

MODEL DEVELOPMENT TO IMPROVE THE PREDICTIVE MAINTENANCE RELIABILITY OF MEDICAL DEVICES

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Abstract. Medical devices are essential in healthcare, and their availability and reliability are crucial for ensuring high-quality service. In most Saudi hospitals, maintenance schedules for these devices follow manufacturer recommendations, which often do not account for Saudi Arabia's unique climate and lifestyle. This research introduces a mathematical model to optimize maintenance schedules tailored to Saudi conditions. Three governmental hospitals in Riyadh, Jeddah, and Madinah were selected for a case study. The research developed the Medical Equipment Maintenance Prioritization Factor (MEMPF) model to enhance maintenance schedules. This model uses ten parameters: device function, failure consequence risk, maintenance complexity, device age, utilization rate, failure frequency, maintenance/repair cost, reason of downtime, backup availability, and downtime duration. These parameters were weighted based on their importance and tested on a dataset of 3,640 medical devices from 54 healthcare sections. The outcomes defined maintenance priorities for each device based on the MEMPF value, categorizing them into high, moderate, low, and very low priority. Implementing this model in the case study hospitals could reduce maintenance costs by 36% over ten years.

Keywords: maintenance management, predictive maintenance, medical devices, predictive maintenance model

OPRACOWANIE MODELU POPRAWY NIEZAWODNOŚCI KONSERWACJI PREDYKCYJNEJ URZĄDZEŃ MEDYCZNYCH

Streszczenie. Urządzenia medyczne są niezbędne w opiece zdrowotnej, a ich dostępność i niezawodność mają kluczowe znaczenie dla zapewnienia wysokiej jakości usług. W większości saudyjskich szpitali harmonogramy konserwacji tych urządzeń są zgodne z zaleceniami producenta, które często nie uwzględniają unikalnego klimatu i stylu życia Arabii Saudyjskiej. Niniejsze badania wprowadzają model matematyczny do optymalizacji harmonogramów konserwacji dostosowanych do warunków panujących w Arabii Saudyjskiej. Do studium przypadku wybrano trzy szpitale rządowe w Rijadzie, Jeddah i Madinah. W ramach badań opracowano model MEMPF (Medical Equipment Maintenance Prioritization Factor) w celu ulepszenia harmonogramów konserwacji. Model ten wykorzystuje dziesięć parametrów: funkcję urządzenia, ryzyko awarii, złożoność konserwacji, wiek urządzenia, wskaźnik wykorzystania, częstotliwość awarii, koszt konserwacji/naprawy, przyczynę przestoju, dostępność urządzeń zastępczych i czas trwania przestoju. Parametry te zostały zważone w oparciu o ich znaczenie i przetestowane na zbiorze danych obejmującym 3640 urządzeń medycznych z 54 działów opieki zdrowotnej. Wyniki zdefiniowały priorytety konserwacji dla każdego urządzenia w oparciu o wartość MEMPF, kategoryzując je na wysoki, umiarkowany, niski i bardzo niski priorytet. Wdrożenie tego modelu w szpitalach objętych studium przypadku mogłoby obniżyć koszty konserwacji o 36% w ciągu dziesięciu lat.

Słowa kluczowe: zarządzanie konserwacją, konserwacja predykcyjna, urządzenia medyczne, model konserwacji predykcyjnej

Introduction

Medical devices are essential elements in healthcare facilities. They can be defined as devices used for the prevention, diagnosis, or treatment of illness in these settings. According to the World Health Organization (WHO), medical devices encompass any item, tool, instrument, or machine utilized in the treatment, diagnosis, or prevention of disease, as well as in the discovery, measurement, or correction of the body's functions for medical purposes [5]. Medical devices significantly impact the quality and effectiveness of healthcare services. Therefore, every healthcare facility strives to ensure that proper maintenance is provided for their medical devices. WHO categorizes the maintenance of medical devices into two main types: inspection & preventive maintenance (IPM) and corrective maintenance (CM) [5]. IPM involves performing all required activities to prevent medical device failures, while CM entails implementing the appropriate actions to repair devices after they have failed. Healthcare organizations must develop effective maintenance planning to meet their objectives. The complexity of the maintenance strategy depends on the size and services provided by the healthcare facility, which can be measured by the number of beds available in the hospital.

Saudi Arabia places significant emphasis on developing healthcare facilities and services. One of the major goals of Vision 2030 is to enhance the healthcare sector, making it more comprehensive and effective than before [13]. As a first step, the Ministry of Health has launched the SEHA Virtual Hospital, which offers telehealth services in more than 30 specialized areas [8]. The SEHA virtual program employs top consultants and practitioners in the field, serving over 400,000 beneficiaries annually. In the last decade, Saudi Arabia invested more than SAR 7 trillion to develop the healthcare sector. In 2023, the Ministry of Health allocated a budget of SAR 80.8 billion, representing 7% of the total government budget [14].

A maintenance strategy refers to the systematic approach that an organization follows to ensure the reliability and performance of its assets. It provides outlines, processes, and activities that guide maintenance procedures within the organization. Additionally, it includes regular inspection, monitoring, and control of assets to reduce failures and extend their lifespan. The goal of a maintenance strategy is to reduce costs and downtime by maximizing the reliability and performance of assets. Common maintenance strategies include reliability-centered maintenance, condition-based maintenance, predictive maintenance, reactive maintenance, and preventive maintenance. Implementing the appropriate maintenance strategy can enhance the reliability and availability of organizational assets, optimize maintenance costs, and extend their lifecycle [9].

Selecting the right maintenance strategy requires consideration of various factors. One useful method is the maintenance strategy matrix, which helps choose a suitable strategy based on the cost of equipment failure and the ease of monitoring the equipment. An alternative approach to formulating an effective maintenance strategy involves several steps: critically assessing assets, developing maintenance objectives, evaluating available resources, assessing the condition and age of assets, analyzing failure history, evaluating cost implications, considering industry benchmarks, and seeking expert opinions. Maintenance strategies require continuous improvement and periodic review to ensure their effectiveness [1].

