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A New Approach of System Engineering to Medical Device Lifecycle Management

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Abstract
Today's, more than 10000 types of different medical devices are currently employed in medium and large hospitals. These devices have an important role in the diagnosis, treatment, and monitoring processes in health centers. An efficient preventative maintenance program of these devices is essential to guarantee the correct functioning and ensure the safe and reliable operation of them. As the maintenance activities increase as increasing the variety of medical devices, the need for a better maintenance management system become more essential than the past. In this paper, a new multi-criteria decision-making model of system engineering to lifecycle management and preventive maintenance priority of medical devices was presented based on a kind of quality function deployment. The model was implemented and tested in three public hospitals in one of the western provinces of Iran. None of the three hospitals had established a proper assessment management program processes to identify their equipment needs and required maintenance priority based on their annual budgets. Our suggested model solved one of the big decision problems in their management system. The results helped them to have a priority list of the medical devices that should be replaced and the preventative maintenance priority of critical devices based on the wards, type and number of them according to the available budget.
Implementation of our proposed model in medical centers could maximize the reliability of equipment and systems among the limitation of organizational resources and budgets.

Keywords Medical devices, Lifecycle, Management, Quality Function Deployment

Introduction

More than 10000 types of different medical devices are currently employed in medium and large hospitals. These devices are used in the diagnosis, treatment, and monitoring processes. Given their functional role, medical devices is considered a main element of the modern health system and all of them must have evidence to demonstrate they meet the essential principles and conformity assessment procedures, [1]. The malfunctioning of medical devices may cause negative consequences such as damage to or even death of patients, and subsequently serious legal consequences for medical centers. In this regard, a main objective of medical devices management is to implement an effective maintenance management system to increase the operational reliability and utilization of medical devices for minimizing their failures and malfunctions and thereby reducing costs and accidents, [2]. In a health safety system, we are dealing with a triangle

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management system whose three vertices are the patient - medical equipment and the operator. Due to the nature of the medical equipment and directly or indirectly contact of them with the patient, an efficient maintenance program could be a solution to achieve higher levels of safety, [3]. In this way, implementation of a proper risk analysis method for inspection program, safety and preventive maintenance is very important, [4-7]. According to some statistics analysis provided by the Ministry of Health of Iran, approximately $ 8.5 to 10 billion of medical equipment is available in the country's public medical centers until 1991. The other studies conducted in Iran have shown about 10 to 20 percent of the value of these goods should be spent on equipment maintenance, which it would reduce costs of medical centers in providing their sources from 30 to 40 percent. However, due to the lack of a defined precise and efficient maintenance procedures, it seems that not only this amount of budget is not allocated for the preventative maintenance plan (PM) in medical centers, but also the use of allocated budgets in many cases has not been in the right way, [7-9].

Monitoring factors affecting the performance of medical devices may provide a novel model for effective management of them throughout their lifecycle from declaration of need to purchase, maintenance, disposal, and replacement. In the meantime, arbitrary management especially in developing countries does not rely on a realistic, scientific, and comprehensive assessment and it causes leading to increased costs of health economics. Accordingly, efforts have been made to propose quantitative models for optimal management of medical devices during their lifecycle, [8]. In this regard, Basem et al. proposed a quantitative model for replacement and disposal of medical devices at the best possible time using the fault tree analysis (FTA), [10]. Their model was not updatable and provided no solution for other management areas of medical devices. By defining productivity in hospital management, Hashem O Al-Fadel has taken effective steps in classifying hospital equipment management processes. He defined productivity as higher safety and reliability of medical devices to reduce their service costs and downtime, [11]. Arsalan focused on the time between preventive maintenance and suggested a solution to obtain risk-based preventive maintenance intervals, [12]. Ridjway et al. noticed that performing PM affects reliability and improves equipment performance, in his model he considered increasing safety, reducing down time, and reducing the cost of repairs as effective factors in determining PM program, [13]. With the help of expert's opinion, some groups were formed to evaluate various factors affecting the risk priority number (RPN) including the occurrence probability, failure severity, and failure detection probability, [14]. Risk factors and subsequently the maintenance priority for various medical devices were obtained by different fuzzy logic approaches, [15]. Taghipour et al. and Hutagalung et al. proposed different models based on a hierarchal process for prioritizing maintenance of medical devices based on the sensitivity of equipment, [16, 17]. Saleh et al. studied preventive maintenance prioritization of medical devices using the quality function deployment (QFD). A two-stage QFD matrix was constructed for determining and weighting critical features in the medical devices management system, and the priority number was obtained for hospital equipment, [18].

