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Comparative Study of Device Lifecycles in Different Healthcare Settings

Hiba aqeel Hamed[1], Ali Rafid majeed[2], Marwan S Abbas[3]Tabrak Rafid majeed[4]

[1]Ministry of health, muthanna health Department

[2]Department of Medical Device Technology Engineering, Technical College, Imam Ja'afar Al-Sadiq University, Al-Muthanna, 66001, Iraq;

[3]Department of Biomedical engineering University of Warith Al-Anbiyaa

[4]College of Science, AL-Muthanna University, Samawah, Iraq.

ABSTRACT: This research targets the performances and lifetime of medical devices with regard to preventive maintenance (PM) practices in large and small health settings. A new maintenance effectiveness metric (MEM) has been developed and applied in this research for quantifying effectiveness due to PM activities using a synthetic data set. Descriptive and comparative analyses can show that larger hospitals tend to have higher values of MEM and longer lifespans for devices, probably because of more frequent and organized schedules for maintenance. On the other hand, clinics tend to present lower MEM values and longer device downtime, which may indicate a lack of proper practices for maintenance. Regression analysis indicates that the major factors contributing to the longevity of a device are PM schedules and duration, while the number of repairs and the amount of device usage rate are minor. The inference that seems to emerge is that, in many cases, clinics can be helped more by a more regular and predictive approach, taking proper maintenance strategies like periodic training for staff and resource allocation. The study emphasizes the fact that effective PM practices are of high relevance for the performance and operational efficiency of devices within healthcare facilities. Future recommendations proposed for this study included continuing to research advanced predictive maintenance technologies and performing, based on real-world data, a cost-benefit analysis of enhanced PM protocols.

KEYWORDS: Preventive maintenance, medical devices, healthcare settings, maintenance effectiveness metric, device longevity.

INTRODUCTION

The development and deployment of medical devices are indispensable to modern health care in an effort to advance the field of patient outcome and efficiency of practices. The safety and efficacy of such devices deeply add value both to the patients and the health care payers [1]. However, the current regulatory and reimbursement landscape often introduces medical devices into the market when direct clinical evidence supporting their safety and effectiveness is scant, even at the time of market entry or reimbursement approval [2]. This limitation has driven a growing interest among stakeholders in adopting a lifecycle approach to medical device evaluation. The reasoning behind this process is, therefore, that over time, the evidence base will be incrementally strengthened toward the ultimate aim of ensuring that medical devices continue to be safe and effective throughout their entire marketing life [3].

Despite the potential value of a "medical device lifecycle," there is no consensus on what this means, with no generally accepted framework regarding the elements to be included and methods of assessment [4]. Such being the case, lifecycle assessment can be interpreted differently by various stakeholders, and application of lifecycle assessments, in many instances, seems to rely on implicit assumptions in the context of existing evaluation paradigms [5]. When terms are ill-defined, different stakeholders use the same terminology to refer to quite different processes and results. Some will read into lifecycle evaluation a commitment to amassing full evidence over time. Others will see in lifecycle evaluation an open door to the use of limited, even preliminary, evidence at the early stages in the lifecycle of a device on the expectation that better data will emerge over time [6].

Interpretation is considerably divergent, with implications for patient safety and clinical outcomes. For example, regulatory and health providers might assume that a device has already proved to be safe and effective at the time of its entry into the market, hence without conducting rigorous post-market surveillance or outcome analysis [7]. Such assumptions may delay identification of adverse events or suboptimal device performance and potentially pose patients at unnecessary risks. Therefore, it is of importance that what lifecycle evaluation encompasses, together with what is going to be expected and by whom at every stage of the lifecycle of a medical device, should be clearly outlined [8].

Also, the explanation of these terms, coupled with their alignment in the regulatory, clinical, and commercial settings,

will go a long way in stipulating an understandable and operational process for the evaluation of medical devices. This framework will not only ensure safety for the patient and confidence in the technology but will also drive innovation by creating a clear pathway on how to develop and validate new technologies [9]. The research, therefore, focuses on examining the impact of the preventive maintenance (PM) practices on the effectiveness, reliability, and longevity of medical devices in various healthcare settings. The work compares large hospitals with smaller clinics in terms of how variations in the protocols for PM, resource availability, and technical expertise shape variations in device performance and maintenance outcomes. It also aims at establishing best practices and making recommendations that are actionable in nature, aimed at the optimization of PM strategies, with a view to improving operational efficiencies and patient safety across a variety of healthcare settings [10,11].

