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A comprehensive fuzzy risk-based framework for replacement of medical devices

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***Abstract* – Replacement analysis is one of the challenging issues in hospital management. Managing thousands of medical devices is time and cost consuming and in some cases this may result in errors which lead to accidents with potentially fatal consequence for patients. Therefore, a robust method for appraising medical equipment replacement is needed to avoid any risk for patient. However, little research in this area exists and proposed methods have some major shortcomings. For example, none of them consider uncertainties and imprecise information associated with experts' opinions when assessing the replacement criteria and the proposed criteria don't consider all risk aspects. Then, this paper proposes a comprehensive risk-based framework for replacement of medical devices by considering uncertainties and several qualitative/quantitative factors. At first, a risk-based method is applied based on probability and severity of failures and by considering several factors. Then, seven miscellaneous dimensions such as use-related hazards, age, and utilization are applied to consider all aspects of hazards and risks. Finally, a diagram is proposed to identify the priority of devices for replacement. Through the proposed framework, managers can easily and more accurately classify medical devices for replacement according to their criticality scores. This framework can be adopted in other critical industries such as aviation by modifying some criteria and dimensions.**

***Keywords* – Fuzzy logic, Medical devices, Risk-based Maintenance, Replacement, MCDM.**

1 INTRODUCTION

Given the limited funding of hospitals, decisions regarding the replacement or maintenance of medical devices is a challenge. If these decisions are not carefully structured, ad hoc judgment can lead to a premature replacement of one piece of equipment while failing to replace other equipment that should have been a higher priority [Dreiss, 2008]. This may increase costs and also risks to patients and/or hospital personnel and visitors. Variety of criteria are proposed for medical devices replacement decisions in the literature and some techniques are developed for evaluating these criteria. However, no attention has been paid to the uncertainties and imprecise information associated with experts' opinions when assessing the replacement criteria. In addition, the proposed methods are either qualitative or quantitative and some influential risk-based criteria such as mean time between failures (MTBF), probability of occurrence of failures, potential risk for the device operator, etc. are not taken into account. One of qualitative approaches compiles a list of medical equipment with its basic data to calculate the cumulative cost of replacement then determine "cut off" line that depends upon the available budget [Yeo, 2005]. Rajasekaran [Rajasekaran, 2005] developed an automated equipment replacement planning system (ERPS) to identify equipment most in need of replacement in order to optimize the utilization of capital budget resources. Taylor and Jackson [Taylor and Jackson, 2005] developed another automated technique called "medical equipment replacement score system (MERS)" based on technical, safety and mission critical rules, where higher scores propose higher priorities to replace. In another effort, Yatsenko and Hritonenko [Yatsenko and Hritonenko, 2008] developed a new approach to model the optimal policies of machine replacement under technological change. They considered a single-machine replacement problem in continuous time and reduced it to a nonlinear integral equation for the variable optimal service life of machine. However, this technique is complicated for medical equipment and lacks for other important factors such as safety and vendor support [Ouda et al., 2010]. A mathematical model using event tree theory for the removal of medical devices from hospital inventory was published

by Miguel [Miguel, 2002]. This model guarantees a warning when a piece of medical equipment needs to be replaced. Despite a significant percentage of success between real-world situation and the mathematical model proposed, the model could not predict certain cases [Cruz and Denis, 2006]. To solve these cases, a so-called α factor was introduced in the model. Although interval values of α were obtained, more comprehensive studies were needed to obtain more generalized α values. To overcome this shortcoming, Cruz and Denis [Cruz and Denis, 2006] used artificial neural network (ANN) to classify the medical equipment life into three zones, depending on its service costs and age factors using software program; zone I: remove equipment, zone II: surveillance, zone III: maintain equipment.

This paper proposes several risk-based criteria and seven miscellaneous dimensions for assessing the replacement of medical devices and presents a comprehensive risk-based framework for replacement of medical devices by considering uncertainties and imprecise information. The proposed framework considers the level of experience and knowledge of experts and it is able to assign different weights to the proposed criteria and dimensions. This framework is explained in section 2.

