maintenance can cause governments a huge amount of loss. Basically, there are two ways for maintenance, Corrective and planned maintenance, the corrective or repair maintenance is use for a broken equipment and planned or scheduled maintenance is done regularly and if device has some sort of damage then it is picked earlier and it prevents from a big loss.[7] The majority of problems can be repaired by trained workers without importing and big expenses. Although, all the complexed machines such as x-rays, ECGs, Ventilators, ultrasound machines, MRIs etc will need to be seen by specialised professional engineers and experts trained in equipment. Generally, vendor companies or any third party gets hired for modification. It is rarely possible to provide this level of services in house. The older equipment requires more cost to be maintained and also risks patient life.[8]

8. Some developed countries have facilities for a good manufacturing of equipment, they can modify and create their own equipment but on the other hand, some countries depend on the donation of medical devices from external sources and require resources to protect their population from unsafe and inappropriate technology. Governments should follow the growing movement towards regulatory system because a proliferation of different nation regulations increases costs, hinders access to health care technologies. In other words, importing an equipment from abroad can cost way too much than modifying your own devices.[7]

9. We need to enhance the system of maintenance of electro medical equipment that we have introduced in Military hospitals and to find ways to increase reliability and feasibility. With the growth and development of Military hospitals and technology progress has led to expansion of hospital inventories. The corps of electrical and mechanical engineering (EME) is responsible for repair/maintenance of electro medical equipment. Moreover, it is also necessary for medical services to provide a cost effective and efficient system of repair/maintenance of electro medical equipment.[9]

10. Maintenance also requires appropriate skilled staff, experience and education. Staff should know how to tackle with equipment and how to apply that on a patient.[2] A programme should be planned with a huge effort to develop a comprehensive layout for healthcare technology management (HTM).[4] The challenge for planner is to balance financial, physical and human resources factors to design a maintenance programme that is appropriate and cost effective for their problems.[2]

Rationale

11. Electro-medical (EM) equipment is essential for provision of good standard treatment and care. Proper maintenance of Electro-medical equipment is essential to obtain sustained benefits to preserve capital investment. The proliferation of Electro-medical equipments have increased the significance of maintenance and repair in the most economical fashion. Purpose of this study is to assess our ability to cope with and improve the system of maintenance of expensive and precious Electro-medical equipment.

Aim

12. To improve the cost effective maintenance of Diagnostic Electro-medical equipment in Military Hospitals.

Objectives

13. The objectives of study are;

a. To analyse the existing system of maintenance of EM Eqpt of Radio and Path depts.

b. To determine the cost-effective maintenance of EM Eqpt in Military hospitals.

c. To make viable recommendations for improvement of maintenance system of EM Eqpt.

Chapter 2

Literature Review

14. The use of technology in health care began to emerge in the early 1960s, right after when computer technology became sophisticated enough to manage large amount of data. Today in all over the world scientists have invented number of technologies. The technology which is playing important role in health care is biomedical engineering. Biomedical engineering/ bioengineering is itself a field, it is a branch of engineering that analyse and solve problems regarding biology and medicine. NH took three significant steps to support biomedical engineering. A programme-project committee was established under the General medical sciences institute to manage programme-project application, in which biophysics and biomedical served. Medical devices that are in use today are manufactured by bioengineers. They have developed a lifesaving technology.[10]

15. Biomedical engineering has evolved over the years in response to advancements in science and technology. It has had a dramatic impact on health care system. It has made easier for health professionals to cure a patient. Although, human body is more complexed than any computerized machine but it works in a magical way to detect a diagnosis than a professional ever could. The biomedical engineers BMEs find modern solutions for modern problems. It is predicted that in future, BMEs demand will be more because an aging population is likely to need more medical care and because of increase in public awareness regarding bioengineering. Biomedical engineers work with doctors, therapists and scientists to solve the problems.[11]

16. Aspects of mechanical engineering, electrical engineering, chemical engineering, material sciences, chemistry, physics, mathematics, computer science and engineering are all intertwined with human in biomedical engineering. Biomedical engineers are doing remarkable job by providing tools (such as prosthetics, surgical devices and systems, implanted devices, artificial organs, imaging methods, diagnostics and therapeutic equipment) that can be use by professionals for diagnosis and alleviation of disease.[8] The Biomedical

engineers work with doctors, therapists and researches to manufacture devices and equipment to solve health care system problems.

17. Bioengineering has a long history; it is developing from decades. One of the earliest examples is the works of Alexander Graham Bell and Thomas Edison on sound transmission and amplification in the late 19th and 20th centuries were applied to make the first tabletop hearing aids. These were followed by first portable (or "luggable") devices using vacuum-tube amplifiers powered by large batteries.[9] However, the first wearable hearing aids had to await the development of the transistor by William Shockley and his team at bell labourites. subsequent development of micro-integrated circuits and advance battery technology has led miniature hearing aids that fit entirely within ear canal.[12]

18. The first artificial heart the Jarvik-7, was successfully implanted in a human body. In 1982, Seattle dentist Dr Barney Clark was the first person implanted with Jarvik-7, the first artificial heart intended to last a lifetime. William DeVries, an American cardiothoracic surgeon, performed the surgery. the patient survived 112 days, "it has been hard, but heart itself has pumped right along," Clark said in the months following his history making surgery.[13]

19. If we take an example from latest technology in 2020, bioengineers are manufacturing devices such as sensors, wires and electronics that are flexible, waterproof and stretchable can be 3D- printed or woven into the fabric.[11] Wearable technologies are becoming more multifunctional and can monitor multiple health parameters, such as pulse rate and blood pressure, which can also be transmitted in real-time to a medical facility.[12] Miniaturization, material innovations, personalized medicine, and additive manufacturing are key engineering trends that biomedical researches are eager to incorporate into their designs. These technologies, in fact, open up a wide array of new design options that were not possible using conventional manufacturing methods.[13] These R&D advances are also happening at an ever-increasing—bioengineers must keep pace with disruptive technology and innovations to make the best products and maintain or boost their market share and brand reputation.[7]

20. All the achievements in biomedical engineering or bioengineering has been done by a society, long ago a biomedical engineering society was established in order to address a need for a society that afforded equal status of representative of both biomedical and engineering interests. Robert Hooke, Leonhard Euler, Thomas young, jean Poiseuille, Herrmann von Helmholtz and Horace lamb are among some of the contributors to the development of engineering as an applied science.The rise in bioengineering field has expanded its type. There are numbers of types in biomedical engineering or bioengineering to explore. Telepath, BioSignal processing, neural engineering, biomaterials, biomechanics, medical imaging, and computational nodding. Bioengineers are predicted to grow 4 percent from 2018 to 2020.[14]

21. **Maintenance and Related Definition** There are many terms related to the maintenance. The definitions of those related to maintenance are stated below:[15]

a. **Health technology.** The application of organized knowledge and skills

in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. It is used interchangeably with health-care technology.

b. **Medical device.** An article, instrument, apparatus or machine that is used for the prevention, diagnosis, or the treatment of illness or disease, or for identification, measurement, restoration, modification or correction of body structure or function for some health purpose. Generally, the purpose of a medical device is not achieved by medication, immunological or metabolic means.

c. **Medical Equipment.** Medical devices requiring calibration, managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece

of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

d. **Acceptance Testing.** The initial inspection performed on a piece of medical equipment prior to it being put into service. When the device first

arrives in the health-care facility, it is checked to ensure it matches the purchase order, it is functioning as specified, the training for users has been arranged and it is installed correctly. If a computerized maintenance management system (CMMS) is available, it is registered into the CMMS.

e. **Calibration.** Some medical equipment, particularly those with therapeutic energy output (e.g. defibrillators, electrosurgical units, physical therapy stimulators, etc.), needs to be calibrated periodically. This means that energy levels are to be measured and if there is a discrepancy from the indicated levels, adjustments must be made until the device functions within specifications. Devices that take measurements (e.g. electrocardiographs, laboratory equipment, patient scales, pulmonary function analyzers, etc.) also require periodic calibration to ensure accuracy compared to known standards.

f. **Clinical Engineer.** A professional who supports and advances patient care by applying engineering and managerial skills to health-care technology (American College of Clinical Engineering). While a clinical engineer is a specialized biomedical engineer, the terms are often used interchangeably.

g. **Clinical Engineering Department/Group.** Engineer/technician or team of engineers/technicians responsible for the management and maintenance of medical equipment.

h. **Failure.** The condition of not meeting intended performance or safety

requirements, and/or a breach of physical integrity. A failure is corrected by repair and/or calibration.

i. **Inspection.** Inspection refers to scheduled activities necessary to ensure

a piece of medical equipment is functioning correctly. It includes both performance inspections and safety inspections. These occur in conjunction with preventive maintenance, corrective maintenance, or calibration but can also be completed as a stand-alone activity scheduled at specific intervals.

j. **Performance Inspections.** These activities are designed to test the operating status of a medical device. Tests compare the performance of the device to technical specifications established by the manufacturer in their maintenance or service manual. These inspections are not meant to extend the life of equipment, but merely to assess its current condition.

k. **Repair.** A process used to restore the physical integrity, safety, and/or performance of a device after a failure. This term is used interchangeably with corrective maintenance. This is further divided into 3 categories:

(1) **1st Line**: This type of repair is minor in nature and can usually be carried out at the equipment location within 30 minutes.

(2) **2nd Line**: This type of repair is major in nature and can usually be

carried out at the ERC. The repair time will be less than 2 hours, and equipment will be returned within 5 working days, subject to spare parts availability.

(3) **3rd Line**: This type of repair is major in nature and may be carried out at the ERC, sent back to the supplier/manufacturer, or a service call. The repair time will usually be less than 4 hours, and equipment will be returned

within 5 working days, subject to spare parts/supplier service availability.

l. **Safety Inspections.** These are performed to ensure the device is electrically and mechanically safe. These inspections may also include checks for radiation safety or dangerous gas or chemical pollutants. When these inspections are done, the results are compared to country or regional standards may be different than planned maintenance and performance inspections, and are usually based on regulatory requirements.[15]

22. **Types of Maintenance.** There are basically two types of maintenance one is reactive and the other one is proactive.

a. **Breakdown Maintenance /Corrective Maintenance /Repair.** This is done to take corrective action in the event of a breakdown of the equipment. The equipment is repaired and calibrated for this sort of maintenance. Corrective maintenance and unscheduled maintenance are regarded as equivalent to the term repair. This sort of maintenance is a reactive type maintenance.[16]

b. **Planned (or Scheduled) Preventive Maintenance (PM).** PM is performed to extend the life of the device and prevent failure. PM is usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, cleaning (e.g. filters) or replacing parts that are expected to wear (e.g. bearings) or which have a finite life (e.g. tubing). The procedures and intervals are usually established by the manufacturer. [17]

c. **Periodic Maintenance. (Time Based Maintenance-TBM).** It consists of periodical inspection, servicing, cleaning, lubricating and replacement of parts to prevent sudden failure of an equipment.

d. **Predictive Maintenance.** This activity involves a forecasting technique to determine the rate of failure of certain types of replaceable components (e.g. batteries, valves, pumps, seals). The maintenance interval is then set so components are replaced

> before they fail, ensuring the equipment continues to operate reliably. In health care this is primarily done in a facility that has a large number of medical devices from a single manufacturer or model.[18]

23. **Role of Diagnostic EM Equipment.** The role of diagnostic medical devices is crucial for efficient healthcare delivery in any country. Devices are highly important in personnel's health and to improve patient's treatment. In addition to physical examinations or patients' descriptions of their symptoms, physicians rely on diagnostic instruments to check for signs of diseases. Therefore, the availability and optimal utilization of medical equipment is important in improving the quality of health services. Studies have been carried out around the globe to assess the maintenance management of medical equipment in general. In developing countries such as Ghana, significant investments are made for the purchase of these equipment but enough attention is not given to the maintenance and repairs of these equipment. As a result, a lot of these equipment are out of service due to high break down rate.[19]

24. The maintenance of medical equipment is as important as its design and development. Usually, much more money is spent on maintaining a piece of equipment over its life span than on its procurement. Medical equipment is extensively (from 5,000 to more than 10,000 different type) used in all aspects of health services, ranging from prevention, screening, diagnosis, monitoring, and therapeutics to rehabilitation. Nowadays, it is virtually impossible to provide health services without them. Unlike other types of healthcare technologies (i.e., drugs, implants, and disposable products), medical equipment requires maintenance (both scheduled and unscheduled) during its useful life. As the sophistication and cost of medical equipment continue to escalate, the complexity and cost of its maintenance have also risen sharply in the last few decades. Studies conducted using data collected from hundreds of acute-care hospitals indicate that on average, each hospital acquired about 15–20 pieces of medical equipment for

Each staffed bed, which translates into a capital investment of around US$200–400,000/staffed bed. Thus, it is common for a 500-bed hospital to own more than US$100–200 million worth of medical equipment and considerably more if it is affiliated with a medical school. The same studies have indicated that annual medical equipment maintenance and management cost is approximately 1% of the total hospital budget, so a 500-bed hospital spends typically around $5 million/year. In addition to its high maintenance costs, medical equipment is often involved in patient incidents that resulted in serious injuries or deaths. In fact, statistics accumulated by The Joint Commission (TJC) show medical equipment-related “sentinel events1” is typically among the top ten types every year. Therefore, Hospitals and healthcare organizations must ensure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance. [20]

25. Maintenance strategies and reliability engineering techniques have been significantly improved in the last two decades, and they have been successfully applied in many industries to improve the performance of equipment maintenance management. Numerous inspection and optimization models are developed and widely used to achieve maintenance excellence, i.e. the balance of performance, risk, resources and cost to reach to an optimal solution. However, most of hospitals and healthcare organizations do not benefit from maintenance excellence as much as other industries. Unnecessary and excessive preventive maintenance could be also loss-making likewise inadequate level of maintenance. The time, which is spent doing the unnecessary preventive maintenance, is robbing an organization of a fraction of one of its most vital resources.[21]

26. **Maintenance Management** Maintenance management is a tool to support the medical and engineering staff in the development, control, and direction of maintenance programs in order to contribute to the improvement of the biomedical practices at an effective cost in the installed technology. Maintenance management of biomedical equipment becomes increasingly important in the world because of the growing demand for hospital services, to

the high cost of technology, and its constant growth and evolution to the need to improve processes in order to be more competitive, and for the improvement of quality processes of high, medium, and low technological equipment; besides, to increase the safety of the patient and the user of the equipment. The cleaner production from work processes is one of the most recently applied methodologies in the institutional health service providers both public and private to generate technological development and innovation of goods and services. These methodologies involve the reduction of impacts on the environment, minimizing the health risks of workers, and the reduction of costs incurred in the production of waste and atmospheric emissions. Consequently, cleaner production is set to become the goal to be achieved through new investments, while the systematic search for continuous improvement will allow it to be a dynamic and systematic process, which is not applied once, but permanently in each of the phases of the life cycle of the product, or in the provision of services.[22]

27. **WHO Maintenance Programme Planning** Planning a maintenance programme is part of a broader effort to establish a comprehensive programme for healthcare technology management (HTM). This planning process includes a review of critical factors. The challenge for planners is to balance these factors to design a maintenance programme that is appropriate and cost-effective for their situation.[15]

28. **Inventory** Medical devices range from relatively simple to highly complex. For example, manual devices to measure blood pressure (sphygmomanometers) have only few components and are easily repaired; assuming that parts, calibration instruments and basic hand tools are available. At the other extreme are advanced imaging and laboratory devices. Repair of a magnetic resonance imaging system requires extensive financial, physical and human resources. Between these extremes are infusion pumps, defibrillators, ECG (electrocardiograph) machines, and hundreds of other types of medical devices of varying complexity. Early in the process of planning a maintenance

programme, it is essential to determine the types of devices that need to be included in the programme. This will depend on the types of facilities to be covered by the programme, ranging from primary care clinics to tertiary hospitals, and the range of devices in those facilities. The clinical engineering department should identify and select the devices to be included in the inventory, and which of those to include in the maintenance programme. While some may prefer to record all equipment in the facility (and some government agencies may require this), studies have shown that not all equipment needs to be tracked in an inventory, inspected or maintained, and very few hospitals or health-care organizations have the manpower to accomplish this level of effort. [23]

29. **Resources** Resources needed for maintenance are difficult to project. This requires a maintenance history, calculations of the staff requirement and knowledge of when a piece of equipment might fail. Maintenance also requires appropriate staff skills, education and experience. Outside vendors are necessary for the maintenance of complex equipment. Maintenance requires access to equipment parts which may be difficult to obtain due to budget limitations and procurement difficulties, particularly
when purchasing from abroad. To prepare for such challenges, it is important to consider in advance the financial, physical and human resources necessary to properly execute the intended activities.[24]

a. **Financial resources** The financial resources required for a maintenance programme (as one component of a comprehensive HTM programme) fall into two categories: initial costs and operating costs. Initial costs are investments that must be made before the programme begins. Operating costs are ongoing expenses required to keep the programme in operation.