Healthcare organizations face a significant challenge in defining a maintenance strategy that maximizes the efficiency of medical equipment while minimizing total costs. Masmoudi et al. [12] developed a procedure for selecting the maintenance strategy for medical equipment, including whether to insource or outsource maintenance and identifying the appropriate contract type. There are four contract types: type A, which includes labor and spare parts; type B, which includes spare parts only; type C,



where the contractor performs corrective maintenance only; and type D, where the contractor performs all types of maintenance.

Multiple Criteria Decision Making (MCDM) is a valuable tool for selecting the appropriate maintenance policy, which is often a challenging task. Goossens et al. [2] assessed the use of the Analytic Hierarchy Process (AHP) for naval maintenance policy selection and investigated the goals and criteria of MCDM. AHP, developed by Saaty in the 1970s, organizes criteria in a hierarchical structure [2]. It consists of four steps: defining the problem, structuring the decision goal hierarchically from the highest to the lowest level, obtaining priorities by constructing a set of pairwise comparisons, and weighting the priorities to identify the alternative at the bottom level. Examples of maintenance policies include calendar-time based maintenance, failure-based maintenance, use-severity based maintenance, use-based maintenance, condition-based maintenance, and load-based maintenance. According to Goossens et al. [2], AHP is an appropriate decision-making tool for selecting effective maintenance strategies in naval contexts.

Selecting the appropriate type of medical equipment is another complex decision. Gören et al. [3] propose a new model to assist decision-makers in healthcare organizations in selecting suitable medical imaging systems based on information axioms.

One important method used to assess the performance of medical equipment is performance testing, a crucial step in ensuring safe procedures for both staff and patients. Performance testing measures the accuracy of medical equipment through reference tests and calibration against known accuracy standards [15]. The aim of performance testing is to determine whether medical equipment functions at the required level according to international standards. Sezdi et al. [15] developed a web-based application known as BMED to analyze the performance of medical equipment and tested the application's feasibility using performance test results. The application was based on the performance measurement results of 1,553 medical devices, and it found that 1,337 devices performed at an acceptable level while 216 did not. This application is designed to help healthcare organizations reduce breakdowns and acquire the right medical equipment. Additionally, it provides easy access for healthcare practitioners via smartphones or computers. The BMED application offers the opportunity to enhance the quality of healthcare services through the analysis of medical equipment performance. Furthermore, Saleh et al. [7] developed a Quality Function Deployment (QFD) model to prioritize maintenance activities for medical equipment based on influential criteria. QFD is a tool of total quality management that integrates customer requirements and specifications to establish appropriate technical requirements.

Failures of medical devices are common and can result from poor maintenance planning, excessive use, environmental issues, improper storage, and random failures [10]. The maintenance of medical devices is typically performed at fixed intervals and includes tasks such as inspection, calibration, and the replacement of consumable parts. Furthermore, maintenance is performed based on manufacturer recommendations, which outline procedures and frequency. Consequently, Saudi Arabia faces a shortage of qualified expertise in medical device maintenance, particularly in the Medina region. Most healthcare facilities either rely on a third-party contractor or the manufacturers themselves for scheduled maintenance of medical devices. These two solutions aim to compensate for the lack of qualified experts in the field. As a result, this situation has increased maintenance costs and affected the quality of services provided. The global medical devices outsourcing market reached over USD 116.7 billion in 2022 [4], and it is projected to grow to USD 352.3 billion in 2023.

Healthcare facilities in Saudi Arabia can adjust maintenance frequency based on local environmental factors and usage. Thus, developing unique predictive maintenance schedules could lead to cost optimization, reduced downtime, and improved service quality across healthcare facilities in Saudi Arabia. Three governmental hospitals located in Riyadh, Jeddah, and Madinah

have been selected for a case study. The Riyadh hospital was established in 1982 and has a total capacity of 1,973 beds, while the Jeddah hospital, also founded in 1982, has 709 beds. The Madinah hospital was established in 2007 and has 215 beds. Healthcare Technology Management (HTM) is responsible for all maintenance tasks related to medical devices. Its primary focus is to ensure that all medical devices remain operational without interrupting hospital services. HTM comprises biomedical engineers and technicians who carry out the necessary maintenance tasks, as well as manage the procurement of new devices and any modifications within the hospital premises.

Based on existing literature regarding improvements in medical device maintenance, three areas have not been sufficiently explored. First, there is a limited number of published papers addressing predictive maintenance improvements for medical devices, and none have focused on healthcare facilities in Saudi Arabia. Second, most published articles in this area center on enhancing maintenance and risk management for healthcare facilities, neglecting the significant issue of medical device maintenance. Lastly, random interviews conducted with biomedical engineers in Saudi Arabia indicate a pressing need for further research to assist healthcare technology management in optimizing costs and resources within the medical device maintenance process.

The primary objectives of this study are to achieve three key goals. First, to establish an accurate model to improve predictive maintenance of medical devices. Second, to enhance the reliability and performance of medical devices by identifying necessary maintenance interventions. Finally, to optimize maintenance costs by modifying current maintenance schedules.

1. Mathematical model

The proposed mathematical model is based on qualitative and quantitative evaluations. The selected variables will represent the qualitative parameters. The parameter selection process is an important step in establishing an accurate model that improves the predictive maintenance of medical devices. Ten input parameters were selected based on findings from the literature to be utilized in the model. The parameters were developed by identifying common themes established in previous studies to ensure that essential aspects of the medical devices were taken into account. The suggested parameters were considered by thoroughly examining all significant aspects in establishing the model. By incorporating the proposed combination of parameters, a precise and accurate assessment can be developed, leading to a predictive model that aligns with national standards. Figure 1 represents the selected parameters and their weighting factors (R). This model is built on the importance, priorities, and usage of the device.