2 METHODOLOGY

In this paper, we propose a novel integrated framework for prioritizing medical devices for replacement based on several risk-based criteria and dimensions. This comprehensive approach first prioritizes medical devices based on their criticality and then propose a diagram for selecting appropriate strategy for medical devices in healthcare organizations. The aim of the proposed approach is to assure high patient and personnel safety for medical devices. The proposed approach is comprised of the three following steps.

2.1 First Step

In first step, we calculate the risk score for each medical device using the Eq. 1 and by considering uncertainties in experts' ideas. In addition, particular weights have been assigned to experts' opinions. Moreover, we have added seven sub criteria to the main criteria in order to consider different aspects of failures in each medical device. It should be highlighted that our proposed model has the ability to consider multiple failures. In this paper, risk score for each medical device is calculated using the following Equation:

$$Risk = probability\ of\ occurence \times consequences \quad (1)$$

2.1.1 Probability of occurrence (O)

The probability of occurrence estimates the frequency of potential failure(s) or risk(s) for a given device. In this paper, we propose two following sub-criteria to be added to the occurrence criterion in order to calculate this probability more precisely; Frequency or mean time between failures (O_1) and Repeatability (O_2).

2.1.1.1 Mean time between failures (O_1)

Mean time between failures ($MTBF$) is one of frequently used basic measures in reliability engineering of repairable devices or components [Rahee and Ishii, 2003]. MTBF reports the expected time between two failures for a repairable system. In this study, $MTBF$ is defined as a chance of failure in a period of time as shown in Table 1.

2.1.1.2 Repeatability (O_2)

In this paper, repeatability is defined as a "same failure occurring in a period of time for a device or component" as shown in Table 1. It is evident from Table 1 that when a same failure occurs in a short period, (e.g. 3 months), its repeatability rating is very high, while when a same failure occurs in a long period of time (e.g. ten years), the repeatability rating is very low.

Table 1. Fuzzy rating for measurement of occurrence sub-criteria

Rating	(O_1)		(O_2)	Fuzzy number
	Chance of failures	Corresponding $MTBF$	Corresponding time	
Very high (VH)	Failure is almost inevitable	< 3 months	same failures in 3 months	(8.5,10,10)
High (H)	Repeated failures	3-6 months	same failures in 3-6 months	(6,7.5,9)
Moderate (M)	Occasional failures	6 months-2 years	same failures in 6-24 months	(3.5,5,6.5)
Low (L)	Relatively few failures	2-10 years	same failures in 2-10 years	(1,2.5,4)
Remote (R)	Failure is unlikely	>10 years	failure is unlikely>10 years	(0,0,1.5)

Table 1 presents our proposal of scales for descriptive assessment of probability of failure occurrence for $MTBF$ and Repeatability. It also indicates the fuzzy triangular numbers associated to each statement.

2.1.3 Consequences of failures (S)

When a device failure occurs in healthcare organizations, the consequences often show three major impacts: impact on patient's safety, impact on the maintenance resources, and economic loss [Jamshidi et al., 2015]. Then, to consider the total consequences of each failure mode, all its potential impacts need to be assessed.

2.1.3.1 Patient safety (S_1)

According to LD.5.2 JCAHO's patient safety standard, "leaders must ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented" [DeRosier et al. 2002]. In addition, possible effects of each failure mode should be identified. To do so, JCAHO proposed Health Care Failure Mode and Effect Analysis (HFMEA) in 2002 [JACAHO, 2005]. In this paper, we consider patient safety as a first sub criterion of severity criterion in our model. The levels of patient safety and the other sub-criteria of consequences (S_2, S_3, S_4) and their associated fuzzy rating are described in Table 2.

2.1.3.2 Potential Risk for the Device Operator and Maintenance Personnel (S_2)

A potential failure or malfunction in a component of device can result in injury, permanent impairment, or even death to the device users or maintenance personnel as well as the patient. Then, in this

paper, the potential risks for the device operator is considered as a second major sub criterion.

