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NEW APPROACH FOR COST-EFFECTIVE RISK REDUCTION OF MEDICAL EQUIPMENT IN DEVELOPING COUNTRIES

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ABSTRACT

In this study we propose new approach for cost-effective risk reduction by developing a risk-based Safety and Performance Test Scheduling Priority Index of Medical Equipment (SPTSPIME) and a risk-based Training Strategy Selection Priority Index of Medical Equipment (TSSPIME). This study can be described as two basic phases. The first phase is to determine the factors which affect the risk and to redefine some of them appropriately for safety and performance test scheduling and training strategy selection applications. The second phase is the risk classification enhancement by considering the risk of applied energy as a new risk classification factor, describing the categories of equipment according to what is found in a real environment during eight years of work as a biomedical engineer, and scoring every category to reveal the [3] real differences between the different categories in a reasonable manner. The percentage of cost reduction by the SPTSPIME model (P_1) is 59.56% of the total cost of safety and performance tests. This percentage will also influence the cost of other related extensive procedures of preventive maintenance. The percentage cost reduction by the TSSPIME model (P2) is 39.29% of the training cost.

KEYWORDS: Medical equipment risk classification, Safety and performance test scheduling, Training strategies selection, Priority index.

1. INTRODUCTION

We can determine the main goal of clinical engineers if we study their responsibilities. Engineers have first decided to consider the clinical engineering within the late Nineteen Sixties as a consequence of worrying about patient safety [1]. For instance, a clinical engineer is defined by the American College

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of Clinical Engineering (ACCE) as "a person who supports and develops healthcare by applying engineering and managerial skills to medical technology" [2].

In general, the main goal of clinical engineers is a cost-effective risk reduction. For example, in the design of hospital stage, the clinical engineer seeks to reduce a risk when he considers infection control as the main criterion [3]. In the needs evaluation stage, he considers a risk as the main criterion for evaluating the need for medical devices [4]. In the installation stage, the pre-installation plan is prepared to reduce any risk on medical equipment caused by improper site requirement preparation. In the training stage, the training of user is needed to avoid the risk of user error. The goal of preventive maintenance and risk-based preventive maintenance in the utilization stage is a cost-effective risk reduction [5, 6]. In the replacement stage, a process for assessing medical device replacement is needed to avoid any risk to patient safety [7].

Finding qualified technicians or clinical engineers in developing countries has been often difficult [8]. Maintenance errors occur due to incorrect repair or preventive actions [9]. Proper maintenance and training are important to assure the safety of medical devices, and to decrease human errors [10]. So, it is required at this point to develop the risk-based Safety and Performance Test Scheduling Priority Index of Medical Equipment (SPTSPIME) and the risk-based Training Strategy Selection Priority Index of Medical Equipment (TSSPIME). The resources which are spent on low-level risk medical equipment training and performance test should be dedicated to high-level risk equipment [11]. Present maintenance plans applied in hospitals are challenged by determining risk levels for different types of medical equipment [12].

2. EXISTING STUDIES ANALYSIS

The common factor used in risk classification which is defined by the Emergency Care Research Institute (ECRI) is physical risk [13]. One of the risk classification studies [14] defined physical risk, function, and maintenance requirement factors. Another study [15] depended upon the physical risk, function, and maintenance requirement with a new description of categories. This study defined new factors which are failure frequency and area criticality. Another study [13] depended

upon the maintenance requirement and ECRI's physical risk. This study defined new factors which are mission criticality and utilization rate. Another study [16] depended upon the function and physical risk factors to define a static risk factor. This study defined new factors which are safety arrangements, insulation, hazard alerts, and contact with a patient. Another study [17] depended upon the device function, physical risk, utilization, availability of alternative devices, recall and hazard alerts, and failure frequency. This study defined new factors which are failure detectability, downtime, cost of repair, and life ratio. Another study [18] depended upon the ECRI's physical risk, maintenance requirements, function, utilization, and availability with an adaptation in the availability calculation using an appropriate method for developing countries called Backup Safety Ratio (BSR). This study defined a new factor which is equipment importance. Another study [19] depended upon the physical risk, function, and maintenance requirement. This study defined new factors which are device complexity and missed maintenance.