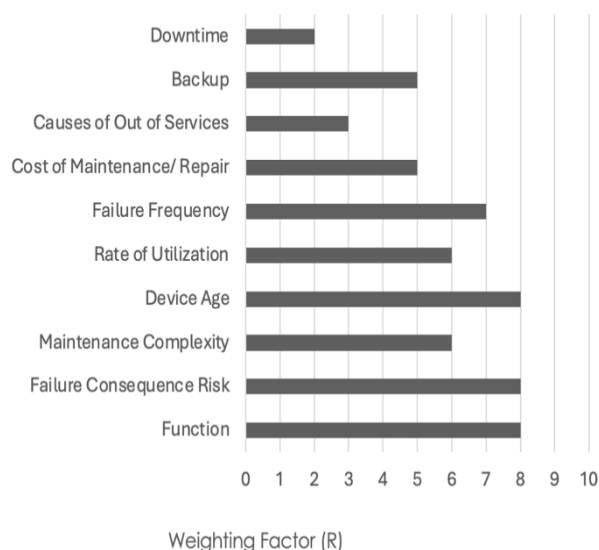


Fig. 1. Model qualitative parameters

1.1. Model parameters

Function

The primary purpose or intended use of medical device known as function [10]. The function of medical devices includes five criteria, as shown in Table 1.

Table 1. Criteria importance levels for function

Criteria	Importance level (S)
Life support	5
Therapeutic	4
Diagnostic	3
Analytical	2
Miscellaneous	1

Failure consequence risk

Failure consequence risk refers to the adverse effect or impact that may arise from the failure of medical device. It is a measure of a device severity of the consequence that can occur if the device fails to perform its function. Under failure consequence risk, five criteria along with their corresponding importance levels are considered, as outlined in Table 2.

Table 2. Criteria importance levels for failure consequence risk

Criteria	Importance level (S)
Patient death	5
Patient-staff injury	4
Wrong diagnosis	3
Treatment delays	2
No significant risk	1

Maintenance complexity

Maintenance complexity refers to the degree of difficulty involved in carrying out maintenance procedures [10]. Three criteria, along with their corresponding importance levels outlined in Table 3, are taken into account, including major maintenance tasks, moderate maintenance tasks, and minor maintenance tasks.

Table 3. Criteria importance levels for maintenance complexity

Criteria	Importance level (S)
Major	5
Moderate	3
Minor	1

Device age

The classification of medical devices based on age and importance level, as depicted in table 4, includes the following categories: devices over 10 years old, 7–10 years old, 5–6 years old, 3–4 years old, and 1–2 years old.

Table 4. Criteria importance levels for device age

Criteria	Importance level (S)
Over 10 years	5
7–10 years	4
5–6 years	3
3–4 years	2
1–2 years	1

Rate of utilization

Rate of utilization refers to the extent to which the device is being used at a specific period of time to perform its intended function. It can be expressed in various ways depend on the context. Rate of utilization of medical device will be indicated by the following categories: daily, weekly, twice monthly, monthly, and other, with each assigned an importance level as illustrated in table 5.

Table 5. Criteria importance levels for rate of utilization

Criteria	Importance level (S)
Daily	5
Weekly	4
Twice Monthly	3
Monthly	2
Others	1

Failure frequency

Failure frequency refers to the number of times that medical device unable to perform its function. Device failure can be occurred due to various reasons such as manufacturer defects, electrical problem, physical damage, or other external factors. Medical device will be categorized based on the total number of failures in the past ten years and their importance level is detailed in table 6, including the following classifications: over 10 times, 8–10 times, 5–7 times, 2–4 times, 1 time, and no failures.

Table 6. Criteria importance levels for failure frequency

Criteria	Importance level (S)
Over 10 times	5
8–10 times	4
5–7 times	3
2–4 times	2
1 time	1
No failures	0

Cost of maintenance / repair

Cost of maintenance / repair refer to the overall cost incurred to maintain and repair the medical device that is not functioning properly. The maintenance and repair costs involves costs of spare parts, labors, and other related costs [6]. The parameter includes three categories high, medium, and low costs along with their corresponding importance levels as indicated in Table 7.

Table 7. Criteria importance levels for cost of maintenance / repair

Criteria	Importance level (S)
High (More than 10% of purchase cost)	5
Medium (5%–10% of purchase cost)	3
Low (Less than 5% of purchase cost)	1

Causes of out of services

Causes of out of service of medical device refers to the underlying factors that contribute to the inability of a device to perform its intended function. These factors can vary but commonly its fall under following reasons namely, lack of materials/spare parts, lack of tooling/misuse, lack of technician/manufacturer error, software/calibration, lack of documentations, and other reasons. The corresponding importance levels are detailed in Table 8. Selected medical devices will be classified based on the provided reasons.

Table 8. Criteria importance levels for causes of out of services

Criteria	Importance level (S)
Lack of materials/spare parts	6
Lack of tooling/Misuse	5
Lack of technician/ Manufacturer error	4
Software/calibration	3
Lack of documentations	2
Others	1
No out of service/ delay of maintenance	0

Backup

Backup devices are temporary devices utilized to deliver medical services when main device failure. Backup medical devices are critical in providing sustainable medical care and prevent any service disruption. These backup devices enable biomedical engineer in providing immediate maintenance for the malfunctioning device without affect the medical services. Selected medical devices will be categorized based on the number of backup devices and their corresponding importance level, as illustrated in Table 9.

Table 9. Criteria importance levels for backup

Criteria	Importance level (S)
No backup	6
One backup	5
Two backups	4
Three backups	3
Four backups	2
Five and more backups	1

Downtime

Downtime refers to the duration where the medical devices cannot intend its function. Downtime starts at failure reporting time and ends at repair work completion time [10]. As downtime increases, it impacts the delivery of medical care services, rendering medical devices unsuitable for safe patient treatment. Downtime can serve as an indicator of the device's performance and functionality [6]. Medical devices will be categorized based on the total days of downtime per year and their corresponding importance level, as demonstrated in Table 10.