b. **Physical resources** A maintenance programme relies on a number of physical resources. These include the workspace, tools and test equipment, supplies, replacement parts and operation and service manuals needed to perform maintenance. When planning a

maintenance programme each of these should be considered individually**.**

(1) **Workspace** The location in which maintenance will take place should be considered when planning the programme. One option is in the location where the equipment usually resides. For some types of equipment such as X-ray systems, laboratory**,** analysers, sterilizers, and surgical lights, going to the equipment is the only option. In this case, planning to take essential tools and test equipment to the work site or equipping a space closer to the equipment is necessary. The second option is to transport the equipment to the clinical engineering department's repair shop to have the IPM or CM performed. This may be a time consuming process, but the clinical engineering department may be the only location where some maintenance can be performed. A good workspace is clean and well-organized. It provides good lighting and access to utility systems required by the equipment (electricity and medical gases, for example). It includes work benches and storage space for tools and test equipment, repair parts and supplies, and equipment awaiting repair. It also includes space for records and documentation, service and operator manuals, and access to whatever computer resources are required. Inclusion of computer resources in the workspace is also important to consider. Basic documentation may be maintained with paper records but the use of a computer spreadsheet, database programme, or computerized maintenance management system (CMMS) supports good record-keeping, performance monitoring and performance improvement. Additionally, when internet access is available, it can be a valuable resource. Many technical resources are

available online at little or no cost, and online educational programmes may be an option to further technical knowledge and facilitate training.1 Furthermore, inexpensive voice communication and e-mail communication enable effective collaboration across wide distances. However, where internet communication is unreliable, keeping in touch by mobile phone can be an effective alternative. The clinical engineering workshop is typically found within the facility itself, but if the programme includes multiple facilities, it may be more economical to establish a centralized repair depot.[25]

(2) **Tools and test equipment** The productivity of biomedical equipment technicians (BMETs) will be limited without appropriate tools and test equipment. An example of an online educational opportunity is the series of courses developed**.** In addition, having the right equipment will greatly increase the reliability of the readings, the accuracy of the calibrations, and the margin of safety for the patients and staff, as well as the efficiency of the staff doing the maintenance. Various tools and test equipment are required to perform IPM and/or CM procedures, depending on the type of equipment in service. It is possible to perform a large proportion of IPM and CM procedures satisfactorily with a basic set of electronic service tools and test equipment (e.g. temperature meter, volt meter, force gauge, oscilloscope, resistance and capacitance substitution boxes, an electrical safety meter). Small hospitals or clinics with a limited amount of medical equipment can run their programme with just several pieces of basic test equipment (e.g. a physiological simulator, safety analyser and some basic tools). In larger facilities with more complex equipment, more advanced tools and test equipment may be necessary. For example, in a

large hospital with more than a few operating rooms and modern electrosurgery equipment, an electrosurgical analyser may be a prudent purchase. Purchasing more advanced tools and test equipment will enable clinical engineering technical staff to calibrate, maintain and repair a wider variety of medical equipment. If it is not possible to procure and maintain certain test equipment, it may not be appropriate to take responsibility for the maintenance of the associated device. The life of tools and test equipment may exceed ten years if they are carefully maintained. Typically, test equipment can be used for about seven years. Highly specialized items, such as troubleshooting software and laptop computers to connect to computer-based laboratory or imaging equipment, may have a shorter useful lifespan because the laboratory and imaging technology changes so quickly.[24]

(3) **Supplies** These primarily consist of cleaning and lubricating supplies, and need to be acquired in sufficient quantities. The manufacturers' service manuals give cautions about using the wrong cleaning agents, which can damage labelling and the plastic surfaces of some equipment.[24]

(4) **Replacement parts** When planning an IPM programme, it is possible to forecast in advance what parts need to be replaced and how often, by referring to the manufacturer's WHO Medical device technical series 19 guidelines. Thus, based on the number of devices at the facility, the replacement parts (or parts kits) to be used during preventive maintenance (e.g. batteries, filters, valves, tubing, seals, etc.) can be ordered many months in advance, optimizing any volume discounts and minimizing shipping

costs. Most importantly, the replacement parts will be on hand when needed. This practice will improve reliability and availability of the equipment and increase the productivity of the staff performing the maintenance. In many countries the problem of obtaining replacement parts at a reasonable cost and in a timely manner can be substantial. However, knowing what will be needed and the associated costs will help in planning maintenance and informing management in advance. This may lead to funds being redirected to critical areas. The use of generic parts instead of the manufacturer's parts is an option if the quality and characteristics of each part is carefully analysed. Purchasing generic parts from specialty medical equipment parts suppliers – who do the engineering analysis and guarantee the parts they sell – is a reasonable solution in many cases, but associated risks (e.g. loss of manufacturer guarantee, non-compliance with equipment specifi cations that leads to device failure) must be carefully considered beforehand.[26]

(5) **Operation and service manuals** Ideally, the maintenance programme will have an operation (user) manual and a service manual for each model of medical equipment. The operation manual is valuable not only for equipment users but also for equipment technicians who need to understand in detail how the equipment is used in clinical practice. The service manual is essential for inspection, preventive maintenance, repair, and calibration. Unfortunately, operation manuals and service manuals are not always available, or may be in a language not spoken by equipment technicians. Therefore, it is important that a clinical engineering department take steps that allow them access to such manuals. For existing equipment, the manuals may be

borrowed from other local hospitals or obtained online. Clinical engineering department managers should, if possible, have access to high-speed Internet service for this purpose. Manuals or advice may be found among the wider health technology management community, such as the Infratech mailing list.2 For new equipment, it is important that these manuals are included as part of the purchase agreement. All manufacturers who sell equipment are required to provide detailed IPM procedures for use by those who buy their equipment. These procedures are usually written very clearly and in many cases with illustrations for performing complete and appropriate IPM. However, manufacturers may not provide specific IPM procedures, maintenance and service manuals, troubleshooting guidelines, parts lists and schematics unless the owner requires them to do so at the time of purchase. Even if the hospital staff does not plan to do maintenance on a particular piece of equipment, having maintenance and service manuals enables the hospital to provide the manuals to external maintenance providers or do the repairs themselves in the future if circumstances change.[25]

c. **Human resources** Developing the human resources necessary to operate an effective maintenance programme is a slow and steady process. The first step is to identify the number and type of staff that a facility (or group of facilities) requires. For example, a small health-care facility may have a single technician who provides services for a small inventory of relatively simple equipment. On the other hand, a clinical engineering department serving a large number of health-care facilities, especially when those facilities include higher level hospitals, will have a large number of technical and management personnel, including specialists in particular

technologies, with multiple levels of supervision. In general, however, there are two categories of clinical engineering personnel: technical and management.[26]

(1) **Technical Personnel** Within the category of technical personnel are engineers and technicians. Biomedical or clinical engineers, are educated in general engineering principles, the physical and biological sciences and their application to medical technology. Similarly, technicians receive technical training with a primary focus on medical equipment maintenance. Biomedical or clinical engineers come into the position after completion of a four to five year bachelor's degree programme, while biomedical equipment technicians often come into the position with two year's post-graduate training and a degree or certificate in biomedical electronics or biomedical equipment technology. Alternatively, particularly in countries with fewer specialized training programmes, engineers and technicians may be trained in a related field (such as industrial engineering or electrical technology) and have taken certificate courses, received training or completed an apprenticeship enabling them to work in the area of medical equipment. Engineers or technicians must have this additional training because medical equipment is highly specialized and if improperly maintained or repaired may have adverse consequences on human life. This type of engineer or technician is usually easier to find in the employment marketplace, but will need more supervision and training to effectively accomplish their work. Overtime and with experience, technicians may become qualified to take a position as a biomedical equipment technician. However, for engineers to become qualified as a biomedical or clinical engineer, they must receive the relevant higher education and degree. In many countries there is a shortage of qualified clinical engineers and biomedical equipment technicians. A long-term solution is to

develop the educational infrastructure so that qualified technical personnel can be created within the country or region. It may be a good idea to include universities within the country or region in human resource planning as they can develop formal degree programmes and provide continuing education for technical personnel. The size of a health-care organization, the number and type of medical equipment in the maintenance programme, the skills found in the local marketplace, and the financial capacity of the organization will be the basis for identifying the correct blend of engineers and technicians. Almost all maintenance programmes will find it necessary to complement the internal staff with external service providers (either the vendor/ manufacturer's service representatives or third-party service representatives). Such providers may perform the IPM and CM for equipment that internal staff are not able to complete. Furthermore, repair work on the most sophisticated These outside vendors should operate under the supervision of in-house biomedical equipment technicians for the purpose of service management, cost control and the opportunity to become increasingly familiar with other equipment.[27]

(2) **Management Personnel** Engineering management staff provide leadership for the maintenance programme. In concert with hospital administration, they set department policies, provide budget recommendations, supervise technical staff, arrange for training, set priorities for the department activities and administer the overall programme. The background of those in this position may include a technical degree (two years) with many years of experience in medical equipment service, but a preferable combination would be someone with a four-year engineering degree and familiarity with the health-care environment and health-care technology. Management personnel can also have a combination of business and technical training. They may be

> engineers or technicians who have additional training and experience in management and supervision. The number of management personnel required in a clinical engineering group depends on the size and structure of the group and is based primarily on maintaining an appropriate 'span of control' for each supervisor and manager.[28]

30. **Contracts for Maintenance** Maintenance is characterized by the plurality of tasks that can be different in nature and durations. These tasks are grouped into 5 levels,8 depending on where they can be carried out (in-house vs outside the hospital) and by which party (internal vs external resources). In addition for these tasks, the complexity and the tools required play a determinant role in the grouping. Levels 1 and 2 are carried out in-house; level 1 by internal resources and level 2 by internal and/or external resources. Level 3 and 4 are carried out inside or outside by internal or external resources. Level 5 is for rare complex tasks and is carried out by the Original Equipment Manufacturers (OEM). In the biomedical maintenance service, there are different human resources, referred to as staff that include operators and engineers. They are considered competent per equipment and per maintenance level if applicable.

For many healthcare institutions in developing countries, contracting maintenance services is inevitable because they often have neither properly trained staff nor the required material to handle the maintenance tasks on their own. Infact, the in-house maintenance needs special tools and test equipment that may not be available or may need additional training costs, especially for the staffs who are typically generalist rather than specialist. Three service/support options are possible for maintaining the medical equipment: in-house biomedical engineering service, OEM, and third-party service provider (with or without contracts). Each contract contains several clauses that formalize the relationship between the in-house biomedical service and the service provider (third-party provider or OEM). The estimation of costs for such contracts is a challenging task, but it is really important to the biomedical maintenance service and the service providers (OEM or third party) for economic reason. The possible types

of contracts differ from one country to another. In developing countries, medical equipment maintenance is costly and partially mastered most of the time because it is usually managed by external service contracts. [29] The types are:

a. **Contract type A**: All tasks of TBM strategy are performed by the subcontractor with labor and spare parts included in the maintenance package.

b. **Contract type B**: In this type, the TBM and/or CBM tasks are performed by the subcontractor with only spare parts included in the package.

c. **Contract type C**: For this contract, there is no package offered. In general, it is used for corrective maintenance when failures are complex.

d. In practice, a fourth type of contract is often preferred by the **in-house biomedical engineering service & Contract type A**: It covers all risks. All maintenance tasks (corrective and preventive) are performed by
the subcontractor and included in the maintenance package.[30]

31. **Maintenance Management Strategies**: Maintenance management approaches may be divided into two categories: preventative and corrective. The first category consists of unplanned repair and installation jobs. The second consists of strategies for both reactive and proactive responses to a crisis. Proactive work covers tasks such as scheduled replacement, predictive maintenance (also known as on-condition maintenance) and scheduled disposal. Failure discovery, reconfiguration and redesigning are all examples of reactive actions that are performed. The type of maintenance management used by any firm is determined by the operating system used, the resources available and the abilities of the employees. "Effective ways to control the unavailability of hospital equipment" must be discovered and implemented in order to build a workable maintenance strategy for hospitals. However, there are many other types of maintenance approaches, including reliability center maintenance (RCM), total production maintenance (TPM) and mixed maintenance plans. Reduced machine

failure is beneficial to the majority of TPM or RCM organizations according to research. This is due to the fact that the technical infrastructure is kept in good working order which allows for the continuation of output. In addition, machine maintenance costs are significantly decreased. TPM is closely aligned with the lean manufacturing idea which is widely accepted in businesses as having the potential to greatly increase productivity by merging operations that are not perceived as adding value to the product. For the United Airlines, it was asserted that the actions recommended, particularly technical machinery park supervision, resulted in a reduced failure rate and an automated increase in equipment capacity due to the significant reduction in downtime. RCM's engineers are responsible for this. TPM was chosen by 71 percent of the companies that responded to the study because 41 percent reported limited machine capacity and 34 percent indicated a high defect rate. As a result, TPM seems to be an upgraded maintenance method that engages users of this equipment in the everyday maintenance of the equipment. This is a unique concept in the field of hospital equipment maintenance, but it has the potential to increase productivity, improve economic dependability and ultimately improve patient outcomes.[31]

32. **Preventive Maintenance**: It can be defined in the context of equipment as all of those actions performed on a planned, periodic, and specific schedule to keep equipment in good working order through the process of checking and reconditioning in order to avoid or minimize breakdowns and depreciation rates. Preventive maintenance (PM), developed by General Electric in the 1950s, is now used by the majority of organizations to accomplish their objectives, which include: maintaining the condition and reliability of operating equipment; minimizing interruptions to production and major breakdowns; and maintaining continuous production. PM is also known as planned maintenance, scheduled maintenance, or planned operations and maintenance. Despite the fact that project management (PM) is extensively employed in organizations, there is a great deal of diversity in the tasks for which it is used and there are divergent views on how successful it is. It is suggested that unified preventive maintenance methods can give the most optimal maintenance plan for managing equipment

failure and the related hazards of medical equipment being unavailable when it is needed. But other experts believe that preventive maintenance (PM) of equipment might not only degrade its reliability, but can even "introduce failure." [24]

33. In addition, it is suggested that planned maintenance (routines) may be inefficient since it is expensive in the long run and may not result in component lifespan being extended to the extent necessary. This implies that, despite the widespread usage of PM, its application should be limited to situations in which the equipment is in good working order. Medical equipment preventive maintenance (PM) entails more than just safety and performance inspections. This involves risk analysis as well as other criteria that are tailored to the specific demands and realities of the healthcare organization in question. Mission criticality or operational impact are examples of other criteria that should be considered. These include the potential to perceive failures, including so-called hidden failures, and the severity of these failures; equipment hazards and recall history occurring outside the healthcare organization; and reliability, which includes failure patterns, statistics, and the availability of medical equipment and spare parts. As previously stated, PM does not prevent all aspects of equipment failure; rather, it focuses on issues arising from degradation of a device's non-durable parts, which are the primary cause of failure. Additionally, the extent to which preventive maintenance (PM) improves equipment reliability when downtime and safety are considered was examined. PM does have an effect on the dependability of some equipment components and that this effect has a beneficial effect on the equipment's uptime. As Ridgway asserts, a well-executed and maintained PM program helps a company by enhancing safety and reducing downtime and the need for costly repairs. However, it is claimed that as medical technology advances in sophistication, PM activities become less critical to its functioning. This is because PM evaluations focus largely on inspection and scheduled maintenance activities, which do not account for age-related failures. As a result, PM is only useful for enhancing the dependability of sophisticated items to a limited extent.[32]

34. **Corrective Maintenance:** The term "Corrective Maintenance" refers to unplanned repairs on reported failures, as well as the replacement of parts to return equipment to operational status. The term "Continuous Maintenance" (CM) is also referred as Repair and Replacement (R&R), "Run-to-Failure," Failure-Based Maintenance, "Fire-fighting Maintenance," or "Breakdown Maintenance". R&M operations are only carried out when an equipment failure has occurred. It is difficult to forecast stochastic and unintended equipment faults and failures as the procedure is complex and time-consuming. A typical CM job may include the repair of stopped motors, the repair of damaged pipes, or simply the replacement of a blown light bulb. In 1957, the system known as CM was established to integrate all measurements in order to enhance the reliability of equipment. The method is still in use today. This technique is particularly useful in situations when the breakdown of equipment and appliances does not pose an unreasonable danger, does not violate workplace safety regulations, and does not result in an increase in investment expenses.[33]

35. When the failure rate is low and the cost of a failure is low, Condition Monitoring (CM) may be an appropriate method. It is less costly in the short period than Preventive Maintenance (PM) whereas it is costlier in the long run because, for example, a sudden breakdown of medical equipment results in idle time while waiting for spare parts, haphazard troubleshooting scenarios, and unscheduled disruptions of the service provider's operations. Maintenance of industrial operations accounts for more than US$300 billion in annual expenditures in the United States manufacturing industry. Approximately 80% of this money is spent on the remedy of recurrent equipment failure, manufacturing activities, and the payment of workers' salaries. As a result, while CM can be beneficial, it is typically a costly choice when utilized in a standalone fashion.[34]

36. **Predictive maintenance:** It is a term that refers to the practice of anticipating problems before they occur. Predictive maintenance (PrM) can be described as the use of statistical modelling to analyze the state of operational equipment and to prevent failures from occurring. This technology may be used

to enhance interruption scheduling, operational flexibility, equipment information quality, improved fuel usage, and more effective spare part management, among other things. Predictive Maintenance operations are carried out when required, and examinations must be conducted out on a regular basis to ensure that maintenance is carried out before equipment malfunctions. Despite the fact that these maintenance actions fall under the purview of the healthcare organization's medical equipment management plan, they should be carried out even if they occur outside of the defined inspection period. For example, a one-month grace period may be applicable to a quarterly inspection period, but a two-month grace period may be applicable to an annual inspection period. Reliability-Centered Maintenance (RCM) is a collection of programs that are used in conjunction with predictive maintenance processes (RCM). Instead than relying on preventative and corrective maintenance procedures to keep equipment running, predictive maintenance actively employs diagnostic tools to reduce the likelihood of a breakdown. Engineers and scientists have access to a variety of diagnostic methods, including visual and optical inspections, temperature, vibration, neutron, lubricant, and magnetic flux leakage studies, radiography, ultrasonic and eddy current testing, and acoustic emission monitoring. [35]