3. METHOD

This study can be described as two basic phases. The first phase is to determine the factors which affect the risk and to redefine some of them appropriately for safety and performance test scheduling and training strategy selection applications. Risk classification factors can be obtained from existing studies of risk-based preventive maintenance, such as the device function, physical risk, area criticality, hazard alert, utilization, life ratio, cost of repair, equipment complexity, and maintenance requirement. Still other factors are obtained from risk-based safety tests, such as the insulation and the contact with patients. On the other hand, the maintenance requirement is redefined as safety and performance test requirement to be appropriate for safety and performance test scheduling. The equipment complexity is appropriately redefined for training strategy selection. The cost of repair is redefined as financial risk to be appropriate for both applications. The second phase is the risk classification enhancement by considering the risk of applied energy as a new risk classification factor, describing the categories of the equipment according to what is found in a real

environment for all new and redefined factors, as well as for some existing factors such as the utilization, and scoring of each category to reveal the real differences between the different categories in a reasonable manner. On the other side, the availability was excluded in this study because of unavailability of standby devices in the hospital which the data were collected. The life ratio was excluded from the training strategy selection classification because the decision of training strategy selection is taken at the beginning of the utilization cycle. The factors that we used will be outlined in the following sections.

3.1 Physical Risk

The Physical risk classification addresses the malfunction caused by equipment failure. The physical risk is categorized [14]. The potential patient death category Table 1 has a highly maximized score because the death of patients is a result of malfunction of equipment in this category.

3.2 Function

The function classification of a device addresses the main purpose for which it is to be used. The function factor is categorized [14]. The life support category in Table 1 has a highly maximized score because the death of patients is a result of absence of equipment function.

3.3 Area Criticality

The area criticality classification depends upon the importance of the clinical area in healthcare delivery. The area criticality is categorized [15]. The operation room category in Table 1 has a highly maximized score due to its high level of risk and high probability of risk in the downtime period.

3.4 Hazard Alert or Recall

The hazard alert or recall is defined as the hazard alert or recall policy for the cancellation of medical equipment acceptance [16]. The categories I, II in Table 1

have highly maximized scores because the concerned medical devices have a probability to cause the death or serious injury of patients.

3.5 Utilization

The utilization refers to the number of hours which the device is used during a day [17]. The utilization categories are proposed according to the Yemeni Governmental hospitals Table 1. The category I) has a highly maximized score because the concerned medical devices are used for 15 hours daily on average.

3.6 Applied Energy Level

The applied energy level refers to that risk level caused by applying energy for therapy or diagnosis. The applied energy is extrapolated to differentiate between the risk level of the defibrillator and the other life support devices without applied electrical energy in therapy. The applied energy categories are proposed according to what is found in a real environment Table 1. Category I) has a highly maximized score because the death of patients is a result of applying improper electrical energy.

3.7 Contact with Patients

The contact with the patient refers to the level of contact of equipment with a patient. It is related to the electrical risk [16]. The high category has a highly maximized score because the devices have a direct conductive path to the heart.

3.8 Insulation

The insulation classification refers to the level of insulation of equipment according to what is stated in the manufacturer's recommendation [16]. The high category has a highly maximized score because in that case there is no insulation to avoid the electrical risk.

3.9 Life Ratio

The life ratio of a device refers to the ratio between the actual and the expected lifetime of a device in years. The expected lifetime of the devices can be gathered from

the manufacturer's recommendation. In general, ten years can be considered as the average lifetime of a piece of equipment [17].

3.10 Financial Risk Classification

The financial risk classification addresses all money losses caused by either equipment failure or maintenance error. Financial risk depends on the price of equipment. The categories are described according to what is found in a real environment and are logically scored in Table 1. The financial risk is adopted from the cost of repair factor of risk-based preventive maintenance [17] as appropriate for both risk-based test scheduling and risk-based training strategy selection applications.

