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A comprehensive fuzzy risk-based maintenance framework for prioritization of medical devices

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ABSTRACT

Medical equipment such as infant incubator, infusion pump, CT scanner, etc. should be maintained properly to meet adequate standards of reliability in healthcare services. This paper proposes a new comprehensive risk-based prioritization framework for selecting the best maintenance strategy. The framework encompasses three steps. In the first step, a fuzzy failure modes and effects analysis (FFMEA) method is applied by considering several risk assessment factors. In the second step, seven miscellaneous dimensions such as use-related hazards, age, and utilization are applied to consider all aspects of hazards and risks in prioritization of medical devices. Finally, a simple method is introduced in the third step in order to find the most suitable maintenance strategy for each device according to the scores produced by the previous steps. A numerical example illustrates the proposed approach and shows that, through the method introduced in this paper, managers can easily classify medical devices for maintenance activities according to their criticality scores. Implementation of this framework could increase the availability of high risk machines in healthcare industries. Moreover, this framework can be applied in other critical industries such as aviation by modifying some criteria and dimensions.

1. Introduction

Nowadays, safety of medical device and the hazards associated with utilization of them is one of the critical issues for healthcare organizations across the world [1]. Medical devices are instruments or machines that are used to diagnosis, monitor, treat, or prevent disease or other conditions. Degradation in the performance of critical medical devices and inadequately maintained medical equipment create an unacceptable risk of patient injury. In addition, there are risks of injury to clinical staff from simple, direct hazards, such as accidental contact with electrified parts or from mechanical failures within the device [3], for example defects in ultrasound machines, defective artificial cardiac valves, leakage of insulin pumps [4], and high number of errors in CT scans which leads to patients receiving 10 times the intended dose of radiation in some cases. Thus, the maintenance of medical devices is fundamental and it calls for an effective and efficient framework to prioritize medical devices for maintenance activities based on key criteria and choose the best maintenance policy for each device.

Clinical engineering departments in hospitals have been developing programs such as Medical Equipment Management Program (MEMP) to reduce risks associated to medical devices and to promote the safety of medical devices in support of patient care. Some risk based MEMP methods have been presented for assessment of devices and are currently in use. These models consider risk in terms of maintenance requirements of medical device, function of medical device, and physical harm/risk. However, other important criteria such as the number of patients served, economic loss, mean time to repair (MTTR), and use-related hazards, among others are overlooked. Rice [5] in his paper mentions that, “although these methods do reduce risks, they are not near optimal”. Besides, in most of the proposed models equal risk levels are assigned to similar devices and the operational and environmental conditions and independently of the hospital’s mission statement are overlooked. This could lead to misclassifying devices, such as steam sterilizers, as low risk [6].

This paper presents a novel fuzzy multi-criteria decision making (FMCDM) approach to the medical device prioritization problem within a risk-based maintenance (RBM) framework. This comprehensive approach first prioritizes medical devices based on their criticality and then propose a diagram for selecting appropriate maintenance strategy in healthcare organizations. The two objectives of this research are (1) to revisit and reassess the major criteria

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and sub criteria that can affect medical devices risk scores, and (2) to propose a three steps approach for clinical engineers to prioritize medical devices and select the best maintenance strategy for them. The first step consists in applying FFMEA method to calculate the risk priority index (RPI_D) for each device. In the proposed FFMEA model, three criteria – severity (S), occurrence (O) and detection (D) – and eight sub-criteria have been considered. In the second step, seven miscellaneous dimensions are applied and total intensity (TI) score is calculated based on weighted sum of seven miscellaneous dimensions in order to take into account other aspects of hazards as well as S, O and D. Finally, in the third step, a maintenance planning diagram is proposed according to the scores produced by the previous steps. The proposed approach is illustrated by an academic example including five medical equipment.

The rest of this paper is organized as follows. Section 2 draws a literature review on the existing approaches to the medical device prioritization problem. Section 3 describes the proposed approach, while Section 4 illustrates its application on an academic numerical example. Conclusions and directions for future research are presented in Section 5.

