A Holistic Approach for Forecasting Medical Equipment Risks Using Monte Carlo Simulation

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Abstract **- As any technology, medical equipment provides benefits to patients, but they also present significant risks that can affect and threaten patient safety. In healthcare organizations, clinical engineering departments play a big role in maintaining the safety and reliability of medical equipment. In order to mitigate failures of such equipment and control risks, a proper Medical Equipment Management Program (MEMP) should be established. The purpose of this paper is to forecast risks by using Failure Mode and Effect Analysis (FMEA) method and apply it on Monte Carlo simulation which adds risks analysis to Excel® by @RISK tool. The data of some medical devices is extracted from a hospital's maintenance management system and are identified according to their likelihood, severity, and difficulty of detection. However, the results of this mathematical simulation are integrated in a probability distribution function that enable us to identify medical equipment risks that affect patients, staff, and the work environment and reduce them by providing contingency plans, policies, strategies, and other tactics [1].**

Keywords - medical equipment; risk management; FMEA; Monte Carlo simulation; HIQMA.

I. INTRODUCTION

As medical technology becomes more complicated, a MEMP must be applied to ensure that medical devices operate according to safety, accuracy, reliability, and performance criteria. Maintenance is one of the most important processes to improve safety, decrease the risk of equipment failure, and minimize the unplanned downtime [2]. However, the money spent on maintenance and failure of equipment is rapidly increasing because of the development of many types of complex medical equipment, the stringent environment they are operating under it, and the lack of proper management.

The management program includes a risk management process, which comprises the identification, assessment, and prioritization of risks (defined in ISO 31000 as the effect of uncertainty on objectives) followed by coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of unfortunate events [3]. The causes of the risks are identified and relevant changes in the system are made accordingly in order to reduce the probability of the error occurring in the future thus reducing harm to patients and providing a safer patient care experience.

Most healthcare organizations follow the manufacturer's recommendations concerning the maintenance program [4]. Campbell and Jardine [5] defined the maintenance excellence as the balance of performance, risk, resource inputs and cost to reach to an optimal solution. In the last decade, maintenance techniques have been notably improving, but most of the healthcare organizations do not profit from the maintenance excellence that Campbell and Jardine established. Moreover, some devices that are similar in their function and design have manufacturer-recommended intervals that vary by one or two factors thus leading to financial and time loss. In addition, excessive maintenance can have the same impact as an insufficient level of maintenance; moderation should be the rule.

The status of research on maintenance of medical devices is presented in different models. Fennigkoh and Smith [6] model classified equipment according to three parameters: function, physical risks, and maintenance requirements. It was known later as risk-based inclusion criteria that allowed clinical engineering professionals to apply maintenance on limited parts of medical devices.

Ridgway, in the beginning, noted that Preventive Maintenance (PM) is an important factor in terms of reliability, but later on, he indicated that PM does not prevent failure for all equipment and it is not the ideal solution. However, Ridgway provided methods for equipment management such as Reliability Centered Maintenance (RCM). This latter is a corporate-level maintenance strategy that is implemented in any healthcare organization to optimize the maintenance program. Endrenyi [7] indicated that RCM selects the critical component in the equipment and starts a maintenance management to correct the failure. Further on, he recognized that RCM is good for indicating the budget and for comparing policies, but it cannot help in achieving real optimization.

According to Hall [8], the two keys of RCM are having a good maintenance history of the medical equipment and the age of the equipment. Further he indicated that RCM is applicable for younger equipment. However, to balance between preventive and corrective maintenance, Condition Based Maintenance (CBM) is presented to observe and

forecast real time status of machines [8]. CBM is performed when some indicators show that the equipment will fail.

Taghipour et al. [9] presented a multi-criteria decision-making model to prioritize medical devices according to their criticality. Furthermore, in terms of prioritization, Jamshidi et al. [10] developed a fuzzy healthcare failure modes and effect analysis (HFMEA). HFMEA is a systematic method that identifies and prevents equipment problems before they occur by ensuring a safe and clinically desirable outcome [11].

To minimize risk and optimize the cost-effectiveness of medical equipment, a maintenance model is suggested by Khalaf et al. [12]. They evaluated both elements and the results showed poor performance concerning cost and risk management. Therefore, Khalaf et al. [13] developed a new model in order to be used in Palestinian hospitals, which is a mathematical model that uses a mixed integer-based approach for maintenance operations schedules for medical equipment. They also proposed a greedy algorithm for an initial solution for the model. In addition, some data extracted from maintenance history of infusion pumps and ventilators were used in a global model that measures the probability of equipment being available and they were analyzed using Matlab. However, this model was validated by developing a model that measures the survival of equipment as function of maintenance and age of equipment using survival analysis approach.