In this study, the effect of various factors on the performance of medical devices is determined as the performance number (PN). A new model is then proposed for managing the lifecycle of medical devices from declaration of need to purchase, maintenance, disposal, and replacement. By defining the PN in the proposed model, the effect of each parameter on the performance of medical devices is quantified. Thereafter, the management number (MN) and subsequently the management marker index (MI) are presented to express a new updatable model of our new system engineering.

2. Proposed model

A new model is proposed for managing the lifecycle of medical devices from declaration of need to purchase, maintenance, disposal, and replacement. By defining the performance number, the effect of each parameter on the performance of a medical devices is quantified. Subsequently, the management number and the management marker index are introduced to express a new updatable model of system engineering for maintenance, inspection, and replacement processes to determining the maintenance priority and proper maintenance intervals for medical devices.

Figure (1) displays an overview block diagram for implementation of our research model.

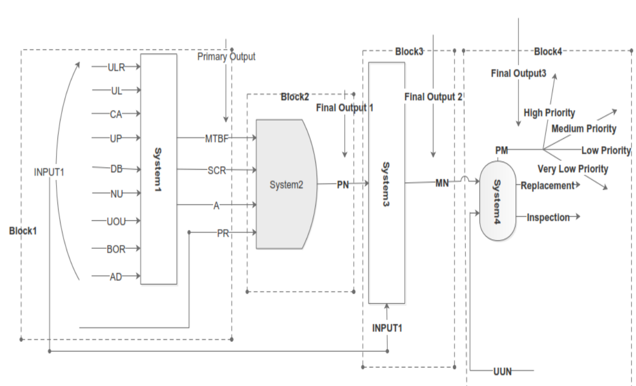


Fig.1 The block diagram of the research model

2.1. The Performance Number (PN)

Three key indicators, namely the Performance Number (PN), Management Number (MN), and Marker Index (MI) are used to determine the roadmap. PN is the result of operations in the first and second blocks. In the first block, nine parameters including the Useful Life Ratio (ULR), Utilization Level (UL), Calibration (Ca), User Proficiency (UP), Device Brand (DB), Number of Users (NU), Used in Other Units (UOU), Bed Occupancy Ratio (BOR), Number of Alternative Devices (AD) were considered inputs to the model as factors affecting the performance of medical devices. These inputs affect the Mean Time Between Failures (MTBF), Service Cost Ratio (SCR), Access time (A), and Physical Risk (PR), i.e. four inputs to the second block. These four factors influence the productivity and performance of medical devices according to the definition presented by Hashem O Al-Fadel. System (1) in Fig. (1) specifies the coefficients of various factors in the PN definition by using Eq. (1).

$$ABW = IMR \times IF \tag{1}$$

Where ABW represents the absolute weight of these four factors affecting the equipment performance, IMR the progress ratio which is equal to the expected level (target) divided by the current satisfaction level in hospitals, and IF (importance factor) represents the importance of each of these four factors in the optimal performance of equipment. The satisfaction rate and target levels are scaled from very poor to very good using ten points. The importance factor (IF) is also scaled from very low to very high.

Accordingly, the absolute weights of the above-mentioned factors were obtained with the help of experts' opinions.

$$ABW\,(MTBF) = 8 \times \frac{7}{9} = 6.2$$

$$ABW\,(SCR) = 7 \times \frac{5}{8} = 4.4$$

$$ABW\,(PR) = 8 \times \frac{6}{7} = 6.9$$

$$ABW\,(A) = 10 \times \frac{4}{5} = 8$$

The normalized ABW values are considered the PN coefficients, i.e. the output of the second block. The performance number (PN) is calculated from Eq. (2):

$$PN = 0.27 \times PR + 0.31 \times A + 0.25 \times MTBF + 0.17 \times SCR \tag{2}$$

Where PN denotes the performance number representing the effect of inputs to the first block on the performance of medical devices.

System (2) shows the procedure to obtain the PN in the form of the effect of the first block inputs on the second block inputs, called the impact factor in Table (1).

Table 1 The impact factor to obtain the performance number

Very high impact	High impact	Moderate impact	Low impact	Very low impact	Impact less
1	0.6	0.4	0.2	0.1	0

The impact factor for each input is obtained from the combination of these three factors, the correlation coefficient, percentage of points out of the expected zones and expert opinion. The final result is obtained by comparing the expert opinion to the results of correlation coefficient and extrema points, in this way:

- If the expert opinion is the same as the results of each of methods; the expert opinion is accepted.
- If all three results are different, and none of them contains outliers; the mean result is considered.
- If two results are the same but differ with the expert opinion; the mean result is considered.
- If one of the results contains outliers in comparison with the other two results, the result containing outliers is eliminated, and one of the above-mentioned methods is used to obtain the final result.