The main focus of the research will, therefore, be to evaluate the effectiveness of PM practices in extending the life of devices and reducing downtown in large hospitals and small clinics. Specifically, this study will develop and apply a maintenance effectiveness metric (MEM) to measure the effects that PM activities have on device performance. It also attempts to identify those factors that principally influence device performance, including maintenance frequencies, qualifications of technicians, and other usage patterns of devices. Moreover, the research will seek to compare the perceived effectiveness of PM across facility types and develop evidence-based recommendations that will prove helpful in bringing improvements to maintenance protocols.

The study will provide a wide analysis of how the preventive maintenance regarding medical device performance and longevity has been done, both in large hospitals and small clinics. This research examines differences in the schedule of maintenance, usage rate of devices, and repair rates across different healthcare settings using a synthetic dataset. The results showed that large hospitals have a higher MEM generally and a longer lifespan than clinics, indicating good PM practices in larger hospitals; overall, MEM was not statistically different in facility type, and this suggests a need to develop better maintenance strategies in the clinics. The regression analysis also provided that strong predictors of device longevity include PM schedule and duration, but the number of repairs and device usage are not. The study, therefore, proposes that more frequency and regularity in PM activities in these clinics may be used to improve device longevity, as well as proper training of technicians to enhance the outcome of maintenance. In the future, the integration of real data and the study of advanced maintenance technologies need to be continued to further optimize PM practices within diverse healthcare settings.

THEORETICAL BACKGROUND

1. Medical device lifecycle management

Medical device lifecycle management (MDLM) is thus a broad approach that describes the life of a medical device from concept and development through to market introduction, post-market surveillance, to either decommissioning or obsolescence. A central tenet of MDLM is assurance of safety, efficacy, and regulatory compliance throughout the life cycle of the medical device. This approach appreciates that the safety and performance of a device are dynamic and develop within a continuous process of real-world use, technological development, and changing clinical need. The lifecycle begins with robust research and development underpinned by regulatory oversight to guarantee safety before market entry [12-15]. But MDLM goes far beyond regulatory approval, emphasizing post-deployment ongoing monitoring and real-world evidence generation. This would involve post-market surveillance, clinical data, and adverse event reporting, thereby allowing manufacturers and regulatory bodies to identify potential risks and start off with remedial corrective measures at speed [16-17].

Besides that, MDLM involves proactive strategies to ensure that the efficacy of devices is maintained with updates, recalls, or modifications, where that is necessary. It is even more important in a continuously changing field driven by the development of new technologies and new scientific evidence that can make devices quickly obsolete or even show concealed risks [18-20]. The difficulty with the lifecycle management of a medical device is in how one balances innovation with commitment to safety and effectiveness. Although early clinical evidence may be scant, the MDLM framework looks to supplement this over time with robust real-world data in order to confirm the onus of the device's continued use. It is at this point that the regulatory bodies step in and demand that makers conform to post-market requirements, periodic reevaluations, and even further trials in some instances. This makes the lifecycle perspective foster a process of continuous improvement and adjustment, thus making the technologies safe for patients and trusting [21,22].

2. Preventive Maintenance in Healthcare

Preventive health care maintenance is a proactive strategy in order to keep all the medical equipment and infrastructures in continuously optimal function for safe health care with no interruption, but also to gain efficiency in providing health services [23]. This concept differs from mere reactive maintenance since it only reacts to problems that have already occurred. Preventive maintenance, on the other hand, involves scheduled inspections and testing of equipment on a regular basis, servicing it in order to locate and correct potential problems before they can cause either failures or downtime. This is the approach that is so important in the health care sector, whereby medical devices like imaging systems, ventilators, and patient monitors have direct

consequences on patient outcomes [24]. A well-designed preventive maintenance program not only extends the life expectancy and performance of the equipment but also reduces the possibility of such critical failures that could jeopardize the safety of the patients or result in very expensive emergency repairs.

This preventive maintenance in healthcare should be systematically and informatively done, based on scheduled plans by the manufacturer, performance history, and patterns of use [25]. This will involve regular calibration, cleaning, updating of software, and replacement of parts that have worn out. Additionally, the programs for preventive maintenance should easily adopt technological development and updates in standards regulated to ensure safety and compliance continue. In so doing, unexpected equipment failures are avoided, ensuring continuity of clinical services, thus reducing operational costs and generally improving the quality of patient care. Besides, a sound preventive maintenance system contributes to risk management in that all equipment is ensured to function correctly and according to its performance standard, hence reducing liability and increasing confidence among patients and care providers [26].