Table 10. Criteria importance levels for downtime

Criteria	Importance level (S)
More than 200 days a year	5
100–200 days a year	4
60–99 days a year	3
20–59 days a year	2
Less than 20 days a year	1
No downtime	0

1.2. Mathematical model formula

The mathematical formula developed by Hernández-López et al. [11] was applied in the present study. However, some modifications based on the selected parameters was applied to assure its suitability for Saudi hospitals in order to meet the objectives of the current study. The formula of the model incorporates all the qualitative selected parameters, represented as weighting factors (R), along with their quantitative importance level (S). The result of this proposed mathematical model is called "Medical Equipment Maintenance Prioritization Factor, MEMPF", and it represented in the following formula:

$$\text{MEMPF} = \frac{\sum_{i=1}^n R_i \times S_i}{N} = \frac{\sum_{i=1}^n R_i \times S_i}{298} \quad (1)$$

where R_i is the weighting factors of the selected parameters = {1, ..., 10}, and S is the relevance importance level of each parameter. The resulted calculated value is divided on normalization factor (N) to get absolute value, where N represents the maximum value as shown in the following:

$$N = R_1 \times S_{\max 1} + R_2 \times S_{\max 2} + R_3 \times S_{\max 3} + R_4 \times S_{\max 4} + R_5 \times S_{\max 5} + R_6 \times S_{\max 6} + R_7 \times S_{\max 7} + R_8 \times S_{\max 8} + R_9 \times S_{\max 9} + R_{10} \times S_{\max 10} = 298 \quad (2)$$

2. Data collection and proposed method

The selected hospitals employed a web-based database to record and store the complete history of their medical devices from the outset of operations. This web-based data system, known as Asset Plan, developed by General Electric, plays a crucial role in managing and overseeing the maintenance of all medical devices according to manufacturer recommendations within the hospital. The collected dataset encompasses a total of 3,640 medical devices across 54 different types, extracted from the systems of the selected hospitals. Figure 2 illustrates the distribution of the selected types of medical devices based on the hospitals' regions. This data, spanning from 2012 to 2023, has been meticulously curated and selected based on specified parameters to create a comprehensive model for the predictive maintenance of medical devices. By ensuring that all relevant parameters are extracted, all 10 parameters from each of the 3,640 medical devices have been collected and are ready to be integrated into the proposed predictive model. The ultimate goal of this model is to enhance and streamline the maintenance management of medical devices within these hospitals by utilizing this data to inform and optimize predictive maintenance practices.

The model will be tested on the 54 selected medical devices to predict the optimal maintenance requirements and interventions for each device. In collaboration with healthcare professionals, including doctors, nurses, and biomedical engineers, a comprehensive assessment was conducted for the selected parameters of each medical device using the collected data.

The medical devices are categorized by region, with 24 devices in Riyadh, 6 in Jeddah, and 24 in Madinah.

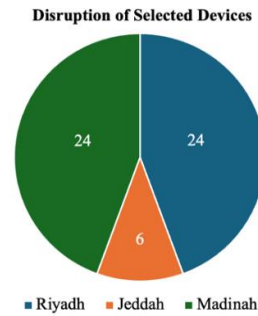


Fig. 2. Distribution of selected devices

3. Data analysis and discussion

3.1. Maintenance schedule

To assess the MEMPF findings, a qualitative scale have been established with four levels of maintenance priority: high, moderate, low, very low. These categories represents the required maintenance schedule for each medical device as illustrated in Table 11.

Table 11. Intervals for maintenance priority

MEMPF Interval	Priority	Maintenance Schedule
[0.75–1]	High	Two maintenance interventions yearly
[0.5–0.74]	Moderate	One maintenance intervention yearly
[0.25–0.49]	Low	One maintenance intervention every two years
[0–0.24]	Very low	One maintenance intervention every three years

3.2. MEMPF utilization

The obtained MEMPF will be utilized to determine the maintenance schedule for each medical device. Specifically, table 12 displays the priority and maintenance schedule for medical devices located in Riyadh, table 13 displays the same information for medical devices located in Jeddah, and table 14 displays the same information for medical devices located in Madinah.

One of the medical devices in Riyadh region categorized as high, and the rest categorized as moderate or low based on MEMPF. Robotic Radiosurgical System Cyberknife categorized as high with two maintenance interventions yearly because it may cause patient or staff injury and there is no backup. Most of the medical devices in Riyadh region categorized as moderate with one maintenance intervention yearly. For example, Linear Accelerator System categorized as moderate since the device failure will not threat patient lives. Furthermore, the device downtime is 45 days for 8 years and there is a backup. On the other hand, 6 medical devices categorized as low maintenance priority. Low priority devices such as Chromatography Systems Liquid need only one maintenance intervention every two years because the device failure may only cause treatment delay and there are 7 devices as backups. Following the same strategy the remaining devices categorized based on the obtained MEMPF.

The maintenance schedules for the selected medical devices in Jeddah region have been modified based on MEMPF value. Incubator and Ventilators categorized as high with two maintenance interventions yearly because they threat patient lives and may cause injury for patient and staff. Additionally, their function also important as life support and therapeutic devices. Heart-Lung Bypass Units, Incubators Infant Transport, and Ventilators Intensive Care Neonatal/Pediatric categorized as moderate priority since the downtime is less than 20 days for 10 years and there are more than 5 backups for each. Cabinets Storage Medicine Computerized categorized as low priority

because no significant risk may result from device failure and there are 123 devices.

In Madinah region, 6 medical devices categorized as high priority with two maintenance interventions yearly. For example, Perfusor Space Syringe Pump categorized as high due to its function as life support device and the potential of causing patient death as a result of device failure. The majority of medical devices in Madinah region categorized as moderate with one maintenance intervention yearly. One of these devices is Infusion Pumps Multitherapy (PNB) which serves as life support device categorized as moderate because the device failure may cause treatment delay and it only fail one time for 6 years. Other moderate devices evaluated using the same technique. Scanning Systems Ultrasound, Injectors Contrast Media, and Intra-Oral X-Ray categorized as low priority devices with one maintenance interventions every two years since the devices not frequently fail and there are backups for them.