2.1.3.3 Mean time to repair (S_3)

Mean time to repair ($MTTR$) is one of the widely used technical measures of the maintainability for repairable devices or components [Wang, 2012]. It is the average time required to perform corrective maintenance in a device or system [Rahee and Ishii, 2003]. *MTTR* in a system is computed as "the total corrective maintenance time divided by the total number of corrective maintenance actions during a given period of time" [Dhillon, 2000]. $MTTR$ is expressed by:

$$MTTR = (\sum_{i=1}^{n} MTTR_i * \lambda_i) / (\sum_{i=1}^{n} \lambda_i) \quad (4)$$

where $i = \{1, \dots, n\}$ is the index for the set of units or medical devices considered, $MTTR_i$ is the time required to repair item or unit i, and λ_i is the number of corrective maintenance actions of item or unit i during the considered period. In this paper, *MTTR* levels and its fuzzy ratings are defined according to the experience of authors and maintenance staff as shown in Table 2.

2.1.3.4 Economic Loss (S_4)

Economic loss in healthcare organizations is a combination of maintenance cost (*MC*) and the hourly loss associated to delaying treatment (*DL*) [Jamshidi et al., 2015]. Maintenance costs (due to a malfunction or failure in a component or medical device) contains fixed costs (e.g., the costs of spare part(s)) and variable costs (e.g., maintenance experts' costs). Therefore *MC* for a given medical device is expressed as:

$$MC = C_f + DT.C_v \quad (5)$$

where C_f and C_v refer to the fixed and variable costs of the failure *f*, and *DT* is the downtime or repair time of the device (hr.).

The delayed loss *DL* can be estimated as a product of downtime *DT* and hourly loss associated to delaying treatment *DLPH*(\$/hr.)

$$DL=DT.\ DLPH \quad (6)$$

$$C_4(for\ each\ failure) = DL+MC \quad (7)$$

$$C_4(for\ each\ device) = \sum_{i=1}^{n}(DL + MC) \quad (8)$$

where *n* represents the number of failures that could happen for each medical device.

Economic loss levels and their related linguistic levels and fuzzy ratings are described in Table 2.

Table 2. Consequences sub-criteria levels and fuzzy ratings

Level	S_1 and S_2	S_3	S_4	Fuzzy rating
Very high (VH)	Death	Order a new device	Economic Loss ≥ \$5000	(8.5,10,10)
High (H)	Debilitating long-term injury	External intervention for repairs	\$2000≤ Economic Loss < \$5000	(6,7.5,9)
Moderate (M)	Moderate injury	1 day ≤MTTR <4 days	\$500≤ Economic Loss < \$2000	(3.5,5,6.5)
Low (L)	Minor injury or illness	1 Hour ≤MTTR<1 day	\$250≤ Economic Loss < \$500	(1,2.5,4)
Remote (R)	Less or no effect	MTTR<1 Hour	\$0≤ Economic Loss <\$250	(0,0,1.5)

2.1.4. Fuzzification and defuzzification

All of criteria and sub criteria are fuzzified using the proposed membership functions in the previous sections. The fuzzy conclusion is then defuzzified to get crisp RPI_D (index D refers to the device number). The higher the value of RPI_D, the more critical the failure. The following paragraphs discuss the fuzzification and defuzzification operations.

Let O_{jkl}^n and S_{jkl}^n be respectively the occurrence and severity values for medical device j, failure mode k and sub criteria l evaluated by expert n. Let us also consider the triangular fuzzy membership function:

$$O_{jkl}^n = (LO_{jkl}^n, MO_{jkl}^n, UO_{jkl}^n), \quad (9)$$
where $0 \le LO_{jkl}^n \le MO_{jkl}^n \le UO_{jkl}^n \le 10$

$$S_{jkl}^n = (LS_{jkl}^n, MS_{jkl}^n, US_{jkl}^n), \quad (10)$$
where $0 \le LS_{jkl}^n \le MS_{jkl}^n \le US_{jkl}^n \le 10$

It should be noted that weighting values w_i are determined for each expert $i \in \{1, \dots, n\}$ according to their experience and knowledge. These values are in the $[0,1]$ interval, and sum of them for all experts must be one. Besides, a pairwise comparison among O and S parameters should be done in order to determine the weights of importance for each criterion (W_O and W_S). Equations 11 and 12 are used to aggregate the experts' opinions (w_i).