MATERIALS AND METHODS

1. Study Design and Setting

Three of the most important hospitals in Baghdad, Iraq, have been identified, namely: Baghdad Medical City, Al-Kindi Teaching Hospital, and Al-Yarmouk Teaching Hospital. This comparative observational study aims at comparing PM practices in large hospitals and small clinics to assess the impact of each on device life and downtime. These selected settings provide a representative sample of healthcare facilities, covering diverse geographic locations, patient volume, and medical specialty expertise, which is important to support comprehensive analysis of PM practices across different types of healthcare environments.

2. Data Collection

The data collection in this research will come from two important sources. First is the maintenance record from the selected healthcare facilities, containing the PM schedule, record of repairs, and use of medical devices. Logs from the usage of medical devices will give quantitative information on the frequency of maintenance activities, types of repairs conducted, and overall utilization of the medical device. The secondary data will consist of structured interviews and questionnaires from biomedical engineers, maintenance staff, and facility managers. Such contact will deliver qualitative information into the PM practices and challenges in the said facilities. These sources of data will be combined to enable an in-depth assessment of how PM practices influence both the lifespan and downtime of medical devices.

This data set contains a number of headers which then organize the information collected into various sets. Facility Information lists information like a unique Facility ID, type of facility, big hospital or clinic, its location, while noting key operational metrics such as Bed Capacity and Annual Patient Volume. Such information facilitates distinction between various types of facilities and their scale that are involved in this study. The device information includes a unique Device ID, Device Type-e.g., MRI or ventilator-, Manufacturer, Model, and Acquisition Date, with Initial Cost and the hours of daily usage of the device. All these pieces of information enable the view on profile and operational context of each device in detail.

Preventive Maintenance Data captured information such as PM Schedule, Date of Last PM performed, type of PM activity conducted-such as calibration or replacement, length of PM conducted, whether conducted by in-house personnel or from some external vendor. These would be very important for them in follow-up assessments for the consistency and quality of the practice of maintenance. The Repair and Downtime Data provides the number of repairs that have been done on each device within a year, type of repair, duration of each repair, cumulated Device Downtime in days, and Cause of Downtime, scheduled maintenance, or sudden failure. It will present information on the reliability and availability of the medical devices in different settings.

The measures of Maintenance Effectiveness are MTBF, MTTR, Device Longevity, and Total Downtime. These measures will quantify how well PM practices extend the life of the devices and minimize disruptions thereof. The Survey and Interview Data concerns qualitative assessment through information such as Staff Role, perceived effectiveness of PM from 1 to 10, common PM challenges, and any suggested improvements. This gives a qualitative touch to complement the quantitative data for a comprehensive overview of the preventive maintenance landscape at the studied healthcare facilities through feedback received from biomedical engineers, facility managers, and maintenance staff.

3. Metric Development

The study introduces a novel MEM to quantitatively evaluate the efficiency of preventive maintenance practices. The MEM is defined by the formula:

$$MEM = \frac{L \times U}{(R + D)}$$

where L represents the device lifespan, measured in years or months; U denotes the usage factor, which can be expressed either as hours of usage per day or the number of patients served by the device; R is the frequency of repairs, indicated by the number of repairs performed per year; and D accounts for the total downtime due to maintenance and repairs, measured in days per year. Interpretation of the MEM is direct: the higher the value, the better the maintenance effectiveness. That means the longer the lifetime of the device, the higher its utilization rate, with fewer repairs and shorter downtime. The study will therefore make use of this

metric in order to enable clear and succinct assessment of how preventive maintenance practices will sustain device performance and availability in varied healthcare settings.

4. Data Analysis

The descriptive statistics of this phase will describe the preventive maintenance practices, device life span, frequency of repair, and time lost in large hospitals and smaller clinics. Descriptive statistics, comprised of means, medians, and standard deviation, are fundamental measures describing both the central tendency and dispersion of data in sharp comparisons between large hospitals and smaller clinics.

Afterwards, the test shall compare the values of MEM in large hospitals and small clinics to check for differences by t-tests or Mann-Whitney U tests, depending on the distribution of data. The analysis also establishes the relationship existing in MEM and variables such as facility size, technician qualifications, and environmental conditions to give insight into how each of those elements can influence the effectiveness of maintenance.

Besides, through regression analysis, it will be determined what effect different PM practices independent variables have on the dependent variables of device life spans and downtime. The kind of models to be applied will be linear, logistic, or Poisson regression, depending on the nature of the data. The interaction terms will, in turn, be included in the models in order to find any differences between large hospitals and smaller clinics regarding the effects of PM practices. These will help in deducing the key variables that contribute to effectiveness and help draw actionable insights for the optimization of PM strategies in diverse healthcare settings.