The studies reported above proposed models that share a common theme; different risks are calculated using a single measure that is defined and used to lead safety, performance inspections, and preventive maintenance activities. These models are simple to use and effective in reducing general risks yet they lack the ability to identify specific risks. They are far from achieving optimal risk minimization. Also, research into comprehensive frameworks for prioritizing critical medical devices or outsourcing of medical device maintenance is still in its infancy. Researchers should apply new risk-based maintenance models including different new uncertainties to replace the traditional empirical models.

In our model, a Complete Risk and Decision Analysis Toolkit from Palisade: "The DecisionTools Suite" is used. It is an integrated set of programs for risk analysis and decision-making under uncertainty that runs in Microsoft Excel®. The main tool that was used is @RISK, which adds risk analysis to Excel® using Monte Carlo simulation. The Monte Carlo simulation is a technique used to understand the impact of risk and uncertainty in financial, project management, cost, and other models which is to identify risks related to medical equipment [14]. FMEA method was also used to prevent failure of equipment. Data related to maintenance and failures of equipment were obtained from a Lebanese hospital to apply them in our model in order to verify its functionality and applicability.

The proposed methodology is presented in Section II. The implementation process is presented in Section III. This latter, includes collecting data, and integrating FMEA method using Monte Carlo simulation. This is followed by results and discussion in Section IV. Finally, a conclusion and our further expectations are presented in Section V.

II. METHODOLOGY

Medical devices are used in healthcare organizations to support patient care in terms of health and safety. Currently, modern medical devices are complex and operate under severe conditions because of the rapid development of equipment. The current strategies in hospitals have difficulties in identifying risks and applying optimal risk reduction activities because they lack proper management processes. Therefore, a well-operated management process can enhance the function of medical devices in healthcare organizations.

The proposed model is meant to identify and assess risks of medical equipment according to mathematical approach using different parameters. It starts with collecting data concerning medical devices from a Lebanese Hospital. The needed numbers such as the likelihood, detectability, and impact of medical equipment failure are then extracted and analyzed.

There are several methods to calculate the risk value, yet FMEA method is used as the preferred choice in the current model. FMEA is selected among other methods because it contributes to improved designs for products and processes, to cost savings, and to the development of control plans, testing requirements, optimum maintenance plans, reliability growth analysis and related activities [15]. The FMEA procedure starts with determining the ways in which the input can go wrong, and then determining effects for each failure mode. After that, it identifies potential causes for each mode and list current controls for each cause. Consequently, risk priority number can be determined and contingency plans and actions should be set accordingly.

After applying the FMEA method, it will be integrated in Monte Carlo simulation tool that includes @Risk toolkit. @Risk adds risk analysis to Excel® using Monte Carlo simulation. Then the simulation will be performed and the results will be assessed to draw a conclusion.

The methodology is depicted in the following flowchart.

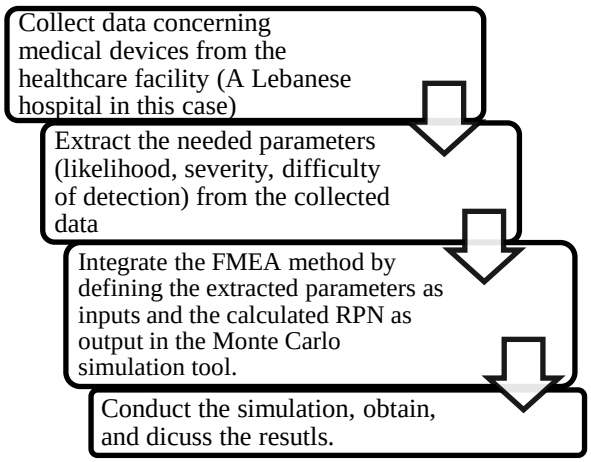

Figure 1. The proposed methodology

Fig. 1 summarizes the required steps to accomplish our evaluation. Such assessment requires some parameters and equations. So, the derivations of all those relations are explained in the subsequent sections.

III. Implementation Process

The implementation process includes three main steps that are "Collecting and Extracting Data", "Integrating FMEA Method in Monte Carlo Simulation Tool", and "Simulation and Results" to be accomplished.

A. Collecting and Extracting Data

First, to apply the FMEA method, specific data concerning medical devices are collected.