Table 12. Priority and maintenance schedule for medical devices located in Riyadh

Asset Name	MEMPF	Priority	Maintenance Schedule
Linear Accelerator System	0.72	Moderate	One Maintenance intervention yearly
Locomat Pro/Unweighing System Robotic	0.62	Moderate	One Maintenance intervention yearly
Infusion Pumps, Multitherapy, Syringe	0.56	Moderate	One Maintenance intervention yearly
Chromatography Systems, Liquid	0.48	Low	One Maintenance intervention every two years
Chromatography Systems, Liquid, Packed Column, High-Pressure	0.53	Moderate	One Maintenance intervention yearly
Robotic Radiosurgical System, Cyberknife	0.77	High	Two Maintenance interventions yearly
Radiographic/Fluoroscopic Unit, Mobile O-Arm	0.71	Moderate	One Maintenance intervention yearly
Scanning Systems, Computed Tomography Mobile CT	0.67	Moderate	One Maintenance intervention yearly
Nucleic Acid Processors, Sequencing	0.72	Moderate	One Maintenance intervention yearly
Template Preparation	0.41	Low	One Maintenance intervention every two years
Workmate Claris	0.64	Moderate	One Maintenance intervention yearly
3D Ensight, 3D-Mapping System	0.67	Moderate	One Maintenance intervention yearly
Intravenous Solution Compounde	0.74	Moderate	One Maintenance intervention yearly
Carto 3 System – Cardiovascular Mapping And Navigation System	0.55	Moderate	One Maintenance intervention yearly
Automated Medication Dispensing Cabinets	0.40	Low	One Maintenance intervention every two years
Automated Medication Dispensing Cabinets, Anesthesia Workstation (AWS)	0.41	Low	One Maintenance intervention every two years
Automated Medication Dispensing Cabinets, Anesthesia Workstation (AWS) Table-Top	0.36	Low	One Maintenance intervention every two years
10 PAN STD Carousel	0.48	Low	One Maintenance intervention every two years
TPN Compounder Machine	0.63	Moderate	One Maintenance intervention yearly
Analyzer Heptic Fibrosis	0.63	Moderate	One Maintenance intervention yearly
Electroencephalo Graphs, EEG	0.64	Moderate	One Maintenance intervention yearly
Electromyographs, EMG	0.57	Moderate	One Maintenance intervention yearly
Injector, PET Isotope (PET Infusion System)	0.59	Moderate	One Maintenance intervention yearly
Injectors, Contrastmedia, Angiography	0.70	Moderate	One Maintenance intervention yearly

Table 13. Priority and maintenance schedule for medical devices located in Jeddah

Asset Name	MEMPF	Priority	Maintenance Schedule
Heart-Lung Bypass Units	0.61	Moderate	One Maintenance intervention yearly
Cabinets, Storage, Medicine, Computerized	0.46	Low	One Maintenance intervention every two years
Incubator	0.81	High	Two Maintenance interventions yearly
Incubators, Infant, Transport	0.65	Moderate	One Maintenance intervention yearly
Ventilators	0.76	High	Two Maintenance interventions yearly
Ventilators, Intensive Care, Neonatal/Pediatric	0.64	Moderate	One Maintenance intervention yearly

Table 14. Priority and maintenance schedule for medical devices located in Madinah

Asset Name	MEMPF	Priority	Maintenance Schedule
Perfusor Space, Syringe Pump	0.77	High	Two Maintenance interventions yearly
Infusion Pumps, Multitherapy (PNB)	0.54	Moderate	One Maintenance intervention yearly
Scanning Systems, Ultrasound	0.44	Low	One Maintenance intervention every two years
Ultrasound Unit, Portable	0.66	Moderate	One Maintenance intervention yearly
Combined 2D Digital Panoramic & Cephalometric	0.70	Moderate	One Maintenance intervention yearly
Dental Delivery Units	0.76	High	Two Maintenance interventions yearly
Omnicaam	0.60	Moderate	One Maintenance intervention yearly
Fundus Camera	0.68	Moderate	One Maintenance intervention yearly
Visual Field Analyzers	0.66	Moderate	One Maintenance intervention yearly
Otorhinolaryngology Operating Microscope	0.85	High	Two Maintenance interventions yearly
Ophthalmology Operating Microscope	0.89	High	Two Maintenance interventions yearly
Optical Coherence Tomographs	0.67	Moderate	One Maintenance intervention yearly
Microscopes, Light, Examination, ENT	0.73	Moderate	One Maintenance intervention yearly
Scanning System Ultrasound OB/GYN	0.69	Moderate	One Maintenance intervention yearly
Scanning Systems, Ultrasonic, Intravascular	0.75	High	Two Maintenance interventions yearly
Intra-Oral X-Ray	0.43	Low	One Maintenance intervention every two years
Injectors, Contrast Media	0.48	Low	One Maintenance intervention every two years
C-Arm Mobile Radiographic Unit	0.80	High	Two Maintenance interventions yearly
Liquid Based Cytology Slide Preparation System	0.56	Moderate	One Maintenance intervention yearly
Slide Stainer, Cytology/Histology	0.59	Moderate	One Maintenance intervention yearly
Cryostat	0.71	Moderate	One Maintenance intervention yearly
Vaccum Infiltration Processor	0.68	Moderate	One Maintenance intervention yearly
Irradiators, Blood	0.50	Moderate	One Maintenance intervention yearly
Mobile X-Ray	0.56	Moderate	One Maintenance intervention yearly

3.3. Discussion

The current maintenance schedules are constructed according to manufacturers' requirements, which may not always represent the most optimal maintenance plans. The developed model considers ten different factors (model parameters) to create a unique maintenance schedule that improves the reliability and availability of medical devices. This model proposes modifications to the current maintenance schedules. Table 15 compares the maintenance interventions of the current schedules with those of the MEMPF model.