Tables (2) and (3) show the correlation coefficients and the percentage of points out of the expected zones, and the corresponding impact factors.

Table 2 The corresponding impact factors for correlation coefficients

Impact Factors	Correlation Coefficients Level.
0.6	Level 1 (Highest level the)
0.4	Level 2
0.2	Level 3
0.1	4 Level (the lowest level)

Table 3 The impact factors related to the percentage of extreme points out of the expected

Impact Factors	Percentage of extreme points in the expected zones
1	100%
0.6	≥70%
0.4	50%≤ ≤70%
0.2	30%≤ ≤50%
0.1	≤30%
0	0

For instance, the impact factor of the ULR (an input to the first block) for the access level (an input to the second block) was calculated for the Defibrillator device and the results are listed in Table (4).

Figure (2) shows the correlation coefficients of input factors based on the access level. As seen, the ULR is at highest level, and according to Table (5), an impact factor of 0.6 is considered in the corresponding column in Table (4).

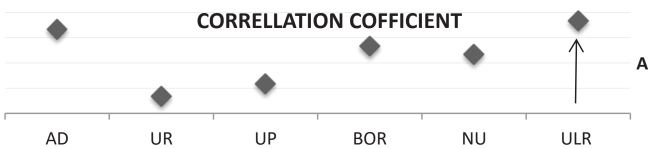


Fig. 3 The correlation coefficients of input and output factors for the Defibrillator device.

In our model, an access level less than 0.85 is considered a low access, and devices with a ULR less than 0.8 (almost old or average) are expected to be in this region. However, of 4 points, only two points (50%) have a ULR of less than 0.8 (Fig. 3). Therefore, an access level of 0.4 is seen in the expected extremum column in Table (4) for a Defibrillator device.

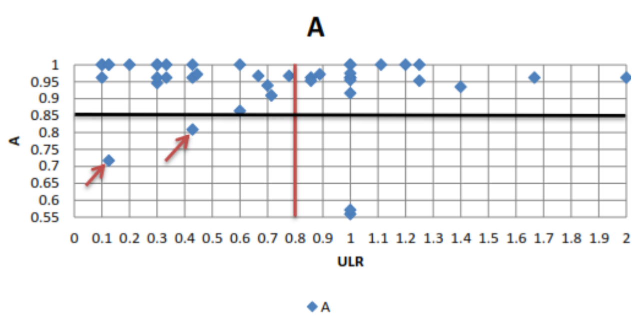


Fig. 3 The useful life ratio versus the access level for the Defibrillator device.

According to Table (4) and mentioned rules, an impact factor of 0.6 is obtained for the ULR (input) relative to the access level (output) for the Defibrillator device.

Table 4 The impact factor of the useful life ratio on the output access level for the Defibrillator device.

Correlation Coefficients	Expected extreme point	Expert opinion	Result
0.6	0.4	0.6	0.6

Based on Eq. (2), performance number (PN) of the Defibrillator device is calculated for the ULR as below.

$$PN = 0.27 \times 0.4 + 0.31 \times 0.6 + 0.25 \times 0.6 + 0.17 \times 0.4 = 0.512$$

The process of obtaining the impact factor of 0.6 (shown by the arrow in above equation) was presented in this paper, and consequently other coefficients for the MTBF, the access time, and service cost ratio (SCR) for other inputs are calculated in the same way to obtain the final value. In the meantime, the impact factor of the physical risk (PR) is obtained for inputs with the help of experts' knowledge. Given the lack of numerical results for three inputs of brand, use in other wards, and calibration, their impact factors were calculated according to the experts' opinions. The results were obtained for the performance number and are normalized to achieve the performance effect percentage.

Tables (5) and (6) show the PN, performance effect percentage, the rank of each parameter in the PN of Defibrillator, and electrocardiograph (ECG) devices respectively, where the performance effect is the normalized performance number.

Table 5 The performance number of the Defibrillator device.

Input Parameter	ULR	UL	CA	UP	DB	NU	UOU	BOR	AD
Performance number	0.512	0.362	0.193	0.175	0.152	0.129	0.129	0.146	0.292
Performance number rank	1	2	4	5	6	8	8	7	3
performance effect percentage	24.50	17.31	9.24	8.37	7.27	6.17	6.17	6.99	13.97

Table 6 The performance number of the ECG.