$$O_{jkl} = \sum_{i=1}^{n} O_{jkl}^i w_i \quad (11)$$

$$S_{jkl} = \sum_{i=1}^{n} S_{jkl}^i w_i \quad (12)$$

After assigning weights W_O and W_S to reflect the relative importance of each criterion, we obtain the fuzzy membership function called μ(RPI):

$$\mu(Risk) = W_O \mu(O_{jkl}) + W_S \mu(S_{jkl}) \quad (13)$$

In order to obtain crisp numbers from the above fuzzy set, (μ(Risk)) should be defuzzified. In this study, Center-of-area (COA) method [Lin, 2014] is used to defuzzify the fuzzy membership functions of O and S (O_{jkl}^n, S_{jkl}^n) and also $\mu(Risk)$. Eqs. 14-15 represent $DO\ and\ DS$.

$$DO = \frac{1}{3}[(UO - LO) + (MO - LO)] + LO \quad (14)$$

$$DS = \frac{1}{3}[(US - LS) + (MS - LS)] + LS \quad (15)$$

Finally, defuzzified RPI for a given device is calculated using $DO\ and\ DS$ in Equation (16).

$$Risk_D = DO \times DS \quad (16)$$

2.2 *Second step*

In the second step, seven important miscellaneous dimensions are considered in order to take into account other factors and aspects strongly related to replacement of medical devices. Most of these dimensions are probabilistic (rated between 0% and 100%) and they are assessed by using device history and based on experts' opinions. For each dimension *d*, several grades or levels are proposed and for each grade, an Intensity (I_d) is associated. Intensities obtained for the seven dimensions need also to be weighted according to their relative importance in order to obtain the total intensity (TI) for the incumbent device. The seven dimensions, the computation of the Intensity score for each dimension and the medical device's TI are detailed in the next subsections.

2.2.1 Age

Reliability of a medical device is a function of the age of a component or system. The failure rate of components and systems depends on time and it is calculated as the number of malfunctions occurring during a period of time. Bathtub curve describes the different rates of failures for a component or system in three distinct regions (Fig. 1). The first region, is the beginning of the life of an electronic device and it is called the "*Infant Mortality* region". As shown in Fig. 1, this period is characterized by decreasing high rate of failures. According to Fries [Fries, 2012], "early failures occur usually within the first 1000 h of operation". Generally, failures occurring in this period are because of poor component quality. In the second region, referred to as the "*Useful Life* region", the failure rate is constant. During this period chance or random failures occur. These failures usually stem from weaknesses in the design, hidden component failures, or improper use of device. The rightmost part of the bathtub curve, known as the "*Wear-out"* region, exhibits an increasing failure rate due to long-term usage of the product or fatigue. In order to consider the life cycle of medical devices for failures, we propose Table 3 for assessing sub dimension age. According to [Taylor and Jackson, 2005], the average life span of medical devices is 10 years. It should be highlighted that the life of equipment and failure rate relation is not the same for all devices.

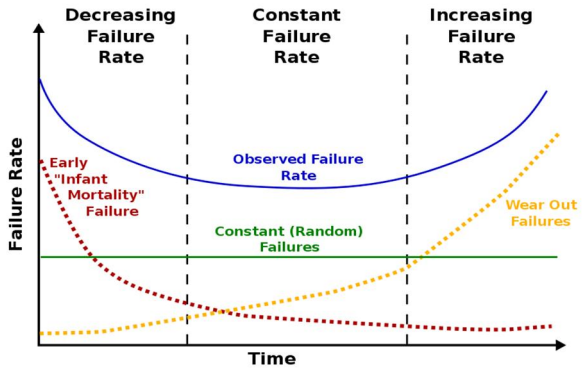

Figure 1. Typical Life Cycle Bathtub Curve for devices' failures

Table 3. Assessing intensity for Age sub dimension

Age	Description	Intensity
Age < 1000 hours of operation	Infant mortality region	0 – 15%
1000hr. ≤ Age < 90000hr.	Useful life	15 – 70%
Age ≥ 90 000 hr. of operation	Wear-out region	70 – 100%

2.2.2 Usage-related Hazards (URH)

According to FDA [FDA, 2000], "hazards associated with device usage are a common and serious problem". Generally, these hazards derive from the complexity of medical device and also user training issues. The FDA's evidences show that the manner in which a device is used determines significantly its overall safety and effectiveness. In addition, evidence from research works indicate that the frequency and consequence of hazards due to medical device misuse might far exceed the device failures. Therefore, usage-related hazards should be identified, assessed and prioritized by experts in order to perform risk management efforts based on their severity. The device's manual helps the analyst to identify use-related hazards. Our model includes use-related hazards as an important dimension in order to capture all the medical device- related hazards. To do so, we have proposed in Table 4 linguistic levels and description of each linguistic level to assess the potential consequences of device- related hazards.