Likelihood of the medical device in this case is the probability of failure of the machine. Fig. 2 shows the number of repeated failures per year with respect to medical devices. These numbers are then converted to a scale of 1-10 as shown in Table I using the following conversion:

Number of repeated failures*(10/ Highest number of repeated failures)

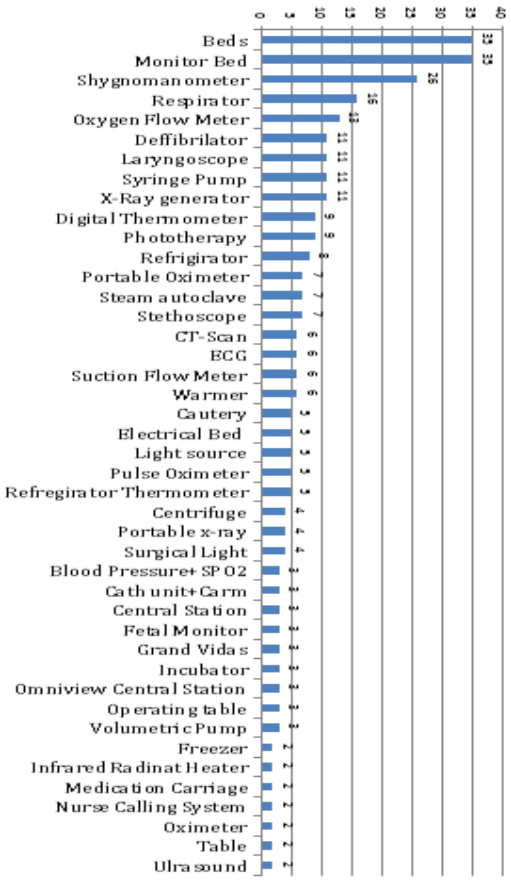

Figure 2. Number of repeated failure.

The scores of likelihood of medical devices failures are assigned according to the following criteria [16]:

{1, 2}: Improbable, manifestations of the hazard are very unlikely

{3, 4}: Remote, manifestations of the hazard are possible but not likely

{5, 6}: Occasional, some manifestations of the hazard are likely to occur

{7, 8}: Probable, hazard will be experienced

{9, 10}: Frequent, hazard likely to occur

Severity of medical device is defined as the extent to which the defect of equipment can affect patients. The scores of severity are assigned according to the following criteria [16]:

{1, 2}: Negligible, no significant risk of injury

{3, 4}: Minor, potential for minor injury

{5, 6}: Moderate, potential for minor injury

{7, 8}: Critical, potential for severe injury

{9, 10}: Catastrophic, likely to result in death

Detection is the ability of the current control scheme to detect and then prevent a hazard from occurring. The scores of detection are assigned according to the following criteria [11]:

{1, 2}: Almost certain (detection probability <100%), potential hazard will almost certainly be detected

{3, 4}: High (detection probability <80%), high chance that potential hazard will be detected

{5,6}: Moderate (detection probability <50%), moderate chance that potential hazard will be detected

{7,8}: Low (detection probability <25%), low chance that potential hazard will be detected

{9, 10}: Remote (detection probability <10%), very remote chance that potential hazard will be detected

Table I. Extracted Parameters.

Equipment	Likelihood	Severity	Difficulty of Detection
Beds	10.00	6	1
Sphygmomanometer	7.43	5	1
Defibrillator	3.14	10	4
Ultrasound	0.57	3	3
Pulse Oximeter	1.43	7	2
Syringe Pump	3.14	10	7

All values of likelihood, severity, and difficulty of detection of equipment are given by the hospital. Table I shows the scores of likelihood, severity, and difficulty of detection for six medical devices on a scale of 1-10.

B. Integrating FMEA Method in Monte Carlo Simulation Tool

The parameters extracted from the collected data will be employed in a systematic technique called FMEA.

FMEA is one of the first highly structured, systematic techniques for failure analysis. It was developed by reliability engineers in the late 1940's to study problems that might arise from malfunctions of military systems [17]. It is a step-by-step systematic approach for identifying all possible failures in a design, a manufacturing or assembly process.

Failures are prioritized according to how severe their consequences are, how likely they may occur and how difficult to detect them. The main purpose of the FMEA is to take preliminary actions to reduce failures, starting with the highest-priority ones [18].

Risk Priority Number (RPN) is a measure used when assessing risk to help identify critical failure modes. The RPN values range from 1 (absolute best) to 1000 (absolute worst). It is the product of three ratings on a scale of 10 (likelihood of occurrence, severity of impact, and difficulty of detection):

$$RPN = Likelihood * Severity * Difficulty\ of\ Detection$$

Table II illustrates the extracted parameters and the calculated RPN for each equipment.

Equipment	Likelihood	Severity	Difficulty of Detection	RPN
Beds	10.00	6	1	60.00
Sphygmomanometer	7.43	5	1	37.15
Defibrillator	3.14	10	4	125.60
Ultrasound	0.57	3	3	5.13
Pulse Oximeter	1.43	7	2	20.02
Syringe Pump	3.14	10	7	219.80

Table II. Calculated RPN.

After calculating the risk priority numbers, the model is now ready to be integrated in the @Risk simulation tool.