Input Parameter	ULR	UL	CA	UP	DB	NU	UOU	BOR	AD
Performance number	0.349	0.234	0.133	0.117	0.179	0.048	0.073	0.048	0.292
Performance number rank	1	3	5	6	4	8	7	8	2
performance effect percentage	23.69	15.87	9.03	7.94	12.15	3.27	4.96	3.27	19.82

2.2. The Management Number (MN)

The output of the third block, the management number (MN), is the second step used for quantifying management of medical devices in hospitals during their lifecycle concerning the need to purchase, status monitoring, maintenance, disposal, and replacement. The inputs to the third blocks are the same inputs to the first block with performance percentages in Tables (5) and (6). The management number for the Defibrillator and ECG are calculated from Eqs. (3) and (4), respectively.

MN(DC)=0.245*ULR+0.1731*UL+0.0924*CA+0.0837*UP+0.0727*DB+0.0617*NU+0.0617*UOU+0.0699*BOR+0.1397*AD (3)

MN(ECG)=0.2369*ULR+0.1587*UL+0.0903*CA+0.0794*UP+0.1215*DB+0.0327*NU+0.0496*UOU+0.0327*BOR+0.1982*AD (4)

The weighted correlation coefficients for the input factors are obtained according to Table (7) to achieve the MN, System (3).

Table 7 The weighting system for the MN parameters.

Utilization Level (UL)			(DB) Device Brand		
Criterion	Description	weighted correlation coefficient	Criterion	Description	weighted correlation coefficient
Very high	Use more than 20 times a week	0.2	Poor	Expert opinion	0.2
High	Between 10 and 20 times a week	0.25	Medium	=	0.4
Medium	Between 4 and 10 times a week	0.55	Good	=	0.8
Low	Less than 4 times a week	1	Very good	=	1

# Alternative Devices (AD)			User Proficiency (UP)		
Criterion	Description	weighted correlation coefficient	Criterion	Description	weighted correlation coefficient
Low	≤ 1	0.3	Poor	≤ 55	0.35
Medium	1≤ ≤ 2	0.7	Medium	55 ≤ ≤ 75	0.7
High	≥ 2	1	Good	≥ 75	1

Calibration (Ca)			Number of Users (NU)		
Criterion	Description	weighted correlation coefficient	Criterion	Description	weighted correlation coefficient
Not done at all	-	0	High	≤ 5	0.5
Done but not on time	-	0.5	Medium	5≤ ≤ 20	0.7
Done according to plan	-	1	Low	≥ 20	1

Bed Occupancy Ratio (BOR)			Used in Other Units (UOU)		
Criterion	Description	weighted correlation coefficient	Criterion	Description	weighted correlation coefficient
High	≥ 75	0.6	Used	-	0
Medium	50 ≤ ≤ 75	0.8	Not Used	-	1
Low	≤ 50	1			

Useful Life Ratio (ULR)		
Criterion	Description	weighted correlation coefficient
Old	≥ 1	0.15
Almost old	0.8 ≤ ≤ 1	0.3
Average	0.5 ≤ ≤ 0.8	0.5
Almost new	0.25 ≤ ≤ 0.5	0.8
New	≤ 0.25	1

2.3. The Management Marker Index (MI)

At the final stage, the fourth block represents the management strategy adopted to create six regions, namely replacement, inspection, high-priority preventive maintenance (PM), medium-priority preventive maintenance, low-priority preventive maintenance, and very low-priority preventive maintenance with boundaries shown in Fig. (4). The management number (MN) with an indicator ,called the ratio number (UUN), are considered as input to the fourth block to achieve the final output under System 4 in Fig. (3).

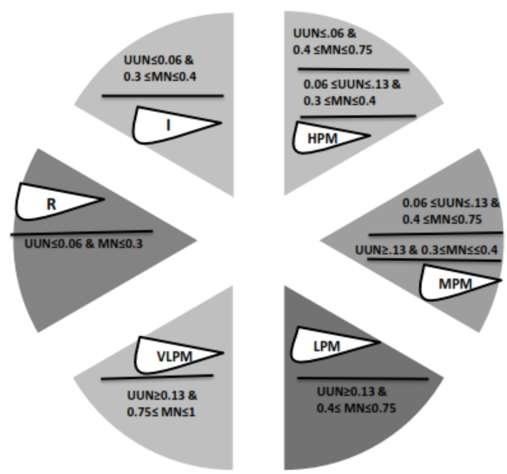


Fig. 4 The regions and corresponding boundaries in managing the lifecycle of medical devices.