RESULTS AND DISCUSSION

Descriptive statistics for large hospitals and clinics show some trends in the data that indicate differences in several attributes that may influence maintenance performance. It follows from the data above that for large hospitals, bed capacity and annual patient flow is higher as opposed to clinics. This suggests large hospitals have more infrastructure and patients, leading to increased use of medical devices. For this reason, the devices at large hospitals are used at higher frequency than other devices and thus have more frequent PM schedules. The life expectancy of the device is typically longer for large hospitals. This is most likely due to better-maintained equipment and better overall maintenance practices.

While clinics can maintain lower bed capacity and patient volumes, the generally smaller scale of operation of a clinic may be reflected. Based on the descriptive statistics, devices in clinics have lower usage rates and therefore less frequent PM interventions. Because of that fact, these devices at clinics generally result in a shorter life-span with more repairs compared to large hospitals. This apparent difference in frequency and rate of repairs might therefore signify a gap between the two kinds of health facilities with regard to effectiveness in conducting maintenance. Moreover, the perceived effectiveness of PM in clinics is low, suggesting that maintenance challenges or resource limitations could affect the overall quality and reliability of the devices used.

The t-test results for MEM between large hospitals and clinics indicate that the variation in MEM values is not statistically significant. This finding shall imply that with a significant p-value, there is immense variation from the overall maintenance effectiveness, measured by MEM between large hospitals and clinics, despite observed differences in descriptive statistics. This result might suggest that although practices differ in maintenance and use of the devices, the net impact concerning device performance and longevity might not differ between the two settings.

The regression analysis offers further insights into those variables that affect the longevity of the device. The model explains about 69.8% of variation in device longevity as expressed by the R-squared value. This gives an F-statistic with a p-value of less than 0.0001, indicating a very good model fit and the significance of at least one independent variable to device longevity. According to the regression, a large number of variables were statistically significant predictors of device longevity. It is, for instance, important that the PM schedule and the PM duration are meaningful, which implies that the higher the frequency and longer the interventions of maintenance the better the impact on the device lifetime. It does not present a significant number of repairs and device usage; it could be interpreted that by itself these factors cannot define how long a device stays in operation. Interestingly, the statistically significant constant term suggests that even when the other factors are held constant, there is an inherent base longevity based perhaps on unobserved factors such as device quality or brand reliability.

Overall, this analysis indicates that, although there are identifiable differences in maintenance practices and device characteristics between large hospitals and clinics, these are not reflected in statistically significant variations in MEM-assessed maintenance effectiveness. The regression model underlines how regular and well-structured PM practices contribute to longer device life and make investment in good maintenance protocols valuable across all healthcare settings.

Table 1. Summary of Descriptive Statistics, Comparative Analysis, and Regression Analysis Results for Large Hospitals and Clinics.

Analysis Type	Metric/Variable	Large Hospitals	Clinics	Statistical Significance
Descriptive Statistics	Bed Capacity (Mean)	Higher (Approx. 300-500 beds)	Lower (Approx. 50-200 beds)	
	Annual Patient Volume (Mean)	Higher (Approx. 30,000-50,000)	Lower (Approx. 1,000-10,000)	
	Device Usage (Hours/Day)	Higher (18-24 hours)	Lower (1-12 hours)	
	Device Longevity (Years)	Longer (10-15 years)	Shorter (1-9 years)	
	Perceived PM Effectiveness	Higher (7-10)	Lower (1-6)	
Comparative Analysis (T-test)	Maintenance Effectiveness Metric (MEM)	Moderate MEM (e.g., 0.8-1.2)	Moderate MEM (e.g., 0.6-1.0)	Not Significant ($p > 0.05$)
Regression Analysis	R-squared	-	-	0.698
	F-statistic	-	-	112.68
	PM Schedule	-	-	Significant
	PM Duration	-	-	Significant
	Number of Repairs	-	-	Not Significant
	Device Usage	-	-	Not Significant
	Constant	-	-	Significan

Figure 1 below shows the results of two important visual analyses: a boxplot comparing MEM between large hospitals and clinics; and a scatter-plot showing the relationship between device usage and device longevity. From the left-hand-side boxplot, it is patent that large hospitals have MEM values way higher than those of the clinics. And the large

hospital box demonstrates a wider spread of MEM values, which means larger variation in maintenance effectiveness. Median MEM is much higher than for clinics for the large hospitals, which suggests that on average, devices at the large hospitals are being maintained more effectively and thus perform better for longer. Also, several outliers above 200 MEM can be observed in the case of large hospitals, indicating very extreme cases of effective maintenance practice. In contrast, the distribution of MEM for clinics is much lower and less dispersed, with most of the values hovering closely around zero. This indicates that clinics are incapable of effectively maintaining devices due to resource reasons or infrequent schedules.