The first step is to insert Table II in an Excel® sheet and define inputs (likelihood, severity and difficulty of detection) as normal distributions. Usually, high standard deviation is selected in situations where resources are limited or gathering real data would be too expensive or impractical. In this situation, the data is extracted from a real hospital management system, hence a very small standard deviation is selected (0.1), as depicted in Fig. 3:

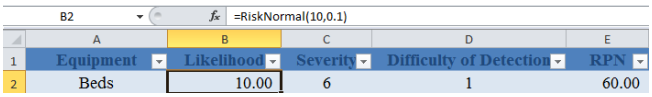

Figure 3. Definition of inputs as normal distributions.

RPN is the output in our model; Fig. 4 illustrates how RPN is defined as an output in the Monte-Carlo simulation tool "RiskOutput("RPN")".

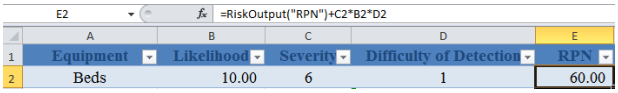

Figure 4. Adding @Risk output.

C. Simulation and Results

@RISK monitors a set of convergence statistics on each output distribution during a simulation. During monitoring, @RISK calculates these statistics for each output at selected intervals (such as: every 1000 iterations) throughout the simulation.

As more iterations run, the amount of change in the statistics becomes less and less until they reach the Convergence Tolerance [19].

Convergence tolerance specifies the tolerance allowed for the statistic being tested. For example, the current applied settings specify that the estimated mean of each output is simulated within 3% of its actual value [19].

In our model in Fig. 5, we will be performing 5000 iterations in one simulation.

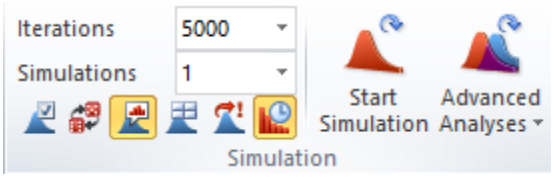

Figure 5. Changing the number of iterations and starting simulation.

At the end of the simulation, the results are integrated in a probability distribution function. A probability distribution is a statistical function that describes all the possible values and likelihoods that a random variable can take within a given range [20]. This range will be between the minimum and maximum statistically possible values, but where the possible value is likely to be plotted on the probability distribution depends on a number of factors, including the distributions mean and standard deviation.

Fig. 6 illustrates one example of the results obtained; the risk priority number of hospital Beds (60) is centered between 49.98 and 70.09 for 90% of the probability distribution. The x-axis represents the possible risk priority numbers and the y-axis represents the probability of occurrence for each probable RPN incrementing by 0.02 on a scale of 0.1.

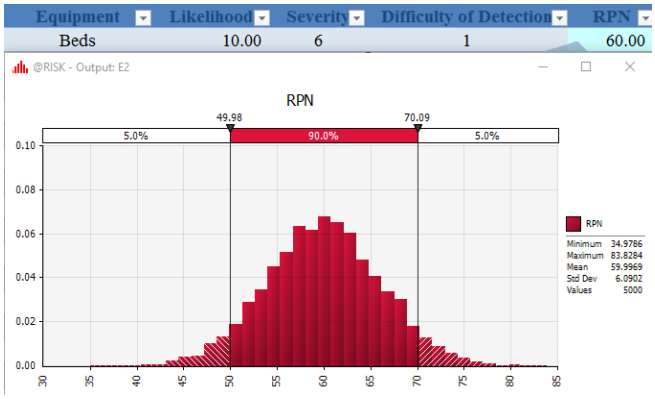

Figure 6. Results after simulation.

IV. Results and Discussion

The result of the Monte Carlo Simulation via @RISK is a probability distribution. Figs. 6, 7, 8, 9, 10, and 11 show the probability density for the chosen examples: beds, defibrillator, ultrasound, syringe pump, sphygmomanometer, and pulse oximeter.

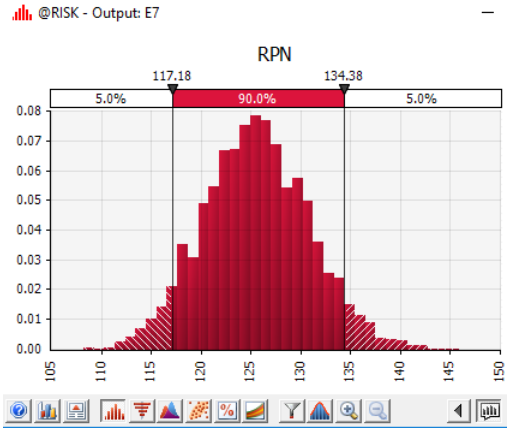

Figure 7. Probability distribution for defibrillator.

Fig. 7 shows the risk priority number of defibrillator (125.60) is centered between 117.18 and 134.38 for 90% of the probability distribution.