In this figure UUN is defined as the correlation coefficient of the ULR multiplied by the correlation coefficient of the ratio represented in Table (7), due to the significance of these two indicators. The boundaries of this indicator are obtained in Fig. (4) with the help of eight special modes in Table (8) for the maintenance of medical devices.

Table 8 The method to obtain UUN boundaries.

UUN	Useful Life Ratio (ULR)	Utilization Level (UL)
0.03	Old	Very high
0.0375	Old	High
0.0825	Old	Medium
.0.06	Almost old	Very high
0.075	Almost old	High
0.06	**Average**	
0.165	Almost old	Medium
0.10	Average	Very high
0.125	Average	High
0.13	**Average**	

Also Given the importance of the ULR and UR in managing the lifecycle of medical devices, the MI for explaining the management process is defined as follow:

$$MI = MN*UUN \tag{5}$$

Then, based on MI values, management decisions will be applied for medical equipment. High Priority Maintenance (HPM), Medium Priority Maintenance (MPM), Low Priority Maintenance (LPM), Very Low Priority Maintenance (VLPM), Inspection (I) and Replacement (R) are the types of these decisions.
According to the six regions shown in Fig. (4), the management process is specified based on the MI in the block diagram Fig. (5).

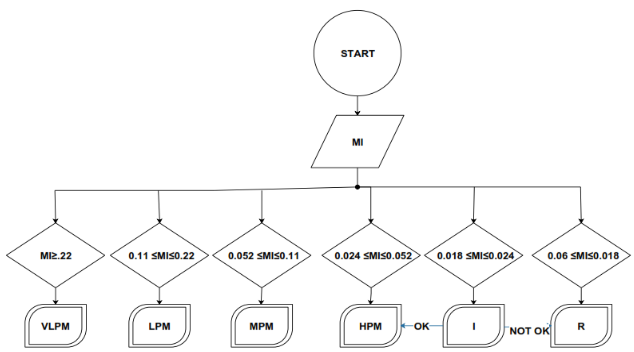


Fig. 5 The block diagram for determining the policy taken of managing medical devices.

The Preventive Maintenance Interval (PMI) of medical devices was calculated from Eq. (6) in terms of day.

$$PMI=100*MI*360(DAYS)/N' \tag{6}$$

Where PMI represents the preventive maintenance interval and N′ is the normalized coefficient. The normalized coefficient, N′, is obtained from linear diagrams in Figs. (6) to (9) noting to the intervals for each of the maintenance priorities in Table (9) reported in the literature.

Table 9 The intervals for four maintenance priorities.

Maintenance Interval(days)	Maintenance Priority
35-55	High
55-80	Medium
80-135	Low
135-180	Very low

For instance, for the high-priority maintenance, we have from Eq. (5):
PMI1= (100*0.024*360/ N'1) = 35 N'HPM= 25

PMI2= (100*0.024*360/ N'2) = 55 N'HPM= 34
The linear diagram for determining N′ in terms of MI for high-priority maintenance is obtained as follows.

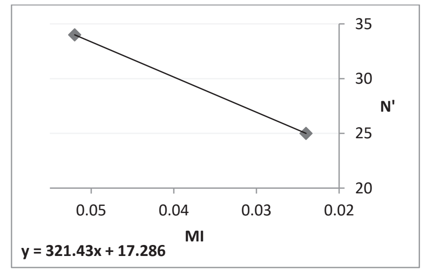


Fig. 6 Calculation of N′ in terms of MI for high-priority maintenance.

Other diagrams for obtaining N′ in terms of MI are achieved in the same way.

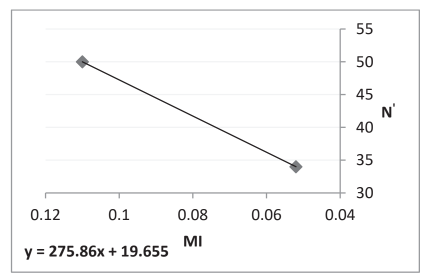


Fig. 7 Calculation of N′ in terms of MI for medium-priority maintenance.

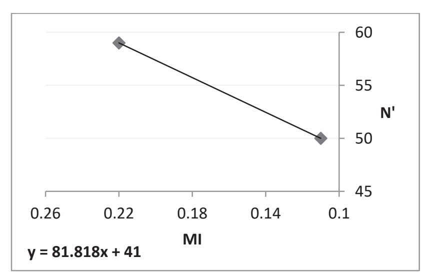


Fig. 8 Calculation of N′ in terms of MI for low-priority maintenance.