37. Each of these approaches has its own set of pros and disadvantages. The detection of anomalies suggestive of future failure of running equipment can be accomplished by the use of continuous inspection, also known as condition monitoring, of operational equipment. Condition monitoring is preferred when it is not possible to predict wear-out patterns with reasonable accuracy through routine checks, when cost effectiveness is required, when off-line inspections are not desirable, and when the significance of a failure justifies maintaining a constant vigil on the medical equipment or service process, among other reasons. Planning and scheduling of maintenance tasks for medical equipment must be flexible when using predictive maintenance to keep the equipment running at peak performance. This is owing to the fact that it is frequently impossible to execute scheduled maintenance operations at an appropriate time due to the usage of the equipment on patients and other exterior control

variables. In order to avoid this situation, it is recommended that a grace period (also known as "slippage") be used to determine when a piece of medical equipment must always be declared late for a planned inspection or maintenance action. Some believe that predictive maintenance is much more evolved than previous maintenance plans since it relies on inspection, condition and risk-based procedures rather than only preventative maintenance. In the past, and in the present, predictive maintenance has been and continues to be confined to situations in which it is either scientifically feasible and cost-effective. This tendency was aided by the fact that condition monitoring technology became more widely available and less expensive. Before, these approaches were restricted for high-risk applications like as aero planes or nuclear power plants, but that has changed. Health organizations, on the other hand, should think about incorporating this concept into their operations.[36]

38. **Condition Based Maintenance**: Equipment is subjected to Condition Based Maintenance (CBM) once it has been subjected to periodic monitoring through the use of non-invasive inspection. At a key point in period whenever the equipment needs maintenance, it is carried out, and it comprises gathering diagnostic information as well as making effective maintenance decisions. In contrast to "Corrective Maintenance," which is concerned with the state of a machine part that may be discovered via observation and analysis, "Preventive Maintenance" is concerned with the compliance with a rigorous maintenance time plan that is observed and analyzed. CBM aids in the identification of incipient defects before they become serious, allowing for more precise planning of preventative maintenance to be carried out. As a result, predictive maintenance is referred to as Condition-Based Maintenance (CBM). “With the assistance of diagnostics and prompt intervention, the CBM method minimizes the likelihood of abrupt random failures. Condition management is essential for the successful implementation of the "zero-failure" approach since it aids in the discovery of failure causes, prospective failures, and failure mechanisms, among other things. One of the most effective fault diagnosis techniques is spectrum analysis, which serves as a foundation for the identification of failure processes,

reasons of loss and system failure in control components, such as rotational and reciprocating machines.” [37]

39. Due to its ability to be conducted without the need to shut down equipment or processes, CBM has the primary benefit of encouraging cost-effective manufacturing. CBM also reduces the number and scope of maintenance work and false reports, removes planned inspections, anticipates useful life span, able to detect impending flaws, allows autonomic logistics and diagnostics, empowers information management, improves reliability, and, as a result, lowers life cycle costs. CBM is also applicable to other industries. As a result, it is seen as a successful asset maintenance approach, and it is becoming increasingly popular among U.S. companies and the US military. There are a variety of causes that contribute to the increased usage of CBM, including the requirement for enhanced equipment availability, protection against critical equipment failure, and decreased maintenance and logistical costs. In the field of asset management, the application of CBM is not a novel strategy. In reality, condition monitoring and control have been utilized to enhance technology, equipment, and processes for the past seventy years. There has been a significant acceleration in technical progress over the previous two decades, and this has had an effect on the relevance and utility of maintenance plans. The technological advancements that have occurred over the past two decades have brought about numerous benefits, including the reduction in size, strength, and cost of data collection and analysis hardware, which has resulted in increased reliability of critical machinery such as military rotorcraft, civilian vehicles, medical equipment, energy electronics, automotive, and oil and gas production industries. However, because to the high expense of CBM, the more traditional maintenance techniques of Corrective and Preventive Maintenance are frequently employed in conjunction with CBM. Given that CBM is concerned with monitoring and replacing components and equipment before they reach the end of their operational lives, it was attempted to develop a model for the most optimum replacement strategy and observation interval possible. [30] They used a variety of models, including the Proportional Hazards Model (PHM), which simulates the failure rate of a computer system. It

is utilized in medical research to determine the best replacement policy and long-run average cost for a system that does not have any information, but it is also employed in other applications. Using CBM, it has been discovered that it may aid in determining both the ideal observation interval of an operation process based on the total long-run average cost and the associated replacement policy that minimizes the total long-run average cost of the replacement observations. According to the results of a survey, one firm employed a strategy based on the failure rate. Planned inspections were found to be the most often used maintenance strategy by 65 percent of the firms who responded to the study. [31]

40. A technical condition evaluation performed by an operator prior to the start of work was implemented by 63 percent of firms. 77 percent of the firms conducted monthly equipment cleaning and general inspections, according to the survey. The integration of several functional levels is required for the CBM application. These levels involve data gathering, data processing, status detection, health assessment, prognostics evaluation, and advice production, amongst other functions. The Condition Monitoring system, which serves as the foundation of CBM, is involved at the data gathering, data processing, and state detection levels. A more efficient CBM program includes levels of diagnosis, prognosis, and advisory generation that integrate a larger variety of new technologies, as well as levels of advisory generation. Asset management (medical equipment) in healthcare organizations requires the adoption of a CBM strategy that combines diagnostic and prognostic techniques. Diagnostics is concerned with determining the state of an individual component, which includes early fault detection, isolation, and identification (e.g., the position and size of the present fracture), whereas prognostics is concerned with predicting the condition of an individual component (how fast and to what extent the diagnosed fault will progress). Prognostics are critical components when it comes to further increasing reliability, decreasing life cycle costs, and adopting automated logistics. Current CBM is mostly diagnostic in nature, as machine condition prognosis is still in its infancy and, by definition, involves a high degree of ambiguity and complexity, as well as a number of unresolved issues. On the

other hand, CBM is the most effective technique for health organizations looking to reduce their overall maintenance and service operating costs.[32]

41. Performance of equipment is substantial to preserve the performance of production process, as the increasing trend on mechanization and automation. Since the current market improved, customer demand high-quality product. The well-maintained equipment ensures the product quality will conform to requirements. Many literatures discussed the roles and advantages of quality inspection and equipment maintenance individually and separately. The investigations on these two aspects reveal their possible interactions. The proposed interaction framework between inspection and maintenance provides logical thinking that may interrelate these aspects to provide better quality assurance. The two approaches provide elaboration accompanying the proposed framework. The inspection becomes a trigger for the demand of maintenance. The rejected lot result from low process capability or producing of nonconforming products, could be the symptoms of the deteriorating process. The appropriate maintenance policy needed to restore the process deterioration back to the acceptable conditions. Thus, determination of maintenance policy based on the demonstrated quality history, rather than the condition of the machine, would provide more reliable maintenance decision. On the other hand, determination of maintenance policy and strategy may affect to the forthcoming product quality. Improper maintenance policy selection may result on not improved product quality. The meaningful of the relationship serves a way to achieve better quality assurance and establishing the performance of production system. Yet it provides a comprehensive managerial thinking in equipment maintenance. It is worth to note, the importance of quality assurance through equipment maintenance becomes increasingly indispensable.[33]

42. **Maintenance Standards**: At international level, maintenance standards are mainly produced by two organizations: ISO (International Standardization Organization) and IEC (International Electrotechnical Commission). The ISO Technical Committees TC108 and TC135 work respectively on mechanical

vibration, shock and condition monitoring and on non-destructive examinations. In addition, the ISO/PC 251 is currently working on Asset Management where maintenance is concerned. The IEC Technical Committee 56 (Dependability) writes standards about maintenance, maintainability and logistics-support applying to all types of equipment (and not exclusively to electrical equipment). At European level, the CEN Technical Committee 319 is dedicated to maintenance and comprises several groups working on terminology, qualification of maintenance personnel, maintenance management, performance indicators, documentation, maintenance contracts, maintenance of buildings and infrastructures, methods for condition assessment of buildings, maintenance within asset management, Risk based Inspection, maintenance process. At national level, each country in Europe has a standardization institute and some of them produce maintenance standards (e.g. DIN, UNI, AFNOR, SFS, BSI, etc.) [38]

38. Standards-based systems and processes provide distinct benefits when compared to proprietary ones, because standards envelop tried-and-true methods that users can incorporate for their own purposes. These benefits include interoperability across systems, easier replication and reuse of systems and best practices, as well as technological longevity. Maintenance systems and processes are no exception. Maintenance standards incorporate proven methods to best perform tasks such as cleaning, lubrication, repairs, components' replacement, data collection and more. They can also instruct professionals on how to create comprehensive checklists of maintenance tasks, as well as on how to structure them into integrated maintenance programs. Standards are useful when applied to technological systems. For example, they can boost the development of interoperable systems that can exchange data and services to boost the replication of maintenance solutions. Such data exchange and sharing is key to sharing visualizations across stakeholders and supporting new cost-effective ideas for remote maintenance.

43. Overall, standards-based systems and processes provide a safe path to successful maintenance practices in a highly diverse landscape of different

plants, equipment, and processes. There are a host of maintenance-related standards, which are developed by various organizations such as the International Standards Organization (ISO), the International Electrotechnical Commission (IEC), the American Nation Standards Institute (ANSI) and others. These standards cover both maintenance procedures and systems, including emerging cyber-physical systems that are part of industry digitization. The latter systems have recently expanded the number and scope of maintenance related standards, since they have given rise to processes for collecting, exchanging and processing data. Given the large number of standards, it would be difficult for one professional to educate himself on all suggested practices. Rather, practitioners tend to selectively focus on limited sets of standards, notably the ones that are suitable for their maintenance tasks at hand. In the following paragraphs, we present five important standards, which maintenance experts should know about.[34]

44. **ISO 55000 Asset Management Standards** Plant equipment and components are physical assets, and fall under the umbrella of asset management systems and disciplines. Asset management is about coordinating and optimizing the management of an asset across its whole lifecycle, including selection, acquisition, development, maintenance, renewal and disposal processes.[38]

45. **ISO 13374 on Condition Monitoring and Diagnostics of Machines** Efficient data sharing and distribution is at the heart of maintenance systems and processes, including condition-based, preventive and predictive maintenance. Moreover, data interoperability is a prerequisite for exchanging data across different systems, but also for deploying systems in a plug-and-play fashion with minimal integration effort. The ISO 13374 series of standards is beneficial to combine a variety of information. It provides unified and interoperable ways for processing, communicating and presenting data across different maintenance systems and in a vendor-independent way. ISO 13374 consists of four parts, dealing with:

a. Presentation of general guidelines for data communication and processing

b. Data-processing requirements

c, Communication requirements

d. Presentation requirements [29]

46. **MIMOSA Open Information Standards** MIMOSA is a not-for-profit trade association, which develops open information standards for Operations and Maintenance (O&M) in sectors such as manufacturing, fleet, and facility environments. MIMOSA comprises a wide range of standards that span almost all aspects of data exchange and integration across diverse O&M systems. [28]

47. **ANSI TAPPI TIP 0305-34:2008** This standard is specified as part of Technical Information Paper TIP 0305-34 and provides guidelines for creating maintenance checklists on a daily, weekly or monthly basis. In practice, maintenance engineers and users are expected to customize these checklists to the needs of their plant taking into account machines, equipment, physical configurations and other characteristics of the plant.

48. **Industrial Internet Consortium Reference Architecture** In earlier posts, we referred to the trend of digitizing industry, including opportunities to leverage the functionalities of the emerging Internet-of-Things (IoT) and BigData technologies. The Industrial Internet Consortium Reference Architecture (IICRA) defines the structuring principles that drive the integration of Industrial Internet applications, as part of the emerging digitization of the industry. The IICRA represents a joint effort between major industrial and IT players worldwide, reflecting their common vision for product interoperability and simplified development of industrial internet systems. The architecture supports use cases in various sectors including energy, healthcare, manufacturing and transportation.[39]

49. **Maintenance of EM Eqpt in Army** There is vast variety of live saving electro medical equipment being used in Military Hospitals in Pakistan Army. There have been tremendous development and improvement in this field in the form of induction of latest equipment to facilitate diagnosis and treatment. On the other hand, repair/maintenance of this latest equipment is becoming more and more difficult and costly as it requires intensive and dedicated training of manpower and more sophisticated tools and test equipment. Corps of Electrical and Mechanical Engineering is the sole agency of repair/maintenance of EM Equipment. EME adopts the generally accepted principles of three tier repair/maintenance.

a. **First line Repair/Maintenance at Hospital level**. This is carried out on the spot by EME staff posted in Hospital electro medical department.

b. **Second Line Repair/Maintenance.** This is carried out by the local workshop, either on spot or in workshop itself.

c. **Third Line Repair /Maintenance.** When the local Workshop is unable to rectify the fault of EM Equipment, then faulty equipment is dispatched to Central Workshop EME on proper work order giving details of fault.

d. **Repair/maintenance of Major and Complex equipment.** Repair / maintenance of major and complex equipment after expiry of warranty period is initiated by concerned hospital and forwarded to Medical Directorate (DMS-2) which after necessary action transfer the case to EME Directorate ME-27 for approval of maintenance contract SLA (Service Level Agreement). After sanctioning the approval, it is referred to DGP Army for final contract with concerned vendors for repair/maintenance as per policy in vogue.

CHAPTER – 3

Materials and Methods

50. To carry out this study project, following methodology was adopted:

a. **Study Design.** Cross sectional, mixed study of descriptive type.

b. **Study Setting.** Military hospitals of Pakistan Army.

c. **Time Duration**. One year (July 2020 to June 2021)

d. **Study Population**. The study population for this study consisted of the following five strata:-

(1) **Policy Makers**: Director Electro Medical Engineering Directorate and Director Medical Services (DMS)-2.

(2) **Hospital Administrators**: Commandants (Comdts), Deputy (Dy) Comdts, Assistant (Asst) Comdts and Medical Officer In Charge (MO I/C) Medical Stores of Military Hospitals.

(3) **Clinical Specialists**: Head of Departments of Radio and Path departments of Military Hospitals.

(4) **Technical Representatives**: Commandant 502 Workshop EME, EME Offrs and staff posted in CMH, OC Base workshop

e. **Sampling Technique**. Convenience sampling method

f. **Sample Size**. Universal sampling used for above strata. Details are as:

Hospitals/Wksps	HCAs	Specs	EME Offrs	EME Staff	Total
CMH Quetta	7	8	-	4	19
CMH Hyderabad	4	4	-	3	11
CMH Sibi	3	2	-	2	7
EME Wksps	-	-	6	9	15

Hospitals/Wksps	HCAs	Specs	EME Offrs	EME Staff	Total
Policy maker	2	-	2	-	4
Total	16	14	8	18	**56**

Table 1: Sample Size

g. **Sample Selection**. Sample selection criteria are laid out as under.

(1) **Inclusion Criteria**: All COs / MOI/C Medical stores of selected hospitals, Comdt 502 Workshop, Dir of EME and Med Dte.

(2) **Exclusion Criteria**: MOI/C Medical Stores with service less than 3 months in selected hospitals.

h. **Data Collection Tools**: Various data collections tools employed for different strata of the study population as per the detail given below.

(1) Policy makers shall be administered in depth interviews.

(2) Hospital administrators and clinical specialists including Head of concerned departments shall be surveyed using structured questionnaires.

I. **Data Collection Procedure**: In depth interviews shall be conducted in person by the researcher. Questionnaires for Hospital administrators and clinical specialists will be distributed and collected after completion.

j. **Plan of Data Analysis:** Descriptive statistics (Structured Questionnaires and IDIs) will be used for data analysis through SPSS version 23

k. **Ethical Considerations:** Ethical approval will be obtained from Institutional Review Board (IRB) of Armed Forces Post Graduate Medical Institute (AFPGMI). Informed consent will be taken from all the participants of the survey, with assured confidentiality regarding identity of participants and their responses to the questions

CHAPTER – 4

Results and Findings

51. This is a mixed study so result section is divided into two main parts i.e results received from the interviews and the results achieved through questionnaire. Policy makers, HoDs Hosps and EME offrs were interviewed in depth whereas Hospital administrators and clinical specialists in 3 Hosp settings were surveyed using structured questionnaires.