2. Literature review

The prioritization of medical devices into risk management programs based on risk scores has become a capital task for healthcare organizations. The medical equipment standards presented by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have forced hospitals in US to use their own risk management tools in order to decide which equipment must be involved in the MEMP [2]. In 1989, Fennigkoh and Smith [10] proposed a device classification scheme based on three criteria: maintenance requirements, physical harm/risk and equipment function. They classified medical equipment by assigning scores to the three criteria and calculating equipment management (EM) number using the summation of values assigned to the three criteria. Their approach includes any device with EM number greater than or equal 12 in the MEMP. In 2004, JCAHO approved the Fennigkoh and Smith method and introduced the standard EC6.10 [11]. This method has been widely used after publication in The Joint Commission. However, this method is not appropriate for risk management because it merely computes an arithmetic average over three factors, and it is rather insensible to changes on the estimated risk of medical equipment. In addition, all of three criteria have the same weight and different experts' opinions are ignored and so on. As Tawfik et al. [7] has mentioned in their recent paper, these shortcoming could causes some critical equipment (such as blood gases analyzers, hematology analyzers, and steam sterilizers) to be classified as low risk because they have low scores in two criteria (physical harm and equipment function).

In 1996, the American Society for Healthcare Engineering (ASHE) [12] presented a classification scheme for ranking medical equipment according to the five criteria; equipment function (E), clinical application (A), preventive maintenance requirements (P), probability of equipment failure (F), and environmental use (U). A total score (T) is calculated for each component using the following equation.

$$T = E + A + \left(\frac{P + F + U}{3}\right) \qquad (1)$$

Wang and Levenson [6] proposed a new interpretation for the equipment function criterion proposed in [10], and they suggested that it should be replaced with 'mission criticality' criterion as the equipment's importance. In addition, they added another criterion called 'equipment utilization rate (UR)' to the Fennigkoh and Smith's equation. Finally, they proposed the following equation for calculating equipment management rating (EMR).

$$\text{EMR} = [\text{UR} \times (\text{mission critical} + 2 \times \text{maintenance})] + 2 \times \text{risk} \qquad (2)$$

where 'risk' scores are obtained from the Emergency Care Research Institute (ECRI) risk classification [6] by assigning score 5 to high risk (H) with 5, score 4 to medium risk (M), and score 1 to low risk (L). Maintenance scores are the same with Fennigkoh and Smith [10] maintenance criterion. Wang and Rice [13] proposed two sampling methods for inclusion of a portion of medical equipment in maintenance activities; a simplified version of gradient risk sampling (GRS) and attributes sampling.

Ridgway [3] discusses that although preventive maintenance (PM) prevents some devices failures, the fact is that it is useful for a relatively few devices and it cannot be used for all of devices failures. He also provides guidelines for MEMP and introduces some tools which successfully have been used in different industries, such as reliability centered maintenance (RCM). Youssef et al. [14] proposed a medical device classification model based on their complexity. Their model consists of two steps: technical complexity and use complexity. Technical complexity includes four criteria about technical perspective such as equipment maintainability, while use complexity consists of nine criteria regarding difficulty at the operation level of medical equipment such as data entry, setup process.

Some authors (Wang and Levenson [6], Hyman [15], Ridgway [16] and Taghipour et al. [17]) have debated that although risk is an important criterion in medical equipment classification, other criteria also should be taken into account such as, equipment utilization rate, availability of identical devices, mission criticality, hazard notice, and recall history. To overcome this problem, Taghipour et al. [17] presented a multi-criteria decision-making (MCDM) method using analytical hierarchy process (AHP) for prioritization of medical equipment based on their criticality. Their proposed AHP method consists of six criteria 'risk', 'age', 'equipment function', 'mission criticality', 'recalls', and 'maintenance requirements'. However, the AHP method has been criticized by many authors for some certain issues such as the need for large number of subjective pairwise comparisons, uncertainties in experts' ideas because of subjectivities in comparison process, etc.

Recently, Corciova et al. [18] provided some guidelines to establish and manage a medical equipment quality assurance program, and presented some procedures for inspection, maintenance, evaluation, and performance testing for medical devices. They considered five risk criteria in their scoring system in relation to patient and staff members. Tawfik et al. [7] developed a fuzzy logic model for classification of medical equipment. They used four criteria (mission criticality status, equipment function, maintenance requirements, and physical risks) in order to calculate the risk scores for each device. Their results show that, in certain cases, the same equipment type may attain different risk scores. In addition, they made a comparison between their classification scheme versus other schemes. This comparison illustrates that in some cases medical equipment may obtain different risk scores.

Despite all these efforts some important points are overlooked and, in our opinion, need to be improved. Among them, special attention should be devoted to the followings aspects.

1) Since prioritization and classification of medical equipment is a MCDM problem, different expert's evaluations should be considered rather than prioritizing based on a sole expert's assessment;
2) Some criteria applied in the literature need to be reassessed and revisited;
3) Some new criteria should be added to the reassessed criteria;
4) The criteria and the tables used in prioritization process should be defined in a more simple and realistic way in order to be understandable for all of clinical experts, because most of