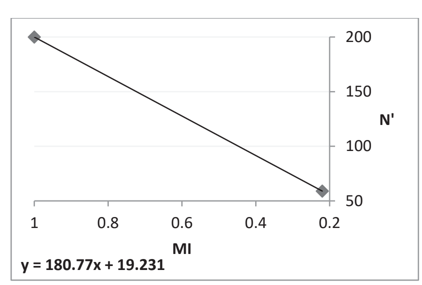


Fig. 9 Calculation of N′ in terms of MI for very low-priority maintenance.

To update the management strategies adopted in various periods (intervals), the adaptation coefficient (AC) is defined as follows:

$$AC = \#PM_{REPAIR} / \#PM_{TOTAL} \quad (7)$$

Where $\#PM_{REPAIR}$ and $\#PM_{TOTAL}$ respectively represent the number of maintenances leading to repair among the last three preventive maintenances as well as the total number of preventive maintenances (Here, 3 maintenances).
If AC equals 1/3 or 0, the maintenance priority is reduced by a level.
If AC equals 2/3, the maintenance priority is not changed.
If AC equals 1, the maintenance priority is increased by a level.
After three stages of Preventative Maintenance (PM), by changing the maintenance priority, the maintenance interval is updated based on different MN and UUN values in accordance with the algorithm in Fig. (10) and the new N′ value.

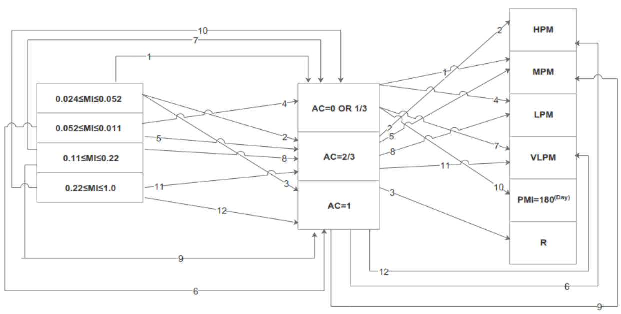


Fig. 10 The block diagram for updating the maintenance priority of medical devices.

3. Results and Discussion

The performance percentage of different factors for the Defibrillator and ECG,based on the results in Tables (5) and (6), is shown in the bar chart Fig (11). It compared the performance effects of the Defibrillator and ECG. The highest impact of the ULR on the performance of Defibrillator and ECG was respectively 24.5 and 23.69. The ULR, UR, and AD play a more important role than other parameters. Auxiliary devices play a more important role than the UR in the case of ECG. An opposite result was observed for the Defibrillator device. The effect of brand on the performance of ECG was twice that on the Defibrillator device.

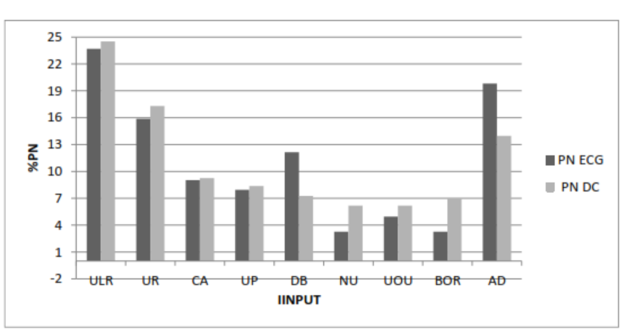


Fig. 11 Comparison of the performance numbers of Defibrillator and ECG to different inputs.

Through implementation of model as a case study on defined devices in various hospital wards, based on the UUN and MN for these equipment, MI, PMI, and management suggestions (SUGGEST) were specified to determine the objectives of the health system roadmap including replacement, inspection, and preventive maintenance prioritization in accordance with Tables (10) and (11).

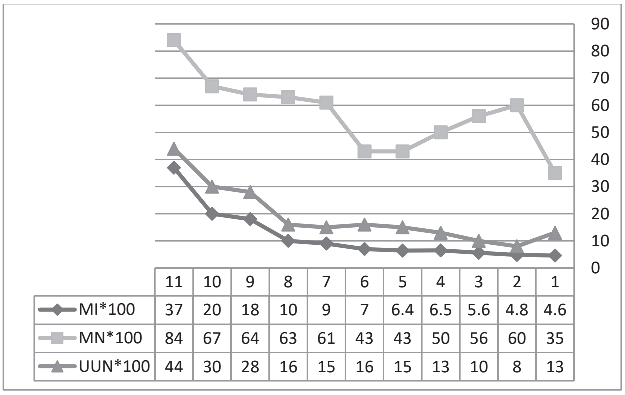
Table 10 The management approach required for Defibrillator devices in various hospital wards.