52. **In Depth Interviews**: In depth interviews were conducted by the researcher to analyze the existing system of diagnostic Electro medical equipment and to determine the cost effective maintenance of diagnostic Electro medical equipment. A total of 25 x sample size was planned for In depth interviews, out of which 4 were policy makers, 6 were HoDs of Hosps and 15 were EME staff (offrs & techs) from EME Wksps. Out of that sample size, 19 were interviewed with response rate of 76 %. 6 x respondents were not aval for interviews with non response rate of 24 %. Out of the total of 4 x Policy makers, 3 were approached which included Director EME Dte, Comdt of Base Wksp Quetta and Dir Medical Services, DMS (S). Apart from this, HoDs of Radio and Path dept were also interviewed from 3 Hosp settings as well as 4 x EME Offrs out of 6 and 6 out of 9 x EME staff were interviewed. Following were the consolidated results of all the in depth interviews conducted:

a. **HoD Pathology:** HoD Pathology of the 3 Hospitals were interviewed and asked about the cost effective maintenance of Laboratory equipment. They all added important details which are required for the cost effective maintenance of equipment which are:

(1) Reagent rental based agreement if made with the companies or vendors for Diagnostic EM eqpt, will be a cost effective step towards the maintenance of the equipment. As a result of this vendors will provide the machine with all the

kits / reagents as well as maintenance and repair services when required.

(2) Machines which do not require reagents or kits should come under the repair / maintenance agreement from the service provider on long term basis.

(3) Outsourcing the repair and maintenance of EM eqpt to well reputed firms should be the done with repair and maintenance of all Diagnostic EM eqpt of the hospital. It will be efficient and also cost effective with prompt and timely response from the service provider.

(4) Exclusive training of the EME offrs and EME staff both inland and abroad if they have to look after the repair and maintenance of EM eqpt of hospital can be a possibility but it will be time demanding.

(5) Cost effective maintenance can be achieved through training on specific machines which are procured throughout Army which will built readiness among the EME for maintenance of latest machines. Staff trained to stay at one station for 5 years and then can be posted with the one who deals with machines of same category.

(6) Long term Vendor rental agreements should be done so that financial burden can be reduced and EME will take a long time to address their issues in terms of capacity enhancement.

(7) Nowadays all the international and few national firms have exclusive biomedical engineers to deal with the issues of repair and maintenance of EM eqpt.

b. **HoD Radiology**: HoD Radiology of the 3 Hospitals were interviewed and asked about the cost effective maintenance of Laboratory equipment. They all added important details which are required for the cost effective maintenance of equipment which are:

(1) Existing system of maintenance and repair of sophisticated and highly modern eqpt is totally dependant on companies with whom agreement is done. Reliance on EME Corps for subject purpose is not possible due to lack of knowledge about the eqpt and staff is not trained enough to handle the eqpt.

(2) Need of the hour is to enhance the capacity of EME staff through increasing Human resource and enhancing the technical capacity.

(3) There is a requirement of expert Biomedical engineers who can deal with repair and maintenance of Diagnostic machines in Radiology department like MRI, CT Scan, Digital X rays, Doppler etc.

(4) Training of EME offrs and staff should be at par with Bio Med engrs of reputed EM manufacturing firms. Training should include local and international modules.

(5) Every machine like MRI, Fluroscopy, CT Scan, Mammography, Digital Radiography etc have a unique and separate operating manual/ system for which training of staff needs to be specific and moreover standardized eqpt should be procured all over Pakistan with specific training and capacity building of EME staff in such diverse machines.

(6) From the time of installation and operationalization of highly sophisticated machines, any untrained staff can lead to even

more problem and further financial burden to the organization.

(7) Renowned companies have their own bioengineering departments and vendor based long term agreements for repair and maintenance of EM eqpt is the need of the hour.

(8) In the era of scientific evolution there are highly sophisticated and artificial Intelligence based modern EM eqpt which cannot be repaired / maintained by orthodox methods and need to be addressed by highly professional and skilled staff.

(9) Highlighting the reasons for faulty maintenance, it was noted that powe fluctuations are playing a major role and secondly preventive maintenance is not sone due to lack of knowledge about the latest machines. Firms like Seimens, Toshiba and Philips provide the system of power generation along with the eqpt to avoid repair frequently which is very expensive.

(10) Batteries and UPSs do not come under warranty. Funds to be given for arrangement of batteries for CT Scans, MRI and other machines.

(11) Direct induction of Bio medical engineers in Pak Army as officers and making a new stream is one important measure for cost effective maintenance of EM eqpt.

c. **EME Representatives** 4 x EME offrs as well 6 x EME staff from Central Workshop at Quetta were interviewed who were of following views:

(1) Mostly maintenance of eqpt at Pathology department is Reagent Rental based. The vendors are responsible to

provide the reagent for the tests and will be responsible for all the repair and maintenance of machines like Chemical Analyzer and Haematology Analyzer.

(2) Very few items are on EME staff responsibility like microscope, water bath, ultra low refrigerators, Blood bank compressor or other accessories from Pathology department. Items on maintenance load from Radiology department include X ray 500Ma, Xray 1000mA etc.

(3) Major machines like CT Scan, MRI and Digital X rays of different companies like Toshiba, Siemens, GE, Aloka Japan are dependant on vendors for maintenance.

(4) EME offrs have to do 3 months Special Eqpt repair Course(SERC) but the course is not sufficient to handle the highly sophisticated equipment available in hospitals nowadays.

(5) There is a need to purchase machines of same specifications and company so that EME is trained on those specified machines to built their capacity for cost effective maintenance.

(6) Training should include software as well as hardware training.

(7) Incentives in the form of promotions, postings and special allowances will help in capacity building.

d. **Policy Makers:** Among the policy makers DMS-2, Dir EME Dte and Comdt Base Wksp EME were asked no of questions regarding cost effective maintenance of diagnostic EM Eqpt. Response as per different questions asked is summarized below:

Q1 **What is the importance of maintenance of Diagnostic Medical Eqpt?**

Policy makers highlighted the importance of maintenance of Diagnostic Electro medical equipment by narrating fol:

(a) It is the backbone of a hosp as diagnostic electro medical equipment (Radiology & Pathology) helps to diagnose the illness of the patient and the possible treatment.

(b) It is very important not only to diagnose but to know the progress of the disease.

(c) It is important to find whether treatment given to the patient is helping the patient and to check about improvement of the disease condition.

(d) Diagnostic EM eqpt maintenance and accurate functioning id directly related to the patient welfare / treatment and outcome of the patient wellbeing.

Q2 **Cite any example where you felt that maintenance of your hospital flawed?**

On asking about the examples where maintenance procedures not carried out properly `in the hosp settings, following was revealed:

(a) CT Scan machines goes out of order multiple times due tto error in voltage supply and batteries life.

(b) X ray machine goes out of order and need to be repaired several times.

(c) Biochemistry analyzer needs robust maintenance and calibration for accurate results in Path dept.

(d) Electrolyte Analyzer an important equipment for Path Lab needs calibration and scientific maintenance.

Q3 **What are the major flaws in the maintenance of diagnostic EM eqpt?**

On interviewing the Policy makers for assessing the factors of cost effective maintenance of diagnostic EM equipment, following factors were deduced to be important for the maintenance:

(a) Maintenance of diagnostic EM eqpt needs a robust system including trained officers from EME Corps, special training of Biomedical engineers from EME

(b) There is acute shortage of trained offrs and staff from EME Corps for maintenance of diagnostic EM eqpt.

(c) The EME wksps has capacity issues, not able to cope with the advanced and sophisticated EM eqpt hed at Military hospitals.

(d) Vendor based maintenance agreements for long duration for maintenance of highly sophisticated and expensive Eqpt.

Q4 **Do you have any suggestions for the improvement of repair / maintenance of Diagnostic EM eqpt?**

Policy makers suggested fol for the improvement of the cost effective maintenance of diagnostic EM Eqpt:

(a) Outsource / vendor based maintenance agreement for the repair and maintenance of EM eqpt should be done for long term.

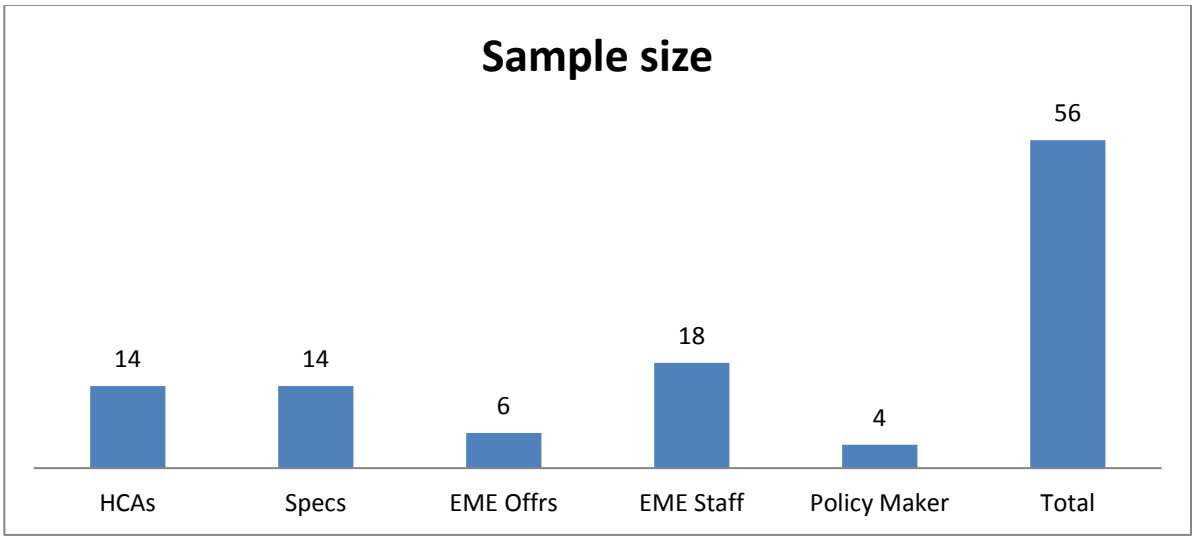
(b) Training of staff / officers from EME Corps for work as Biomed engineers from local and abroad well-known institutes be done.

(c) To increase the capacity of EME workshops to deal with highly sophisticated and expensive electro medical equipment.

(d) To improve the channel/process of repair and maintenance of the electro medical eqpt converting into a quick, smooth/robust and time/cost efficient system of maintenance of EM eqpt

53 **Questionnaires** A total of 31 respondents in 3 hospitals were sent the questionnaires who were surveyed to assess the existing system of diagnostic EM eqpt and cost effective maintenance of diagnostic EM eqpts. 25 x questionnaires were filled in complete by the specialists, HCAs and EME staff of 3 hospitals. Response rate was 86 % whereas 2 x questionnaires sent were rejected being incomplete and 4 x questionnaires were not received. 14 x HCAs, 8 x specs and 9 x EME Staff were sent questionnaires. Response in complete was received from 13 x HCAs, 6 x specs and 6 x EME Staff. Incomplete response was received from 2 x EME Staff

54. **Demographic Profile** A total of sample size (n=31) for quantitative analysis and sample size (n = 25) for In depth Interviews making a total sample of 56 with fol details:

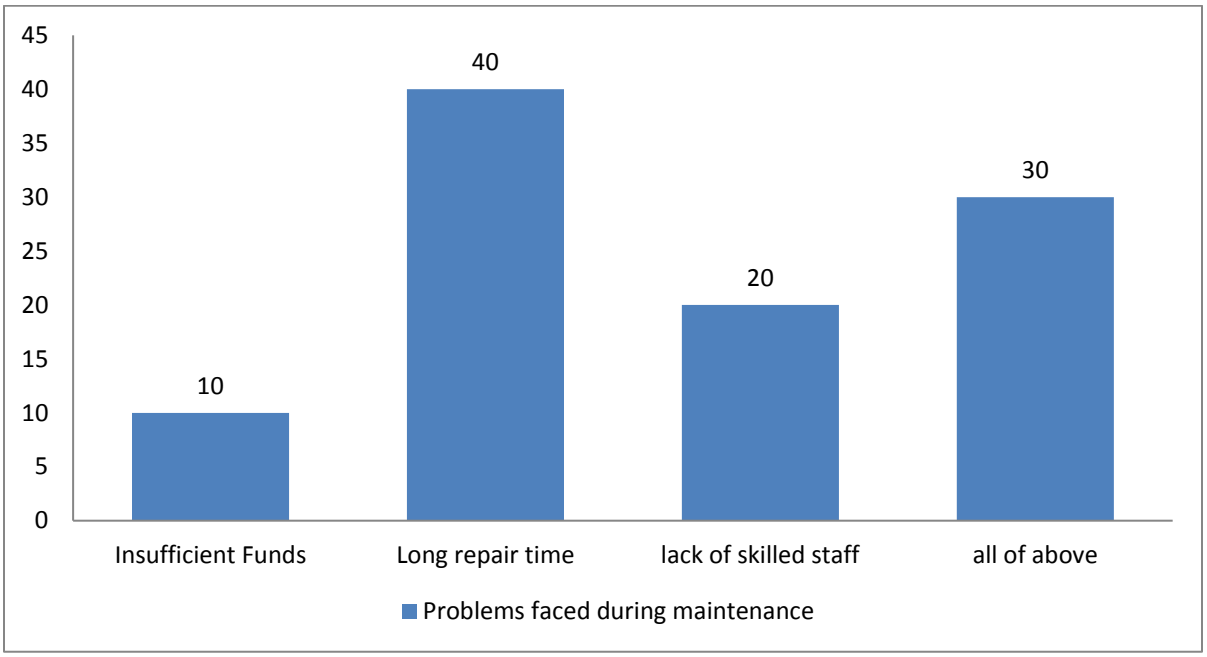


Graph 1: Sample Size

Deductions

A total sample size under study was 56. Out of 56, 31 x respondents were given questionnaires whereas 25 x respondents were interviewed.

Q.1 What can be the problems you might have to face while repair/ maintenance of medical equipment?

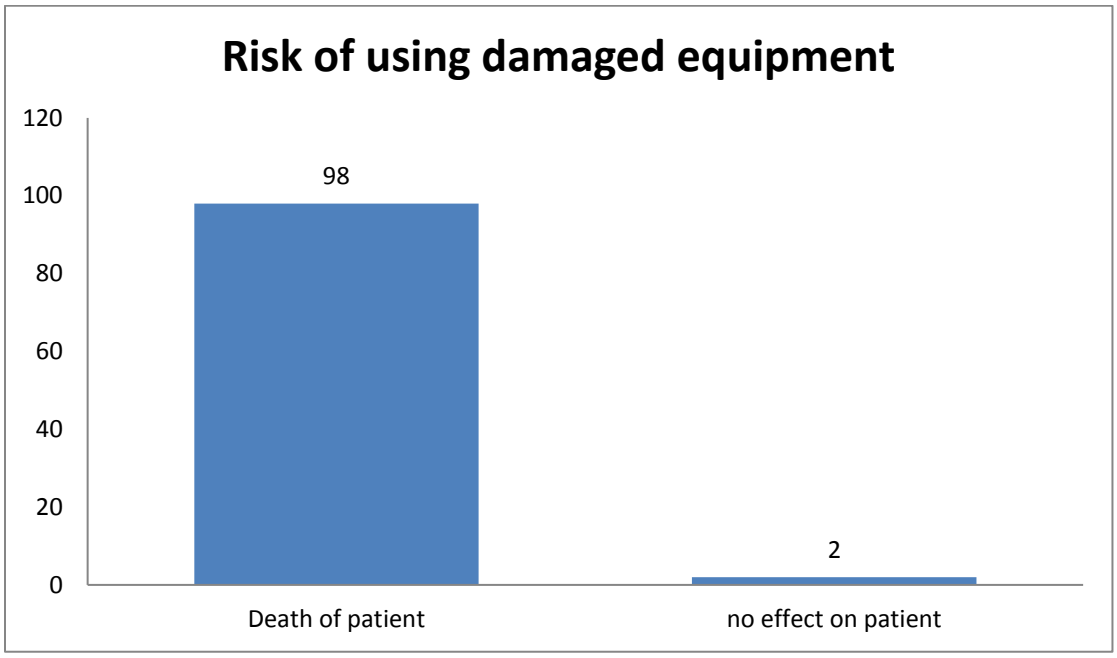


Graph 2: Problems faced during Maintenance

Deduction

Max participants highlighted long repair time as the major problem faced by hosp during maintenance whereas most of the respondents were of the view that insufficient funds as well as lack of skilled staff also poses problem

Q2 Is it risky to use damaged diagnostic equipment on patient due to negligence regarding repair / maintenance.

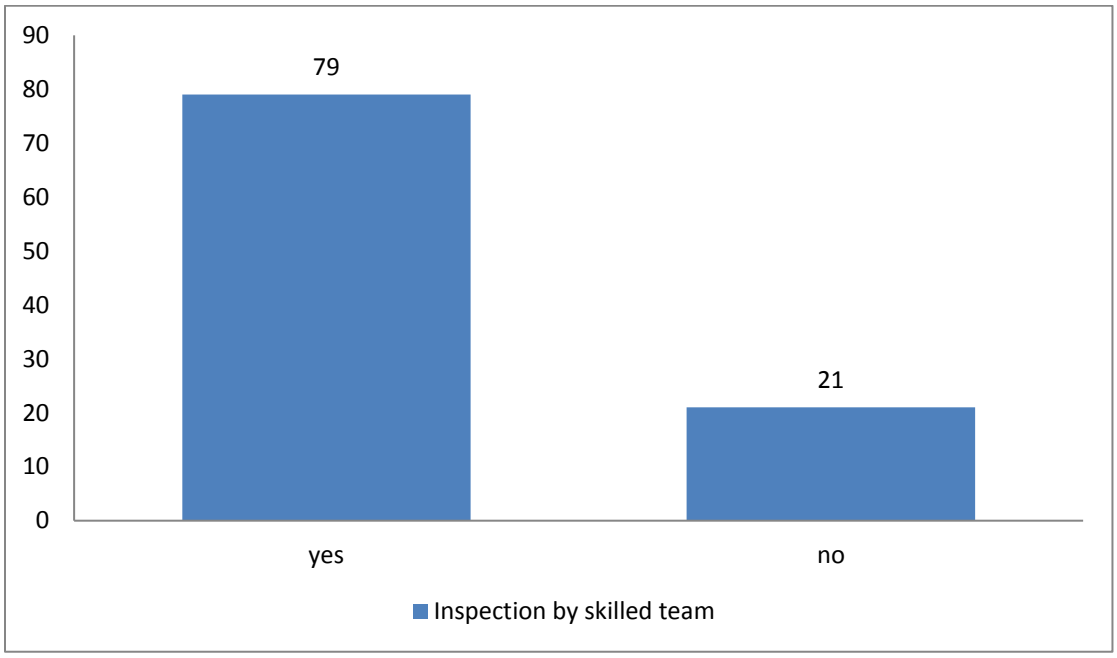


Graph 3: Risk of using damaged eqpt

Deduction

98 % of the respondents believe that use of damaged diagnostic eqpt due to negligence of lack of repair or maintenance can lead to death of a patient.