Table 15. Current VS. new maintenance schedules

Asset Name	Current Maintenance Schedule	New Maintenance Schedule
Linear Accelerator System	Two Maintenance interventions yearly	One Maintenance intervention yearly
Locomat Pro/Unweighing System Robotic	One Maintenance intervention yearly	One Maintenance intervention yearly
Infusion Pumps, Multitherapy, Syringe	One Maintenance intervention yearly	One Maintenance intervention yearly
Chromatography Systems, Liquid	Two Maintenance interventions yearly	One Maintenance intervention every two years
Chromatography Systems, Liquid, Packed Column, High-Pressure	Two Maintenance interventions yearly	One Maintenance intervention yearly
Robotic Radiosurgical System, Cyberknife	Four Maintenance interventions yearly	Two Maintenance interventions yearly
Radiographic/Fluoroscopic Unit, Mobile O-Arm	Two Maintenance interventions yearly	One Maintenance intervention yearly
Scanning Systems, Computed Tomography Mobile CT	Two Maintenance interventions yearly	One Maintenance intervention yearly
Nucleic Acid Processors, Sequencing	Two Maintenance interventions yearly	One Maintenance intervention yearly
Template Preparation	One Maintenance intervention yearly	One Maintenance intervention every two years
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Carto 3 System – Cardiovascular Mapping And Navigation System	One Maintenance intervention every two years	One Maintenance intervention yearly
Automated Medication Dispensing Cabinets	One Maintenance intervention yearly	One Maintenance intervention every two years
Automated Medication Dispensing Cabinets, Anesthesia Workstation (AWS)	One Maintenance intervention yearly	One Maintenance intervention every two years
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10 PAN STD Carousel	One Maintenance intervention yearly	One Maintenance intervention every two years
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Heart-Lung Bypass Units	Two Maintenance interventions yearly	One Maintenance intervention yearly
Cabinets, Storage, Medicine, Computerized	Two Maintenance interventions yearly	One Maintenance intervention every two years
Incubator	One Maintenance intervention yearly	Two Maintenance interventions yearly
Incubators, Infant, Transport	One Maintenance intervention yearly	One Maintenance intervention yearly
Ventilators	One Maintenance intervention yearly	Two Maintenance interventions yearly
Ventilators, Intensive Care, Neonatal/Pediatric	One Maintenance intervention yearly	One Maintenance intervention yearly
Perfusor Space, Syringe Pump	One Maintenance intervention every two years	Two Maintenance interventions yearly
Infusion Pumps, Multitherapy (PNB)	One Maintenance intervention every two years	One Maintenance intervention yearly
Scanning Systems, Ultrasound	Two Maintenance interventions yearly	One Maintenance intervention every two years
Ultrasound Unit, Portable	Two Maintenance interventions yearly	One Maintenance intervention yearly
Combined 2D Digital Panoramic & Cephalometric	One Maintenance intervention yearly	One Maintenance intervention yearly
Dental Delivery Units	One Maintenance intervention yearly	Two Maintenance interventions yearly
Omnacam	One Maintenance intervention yearly	One Maintenance intervention yearly
Fundus Camera	Two Maintenance interventions yearly	One Maintenance intervention yearly

Asset Name	Current Maintenance Schedule	New Maintenance Schedule
Visual Field Analyzers	One Maintenance intervention yearly	One Maintenance intervention yearly
Otorhinolaryngology Operating Microscope	One Maintenance intervention yearly	Two Maintenance interventions yearly
Ophthalmology Operating Microscope	One Maintenance intervention yearly	Two Maintenance interventions yearly
Optical Coherence Tomographs	One Maintenance intervention yearly	One Maintenance intervention yearly
Microscopes, Light, Examination, ENT	One Maintenance intervention yearly	One Maintenance intervention yearly
Scanning System Ultrasound OB/GYN	Two Maintenance interventions yearly	One Maintenance intervention yearly
Scanning Systems, Ultrasonic, Intravascular	Two Maintenance interventions yearly	Two Maintenance interventions yearly
Intra-Oral X-Ray	One Maintenance intervention yearly	One Maintenance intervention every two years
Injectors, Contrast Media	One Maintenance intervention yearly	One Maintenance intervention every two years
C-Arm Mobile Radiographic Unit	Two Maintenance interventions yearly	Two Maintenance interventions yearly
Liquid Based Cytology Slide Preparation System	One Maintenance intervention yearly	One Maintenance intervention yearly
Slide Stainer, Cytology/Histology	One Maintenance intervention yearly	One Maintenance intervention yearly
Cryostat	One Maintenance intervention yearly	One Maintenance intervention yearly
Vaccum Infiltration Processor	One Maintenance intervention yearly	One Maintenance intervention yearly
Irradiators, Blood	Two Maintenance interventions yearly	One Maintenance intervention yearly
Mobile X-Ray	Two Maintenance interventions yearly	One Maintenance intervention yearly

Based on the proposed maintenance schedules, medical devices are classified into high, medium, and low priority categories with the required maintenance interventions. None of the devices categorized as very low priority due to the severity of medical devices in any healthcare organization. A total of nine devices have been categorized as high priority based on the analysis. The Perfusor Space Syringe Pump and Ventilators are classified as high priority due to their critical function as life support devices and the potential risk to patient lives. The Otorhinolaryngology Operating Microscope, Ophthalmology Operating Microscope, Scanning Systems Ultrasonic Intravascular, and Robotic Radiosurgical System Cyberknife are categorized as high priority because any failure could significantly impact the quality of medical services and there are no backups for these devices. The Dental Delivery Units, C-Arm Mobile Radiographic Unit, and Incubator are also classified as high priority due to their high maintenance costs and the frequency of failures exceeding ten times during device use. The model suggest conducting two maintenance interventions yearly to avoid any failures. Most of these critical nine devices have changed the maintenance interventions to be two yearly based on our model. Currently, most of these devices undergo one maintenance yearly, except Scanning Systems Ultrasonic Intravascular, C-Arm Mobile Radiographic Unit, and Robotic Radiosurgical System Cyberknife. The Scanning Systems Ultrasonic Intravascular and C-Arm Mobile Radiographic Unit currently undergo two maintenance interventions yearly. The Robotic Radiosurgical System Cyberknife in the current system has an over maintenance schedule (four times a year), and the device rarely used. Therefore, the maintenance will be changed to be two interventions yearly and visual inspection done quarterly. This change will not affect negatively the medical services. On the other hand, Otorhinolaryngology Operating Microscope and Ophthalmology Operating Microscope have a maintenance once a year in the current system. These devices are very important and essential for the medical service and in case of damage or out of service, it will threat the safety of patient and staff, and there is no back up for them. Other devices which undergo one maintenance yearly will change to be