ULR	UL	CA	UP	DB	NU	UOU	BOR	AD	MN	UUN	MI	SUGEST	PMI
0.50	0.55	0.50	0.70	0.80	0.70	1.00	0.80	0.70	0.64	0.28	0.18	LPM	116
0.30	0.25	0.00	0.35	0.40	0.50	0.00	0.60	0.30	0.29	0.07	0.02	I	-
0.15	0.20	0.00	0.35	0.20	0.50	0.00	0.60	0.30	0.23	0.03	0.007	R	-
0.50	0.25	0.50	0.70	0.40	0.70	0.00	0.80	0.70	0.50	0.13	0.065	MPM	62
0.50	0.25	0 .00	0.70	0.20	0.50	0.00	0.60	0.30	0.35	0.13	0.046	HPM	52
0.80	0.55	1.00	1.00	0.80	1.00	1.00	0.80	1.00	0.84	0.44	0.37	VLPM	155
0.15	1.00	0.50	0.70	1.00	1.00	1.00	0.80	0.30	0.61	0.15	0.09	MPM	73
0.30	0.25	1.00	1.00	1.00	0.50	1.00	0.60	0.70	0.60	0.08	0.048	HPM	53
0.30	0.20	0.50	0.70	0.20	0.50	1.00	0.60	0.30	0.40	0.06	0.024	I	-
0.50	0.20	0.50	0.70	0.80	0.70	1.00	0.60	0.70	0.56	0.10	0.056	MPM	57
0.80	0.20	0.50	0.70	0.80	0.50	1.00	0.60	0.70	0.63	0.16	0.1	MPM	76
0.80	0.20	0.00	0.35	0.80	0.50	0.00	0.60	0.30	0.43	0.16	0.07	MPM	65
0.15	1.00	0.50	0.35	0.40	0.50	0.00	0.60	0.30	0.43	0.15	0.064	MPM	62
0.30	1.00	1.00	1.00	0.40	1.00	1.00	0.80	0.30	0.67	0.30	0.2	LPM	126

Table 11 The management approach required for ECGs in various hospital wards.

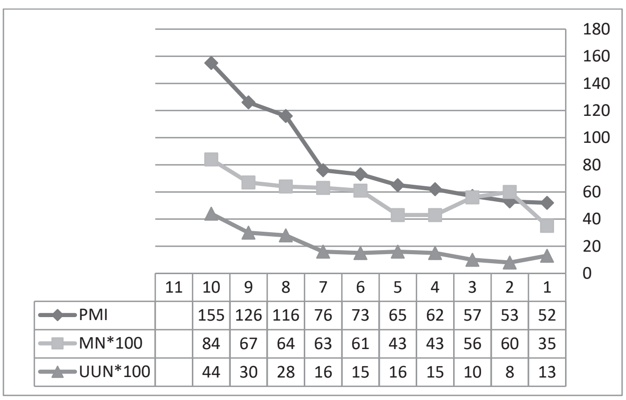
ULR	UL	CA	UP	DB	NU	UOU	BOR	AD	MN	UUN	MI	SUGEST	PMI
0.50	0.25	0.50	0.70	0.40	0.70	1.00	0.80	0.70	0.54	0.13	0.07	MPM	65
0.50	0.20	0.00	0.35	0.20	0.50	0.00	0.60	0.30	0.30	0.10	0.03	HPM	40
0.15	0.20	0.00	0.35	0.20	0.50	0.00	0.60	0.30	0.21	0.03	0 .0063	R	-
1.00	1.00	0.00	0.35	0.20	0.50	0.00	0.60	0.30	0.54	1.00	0.54	VLPM	166
1.00	1.00	1.00	0.35	1.00	0.50	0.00	0.60	0.30	0.73	1.00	0.73	VLPM	174
1.00	0.25	0.00	0.35	0.40	0.50	0.00	0.60	0.30	0.45	0.25	0.112	LPM	81
0.30	0.25	0.50	0.70	0.40	0.70	1.00	0.80	0.70	0.50	0.07	0.035	HPM	44
0.30	0.55	0.50	0.70	0.40	0.70	1.00	0.80	0.70	0.55	0.17	0.09	MPM	73
0.15	0.55	0.00	0.35	0.80	0.50	0.00	0.60	0.30	0.34	0.08	0.028	HPM	38
0.15	1.00	0.50	0.70	0.80	0.50	1.00	0.60	0.70	0.62	0.15	0.093	MPM	74
0.80	0.20	0.00	0.35	0.20	0.50	0.00	0.60	0.30	0.37	0.16	0.06	MPM	60
0.80	0.25	0.50	0.70	0.40	0.70	1.00	0.80	0.70	0.62	0.20	0.124	LPM	87
0.80	0.20	1.00	1.00	1.00	0.50	1.00	0.60	0.30	0.66	0.16	0.1	MPM	76
0.80	1.00	0.50	0.35	0.80	0.50	0.00	0.60	0.30	0.61	0.80	0.49	VLPM	164