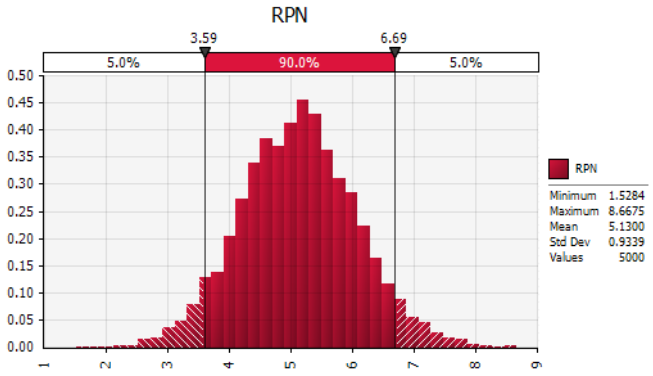

Figure 8. Probability distribution for ultrasound.

Fig.8 shows the risk priority number of ultrasound (5.13) is centered between 3.59 and 6.69 for 90% of the probability distribution.

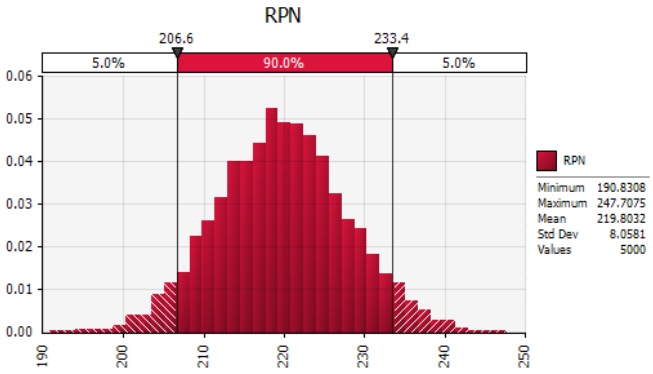

Figure 9. Probability distribution for syringe pump.

Fig.9 shows the risk priority number of syringe pump (219.80) is centered between 206.6 and 233.4 for 90% of the probability distribution.

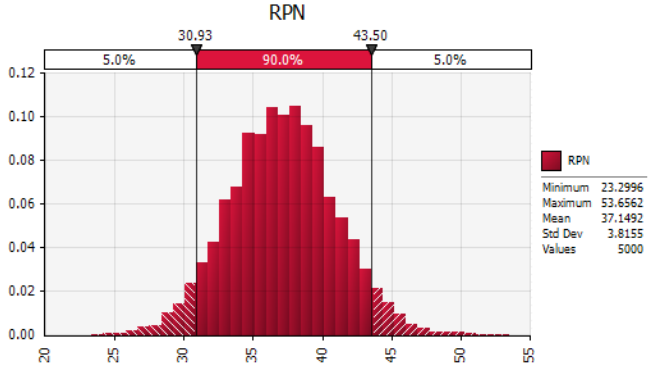

Figure 10. Probability distribution for sphygmomanometer.

Fig.10 shows the risk priority number of sphygmomanometer (37.15) is centered between 30.93 and 43.50 for 90% of the probability distribution.

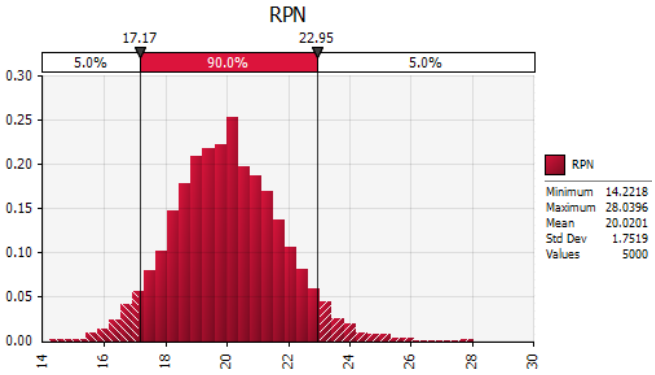

Figure 11. Probability distribution for pulse oximeter.

Fig.11 shows the risk priority number of pulse oximeter (20.02) is centered between 17.17 and 22.95 for 90% of the probability distribution.

	Minimum	Maximum	Mean
Beds	34.97	83.82	59.99
Sphygmomanometer	23.29	53.66	37.15
Defibrillator	108.23	145.19	125.6
Ultrasound	1.53	8.67	5.13
Pulse Oximeter	14.22	28.04	20.02
Syringe Pump	190.83	247.70	219.80

Table III. Summary of the Results.

The results presented in Figs. 6, 7, 8, 9, 10, and 11 and Table III is interpretable as follows:

1. The mean figure for RPN will be 60 for beds, 37.15 for sphygmomanometer, 125.6 for defibrillator, 5.13 for ultrasound, 20.02 for pulse oximeter and 219.80 for syringe pump. That means, the simulated result will be equal to the original calculated RPN.