two yearly. These devices incur high maintenance cost; therefore, more maintenance interventions can help avoid major failures, which would subsequently reduce the overall maintenance expenditures. For that reason, our model suggests performing maintenance two times a year.

Most of the selected medical devices categorized as moderate priority based on the assessment of MEMPF value. Thirty-five medical devices categorized as moderate priority which required only one maintenance intervention yearly. Despite the fact that the failure consequences of the Incubators Infant Transport and Ventilators Intensive Care Neonatal/Pediatric may lead to patient death, these two devices have been categorized as moderate priority because they do not experience a high frequency of failures. The Optical Coherence Tomographs, Cryostat, Vaccum Infiltration Processor, Irradiators Blood, Heart-Lung Bypass Units, Intravenous Solution Compounds, Injector PET Isotope (PET Infusion System), and Injectors Contrastmedia Angiography are classified as moderate priority due to the potential for causing patient or staff injury if they fail. The Infusion Pumps Multitherapy (PNB), Locomat Pro/Unweighing System Robotic, Infusion Pumps Multitherapy Syringe, and TPN Compounder Machine also classified as moderate priority because they may cause treatment delays if they not functioning properly. For the other twenty-one medical devices categorized as moderate priority as they may cause wrong diagnosis if they not get the required maintenance. Fifteen medical devices out of thirty-five have change the maintenance interventions to be once yearly based on our model. On the other hand, twenty medical devices kept with same maintenance interventions as once yearly. Currently, Infusion Pumps Multitherapy (PNB) and Carto 3 System – Cardiovascular Mapping and Navigation System receiving one maintenance intervention every two years based on the current maintenance schedule. Despite the fact that the two devices does not experience frequent failures, but the devices' function is important since one serve as life support device and the other serve as therapeutic device. Therefore, due to the severity of the two devices our model suggest changing the maintenance interventions to be once yearly. Furthermore, devices such as Mobile X-Ray has an over maintenance schedule (two maintenance intervention yearly) based on the current system. Our model suggest adjusting the maintenance interventions to be once yearly since the device has backups and there is no risk from device failure. Other devices which currently receiving over maintenance, the maintenance interventions can be changed to be once yearly, and visual inception done every six months to prevent unexpected failures.

Ten of the selected medical devices categorized as low priority which required one maintenance intervention every two years. The Cabinets Storage Medicine Computerized, Automated Medication Dispensing Cabinets, Automated Medication Dispensing Cabinets Anesthesia Workstation (AWS), and Automated Medication Dispensing Cabinets Anesthesia Workstation (AWS) Table-Top categorized as low priority due to no significant risk may result from the device failure and their function are miscellaneous. For the other six devices categorized as low since none of them threat patient lives. Additionally, they do not serve as life support devices and have not experienced frequent failures during their years of use. Currently, majority of low priority devices (seven devices) undergo one maintenance interventions yearly. Our model proposes to change the maintenance intervention to be once every two years. One of these devices is Automated Medication Dispensing Cabinets Anesthesia Workstation (AWS) Table-Top receiving over maintenance intervention (one maintenance yearly) based on current maintenance schedule. Our model adjusts the maintenance interventions to be once every two years since the device experienced zero failure during the past seven years and there is no significant risk from device failure. Moreover, there are more than five devices as backups. Scanning Systems Ultrasound also receives over maintenance intervention (two maintenance

interventions yearly) based on the current maintenance schedule. Our model proposes one maintenance intervention every two years since the device function considered as miscellaneous with no failure history and the device has three backups. Consequently, our model suggests performing one maintenance intervention every two years for low priority devices.

The developed model proposes several modifications to the current maintenance interventions, which strictly follow manufacturers' requirements. Maintenance interventions have been reduced for some medical devices, while others have seen an increase in maintenance interventions to optimize the maintenance process and enhance the reliability of medical devices. The model aims to improve the predictive maintenance of medical devices to enhance the quality of healthcare services. The current maintenance schedules are estimated to incur a cost of approximately SR 92,426,715.93 over a ten-year period, whereas the proposed model is expected to result in a cost of around SR 59,149,342.71 over the same time frame. Figure 3 illustrates the current and new maintenance costs over 10 years. However, if the proposed model adopted by the three hospitals for the next ten years, 36% reduction in maintenance expenditure will be saved compared to the current maintenance schedules.

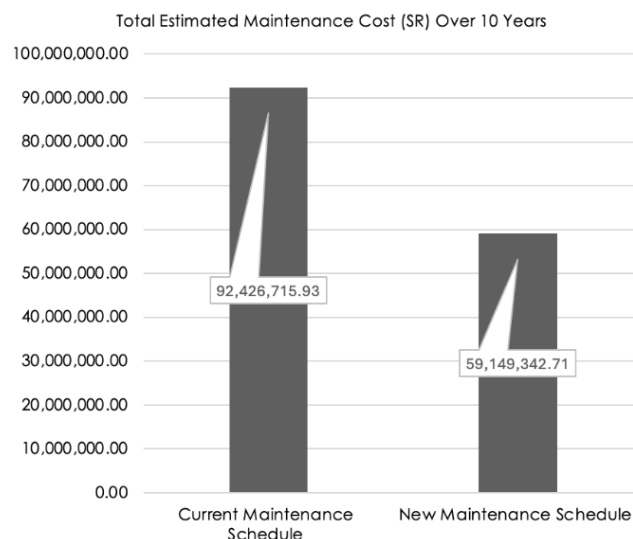


Fig. 3. Maintenance costs over 10 years

4. Future directions

The present study has attempted to make a significant contribution in the development of maintenance management of medical devices. The implementation of the model has brought some changes in the current maintenance schedules at the case study hospitals. During this study it was found that there was a lack of investigation on applying predictive maintenance on medical devices. Developing of such models can improve healthcare services in Saudi Arabia.