Q3. Is electro medical equipment in military hospitals regularly inspected by skilled team?

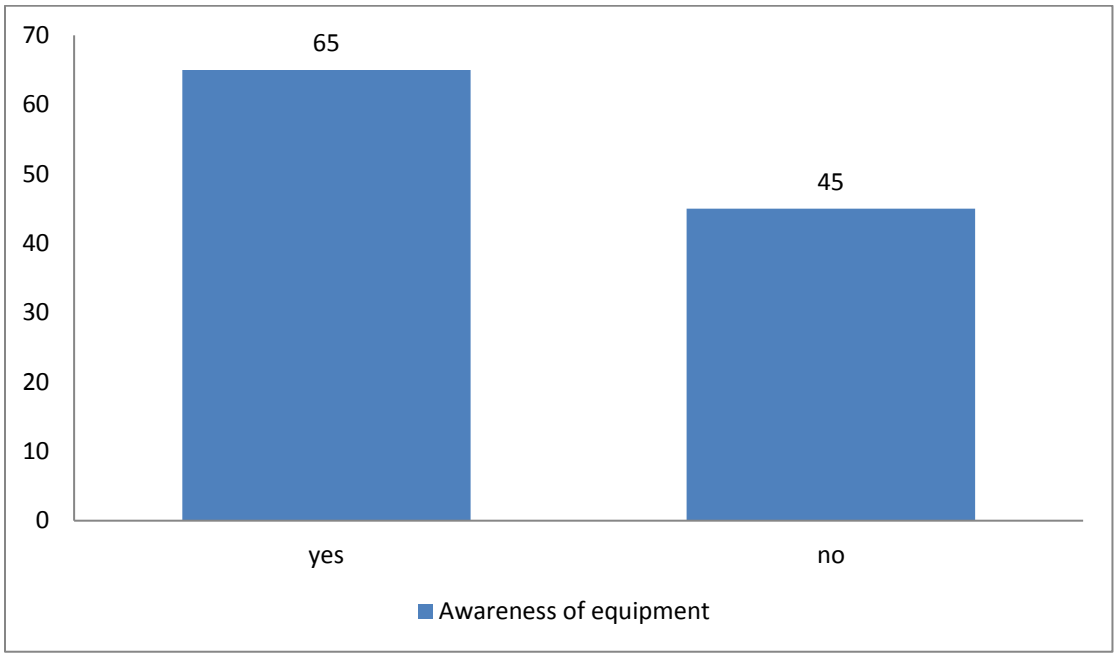


Graph 4 Insp by skilled team

Deductions

79 % of the respondents are of the view that electro medical equipment in military hospitals is regularly inspected by skilled team. Only 21 % are against it.

Q4. Are you aware of advantages and disadvantages of equipment held in your hospital?

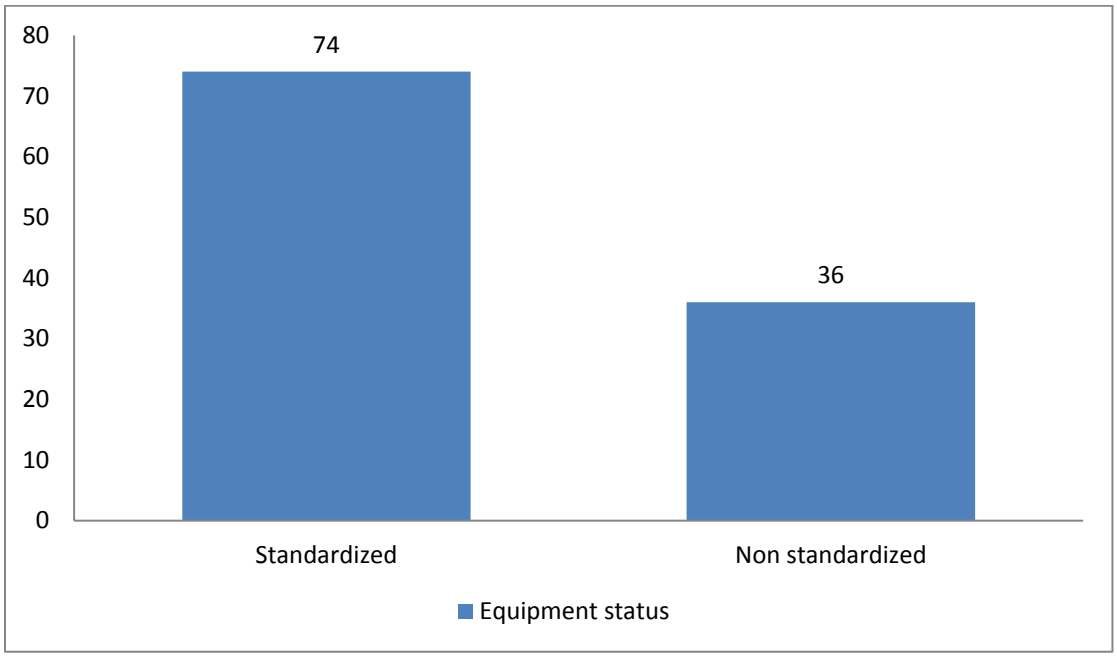


Graph 5 Awareness of eqpt

Deductions

65% of the respondents are aware of the advantages and disadvantages of the electro medical equipment in the hospital settings.

Q5 Electro medical equipment you currently have in your hospital is standardised?

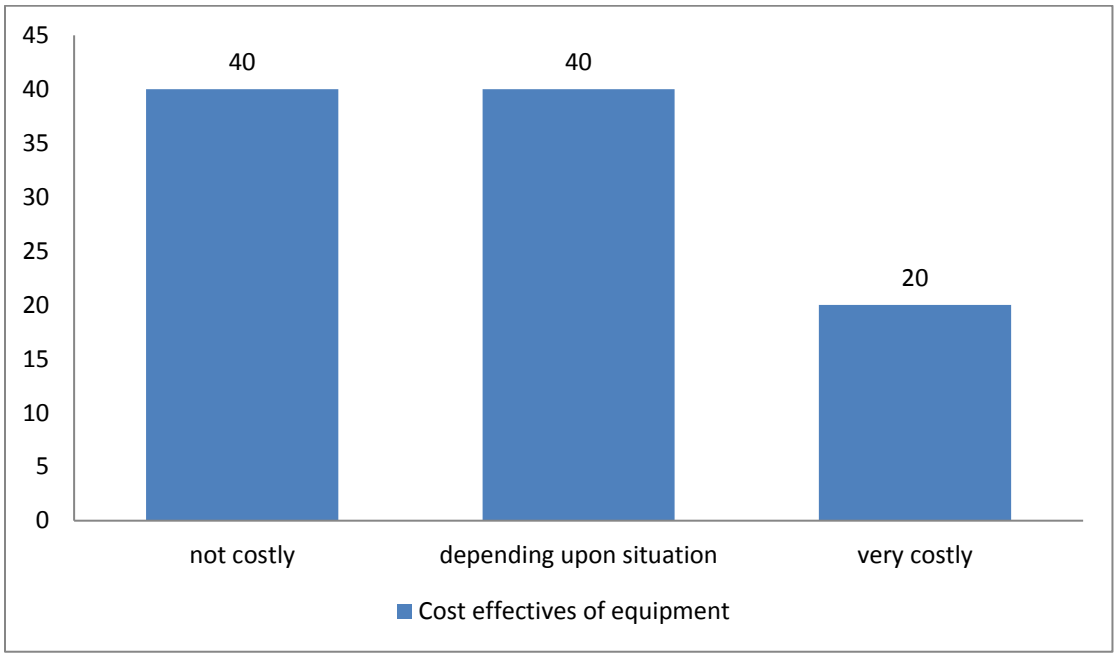


Graph 6 Eqpt status

Deduction

Max respondents state that the hosp equipment is standardized whereas only 36 % are against it.

Q 6 If equipment is being manufactured in own country then it is costly for government?

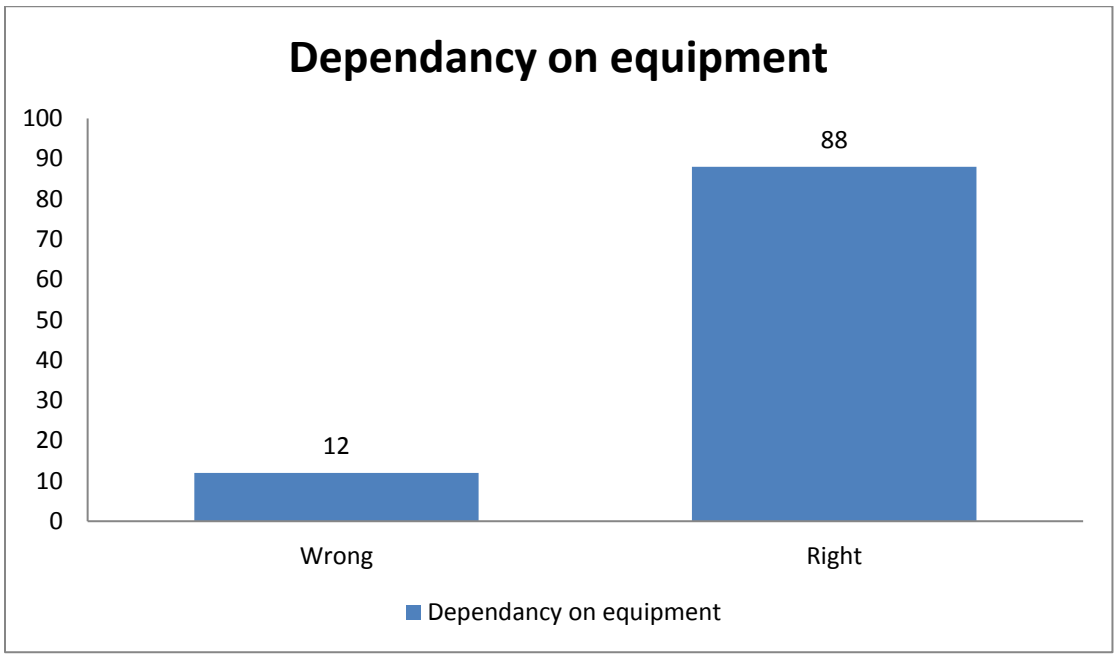


Graph 7 Cost of Eqpt

Deduction

40% of the respondents believe either the equipment manufactured in own country is beneficial or costly depending upon the situation whereas only 20 % feels it as very costly for the government.

Q 7 Is it right that health care system is dependent on electro medical equipment for better treatment?

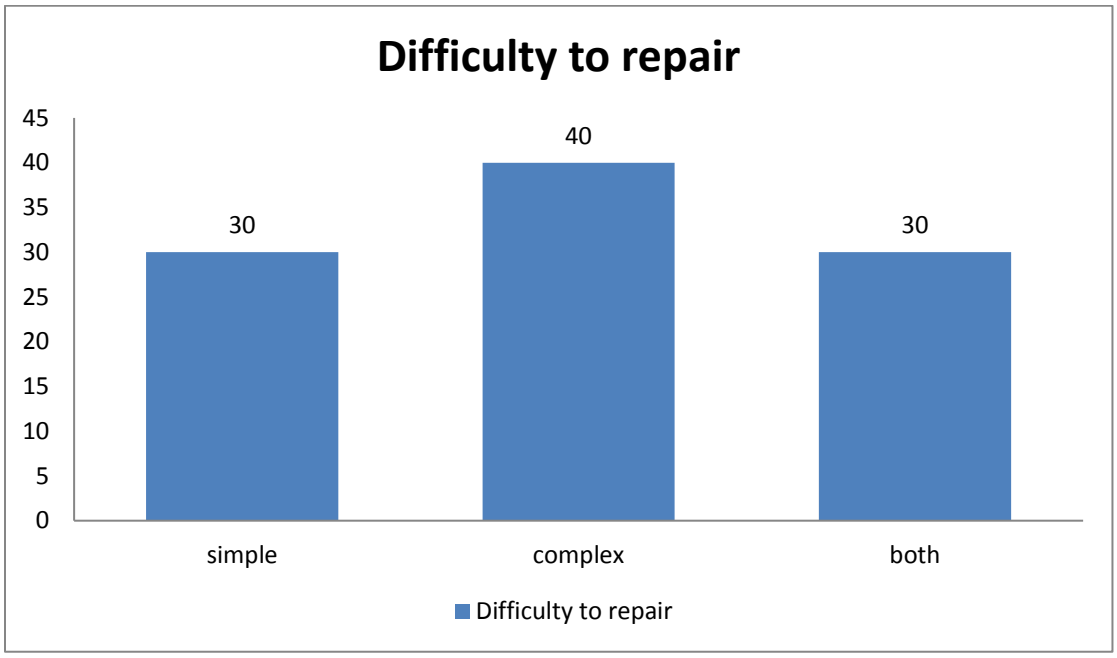


Graph 8 Dependency in eqpt

Deduction

88 % participants stated that Health care system is dependent on electro medical equipment for better treatment.

Q 8 Simple devices or complexed devices; which one is hard to repair / maintain?

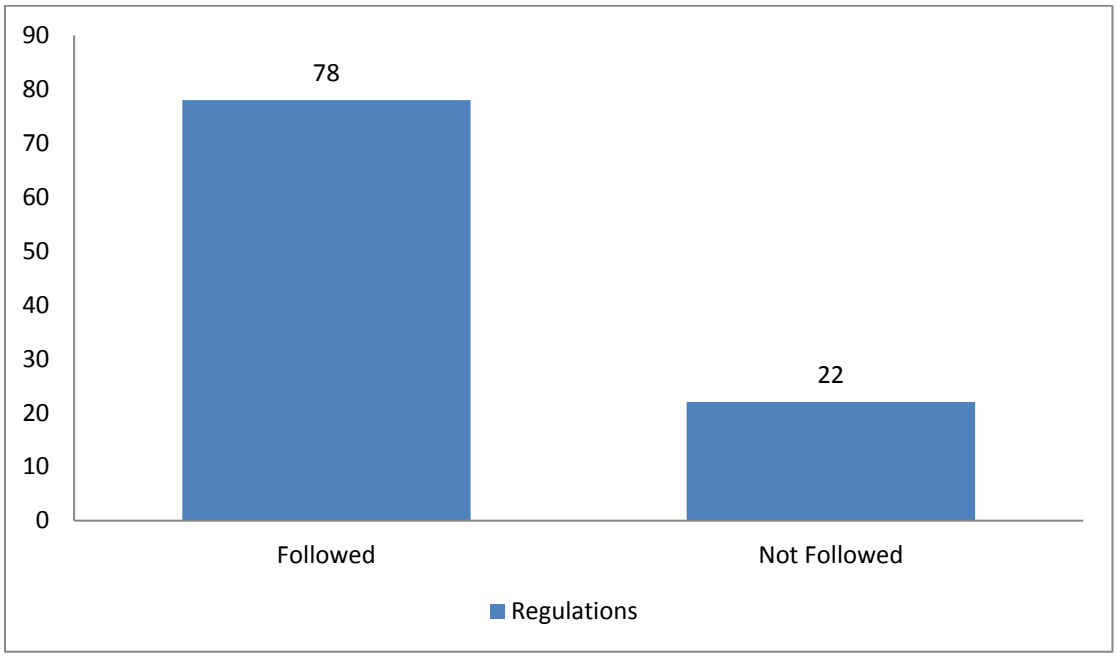


Graph 9 Difficulty to repair

Deduction

40 % of the respondents are of view that complex devices are difficult to repair whereas 30 % think it is the other way. Moreover 30 % state that both simple and complex devices are difficult to repair.

Q9 Regulations regarding electro medical equipment are followed in your hospital?