Table 4. Intensities for assessing of usage-related hazards

Level	Description	Intensity
Very high	Death	100%
High	long-term injury	70 – 90%
Moderate	Moderate injury	40 – 70%
Low	Minor injury	10 – 40%
Remote	Less or no effect	< 10%

2.2.3 Utilization (U)

Calculating medical device utilization rate can vary depending on the device, what it is used for, and how often among others. Utilization is a compound measure based on the weighted sum of two indicators. The first indicator is the average daily utilization rate of the device, and the second indicator, is calculated as "the proportion between the number of patients served per day and the maximum number of patients that the device may treat". After proposing these indicators to a group of experts in the field of healthcare devices maintenance, they suggested to assign weights of 0.4 and 0.6 to these indicators, respectively, in order to calculate U, the medical device utilization sub dimension. As in the previous paragraphs, we suggest in Table 5 several Utilization levels and the corresponding Intensity allowing experts estimating Utilization intensity for each medical device.

Table 5. Assessing intensity for sub dimension utilization

Daily utilization rate of device *i*	Intensity
0 ≤ U < 0.4	0 - 40%
0.4 ≤ U < 0.7	40 – 70%
0.7 ≤ U	70 – 100%

2.2.4 Number of available identical devices

As pointed out by Taghipour [Taghipour et al., 2011], having several identical medical devices does not always guarantee higher availability. In fact, the number of patients served each day by these devices is the major aspect impacting the availability of these devices. For example, if five similar MRI devices are available in a hospital and all of them are used at the same time, if either fails, none of the others can be substituted with the failed device. Availability of identical devices' can be computed as a function of the number of identical devices and their demand per unit of time. Therefore, we propose a modified version of the *Overall Equipment Effectiveness* (OEE) indicator to compute the availability of identical devices. OEE is a major key performance indicator defined as the product of three constituent aspects [ATS, 2010]:

$$OEE = Availability \times Performance \times Quality \quad (17)$$

Availability is defined as the expected proportion of time that a device is in a functioning condition. Given n as identical devices, we compute its Availability during a period of length t as:

$$Availability = 1 - \frac{\sum_{i=1}^{n} Down_i}{n \times 24h} \quad (18)$$

where $Down_i$ is the sum of downtimes incurred by the n concerned devices during period t.

$$Performance = \frac{Avrage\ number\ of\ patients\ served\ by\ the\ n\ devices \times Ideal\ cycle\ time\ per\ patient}{Average\ Operation\ Time\ of\ n\ devices} \quad (19)$$

where "Ideal cycle time per patient" I the number of minutes that each patient is served by medical device i.

Finally, we assume that the Quality of treatment is the same for all the patients and we set its value to 100%.

Hence, once the modified OEE indicator for measurement of availability of identical medical devices has been computed, Table 6 allows obtaining intensity values.

Table 6. Intensity associated to Modified OEE values

Modified OEE	Intensity
0 ≤ OEE < 0.5	70 - 100%
0.5 ≤ OEE < 0.7	20 – 70%
0.7 ≤ OEE	10 – 20%

2.2.5 Recalls and hazard alerts

Recalls are issued by manufacturers or the FDA to address problems in equipment that can pose risks to health or violate FDA regulations. Recalls should be considered as an important dimension in ranking medical devices for replacement. This dimension could be considered as the function of the number and levels of recalls for a device. FDA has categorized recalls into three classes according to the level of hazard involved [ATS, 2010].

- *"Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death".*
- *"Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote".*
- *"Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences[1]".*

Based on these categories, Table 7 proposes intensity values for the sub dimension Recalls and hazard alerts.

Table 7. Intensity values of sub dimension Recalls.