In addition to that, some other issues were found during this study, such as lack of spare parts when unexpected failure occurs which may result in rescheduling of patient appointments. Thus, healthcare organization in Saudi Arabia should develop strategies to manage medical devices spare parts efficiently.

Furthermore, more research needed in showing the importance of maintenance strategy on maintenance management especially in healthcare sectors. Developing of unique maintenance schedules based on medical device history need to be adopted by HTM department.

Further investigations should also be focused on the significance of maintenance on medical device performance and its relationship with the quality and reputation of healthcare organizations.

5. Conclusion

The present study aims to develop a model to improve predictive maintenance of medical devices at three hospitals in Kingdom of Saudi Arabia as a case study. The three hospitals were considered due to its size and strategic importance to Saudi government. One of the objectives of the present study was to create an accurate model to improve predictive maintenance of medical devices. The second objective was to improve medical device's reliability and performance by identifying required maintenance interventions. The third objective was to optimize maintenance cost of medical devices by modifying current maintenance schedules. The results investigation indicate that these objectives have been successfully met.

MEMPF provides a new model to find the required maintenance interventions of medical devices. The model requires the following parameters regarding medical device to operate efficiently: function, failure consequence risk, maintenance complexity, device age, rate of utilization, failure frequency, cost of maintenance / repair, causes of out of services, backup, and downtime. MEMPF was tested on 54 different medical devices extracted from the three hospitals, comprising 24 devices from Riyadh hospital, 6 devices from Jeddah hospital, and 24 devices from Madinah hospital. The most important parameters that influence the assessment of medical device maintenance priority are function, failure consequence risk and device age. The maintenance priority allows to define the optimum maintenance interventions for each medical device based on the MEMPF value.

Medical devices are the most important and costly assets in any healthcare organizations. They directly affect the quality of provided medical services. The results of the present study should improve the quality of provided medical services by enhancing performance and lifespan of medical devices. The model should achieve a 36% reduction in maintenance costs over a ten-year period, if implemented by Riyadh, Jeddah, and Madinah hospitals.

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References

- [1] Goossens A. J. M. et al.: Exploring Maintenance Policy Selection Using the Analytic Hierarchy Process: An Application for Naval Ships. *Reliability Engineering & System Safety* 142, 2015, 31–41.
- [2] Gören H. G., Kulak O.: A New Fuzzy Multi-Criteria Decision Making Approach: Extended Hierarchical Fuzzy Axiomatic Design Approach with Risk Factors. *Lecture Notes in Business Information Processing* 184, Springer Verlag, 2014 [https://doi.org/10.1007/978-3-319-11364-7_13].
- [3] Hernández-López L. A. et al.: An Index to Prioritize the Preventive Maintenance of Medical Equipment. *Health Technol.* 10, 2020, 399–403 [https://doi.org/10.1007/s12553-019-00371-y].
- [4] Masmoudi M. et al.: Decision Support Procedure for Medical Equipment Maintenance Management. *Journal of Clinical Engineering* 41(1), 2016, 19–29 [https://doi.org/10.1097/JCE.000000000000135].

- [5] Rahman N. H. A. et al.: Predicting Medical Device Failure: A Promise to Reduce Healthcare Facilities Cost through Smart Healthcare Management. *PeerJ Computer Science* 9, 2023, e1279 [https://doi.org/10.7717/PEERJ-CS.1279].
- [6] Saleh N. et al.: Preventive Maintenance Prioritization Index of Medical Equipment Using Quality Function Deployment. *IEEE Journal of Biomedical and Health Informatics* 19(3), 2015, 1029–1035 [https://doi.org/10.1109/JBHI.2014.2337895].
- [7] Salman K., Al Saud A.: Health Sector Transformation Program. 2021 [https://www.vision2030.gov.sa/media/x3jbf45y/2021-2025-health-sector-transformation-program-delivery-plan-en.pdf].
- [8] Sezdi M., Ozdemir E.: BMED: A Web-Based Application to Analyze the Performance of Medical Devices. *Biomedical Engineering - Applications, Basis and Communications* 26(3), 2014, 1450036 [https://doi.org/10.4015/S1016237214500367].
- [9] Zamzam A. H. et al.: Prioritisation Assessment and Robust Predictive System for Medical Equipment: A Comprehensive Strategic Maintenance Management. *Frontiers in Public Health* 9, 2021, 782203 [https://doi.org/10.3389/fpubh.2021.782203].
- [10] A Step By Step Guide to Choosing the Right Maintenance Strategy for Your Equipment. 2020 [https://upkeep.com/blog/choosing-the-right-maintenance-strategy/].
- [11] Market.us. "Medical Device Outsourcing Market Size | CAGR of 12.0%". 2023 [https://market.us/report/medical-device-outsourcing-market/].
- [12] Medical Equipment Maintenance Programme Overview. WHO Medical Device Technical Series, 2011.
- [13] Saudi MOH. About the Ministry - Budget. 2023 [https://www.moh.gov.sa/en/Ministry/About/Pages/Budget.aspx].
- [14] Seha Virtual Hospital [https://www.moh.gov.sa/en/Ministry/Projects/Documents/Seha-Virtual-Hospital.pdf].
- [15] Types of Maintenance: The 4 Main Maintenance Strategies - EMaint CMMS. 2022 [https://www.emaint.com/blog-four-maintenance-strategies/].

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