3.11 Equipment Complexity

The equipment complexity is redefined from risk-based preventive maintenance in [19] as being dependent on only the difficulty of maintenance and the number of system units, and used appropriately for a training strategy selection priority index. There are three equipment complexity categories described according to what is found in a real environment and are logically scored in Table 1.

3.12 Safety and Performance Test Requirement

The safety and performance test requirement classification addresses the required safety and performance test frequency of a device according to manufacturer's recommendation. This factor is adopted from the maintenance requirement factor of risk-based preventive maintenance scheduling [17] to be appropriate for risk-based safety and performance test scheduling application. Table 1 presents all of the classification factors categories and the relevance percentage of categories. Observe that for each classification factor, the normalized score for a category is a ratio between the category’s importance and the maximum importance for that factor

Table 1. Classification factors categories and relevance percentages.

Classification Factor	Categories Description	Importance %	Normalized Score
Physical Risk (PR)	Potential patient death	60	1
	Potential patient injury	20	0.333
	Inappropriate therapy or misdiagnosed	15	0.25
	No significant identified risk	5	0.08
Function (F)	life support	55	1
	Therapeutic	25	0.455
	Diagnostic	15	0.273
	Miscellaneous-patient related	5	0.091
	Miscellaneous-non patient related	0	0
Area Criticality (AC)	Operation room	50	1
	Intensity care units	25	0.5
	Outpatient, radiology, and labs	15	0.3
	Inpatient room and general care areas	10	0.2
	Non clinical area	0	000
Recall or Hazard alert (RA)	Category I: Reasonable probability of serious injury or death	55	1
	Category II :Remote probability of serious health consequences	40	0.72
	Category III: No serious consequences	5	0.09
Utilization (U)	Category I: Hours per day > 5	70	1
	Category II: 0< Hours per day ≤5	23	0.3
	Category III: No use	7	0.1
Applied Energy (AE)	Category I: Electrical energy	60	1
	Category II: Unsafe Radiation energy	30	0.5
	Category III: No applied energy Or energy with no significant risk	10	0.167

Table 1.Classification Factors Categories and Relevance Percentages (cont.)

Classification Factor	Categories Description	Importance %	Normalized Score
Contact with Patient (CL)	Direct conductive path to the heart	60	1
	Low impedance external connection	30	0.5
	More than a casual contact	10	0.167
Insulation (EI)	Need a protective earth	50	1
	Has a double insulation	40	0.8
	Work only with voltages less than 25 VAC or 60 VDC	10	0.2
Life Ratio (LR)	Ratio > 1	50	1
	0.5< Ratio ≤1	30	0.6
	Ratio<0.5	20	0.2
Financial Risk (FR)	(Total price > 500000 $)	67.5	1
	(100000< Total price <500000 $)	27.5	0.4
	(10000< Total price <100000 $)	4.6	0.07
	(Total price <10000 $)	0.4	0.006
Equipment Complexity (EC)	Difficult to maintain and multi- unit	60	1
	Difficult to maintain or multi- unit	30	0.5
	Easy to maintain and simple- unit	10	0.1
Safety and Performance Test Requirement (TR)	3 months	50	1
	6 months	25	0.5
	12 months	12.5	0.25
	More than 12 months	10	0.2
	No required safety & performance test	2.5	0.05

In this study 28 of medical device types were appropriately classified. For example, the anesthesia units were classified according to physical risk classification with the patient death category obtaining 1 as a score. They were classified according to function with the life support category obtaining 1 as a score, and so on. After all of

the devices were categorized and scored, the SPTSPIME and TSSDPIME were calculated according to Eqs. (1) and (2) respectively.

$$PI_1 = F + PR + AC + RA + AE + U + CL + EI + LR + TR + FR \quad (1)$$

$$PI_2 = F + PR + AC + RA + AE + U + CL + EI + EC + FR \quad (2)$$

where PI_1 is the SPTSPIME**,** F is a function score, PR is a physical risk score**,** AC is an area criticality score, RA is a recall score**,** AE is an applied energy score, U is a utilization score, CL is a patient contact score, EI is an insulation score**,** LR is a life ratio score, TR is a safety and performance test requirement score, FR is a financial risk score**,** PI_2 is the TSSDPIME, and EC is an equipment complexity score.