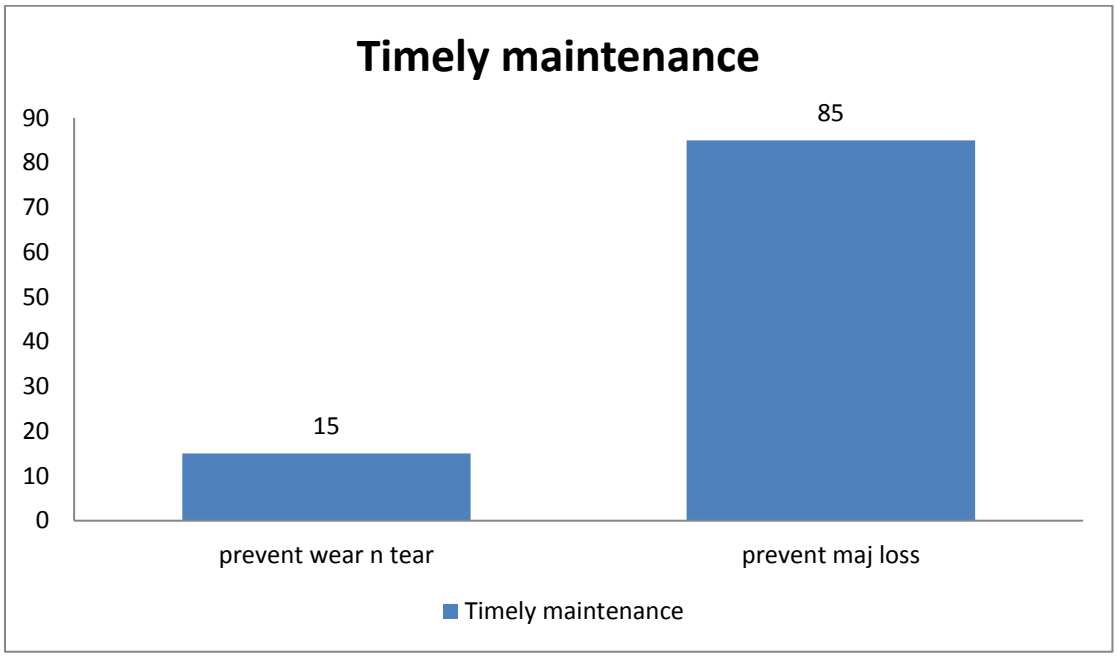


Graph 10 Regulations

Deductions

78 % of the participants are of view that Regulations are followed by the hosps regarding diagnostic equipment whereas the remaining are against it.

Q10 Repair/ maintenance on time period of equipment can be beneficial or not?

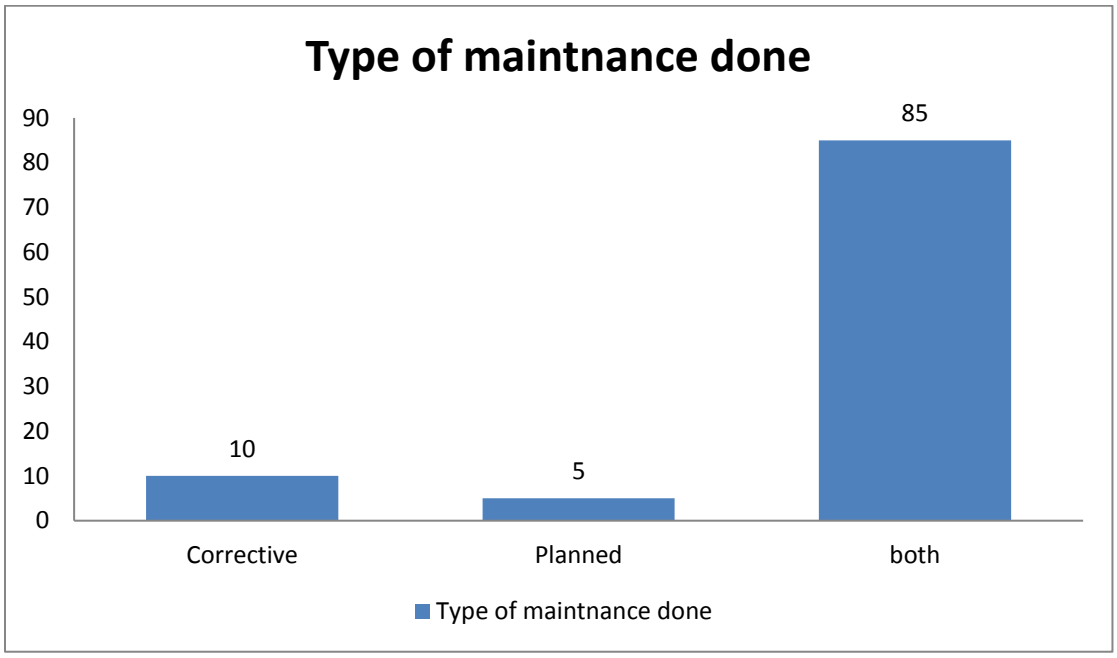


Graph 11 Timely Maint

Deductions

Majority (85%) of the applicants state that repair and maintenance on time has a major effect in preventing lost and is not a waste of time.

Q11 Which repair/ maintenance of medical equipment is being done in your hospital?

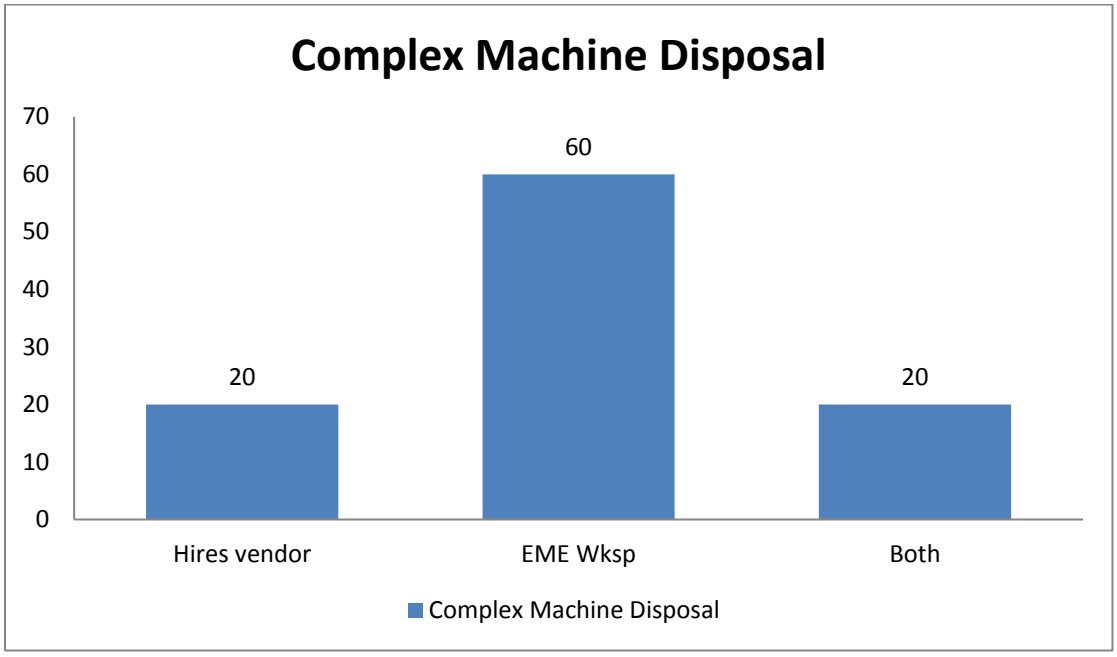


Graph 12 Type of maint done

Deductions

It is deduced from the results that Both type of maintenance is being done in the hospitals.

Q12 What your management do when a complexed machine needs repair?

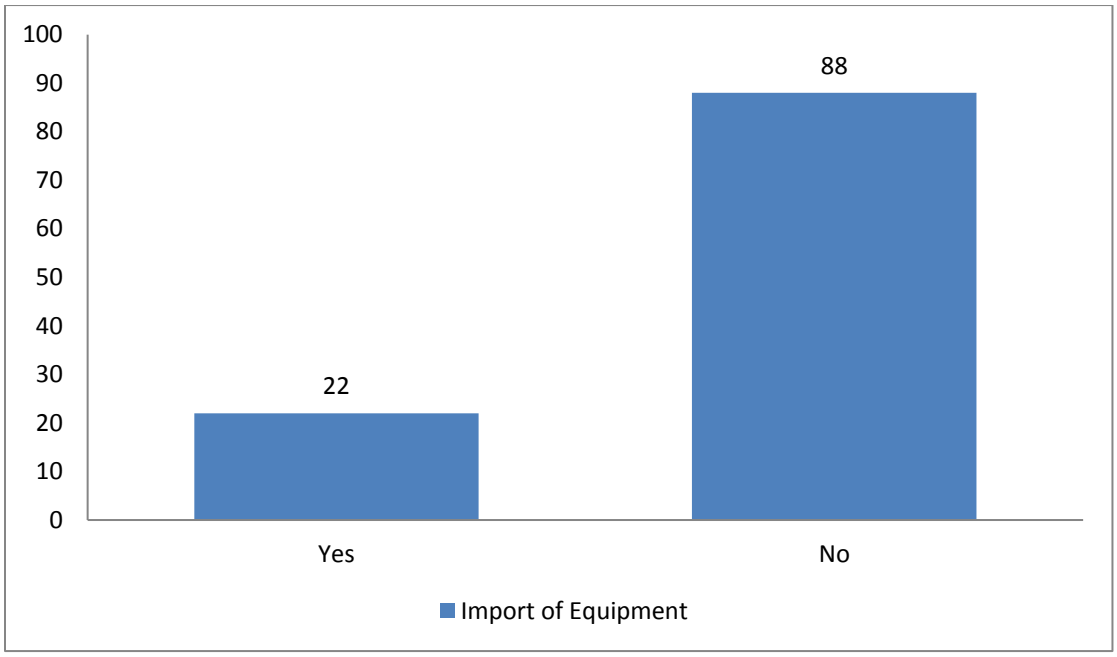


Graph 13 Complex Machine Disposal

Deduction

60 % of the respondents believe that management send it to EME Wksp when a complexed machine needs repair whereas only 20 % think that svcs of a vendor is hired and 20 % thinks both ways.

Q13 Does your hospital imports equipment from abroad?

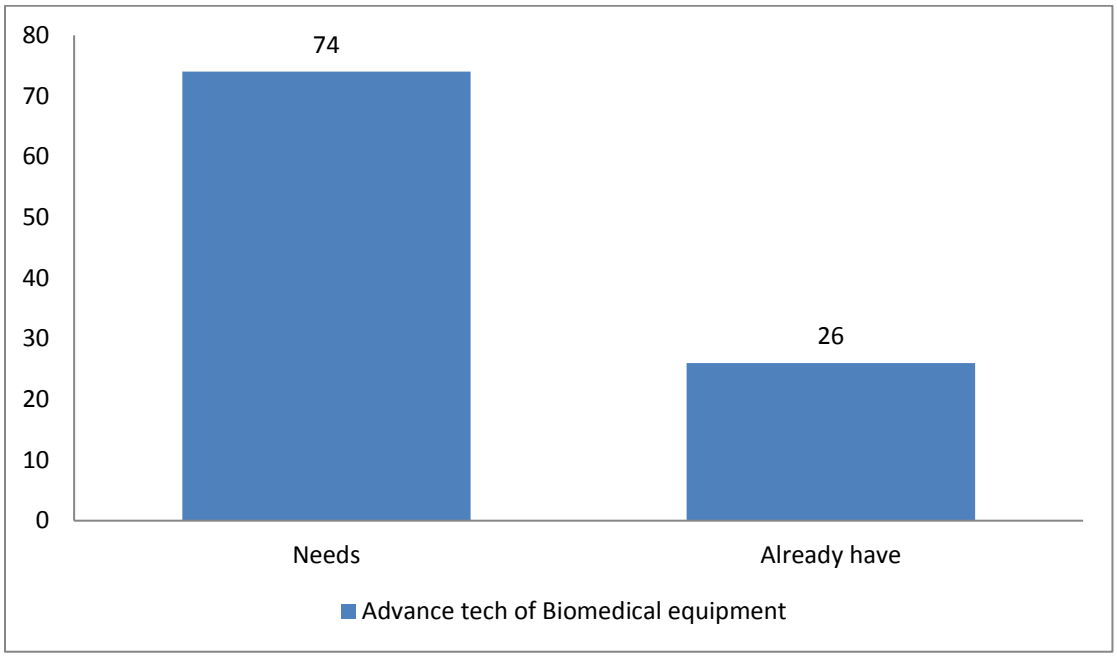


Graph 14 Import of eqpt

Deductions

88 % of the sample states that hospital rely on local manufactured electro medical equipment.

Q14 Does your hospital has all advanced technology of biomedical equipment?

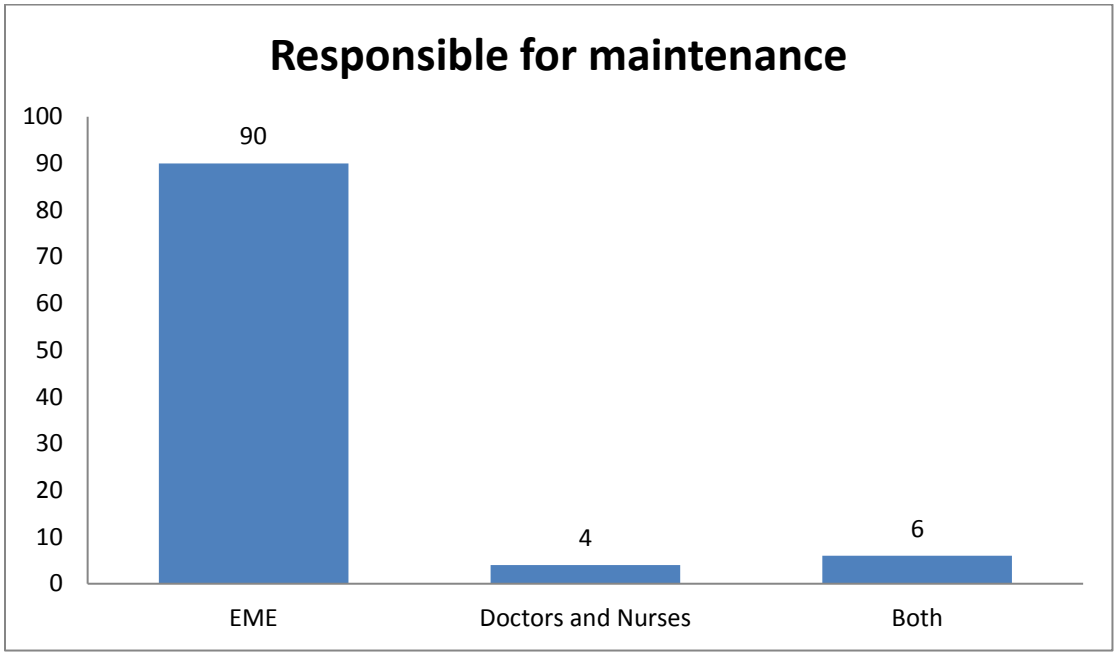


Graph 15 Adv tech of Biomed eqpt

Deduction

74 % of the sample size believe that advance tech is required by the hospitals and only 26 % are against it.

Q15 Who is responsible for repair/ Maintenance of electro medical equipment?

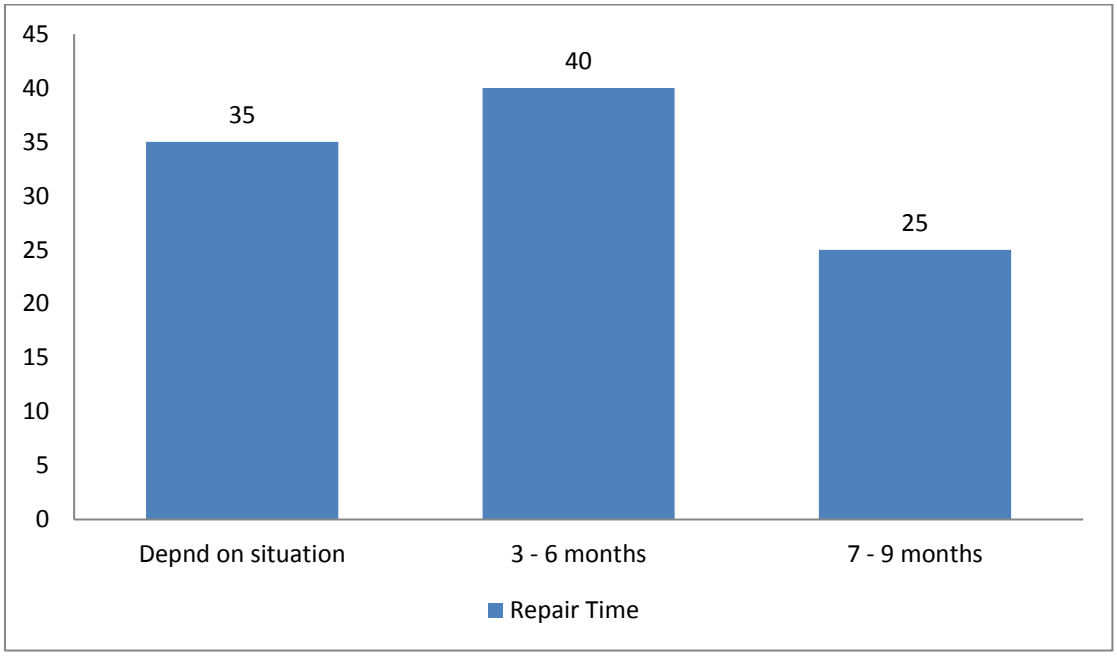


Graph 16 Resp for maint

Deduction

Maximum of the respondent give responsibility of the maintenance of equipment to EME Department whereas only 4 % think it is the responsibility of doctors and nurses. 6 % however gives the responsibility to both.