2. The minimum figure for RPN will be 34.97 for beds, 23.29 for sphygmomanometer, 108.23 for defibrillator, 1.53 for ultrasound, 14.22 for pulse oximeter and 190.83 for syringe pump. That means, the minimum probability will be lower than the calculated RPN by 25.03 for beds, 13.86 for sphygmomanometer, 17.37 for defibrillator, 3.6 for ultrasound, 5.8 for pulse oximeter and 28.97 for syringe pump. But theses figure are the bottom lines and will only be achieved if all negative circumstances would occur. Hence, with a probability of 5 %, the figure for RPN will fall low to 34.97, 23.29, 108.23, 1.53, 14.22, and 190.83. In other words, with a probability of 95 % the RPN will not fall below these numbers.

3. The maximum figure for RPN will be 83.82 for beds 53.66 for sphygmomanometer, 145.19 for defibrillator, 8.67 for ultrasound, 28.04 for pulse oximeter and 247.70 for syringe pump. That means, the maximum probability will be higher than the calculated RPN by 23.22 for beds, 16.51 for sphygmomanometer, 19.59 for defibrillator, 3.54 for ultrasound, 8.02 for pulse oximeter and 27.9 for syringe pump. But these figures are the upper limits and will only be achieved if all positive circumstances would occur. Hence, with a probability of 95 %, the figure for RPN will not exceed 83.82, 53.66, 145.19, 8.67, 28.04, and 247.70. In other words, with a probability of 5% the RPN will exceed these numbers.

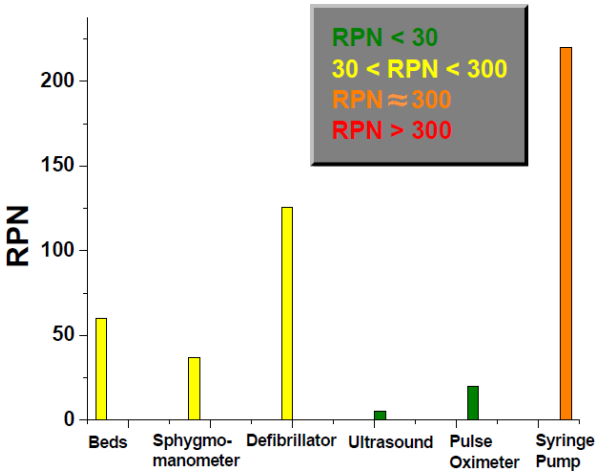

Figure 12. Histogram of RPNs

Fig. 12 shows a histogram illustrating each device's RPN. This histogram helps us track the severity of risks on each device in order to solve the problem before happening. Each of the RPN scores will fall under one of the categories, for which different colors have been used. Here are some details on each of the categories:

High Risk: It represents the red color which is the most dangerous category. Example: Syringe pump: almost in the high risk category (presented in orange).

Medium Risk: The yellow category has less priority than the one before but also plans and decisions must be set to handle those risks. Example: Beds, Sphygmomanometer, and Defibrillator.
Low Risk: The last category that represents the green color has the lowest priority where risks can be monitored minimally, and do not cause serious problems. Example: Ultrasound, Pulse oximeter.

After analyzing the results, some recommendations could be set to reduce risks such as having alternative or redundant devices in the healthcare facility, pay special attention to the to the life span of the equipment and its working hours when purchasing used devices, and to have a well operated maintenance program. Moreover, hospitals must be kept financially healthy while achieving financial-related risk management goals for healthcare organizations by reducing the malpractice claims and the number of failures.

An additional evaluation is possible to show where individual risk has a main influence of the final risk priority number. Figs. 12, 13, 14, 15, 16, and 17 show the results of those evaluations as regression coefficients. This indicates that difficulty of detection has a huge influence of the RPN of beds and the likelihood has the higher influence on the RPN of the defibrillator. Therefore, these risk factors have to be monitored very carefully within an effective healthcare management system.

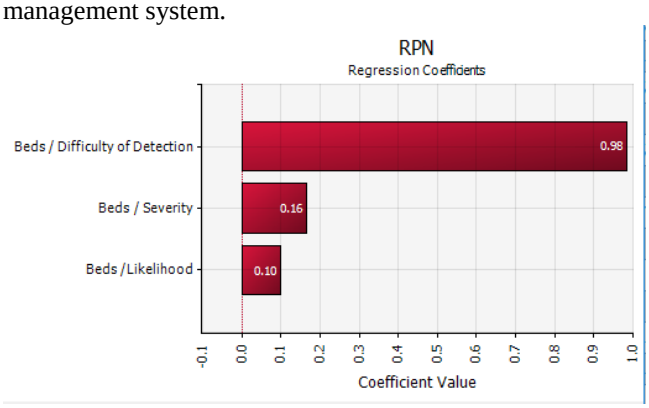

Figure 13. Regression coefficients for beds.