The medical devices were classified into three categories according to the priority index concerning the safety and performance test scheduling. Each of the first and second categories included 40% of the studied devices. We had to ensure that the highest number of the devices will be tested by an appropriate safety and performance test frequency. The medical devices were classified into six categories according to the priority index concerning training strategy selection. The first and second categories included 35% and 25% of the studied medical devices, respectively. We also had to assure that the highest number of the devices will be tested and maintained in a more reliable and safe manner.

4. RESULTS

4.1 Safety and Performance Test Scheduling Priority Index (SPTSPIME)

The Joint Commission (TJC) [20] states that the medical devices can be tested only every six months or less than that if a different interval is approved. As a result of that, the first category can be tested every month. The second category can be tested every 3 months. The last category can be tested every 6 months.

4.2 Training Strategies Selection Decision Priority Index of Medical Equipment (TSSDPIME)

The training strategies are listed from the most expensive strategy to least expensive [21]. Following the most expensive training strategy engineers who are specialized of medical equipment of the first category can be trained according to the manufacturer's training program. According to the second most expensive training strategy engineers who are specialized of medical equipment of the second category can be trained by a third-party training program. The third most expensive strategy implies training inside the hospital by one of the manufacturer's trainers for engineers who are specialized of medical equipment of the third category. According to the next ranking strategy engineers who are specialized of medical equipment of the fourth category can be trained inside the hospital by a specialized outside trainer. As for the fifth strategy, engineers who are specialized of medical equipment of the fifth category can be trained by a highly skillful engineer from inside hospital. The last strategy's engineers can be trained by self-study of the equipment service manuals, material prepared by the manufacturer, and material prepared by a third party. Table 2 presents PI_1 with an appropriately suggested safety and performance test frequency category number and PI_2 with an appropriately suggested training strategy number.

Table 2. Performance test and training priority indexes

No	Device	PI_1	Performance Test Category Number	PI_2	Training Strategy Number
1	Anesthesia	7.837	1	7.237	1
2	OR Ventilator, SAVINA	7.837	1	7.237	1
3	CCU Ventilator, SAVINA	7.337	1	6.737	1
4	ICU Ventilator, SERVO I	7.004	1	6.404	1
5	Emergency, Ventilator, SERVO I	7.004	1	6.404	1
6	Heart-lung machine	8.837	1	7.737	1
7	OR, Defibrillator	9.606	1	8.106	1
8	ICU, Defibrillator	9.106	1	7.606	1

9	Syringe pump	5.520	2	4.770	3
10	Infusion pump	5.520	2	4.770	3
11	Monitor	6.86	1	6.51	1
12	Cardiology, Ultrasound, IE33	5.547	2	5.197	2
13	Outpatient ECG	5.956	2	4.956	2
14	Stress ECG	5.956	2	4.956	2
15	CATH Lab	9.487	1	9.22	1
16	Inpatient ECG	6.556	2	5.556	2
17	Chemistry analyzer	4.054	3	2.954	4
18	ESU	8.936	1	7.436	1
19	Operating table	5.538	2	4.928	3
20	Surgical light	3.911	3	2.901	5
21	Body weight	1.711	3	1.201	6
22	Telemedicine	4.355	3	3.995	4
23	X-ray	5.517	2	4.417	3
24	CT	6.117	2	5.517	2
25	MRI	5.784	2	5.184	2
26	Radiology, Ultrasound, IU22	4.714	3	4.364	4
27	Lithotripsy	6.032	2	4.932	3
28	Hospital bed	3.451	3	2.701	5

5. DISCUSSION

The obtained results differ from the previous prioritization studies, by redefining appropriately the factors and enhancing the risk classification as mentioned in the method section, besides the dynamic factors which are changed from one case study to another, such as the utilization, availability, and age.