Q16 How much time repair of a broken equipment takes?

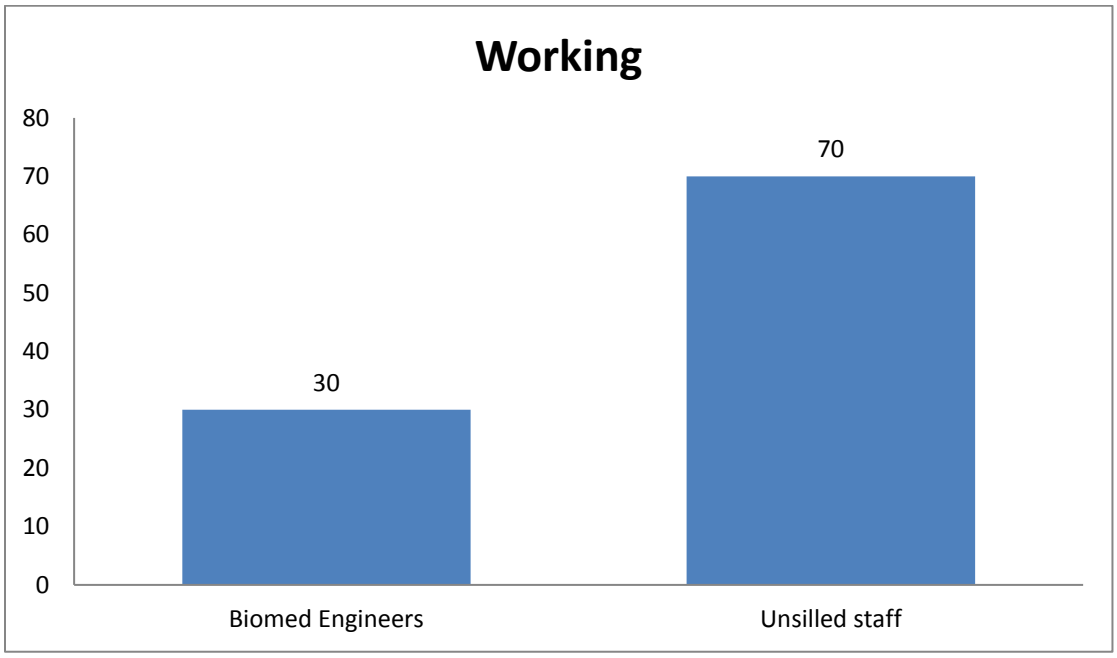


Graph 17 Repair time

Deduction

About 40 % thinks that 3 to 6 months is the time an equipment takes to get repaired but 35 % think that it depends situation to situation. Remaining25 % do not agree with this and thik max 9 months required to get the equipment repaired.

Q17 In military hospitals, professionals' bioengineers are working or unskilled staff?

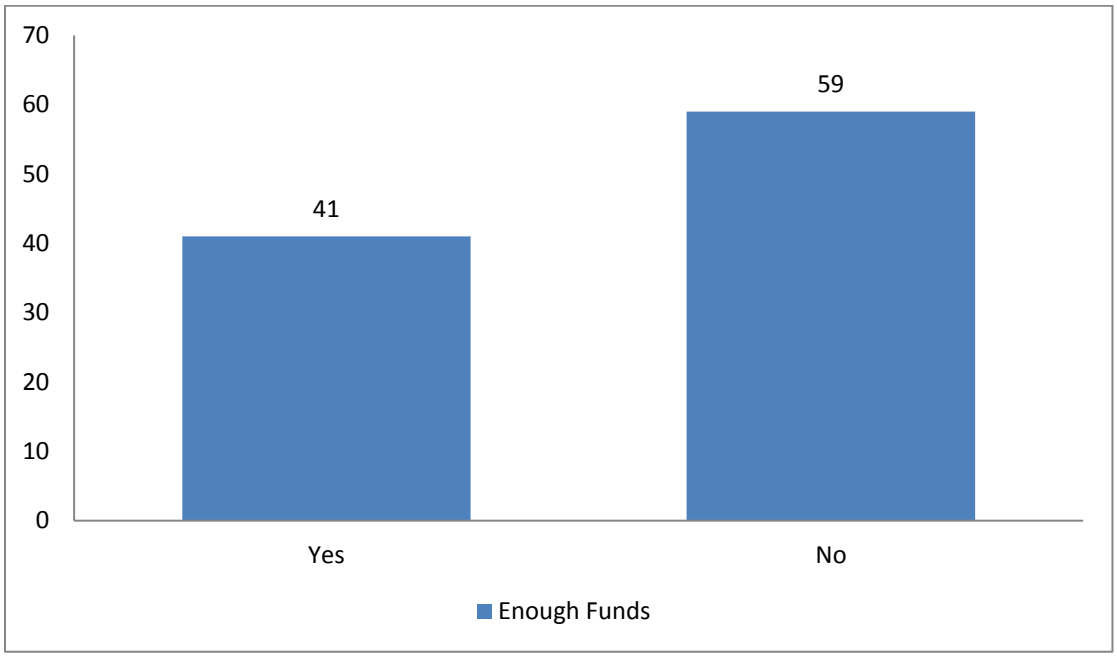


Graph 18 Working

Deduction

70 % of the respondent feel that there are unskilled staff in hospitals for the purpose of maintenance.30 % feel that Biomed engineers are in the hospitals for maintenance of electro medical equipment.

Q18 Does your hospital has enough funds for repair/maintenance of medical equipment?

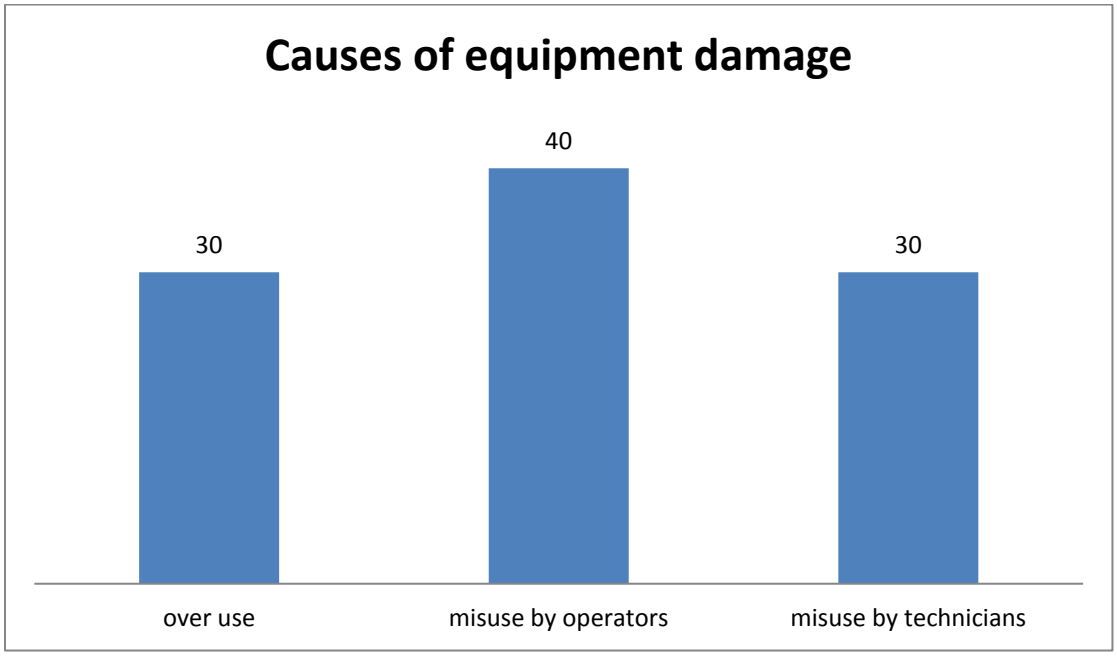


Graph 19 Enough funds

Deductions

59 % of participants feel that enough funds are not there for maintenance of equipment, whereas 41 % are in the favour of sufficient funds existing with hospitals.

Q19 What can damage the electro medical equipment most?



Graph 20 Causes of eqpt damage

Deduction

It is deduced that commonest cause of damage is misuse by operators followed by misuse by technicians as well as over use of equipment.

Q20 If you have suggestions regarding repair/ maintenance of electro medical equipment in better way then do share it

Deductions

On checking the complete response from the questionnaires surveyed, it was deduced that maximum of the respondents (82%) have suggested that there should be posting of a Biomed Offr in the hosp setup for the purpose of repair and maintenance of diagnostic electro medical equipment.

CHAPTER 5

DISCUSSION, RECOMMENDATIONS AND CONCLUSION

55. The results of study were divided into two parts: In Depth Interviews and Questionnaire. Policy makers, EME offrs / staff and HoDs were interviewed in depth whereas Hospital administrators and specs concerned in 3 Hosp settings were surveyed using structured questionnaires. Study was carried out in 3 x military hospitals. The aim of study was to improve the cost effective maintenance of Diagnostic Electro-medical equipment in Military Hospitals. The objectives of the study were to analyze the existing maintenance system of Diagnostic Electro-medical eqpt and to determine the cost effectiveness of maintenance of diagnostic Electro-medical equipment with the help of a structured questionnaire distributed to specs and Health care administrators in selected hospitals.

56. A total population of 56 participants including Health care administrators, HoDs / specs of Pathology & Radiology dept and EME Officers / staff were included in study using convenient sampling method. Universal sampling was used to collect samples. A semi structured questionnaires were used to collect data. A total of 31 respondents in 3 hospitals were sent the questionnaires who were surveyed to assess the existing system of diagnostic EM eqpt and cost effective maintenance of diagnostic EM eqpts. 25 x questionnaires were filled in complete by the specialists, HCAs and EME staff of 3 hospitals. Response rate was 86 % whereas 2 x questionnaires sent were rejected being incomplete and 4 x questionnaires were not received. 14 x HCAs, 8 x specs and 9 x EME Staff were sent questionnaires. Response in complete was received from 13 x HCAs, 6 x specs and 6 x EME Staff. Incomplete response was received from 2 x EME Staff. Data of complete questionnaires (n = 25) was entered into the SPSS and analyzed. A total of 25 x sample size was planned for In depth interviews, out of which 4 were policy makers, 6 were HoDs of Hosps and 15 were EME staff (offrs & techs) from EME Wksps. Out of that sample size, 19 were interviewed with response rate of 76 %. 6 x respondents were not aval for interviews with non

response rate of 24 %. Out of the total of 4 x Policy makers, 3 were approached which included Director EME Dte, Comdt of Base Wksp Quetta and Dir Medical Services, DMS (S). Apart from this, HoDs of Radio and Path dept were also interviewed from 3 Hosp settings as well as 4 x EME Offrs out of 6 and 6 out of 9 x EME staff were interviewed.

57. **Importance of Diagnostic EM eqpt:** As per the Literature review, devices are highly important in personnel's health and to improve patient's treatment. In addition to physical examinations or patients' descriptions of their symptoms, physicians rely on diagnostic instruments to check for signs of diseases. Therefore, the availability and optimal utilization of medical equipment is important in improving the quality of health services. Studies have been carried out around the globe to assess the maintenance management of medical equipment in general.[19] The maintenance of medical equipment is as important as its design and development. Usually, much more money is spent on maintaining a piece of equipment over its life span than on its procurement. Medical equipment is extensively (from 5,000 to more than 10,000 different type) used in all aspects of health services, ranging from prevention, screening, diagnosis, monitoring, and therapeutics to rehabilitation. Nowadays, it is virtually impossible to provide health services without them. Unlike other types of healthcare technologies (i.e., drugs, implants, and disposable products), medical equipment requires maintenance (both scheduled and unscheduled) during its useful life.[20]

58. Policy makers in this study also validate the importance of maintenance of Diagnostic Electro medical equipment which is evident from their fol statements:

a. It is the backbone of a hosp as diagnostic electro medical equipment (Radiology & Pathology) helps to diagnose the illness of the patient and the possible treatment.

b. It is very important not only to diagnose but to know the progress of the disease.

c. It is important to find whether treatment given to the patient is helping the patient and to check about improvement of the disease condition.

d.. Diagnostic EM eqpt maintenance and accurate functioning is directly related to the patient welfare / treatment and outcome of the patient well being.

e. 98 % of the respondents believe that use of damaged diagnostic eqpt due to negligence of lack of repair or maintenance can lead to death of a patient.

f. 65% of the respondents are aware of the advantages and disadvantages of the electro medical equipment in the hospital settings.

g. 88 % participants stated that Health care system is dependant on electro medical equipment for better treatment.

h. Majority (85%) of the applicants state that repair and maintenance on time has a major effect in preventing lost and is not a waste of time.

59. **Examples of Flawed maintenance of Diagnostic EM Eqpt in Military Hosps** Studies have been carried out around the globe to assess the maintenance management of medical equipment in general. In developing countries such as Ghana, significant investments are made for the purchase of these equipment but enough attention is not given to the maintenance and repairs of these equipment. As a result, a lot of these equipment are out of service due to high break down rate.[19] Medical equipment is extensively (from 5,000 to more than 10,000 different type) used in all aspects of health services, ranging from prevention, screening, diagnosis, monitoring, and therapeutics to rehabilitation. Nowadays, it is virtually impossible to provide health services without them. Unlike other types of healthcare technologies (i.e., drugs, implants, and disposable products), medical equipment requires maintenance (both

scheduled and unscheduled) during its useful life. As the sophistication and cost of medical equipment continue to escalate, the complexity and cost of its maintenance have also risen sharply in the last few decades. Studies conducted using data collected from hundreds of acute-care hospitals indicate that on average, each hospital acquired about 15–20 pieces of medical equipment for each staffed bed, which translates into a capital investment of around US$200–400,000/staffed bed. Thus, it is common for a 500-bed hospital to own more than US$100–200 million worth of medical equipment and considerably more if it is affiliated with a medical school. The same studies have indicated that annual medical equipment maintenance and management cost is approximately 1% of the total hospital budget, so a 500-bed hospital spends typically around $5 million/year. [20] Maintenance strategies and reliability engineering techniques have been significantly improved in the last two decades and they have been successfully applied in many industries to improve the performance of equipment maintenance management. Numerous inspection and optimization models are developed and widely used to achieve maintenance excellence, i.e. the balance of performance, risk, resources and cost to reach to an optimal solution. However, most of hospitals and healthcare organizations do not benefit from maintenance excellence as much as other industries. Unnecessary and excessive preventive maintenance could be also loss-making likewise inadequate level of maintenance. The time, which is spent doing the unnecessary preventive maintenance, is robbing an organization of a fraction of one of its most vital resources.[21]

60. Coming back to this study, a no of participants have highlighted the same issues of maint of Diagnostic EM eqpt as mentioned in literature review which is quite evident from the interviews conducted. Policy makers have revealed following:

a. CT Scan machines goes out of order multiple times due to error in voltage supply and batteries life.

b. X ray machine goes out of order and need to be repaired several times.

c. Biochemistry analyzer needs robust maintenance and calibration for accurate results in Path dept.

d. Electrolyte Analyzer an important equipment for Path Lab needs calibration and scientific maintenance.