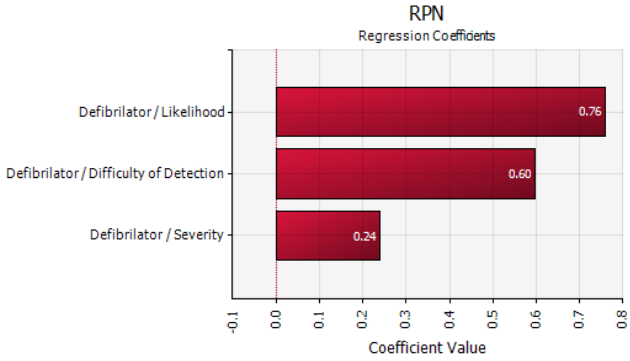

Figure 14. Regression coefficients for defibrillator.

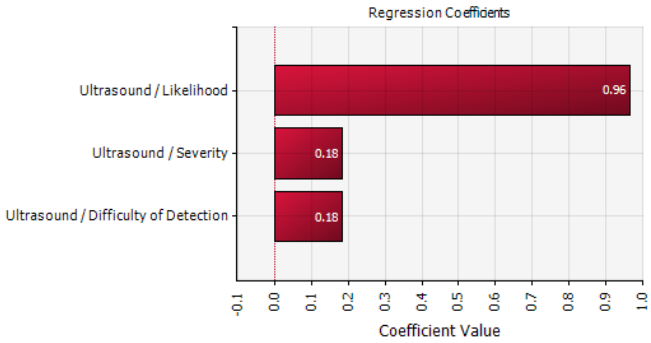

Figure 15. Regression coefficients for ultrasound.

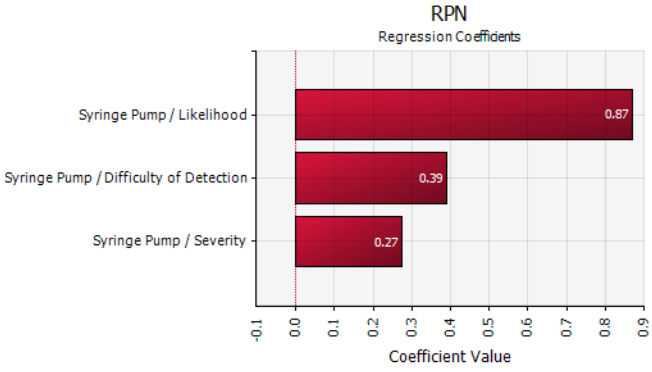

Figure 16. Regression coefficients for syringe pump.

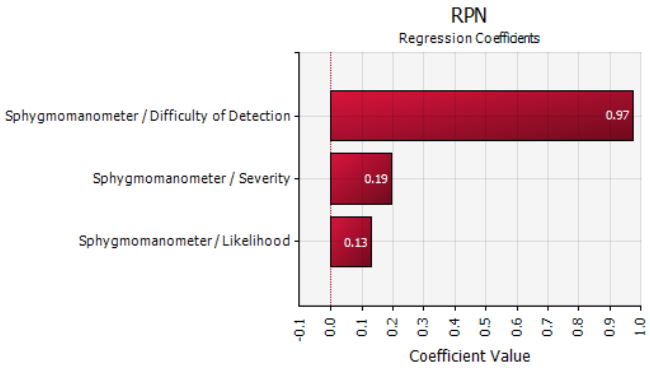

Figure 17. Regression coefficients for sphygmomanometer.

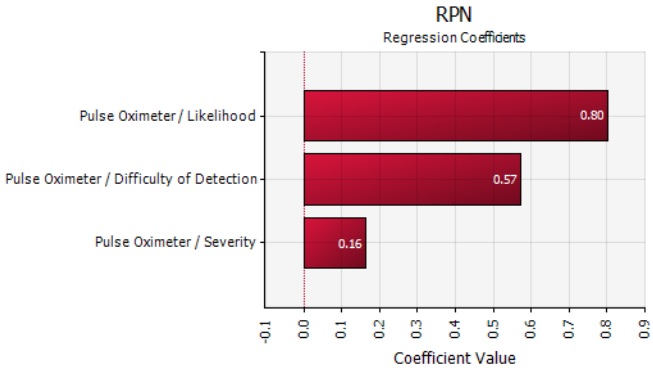

Figure 18. Regression coefficients for pulse oximeter.

However, this model could be integrated in the HIQMA (Hospital Institution Quality Management) system. HIQMA was deployed for the first time in Lebanon in early 2011 to enhance medical and healthcare services ensuring quality [21]. The principle objective is to guarantee patients' safety through viable and effective quality management in system includes scalability and customizability traits. The framework properties incorporate a few applications, beginning with the individual beneficiary organizations, proceeding with the reformed professional training and advisory services concepts, and ending with the created administration rules [21].