For instance, the normalized score of Electric Surgical Unit (ESU) (Storz, AUTOCON 200) in our model is 0.812 which is higher than the normalized scores of ECRI and Wang-Levenson classifications, due to its high category regarding applied energy, isolation, and contact with patient factors which are not considered in other studies in comparison, besides the high level of hazard alert according to FDA's database of medical equipment hazard alert reports. The normalized score of infusion the pump (B. Braun, INFUSOMATI) is lower than the normalized scores of other studies considered in comparison due to its low category of safety and performance

requirement factor. The normalized score of Computed Tomography (CT) (Philips, Brilliance 64 slices) in this study is 0.556 which is lower than the normalized scores of other studies considered in comparison due to a low utilization level which is less than 5 hours per day. Low life ratio of all studied medical devices in centers of cardiology and radiology also affected the risk scores of studied medical devices. Operation Room (OR) ventilator (Drager, SAVINA) got a score higher than Critical Care Unit (CCU) ventilator (Drager, SAVINA) due to consideration of area criticality in this study. Table 3 presents the differences between normalized scores of medical devices according to ECRI, Fennigkoh & Smith, Wang & Levenson, and SPTSPIME models. The normalized score for each device can be calculated if we divide its score in each model by the maximum score in the same model.

Table 3.Result comparison between SPTSPIME and other models.

Device	ECRI	Fennigkoh & Smith		Wang & Levenson		SPTSPIME		
		Score	Normalized Score	Score	Normalized Score	Score	Normalized Score	Category
OR Ventilator, SAVINA	H	20	1	29	0.967	7.837	0.712	H
CCU Ventilator, SAVINA	H	20	1	29	0.967	7.337	0.667	H
ICU Ventilator, SERVO I	H	20	1	29	0.967	7.004	0.637	H
Emergency, Ventilator, SERVO I	H	20	1	29	0.967	7.004	0.637	H
OR, Defibrillator	H	19	0.95	28	0.933	9.606	0.873	H
ICU, Defibrillator	H	19	0.95	28	0.933	9.106	0.828	H
Infusion pump	H	14	0.7	22	0.733	5.520	0.502	M
Monitor	H	13	0.65	23	0.767	6.86	0.624	H
Cardiology, Ultrasound, IE33	M	14	0.7	25	0.833	5.547	0.504	M
Outpatient ECG	M	13	0.65	20	0.667	5.956	0.541	M
Stress ECG	M	13	0.65	20	0.667	5.956	0.541	M
CATH Lab	H	18	0.9	29	0.967	9.487	0.862	H
Inpatient ECG	M	13	0.65	20	0.667	6.556	0.596	M
Chemistry analyzer	M	13	0.65	26	0.867	4.054	0.369	L

ESU	L	16	0.8	15	0.5	8.936	0.812	H
Surgical light	L	13	0.65	8	0.267	3.911	0.356	L
Body weight	L	7	0.35	9	0.3	1.711	0.156	L
CT	H	14	0.7	30	1	6.117	0.556	M
Radiology, Ultrasound, IU22	M	14	0.7	25	0.833	4.714	0.429	L

The two models were tested with 405 of medical devices from 28 different types in cardiology, radiology, and general surgery centers at the Military Hospital in Sana'a, Yemen. The percentage of cost reduction by the SPTSPIME model (P_1) is 59.56% from the total cost of safety and performance tests of the total number of studied medical devices. This percentage of cost reduction will also influence the cost of other related extensive procedures of preventive maintenance such as replacement of seals, filters, lamps, oxygen and reaction cells, flow meters, regulators, vaporizers, and other calibration tasks by linking the execution of those procedures to the result of safety and performance tasks. The percentage of cost reduction by the TSSPIME model (P_2) is 39.29% from the training cost of all types of studied medical devices. The percentages of cost reduction by two models P_1 and P_2 were calculated according to Eqs. (3) and (4) respectively.