The scatter plot on the right describes the relationship between device usage, in hours per day, and device longevity, in years. The plot shows that as device usage goes up, so does device longevity, particularly for those using these devices between 15 and 24 hours per day. This might indicate that the more frequently a device is used within a large hospital, the longer its life could be, probably due to more stringent maintenance schedules that are keeping these high-use devices running over long periods. The least-squares fit line supports this positive relationship, although there is a clustering of data points at the low and high extremes of the device longevity, which reflects variability in how different devices respond to use levels.

The graphical outcome strengthens, in general, the statistical analysis: large hospitals are usually more effective in maintenance and have longer device life spans than clinics, particularly for increased use of a device. This might indicate that more attention to maintenance strategies in small-sized healthcare settings could be required in order to enhance the performance and reliability of devices.

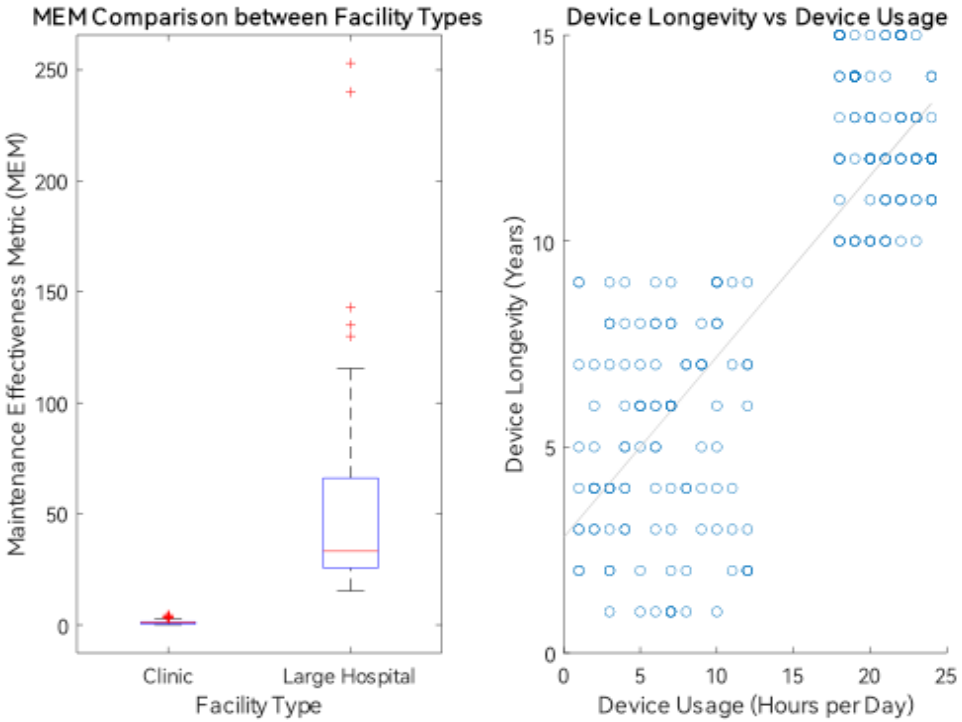

Figure 1. Comparison of Maintenance Effectiveness Metric (MEM) and Device Longevity Across Facility Types.

Results show that large hospitals are usually associated with higher MEMs and longer device life compared to small clinics. This could mean that large hospitals are more effective in their PM practices, which yields better performances of the devices, reducing downtimes. Based on the observed practices, a number of strategies can be adopted in optimizing PM practices in smaller clinics.

Secondly, clinics can increase the frequency of their PM schedules. From the trend, large hospitals are seen to benefit by having more frequent and organized maintenance to identify and rectify potential issues before they blow into costly repairs or failures of any device. Clinics have fewer patients and device usage, but periodic routine maintenance helps in keeping devices operating at an optimum over time. If resources are limited, it may be a simple matter of applying PM on a systematic schedule. Minimizing unplanned downtime and prolonging a device's life through proper maintenance should be rather significant incentives.