61. **Existing system of maintenance of Diagnostic EM eqpt:** As per the literature review, Maintenance is characterized by the plurality of tasks that can be different in nature and durations. These tasks are grouped into 5 levels depending on where they can be carried out (in-house vs outside the hospital). Levels 1 and 2 are carried out in-house; level 1 by internal resources and level 2 by internal and/or external resources. Level 3 and 4 are carried out inside or outside by internal or external resources. Level 5 is for rare complex tasks and is carried out by the Original Equipment Manufacturers (OEM). In the biomedical maintenance service, there are different human resources, referred to as staff that include operators and engineers. They are considered competent per equipment and per maintenance level if applicable. For many healthcare institutions in developing countries, contracting maintenance services is inevitable because they often have neither properly trained staff nor the required material to handle the maintenance tasks on their own. Infact, the in-house maintenance needs special tools and test equipment that may not be available or may need additional training costs especially for the staffs who are typically generalist rather than specialist. Three service/support options are possible for maintaining the medical equipment: in-house biomedical engineering service, OEM, and third-party service provider (with or without contracts). Each contract contains several clauses that formalize the relationship between the in-house biomedical service and the service provider (third-party provider or OEM). The estimation of costs for such contracts is a challenging task, but it is really important to the biomedical maintenance service and the service providers (OEM or third party) for economic reason. The possible types of contracts differ from

one country to another. In developing countries, medical equipment maintenance is costly and partially mastered most of the time because it is usually managed by external service contracts. [29]

62. This study also revealed from interviews with HoDs of hospitals and EME Offrs of Workshops regarding the existing system of maintenance of EM eqpt as mentioned in Literature review:

a. Existing system of maintenance and repair of sophisticated and highly modern eqpt is totally dependant on companies with whom agreement is done. Reliance on EME Corps for subject purpose is not possible due to lack of knowledge about the eqpt and staff is not trained enough to handle the eqpt.

b. Mostly maintenance of eqpt at Pathology department is Reagent Rental based. The vendors are responsible to provide the reagent for the tests and will be responsible for all the repair and maintenance of machines like Chemical Analyzer and Haematology Analyzer.

c. Very few items are on EME staff responsibility like microscope, water bath, ultra low refrigerators, Blood bank compressor or other accessories from Pathology department. Items on maintenance load from Radiology department include X ray 500Ma, Xray 1000mA etc.

d. Major machines like CT Scan, MRI and Digital X rays of different companies like Toshiba, Siemens, GE, Aloka Japan are dependant on vendors for maintenance.

e. Every machine like MRI, Fluroscopy, CT Scan, Mammography, Digital Radiography etc have a unique and separate operating manual/ system for which training of staff needs to be specific and moreover standardized eqpt should be procured all over Pakistan

with specific training and capacity building of EME staff in such diverse machines.

f. From the time of installation and being operational esp highly sophisticated machines, any untrained staff can lead to even more problem and further financial burden to the organization.

g. Renowned companies have their own bioengineering departments and vendor based long term agreements for repair and maintenance of EM eqpt is the need of the hour.

h. There is requirement of expert Biomedical engineers who can deal with repair and maintenance of Diagnostic machines in Radiology department like MRI, CT Scan, Digital X rays, Doppler etc.

i. Need of the hour is to enhance the capacity of EME staff through increasing Human resource and enhancing the technical capacity.

j. Training of EME offrs and staff should be at par with Bio Med engrs of reputed EM manufacturing firms. Training should include local and international modules.

k. In the era of scientific evolution there are highly sophisticated and artificial Intelligence based modern EM eqpt which cannot be repaired / maintained by orthodox methods and need to be addressed by highly professional and skilled staff.

l. Nowadays all the international and few national firms have exclusive biomedical engineers to deal with the issues of repair and maintenance of EM eqpt. EME offrs have to do 3 months Special Eqpt repair Course (SERC) but the course is not sufficient to handle the highly sophisticated equipment available in hospitals.

m. 79 % of the respondents are of the view that electro medical equipment in military hospitals is regularly inspected by skilled team. Only 21 % are against it.

n. Max respondents state that the hosp equipment is standardized whereas only 36 % are against it.

o. 40 % of the respondents are of view that complex devices are difficult to repair whereas 30 % think it is the other way. Moreover 30 % state that both simple and complex devices are difficult to repair.

p. 78 % of the participants are of view that Regulations are followed by the hosps regarding diagnostic equipment whereas the remaining are against it.

q. 60 % of the respondents believe that management send it to EME Wksp when a complexed machine needs repair whereas only 20 % think that svcs of a vendor is hired and 20 % thinks both ways.

r. 74 % of the sample size believe that advance tech is required by the hospitals and only 26 % are against it.

s. Maximum of the respondent give responsibility of the maintenance of equipment to EME Department whereas only 4 % think it is the responsibility of doctors and nurses. 6 % however gives the responsibility to both.

t. About 40 % thinks that 3 to 6 months is the time an equipment takes to get repaired but 35 % think that it depends situation to situation. Remaining25 % do not agree with this and thik max 9 months required to get the equipment repaired.

u. 70 % of the respondent feel that there are unskilled staff in hospitals for the purpose of maintenance.30 % feel that Biomed engineers are in the hospitals for maintenance of electro medical equipment.

63. **Major Flaws in maintenance of Diagnostic EM Eqpt :** Medical devices range from relatively simple to highly complex. For example, manual

devices to measure blood pressure (sphygmomanometers) have only few components and are easily repaired, assuming that parts, calibration instruments and basic hand tools are available. At the other extreme are advanced imaging and laboratory devices. Repair of a magnetic resonance imaging system requires extensive financial, physical and human resources. [23] Resources needed for maintenance are difficult to project. This requires a maintenance history, calculations of the staff requirement and knowledge of when a piece of equipment might fail. Maintenance also requires appropriate staff skills, education and experience.[24] Developing the human resources necessary to operate an effective maintenance programme is a slow and steady process. The first step is to identify the number and type of staff that a facility (or group of facilities) requires. For example, a small health-care facility may have a single technician who provides services for a small inventory of relatively simple equipment. On the other hand, a clinical engineering department serving a large number of health-care facilities, especially when those facilities include higher level hospitals, will have a large number of technical and management personnel, including specialists in particular technologies, with multiple levels of supervision. The management of medical equipment maintenance is a critical problem for the safety and cost of medical devices, as well as for the achievement of medical device system objectives. A systematic assessment of the literature reveals that there are a number of important elements that influence the management of medical equipment maintenance. Seven types of factors have been identified, including quality control and management; inspection; information bank; education; resources; and service. Quality control and management are among the factors identified. These categories are divided according to concerns such as the medical equipment management cycle, which begins with the procurement of equipment and continues with risk management, management of spare parts, and maintenance priorities, as well as a variety of maintenance techniques, among others.[26]

64. On interviewing the Policy makers for assessing the factors of cost effective maintenance of diagnostic EM equipment, following factors were deduced to be important for the maintenance:

a. Highlighting the reasons for faulty maintenance, it was noted that power fluctuations are playing a major role and secondly preventive maintenance is done due to lack of knowledge about the latest machines. Firms like Seimens, Toshiba and Philips provide the system of power generation along with the eqpt to avoid repair frequently which is very expensive.

b. Maintenance of diagnostic EM eqpt needs a robust system including trained officers from EME Corps, special training of Biomedical engineers from EME

c. There is acute shortage of trained offrs and staff from EME Corps for maintenance of diagnostic EM eqpt.

d. The EME wksps has capacity issues, not able to cope with the advanced and sophisticated EM eqpt held at Military hospitals.

e. Vendor based maintenance agreements for long duration for maintenance of highly sophisticated and expensive Eqpt.

f. Max participants highlighted long repair time as the major problem faced by hosp during maintenance whereas most of the respondents were of the view that insufficient funds as well as lack of skilled staff also poses problem.

g. 59 % of participants feel that enough funds are not there for maintenance of equipment, whereas 41 % are in the favour of sufficient funds existing with hospitals.

h. It is deduced that commonest cause of damage is misuse by operators followed by misuse by technicians as well as over use of equipment.

65. **Suggestions for maintenance of diagnostic EM Eqpt:** Following was suggested:

a. Direct induction of Bio medical engineers in Pak Army as officers and making a new stream is one important measure for cost effective maintenance of EM eqpt.

b. Reagent rental based agreement made with the companies or vendors for Diagnostic EM eqpt, which will be a cost effective step towards the maintenance of the equipment. As a result of this vendors will provide the machine with all the kits / reagents as well as maintenance and repair services when required.

c. Machines which do not require reagents or kits come under the repair / maintenance agreement from the service provider on long term basis.

d. Outsourcing the repair and maintenance of EM eqpt to well reputed firms should be done with repair and maintenance of all Diagnostic EM eqpt of the hospital. It will be efficient and also cost effective with prompt and timely response from the service provider.

e. Exclusive training of the EME offrs and EME staff both inland and abroad if they have to look after the repair and maintenance of EM eqpt of hospital can be a possibility but it will be time demanding.

f. Cost-effective maintenance can be achieved through training on specific machines, which are procured throughout Army, which will built readiness among the EME Corps for maintenance of latest machines. Staff trained by this mechanism to stay at one station for 5 years and then can be posted with the one who deals with machines of same category.

g. Long term Vendor rental agreements should be done so that financial burden can be reduced, as EME Corps will take a long time to address their issues in terms of capacity enhancement.

h. There is a need to purchase machines of same specifications and company so that EME is trained on those specified machines to built their capacity for cost effective maintenance.

i. Training should include software as well as hardware training.

j. Incentives in the form of promotions, postings and special allowances for EME Corps will help in capacity building.

k. On checking the complete response from the questionnaires surveyed, it was deduced that maximum of the respondents (82%) have suggested that there should be posting of a Biomed Offr in the hosp setup for the purpose of repair and maintenance of diagnostic electro medical equipment.

66. **Limitations of the Study** The major limitations of the study were as under: -

a. This study was limited to 3 x military hospitals (1 x each Class A, B and D type) in the country and not included any Class C military hospital .

b. The study was limited to military hospitals only and was not compared with any government or public hospital in the country.

c. Further the study was not compared with the international hospitals for a better comparison.

d. There were Covid restrictions in the country which disturbed the plan of study and time was not enough to compile the results comprehensively.

e. This study focused only the cost effective maintenance of diagnostic EM equipment being followed in military hospitals.

Important aspect of equipment wise instructions of effective maintenance may be explored if the study is conducted in future.

67. **Strengths** Study was conducted in Healthcare facilities of Army including hospital of each category i.e. class A, B and D military hospitals which are far from the centre of excellence. Difficulties highlighted in the region may be of considerable help for improving the maintenance procedures in Army.

68. **Recommendations**

a. Reagent rental based agreements to be made with the renowned companies or vendors for Diagnostic EM eqpt, which will be a cost effective step towards the maintenance of the equipment. As a result of this vendors will provide the machine with all the kits / reagents as well as maintenance and repair services when required.

b. Machines which do not require reagents or kits must have agreements other than the warranty period for cost-effective repair / maintenance from the service provider on long term basis.

c. Outsourcing the repair and maintenance of EM eqpt to well reputed firms should be done centrally with repair and maintenance of all Diagnostic EM eqpt of the hospital. It will be efficient and also cost effective with prompt and timely response from the service provider.

d. Standardization of the eqpt should be given the top most priority and for this purpose master planning to be done after necessary coordination with all the stakeholders so that equipment of same specifications and company are procured and then in next step training on the repair and maintenance of equipment is carried out. It will result in improving the maintenance system of EME with reduction in dependence on vendors.

e. Induction of the qualified EME Officers in the Army with experience at par of Biomed Engineers will be an important step towards the capacity building of Human resource for maintenance of EM eqpt.

f. Recruitment of Civ qualified Biomed technicians with diploma or engineering qualification will also boost the maintenance process of EM Eqpt.

g. Already available EME Offrs may be offered courses at local and international well reputed institutes to improve their qualification and boosting their confidence level in maint and repair of EM eqpt.

h. Posting of Biomed Offrs and Techs at Class A , B and C Hosps will enhance the maint procedures with less dependency on vendors.

i. Procurement of the spare parts which are required frequently along with availability of the test tools and eqpts for the purpose of repair at Hosp repair shops will boost the repair and maintenance of Diagnostic EM eqpt.

j. Cost-effective maintenance can be achieved through training on specific machines which are procured throughout Army which will built readiness among the EME Corps for maintenance of latest machines. Staff trained by this mechanism to stay at one station for 5 years and then can be posted with the one who deals with machines of same category.

k. Trg of EME staff both inland and abroad if they have to look after the repair and maintenance of EM eqpt of hospital can be a possibility but it will be time demanding.

j. All EME staff should focus on software as well as hardware training.

k. Preventive maintenance culture should be introduced in the hospitals with all the staff trained on the importance of maintenance of EM Eqpt.

l. Measures should be taken to address the issues of power fluctuations. Use of batteries and UPSs should be ensured in all expensive and critical equipment.

m. Funds to be planned and demanded for maintenance and purchase of generators and UPSs to avoid damage to EM Eqpt.

69. **Conclusion**

Diagnostic EM eqpt maintenance and accurate functioning is directly related to the patient welfare / treatment and outcome of the patient well being. Existing system of maintenance and repair of sophisticated and highly modern eqpt is totally dependant on companies with whom agreement is done. Reliance on EME Corps for subject purpose is not possible due to lack of knowledge about the eqpt and staff is not trained enough to handle the eqpt. There is acute shortage of trained offrs and staff from EME Corps for maintenance of diagnostic EM eqpt. Outsourcing the repair and maintenance of EM eqpt to well reputed firms should be done with repair and maintenance of all Diagnostic EM eqpt of the hospital. It will be efficient and also cost effective with prompt and timely response from the service provider. Need of the hour is to enhance the capacity of EME staff through increasing Human resource and enhancing the technical capacity. Cost-effective maintenance can be achieved through training on specific machines which are procured throughout Army which will built readiness among the EME Corps for maintenance of latest machines. Staff trained to stay at one station for 5 years and then can be posted with the one who deals with machines of same category. Induction of the qualified EME Officers in the Army with experience at par of Biomed Engineers will be an important step towards the capacity building of Human resource for maintenance of EM eqpt.

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Annexure ‘A

INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL FORM

Annexure 'B

INFORMED CONSENT FORM
COST EFFECTIVE MAINTENANCE OF DIAGNOSTIC ELECTRO MEDICAL EQUIPMENT IN MILITARY HOSPITALS - A CRITICAL ANALYSIS

Introduction

1. You are requested to participate in a study about the Cost-Effective Maintenance of Diagnostic Electro Medical Equipment In Military Hospitals - A Critical Analysis. Your contribution will require responding to the attached questionnaire. You are likely to require 10-15 minutes to indicate your answers.

Purpose of the study

2. To improve the cost-effective maintenance of Diagnostic Electro-medical equipment in Military Hospitals

Confidentiality and Right of Refusal

3. Your responses to the questionnaire will remain confidential, and your name will not be associated with the research findings. Your identity will not be disclosed. The decision to participate in this study is entirely up to you. You may refuse to take part or may withdraw from the study at any time.

Additional Information

4. Please do not hesitate to ask anything before participating or during the study. I, Lt Col Muhammad Kamran, may be contacted by phone on 0345-5120195 and my email address is dr_kamran75@yahoo.com.

Consent

5. Your signatures below confirm that you have read and understood the information provided in this form and that you are willing to participate in the study.

Date: Signature

Name (Optional)

Annexure 'C'

IN DEPTH INTERVIEW OUTLINE

Required Information

Rank _____ Name _____ Unit _____

Gender _____ Age _____

Please answer the following questions as accurately as possible.

Areas for Discussion

1. What is the importance of maintenance of Diagnostic Medical Equipment?
2. Cite any example where you felt that maintenance of your hospital's equipment is flawed.
3. What are the major flaws in the maintenance of Diagnostic Electro Medical Equipment?
4. Do you have any suggestions for the improvement of Repair/Maintenance of Diagnostic Electro Medical Equipment?

Annexure 'D'

QUESTIONNAIRE

Required Information

Rank _____ Name _____ Unit _____

Gender _____ Age _____

Please answer the following questions as accurately as possible.

1. What can be the problems you might have to face while repair/ maintenance of medical equipment?
   a. Insufficient funds
   b. Long-time procedure of repair
   c. Lack of skilled staff
   d. All of the above
2. Is it risky to use a damaged diagnostic equipment on patient due to negligence regarding repair/ maintenance?
   a. It can lead to death of patient
   b. It can not do harm to patient.
3. Is electro medical equipment held in military hospitals inspected regularly by skilled team?
   a. It is being inspected
   b. It is not getting inspected.
4. Are you aware of advantages and disadvantages of equipment held in your hospital?
   a. Yes, I am aware
   b. No I am not
5. Electro medical equipment you currently have in your hospital is standardised?
   a. All equipment is standardised
   b. All equipment is not standardised

6. If equipment is being manufactured in own country then it is costly for government?
    a. No rather its beneficial for government.
    b. It can be costly or cannot be depending upon situation.
    c. It is very costly for government.
7. Is it right that health care system is dependent on electro medical equipment for better treatment?
    a. It is wrong
    b. It is absolutely right.
8. Simple devices or complexed devices; which one is hard to repair/maintain?
    a. Simple devices
    b. Complexed devices.
    c. Both
9. Regulations regarding electro medical equipment are followed in your hospital?
    a. Regulations are followed
    b. Regulations are not followed
10. Repair/ maintenance on time period of equipment can be beneficial or not?
    a. It can not prevent the wear and tear of equipment
    b. It prevents major loss.
11. Which repair/ maintenance of medical equipment is being done in your hospital?
    a. Repair or corrective maintenance
    b. Planned or scheduled maintenance
    c. Both
12. What your management do when a complexed machine needs repair?
    a. Hires vendor companies
    b. Keep it in EME workshop

c. Both depends on situation

13. Does your hospital imports equipment from abroad?
    a. Yes, equipment may be demanded through proper channel
    b. No we rely on equipment already held
14. Does your hospital has all advanced technology of biomedical equipment?
    a. Hospital needs to have advanced technology
    b. Hospital already has all advanced technology.
15. Who is responsible for repair/ Maintenance of electro medical equipment?
    a. EME Department
    b. Doctors and nurses
    c. Both of them
16. How much time repair of a broken equipment takes?
    a. It depends on situation
    b. Minor repair takes 1-3 months
    c. Major repair takes 6-9 months
17. In military hospitals, professionals' bioengineers are working or unskilled staff?
    a. Biomedical engineers
    b. Unskilled staff
18. Does your hospital has enough funds for repair/maintenance of medical equipment?
    a. Hospital always in need of more funds
    b. Hospital has enough funds for repair/ maintenance of EM Eqpt
19. What can damage the electro medical equipment most?
    a. Over usage
    b. Misuse by operators
    c. Misuse by technicians

20. If you have suggestions regarding repair/ maintenance of electro medical equipment in better way then do share it

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Annexure 'E'

TIMELINE OF RESEARCH PROJECT

Activities	2020						2021			)20			
	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
Approval of Synopsis													
Refining Literature Search													
Data Collection													
Data Analysis													
Report Writing													
Printing Report													
Thesis Defense													

Annexure 'F'

ESTIMATED BUDGET FOR RESEARCH PROJECT

Serial No	Budget Head	Total (Rs.)
1	Transport	10000
2	Stationary	30000
3	Media/Telephone/Internet	20000
4	Food and Refreshment	15000
5	Miscellaneous	5000
6	Accommodation / Stay	10000
7	Personnel	10000
	Total	**100,000**