$$P_1 = P_{12} \times N_{12} + P_{13} \times N_{13} \quad (3)$$

$$P_2 = P_{22} \times N_{22} + P_{23} \times N_{23} + P_{24} \times N_{24} + P_{25} \times N_{25} + P_{26} \times N_{26} \quad (4)$$

Where P_{12} and P_{13} are the minimized cost percentages concerning safety and performance tests for each device in categories 2 and 3, respectively, which are calculated by dividing the number of cancelled safety and performance tasks in each category for every device during six months by the maximum number of safety and performance tasks for each device during the same period. N_{12} and N_{13} are ratios between the number of medical devices in categories 2 and 3 respectively and the number of studied medical devices. P_{22}, P_{23}, P_{24}, P_{25}, and P_{26} are percentages of minimized cost concerning training by applying third party training, one of the manufacturer's trainers inside hospital, specialized outside trainer inside hospital, a highly skillful engineer from inside hospital, and self-study of the equipment service

manuals strategies, respectively. We assumed them to be 40%, 50%, 80%, 90%, and 100% respectively of the manufacturer training cost because of the differences between prices of surveyed companies for each category. N_{22}, N_{23}, N_{24}, N_{25}, and N_{26} are ratios between the number of different types of medical devices in categories 2, 3, 4, 5, 6 respectively and the number of different types of studied medical devices. In this study P_{12} is equal 4/6, N_{12} is equal 86/405, P_{13} is equal 5/6, N_{13} is equal 221/405, P_{22} is equal 0.4, P_{23} is equal 0.5, P_{24} is equal 0.8, P_{25} is equal 0.9, P_{26} is equal 1.0, N_{22} is equal 6/28, N_{23} is equal 5/28, N_{24} is equal 3/28, N_{25} is equal 3/28, N_{26} is equal 1/28.

6. CONLUSION AND FUTURE WORK

In this work, using specific and enhanced risk classifications, we propose new approach for cost-effective risk reduction by developing new safety and performance test scheduling and training strategy selection priority indexes. We conclude that risk can be minimized, even considering the limited resources problem in developing countries. In the future, we will try to propose specific risk classification to reduce the risk of user errors even taking into account the limited resources problem.

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منهاج شامل نحو تقليل خطر الأجهزة الطبية فى الدول النامية بتكلفه اقل

يقدم البحث منهجية جديدة لتقليل الخطر بدراسة وتقييم الخطر وبناء علية تحديد الأولوية فى الاحتياج لفحص الأمان والأداء والتدريب حيث تعتمد تقييم المخاطر على خبرة الباحث ويمكن تقسيمها ألى مرحلتين رئيسيتين المرحلة الأولى تحديد وجمع العوامل التى سيتم بناء عليها تقييم المخاطر معتمدين على الدراسات السابقة مع أعادة تعريف بعض العوامل لكى تكون مناسبة للتطبيقين قيد الدراسة، والمرحلة الثانية هى تحسين عملية تقييم المخاطر بإضافة الطاقة المستخدمة كمعيار جديد من خلال توصيف الفئات المختلفة لكل عامل على حده وبما يتوافق مع ما هو موجود على ارض الواقع وما هو موجود فى العينة من الأجهزة الطبية المدروسة فى البحث وكذلك وضع الدرجة المناسبة لكل فئة من الأجهزة الطبية والتى تعكس الفارق الحقيقى بين كل فئة وأخرى، وقد انخفضت التكلفة بأستخدام نموذج SPTSPIME بنسبه ٥٩.٥٦% من التكلفة الكلية لفحص الأمان والأداء وهذه النسبة ستؤثر في تكلفة باقي اجراءات الصيانة الوقائية المرتبطة بنتائج الفحص كما انخفضت التكاليف بأستخدام نموذج TSSPIME بنسبة من التكلفة الكلية للتدريب.