Figure (12) displays the relationship of UUN, MN, and MI. As seen, there is a significant difference between the variation slops of MI as an indicator for management decisions and MN as a number obtained based on the factors affecting the performance of medical devices. This can be related to the effect of UUN as the most important factor on the performance of equipment. It also indicated the most deterministic role of the UUN in decisions on medical devices. This can be clearly seen from the same slopes of the two diagrams for the UUN and MI.
Figure (13) shows the linear diagrams for the MN, UUN, and PMI of medical devices. At points where there are significant variations in the MN and UUN, the maintenance intervals are also considerably increased. In contrast, at points where at least one of these numbers show less variations, maintenance intervals vary slightly. This indicates the simultaneous effect of ULR and UR, and other factors affect the performance of equipment on the maintenance intervals.



	11	10	9	8	7	6	5	4	3	2	1
MI*100	37	20	18	10	9	7	6.4	6.5	5.6	4.8	4.6
MN*100	84	67	64	63	61	43	43	50	56	60	35
UUN*100	44	30	28	16	15	16	15	13	10	8	13

Fig. 12 Relationship of Utilization Ratio & Useful Life Ratio Number (UUN), Management Marker Index (MI) and Management Number (MN)



	11	10	9	8	7	6	5	4	3	2	1
PMI		155	126	116	76	73	65	62	57	53	52
MN*100		84	67	64	63	61	43	43	56	60	35
UUN*100		44	30	28	16	15	16	15	10	8	13

Fig. 12 Relationship of Utilization Ratio & Useful Life Ratio Number (UUN), Management Marker Index (MI) and Management Number (MN)

In other words, a long maintenance interval can be considered for a relatively new equipment with a medium or even low UR, even when other factors affecting the performance are not very desirable. A long maintenance interval can be also considered for an almost old equipment with a medium or high UR if other factors affecting the performance are desirable.

The proposed model is an adaptive and highly flexible model, if necessary, the model is able to suggest a financially optimal solution for the system by changing one or more elements influencing the performance of medical devices. For example, if a device operating in the emergency ward is candidate for replacement, to avoid financial burden to the system, the device is transferred to another ward. It should be noted that its MI shall not be a replacement candidate in that ward considering other elements. This can be done not by an empirical method but using exact management numbers. Furthermore, this adaptive method is updatable based on the last three PM intervals. For instance, if a device in the internal ward is detected due to need high-priority maintenance, and an AC of 1/3 is obtained after three PM intervals, its maintenance priority is automatically changed to medium, and PM intervals are also changed. Hence, this method provides a novel index for these two devices in management processes.

4. Conclusion

Efforts were made to develop a quantitative model with a new model for planning the management processes of medical devices in health centers concerning the need to purchase, maintenance prioritization, and replacement. Factors affecting the performance of Defibrillator and ECG were evaluated. The most important factors affecting the performance of Defibrillator devices were the useful life ratio (ULR) and usage ratio (UR). On the other hand, the ULR and auxiliary device (AD) were the key factors influencing the performance of ECGs.

In this paper, an adaptive method was proposed for managing medical devices throughout their lifecycle. The proposed method is a highly flexible model without complex mathematical calculations and able to suggest a financially optimal solution for the system by changing one or more elements influencing the performance of medical devices. The model was implemented and tested in three public hospitals and it solved one of the big decision problems in their management systems. The results helped them to have a priority list of the medical devices that should be replaced and the preventative maintenance priority of critical devices based on the wards, type and number of them according to the available budget. Implementation of our proposed model, in medical centers, could maximize the reliability of equipment and systems among the limitation of organizational resources and budgets. In the meanwhile, using an efficient strategy for all of medical devices ,as a comprehensive guideline in the management processes, is an important key step in managing health financial system and safety management.

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Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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