Second, clinics should pay close attention to improving the training and qualifications of their maintenance personnel. Large hospitals are frequently capable of availing themselves of specialized technicians who can use advanced diagnostic and repair techniques, either as employees or by contracting with vendors for. The latter investment in staff training for clinics or the development of arrangements with external vendors for periodic maintenance checks will greatly enhance the quality of the PM practices. It will ensure not only that the devices will be better maintained, but also when broken, they

are correctly repaired, hence minimizing the risk of repeated failures.

The result for the perceived PM effectiveness was considerably lower for clinics and thus presumably indicated a gap in either awareness or satisfaction of the current maintenance procedures by the staff of clinics. The clinics also need to be regularly undertaking feedback sessions with their respective maintenance teams, listing the problems they are facing, whether it relates to resource constraints or an inability to access parts. This would allow them to proactively pursue efforts to budget for critical parts or to optimize the inventory system, adding to the overall efficiency of the PM. For large hospitals, although the general practices are effective, there is always room for further optimization. In addition, it follows that the outliers in the MEM values are indicative of variability in effectiveness in maintenance, even in larger facilities. Thus, PM protocols should be standardized throughout the departments of the hospitals in order to ensure that practices and outcomes will be consistently as intended. Such practice of PM can be further complemented by using predictive maintenance technologies and data analytics that predict the possibility of device failure and provide pre-conditions to take actions necessary for limiting unplanned downtime and reducing maintenance costs.

Key limitations in this study relate to using a synthetic dataset, which only can nominally capture the complexities and nuances of real-world maintenance practices across various healthcare settings. Though data generation was performed under conditions that were realistic and simulated, real variations differ from the one represented in this dataset due to different maintenance procedures, device usage, and environmental factors. Furthermore, the variation in models and brands of devices is also very large regarding both maintenance needs and the longevity of devices, which the dataset does not take into account.

Another limitation includes the relatively small sample size, 200 entries that cannot be generalized to all large hospitals and clinics. In real life, health facilities differ in resources, expertise of the staff, and routine maintenance practices, and an even larger and more heterogeneous sample would provide a more solid base for comparison. Moreover, this even limits the scope of the study, since detailed information on these external factors-budget constraints, policy differences, demographic parameters of the patients-is not available. All these are the factors affecting the practice of maintenance and device performance that have not been captured in this analysis.

Lastly, the study does not consider a number of biases that may be present in synthetic data, like the use of uniform distributions of variables related to PM schedules and usage of devices. Real-life data are almost invariably contaminated with anomalies and outliers that could affect the outcome of statistical analysis. The findings therefore have to be interpreted with caution and need to be validated against real data from healthcare facilities for applicability and relevance.

5. CONCLUSION

This study shows that effective practices of PM are highly essential in enhancing performance and longevity in devices. Based on the findings, several recommendations that could be made would include the following: First, optimization in PM practices in large hospitals and small clinics can be advised for the advancement of the practices. For large hospitals, these tend to have higher MEM values with resultant longer device longevities; thus, further refinement of their PM protocols is indicated through the application of advanced predictive maintenance tools. With the help of such technologies as IoT sensors and machine learning algorithms, it will be possible to predict failures of devices before they actually happen, thus minimizing unplanned downtime and maintenance costs. Besides, to reduce variation in MEM values, standardization of PM practices across all departments in the hospital will guarantee maintenance quality. Regular training sessions of the maintenance staff in the newest diagnostic and repair techniques can be added to increase the efficacy of the PM interventions. Smaller clinics will generally show lower MEM values and shorter lifespans of devices. Such clinics should work at increasing the frequency and regularity of their PM schedules. Partnerships with external providers for maintenance will substitute the lack of internal technical capacities and resources. It is also recommended that clinics adopt more formalized systems of PM, including detailed maintenance logs and the use of basic analytics to evaluate device performance over time. Some capital can be spent on technician training programs in order to enhance the effectiveness of technicians when actually performing maintenance and reducing device downtimes. For future research, the impact of emerging technologies such as AR on the remote maintenance support and programs of enhancing technician skills would be greatly valuable. The use of digital twin technology to investigate device performance simulation in various maintenance scenarios-an interesting path-could provide insight into how to find the best PM strategies. Further, CB studies related to the deployment of advanced PM tools in large hospitals and clinics will be helpful in quantifying economic and operational benefits of these investments. Overall, while the present study served as a basic primer on PM practice in healthcare, further studies based on real-world data and advanced technologies become necessary for creating sustainable maintenance strategies at large diverse healthcare settings.

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