Recalls numbers & classes	Intensity
Total number of Class I recalls (per year)≥1	100%
3≤Total number of Class II & III recalls(per year)<5	20 – 60%
1≤Total number of Class II & III recalls(per year)<3	10 – 20%

2.2.6 Function

The classification of medical devices is a 'risk based' system linking the vulnerability of the human body to the potential risks associated with the devices. The Medical Devices Bureau (MDB) of Health Canada has classified medical devices into four classes based on the safety and effectiveness; Devices placed in Class I, have the lowest potential risk, while Class IV devices present the highest risk. In addition, the Association for the Advancement of Medical Instrumentation (AAMI) classified equipment into six categories [Li et al. 2011]. Recently, Taghipour [Taghipour et al., 2011] proposed five classes as function categories in order to describe more explicitly the function of medical devices. In this study we elected to use Taghipour's classification to support the functional risk and proposed related intensities for each class as shown in Table 8.

Table 8. Intensity values of sub dimension Function

Class	Intensity
Life support	100%
Therapeutic	40 – 50%
Diagnosis	30 – 40%
Analysis	20 – 30%
Others	10%

2.2.7 Maintenance requirements

Each medical device has its own maintenance requirements. According to [Li et al. 2011], a device's maintenance task involves resources of three different natures: tools, materials, and skills. In [Wang, 2012], authors classified maintenance requirements for medical devices into three grades (high, medium

[1] U.S.A. Department of Health and Human Services, U.S. Food and Drug Administration (http://www.fda.gov/safety/recalls/ucm165546.htm) accessed on line 2015/06/09.

and low). In this paper, we adopt the maintenance's resources categories proposed by [Li et al. 2011], and assign to each kind of resource potential grades and scores as shown in Table 9.

Table 9. Maintenance ressources evaluation [Li et al. 2011]

Maintenance tools	Score	Maintenance materials	Score	Maintenance skills	Score
General tools (multiple alternatives)	1	No special requirements	1	No special requirements	1
General tools (no alternatives)	2	Special requirements	2	Level requirements	2
Special tools	3			High requirements	3

Total Maintenance requirements intensity is computed as the product of maintenance tools, maintenance materials, and maintenance skills scores. Since the intensities achieved by this dimension are not probabilistic, they are not adjusted to the other dimensions intensities. Then, we normalize the intensity values of the dimension *Maintenance requirement* by dividing the *Total Maintenance requirement* intensity (assigned by each expert) by the sum of all intensities assigned by different experts for each device.

2.2.8. Intensity scores and medical device's TI computation

After acknowledging the dimensions, grades and intensities of each of the dimensions, each expert should assess each device with respect to every dimension $d \in \{1, \dots, 7\}$. Assuming that n experts are consulted, the *Intensity score for each dimension*, I_d is computed as:

$$I_d = \sum_{i=1}^{n} w_i I_{di} \quad (23)$$

where I_d is the intensity score obtained for dimension d based on the judgement of expert i, and w_i are the weights assigned to the experts according to their experience and knowledge.

After finding the intensity score for each dimension, the TI of a medical device can be calculated using a weighted sum of dimensions. To do so, an analytical hierarchy process (AHP) method has been employed to determine the set of weights W_d reflecting the relative importance of each dimension. Weights must be in the [0,1] interval and total weights for all dimensions should be equal to one. Applying this process led to the weights given in Table 10.

Table 10. Weights assigned to the seven dimensions

Dimension	Weight
Age	0.06
Usage-related Hazards	0.16
Utilization	0.07
Number of available identical devices	0.03
Recalls	0.16
Function	0.43
Maintenance requirements	0.48

It should be pointed out that the different weights might be assigned to the above dimensions by participation of different experts from other departments, because their opinions generally differ [Mobley, 2002].

Finally, the TI of a medical device is calculated as:

$$TI = \sum_{j=1}^{d} W_d I_d \quad (24)$$

2.3 *Third step*

After ranking all of considered medical devices, the final step is to identify which device should be replaced. In this paper we propose a Replacement Planning Diagram (see Fig. 2) to identify the critical medical devices in need for replacement. This Diagram uses the $Risk_D$ and TI scores which are achieved from the first and second steps of our approach. The abscissa reports the risk scores, valued by $Risk_D$, while the ordinate reports the TI scores achieved by the second step of the proposed method.