HIQMA is a centralized management system that provides a gateway to critical quality information and facilitates quality performance improvement through requirement tracking, notifications and real-time management reporting [21]. This system increases marketability, customer satisfaction and service; it also saves time, money and resources. Moreover, it improves internal communication and operational performance and provides better management control [22].

Biomedical engineers and technicians using HIQMA are providing the system with important dated information included in their reports about each equipment failure, thus providing enough data to calculate its probability of occurrence. Also, they are mentioning the severity and consequences of each occurred failure. The only missing information in the reports is the difficulty of detection; it can be collected from their experience in a questionnaire included in each technical report on a scale from 1-10.

Finally, a risk severity matrix is employed to raise awareness and increase visibility of risks so that sound decisions on certain risks can be made. The risk matrix is shown in Fig. 18. Once the risks have been placed in the cells of the matrix that corresponds to the appropriate likelihood, severity and difficulty of detection, it becomes visibly clear as to which risks must be managed at what priority.

Each of the risks will fall under one of the categories, for which different colors have been used. Table IV represents the letter of each device and under what color it falls. Here are some details on each of the categories:

High: The risks that fall in the cells colored in red are the risks that are most critical and that must be addressed on a high priority basis. Example: ‘X’ Defibrillator, ‘Y’ Syringe Pump.
Medium: If a risk falls in one of the yellow cells, it is best to take some reasonable steps and develop risk management strategies in time, even though there is no hurry to have such risks dealt with early. Example: ‘C’ Sphygmomanometer, ‘I’ Beds and ‘O’ Pulse Oximeter.
Low Risk: The risks that fall in the green cells can be minimally monitored as they usually do not pose any significant problem. However, if some reasonable steps can help in fighting these risks, such steps should be taken to improve overall performance Example: ‘A’ Ultrasound Machine.

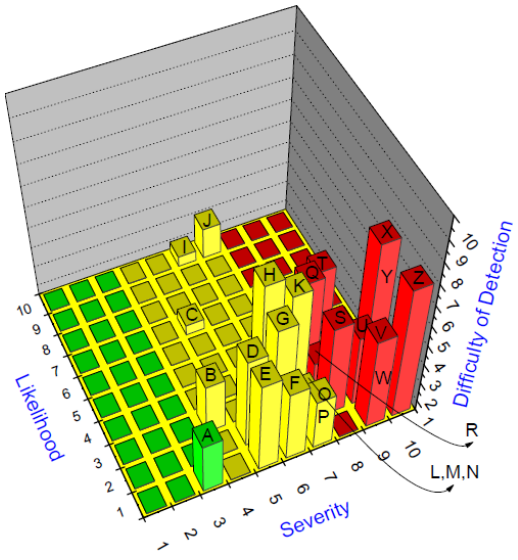

Figure 19. Risk severity matrix.

Table IV. Legend for the risk severity matrix.

Ultrasound	A	
X-Ray Generator	B	
Sphygmomanometer	C	
CT-Scan	D	
Portable X-Ray	E	
Centrifuge	F	
Warmer	G	
Digital Thermometer	H	
Beds	I	
Monitor Bed	J	
Phototherapy	K	
Portable Oximeter	L	
Stethoscope	M	
ECG	N	
Pulse Oximeter	O	
Blood Pressure + SPO2	P	
Oxygen Flow Meter	Q	
Laryngoscope	R	
Suction Flow Meter	S	
Respirator	T	
Cautery	U	
Cath Unit	V	
Incubator	W	
Defibrillator	X	
Syringe Pump	Y	
Volumetric Pump	Z	

After analyzing the results, some recommendations could be set to reduce risks such as having alternative or redundant devices in the healthcare facility, pay special attention to the to the life span of the equipment and its working hours when purchasing used devices, and to have a well operated maintenance program.

V. Conclusion and Future Work

The rapid evolution of medical equipment had a huge impact on the improvement and progress of medical services. Accordingly, medical devices are expected to operate under safety, accuracy, and reliability criteria to ensure a protected and efficient environment for patients, staff, and the surrounding work environment. As such, this research work provided a new methodology for identifying and assessing risks based on a mathematical approach and not only empirical ones. This method results in a more precise scheme that would most likely reduce the risks resulting from medical equipment and further provide a proper management in healthcare organizations. Moreover, this model can be integrated in healthcare facilities to identify and forecast risks according to risk distribution of Monte Carlo simulation and risk severity matrix that classifies and prioritizes medical devices risks.

This proposed assessment maybe be further enhanced to achieve risk response development, and risk response control of medical equipment by developing a complete tool that can be used in the medical equipment industry across the world. There should also be a further research in the field of optimal outsourcing of medical devices. Thus, manufacturers, organizations, and clinical engineering departments can use this tool in planning for maintenance and for the development of medical equipment. Also, it can be deployed as monitoring system in service at healthcare facilities where it can provide real time data on the risks of operating medical equipment.

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