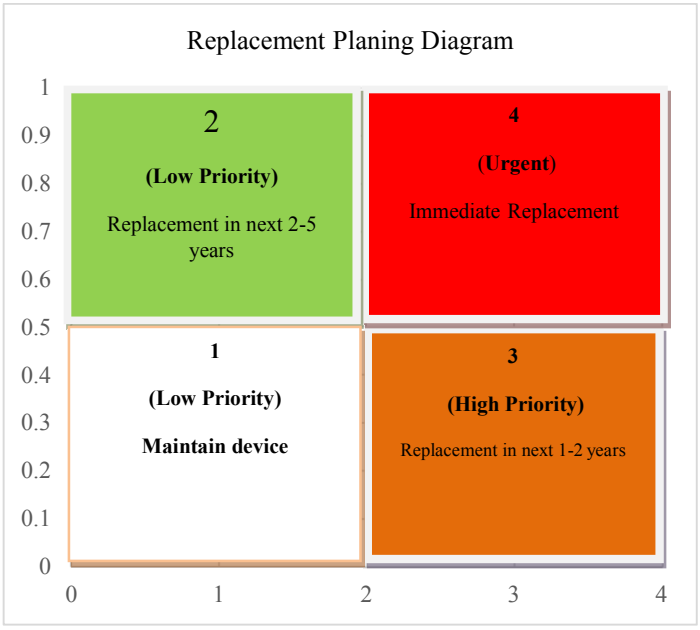

Figure 2. The TI-Risk diagram

To make a classification, the position of each medical device should be first determined on the TI-Risk diagram (by using $Risk_D$ and TI scores). The points (coordinates) placed on the diagram display medical devices and their disposition on each of four quarters presents information regarding the criticality of each medical device for replacement. Figure 2 shows 4 zones; Zone 1 comprises a 'Low Priority' area where both TI and $Risk_D$ have low scores. Zone 2 shows a second 'Low Priority' zone, including high TI scores and low $Risk_D$ scores. Zone 3 is a 'High Priority' area including high $Risk_D$ and low TI scores. Last, zone 4 is a 'Urgent' area. Devices within this zone have very high RPI and TI scores, and therefore they are critical and need to be replaced as soon as possible. Devices located in zone 3 are less critical than zone 4, but they are close to the replacement and therefore they should be considered in the next 1-2 years. Since devices within zone 2 have low priority, they could be considered for replacement

in the next 2-5 years. Devices within zone 1 very low priority for replacement and they could be maintained periodically. Note that the limited budget of organization should be considered when planning for replacement.

3 CONCLUSION

Although the concept of capital equipment planning and replacement are well established in different industries, replacement planning of medical devices has received the least attention. According to the literature, very few hospitals have any formal process for evaluating medical devices replacement. In addition, there are some major shortcomings in currently used tools in hospitals, while this may result in errors which lead to accidents with potentially fatal consequence for patients and even device operator or maintenance personnel.

Considering the patient safety and limited budget of healthcare organizations, the risk-based prioritization of medical devices for maintenance activities or replacement is valuable and essential. Therefore, this paper proposes a comprehensive fuzzy risk-based framework for replacement planning of medical devices. In contrast with other existing methods, the proposed framework offers the following strengths and main features; 1) it contains several qualitative and quantitative risk-based criteria and dimensions in order to consider all possible aspects of risks in replacement of devices, 2) the expert's judgement using linguistic terms and assigning weights to their knowledge and experience is an efficient way to obtain more precise results, 3) several experts can scale on both importance of criteria and evaluation of devices, 4) the proposed framework is able to consider both qualitative and quantitative criteria/ sub criteria, and 5) to the best of our knowledge this is the first paper that consider uncertainties in replacement of medical devices.

This is an original and innovative framework and the above features, distinguish it from other methods. This framework produces more precise and reliable prioritization results and not only a simple ordering. The findings of this research are very beneficial both academically and to other critical industry such as aviation, petroleum and etc. by modifying some criteria and dimensions.

4 ACKNOWLEDGEMENTS

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