Journal of the Operational Research Society (2010), 1–22

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Prioritization of medical equipment for maintenance decisions

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Clinical engineering departments in hospitals are responsible for establishing and regulating a *Medical Equipment Management Program* to ensure that medical devices are safe and reliable. In order to mitigate functional failures, significant and critical devices should be identified and prioritized. In this paper, we present a multi-criteria decision-making model to prioritize medical devices according to their criticality. Devices with lower criticality scores can be assigned a lower priority in a maintenance management program. However, those with higher scores should be investigated in detail to find the reasons for their higher criticality, and appropriate actions, such as 'preventive maintenance', 'user training', 'redesigning the device', etc, should be taken. In this paper,we also describe how individual score values obtained for each criterion can be used to establish guidelines for appropriate maintenance strategies for different classes of devices. The information of 26 different medical devices is extracted from a hospital's maintenance management system to illustrate an application of the proposed model.
Journal of the Operational Research Society advance online publication, 11 August 2010
doi:10.1057/jors.2010.106

Keywords: medical devices; hospitals; criticality prioritization; maintenance decisions; risk; MCDM; AHP

Introduction

The ever-increasing number and complexity of medical devices demands that hospitals establish and regulate a *Medical Equipment Management Program* (MEMP) to ensure that critical devices are safe and reliable and that they operate at the required level of performance. As fundamental aspects of this program (Stiefel, 2009) inspection, preventive maintenance, and testing of medical equipment should be reviewed continuously to keep up with today's technological improvements and the increasing expectations of healthcare organizations.

No longer content to merely follow manufacturers' recommendations, hospital clinical engineering departments all around the world including Canada, Australia, and United States have begun to employ more efficient and cost-effective maintenance strategies. Gentles *et al* (2010) have begun to develop a unique database to collect comparative data on inventory and maintenance of the most critical devices used in hospitals across Canada and the United States. This project will provide a large statistical failure data set which could be used to establish optimum intervals for routine maintenance scheduling. Ridgway (2009) provide concise guidelines for maintenance management of medical equipment and address methods which have been used for a long time in other industry segments, such as *Reliability Centered Maintenance* (RCM). RCM is a structured methodology for determining the maintenance requirement of a physical asset in its operating context through a thorough and rigorous decision process, as shown in Figure 1 (Jardine and Tsang, 2006).

Steps 2–5 in Figure 1 show the process of *Failure Mode and Effect Analysis* (FMEA). The results of FMEA are used to select appropriate maintenance tactics using RCM logic for the various functional failures. Asset criticality analysis is the first step of applying RCM in an organization, especially when a large number of different devices exist and the worst problems in terms of failure consequences are not obvious.

Criticality is a relative measure of the importance of an object based on some factors considered in a particular context. For example, the importance or criticality of a failure mode depends on the combined influences of several factors such as severity, probability, detectability, cost and timing, and all these factors play a part in determining the amount of attention that a failure mode requires (JACAHO, 2005). Asset criticality is a function of the operational impact to the organization's mission due to the loss, damage, or destruction of an asset (Vellani, 2006). Dekker *et al* (1998) define the equipment criticality as a function of the use of equipment, rather than of equipment itself and explain how a certain device may be in one case critical and in another auxiliary.

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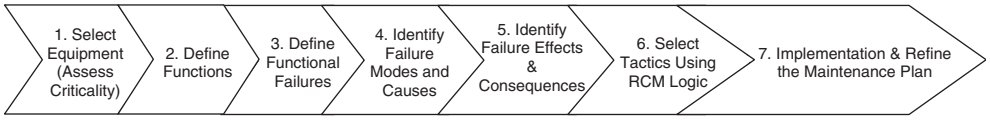

Figure 1 The RCM process.

Significant and critical assets should be identified and prioritized, and many techniques have been developed for criticality assessment of devices. Most use some variation of the probability risk number or PRN (Moubray, 1997), a product of the probability of failure of an asset, severity of the consequence of the failure, and detectability of the failure:

$$\text{PRN} = \text{Probability of failure} \times \text{Severity} \times \text{Detectability} \quad (1)$$

In hospitals, risk is a criterion in criticality assessment of medical devices, but the definition of risk differs from that used in RCM. After running an evaluation on medical devices, clinical engineers decide which should be included in the MEMP of the hospital based on their risk scores.

Fennigkoh and Smith (1989) proposed a risk assessment method to group medical devices on the basis of their *Equipment Management* (EM) *numbers*, or the sum of the numbers assigned to the device's critical function, physical risk, and required maintenance:

$$\text{EM} = \text{Critical Function} + \text{Physical Risk} + \text{Required Maintenance}. \quad (2)$$

Devices with an EM number above a critical value ($\geqslant 12$) are considered to have critical risk and thus are included in inspection and maintenance plans. In 1989, the *Joint Commission on Accreditation of Healthcare Organizations* recognized importance of this method (Fennigkoh and Smith, 1989) and eventually in 2004 approved it as the standard (EC6.10) (JACAHO, 2004). This standard allows hospitals not to perform scheduled inspection or maintenance tasks for certain pieces or types of medical equipment, if these tasks are not needed for safe and reliable operation (Wang, 2006). Since then, Fennigkoh and Smith's method or its many variations have been used by clinical engineers (Rice, 2007). Ridgway (2009) in his recent paper emphasizes that preventive maintenance can provide a benefit for just a relatively few devices, and a significant number of repair calls are made due to random failures of device's components. Wang and Rice (2003) propose simplified version of gradient risk sampling and attribute sampling to select a portion of equipment for inclusion.

Clinical engineers believe that risk is not the only inclusion criterion, however, even though it is the most important one (Hyman, 2003). Other criteria which reflect the needs and reality of a hospital should be considered, including mission criticality, availability of backup, hazard notice, and recall history (Wang and Levenson, 2000; Ridgway, 2001). Moreover, current maintenance strategies employed in hospitals have difficulty identifying specific risks and applying optimal risk reduction activities (Rice, 2007).

In this paper, we present a multi-criteria decision-making model which can be used to prioritize medical devices and establish guidelines for selecting appropriate maintenance strategies.

Multi-Criteria Decision Making (MCDM) is a well-known branch of decision making, divided into multi-objective and Multi-Attribute Decision Making (MADM) (Triantaphyllou, 2000). A MADM is making preference decisions such as evaluation, prioritization, and selection over available alternatives, characterized by multiple attributes (Yoon and Hwang, 1981). *Analytical Hierarchy Process* (AHP) (Saaty, 1980, 1990), a MADM methodology used widely by practitioner and researchers (Leung and Cao, 2001), is a theory of measurement through pairwise comparisons which relies on the experts judgments to obtain priority scales (Saaty, 2008). AHP, briefly is a three-step process: it decomposes a complex problem into a hierarchy, in which the overall decision objective lies at the top and the criteria, sub-criteria and decision alternatives are on each descending level of the hierarchy (Partovi *et al*, 1989) composing of specific factors. Decision makers then compare each factor to all other factors at the same level of the hierarchy using a pairwise comparison matrix to find its weight or relative importance. The optimal solution is the alternative with the greatest cumulative weight (Saaty, 1990).

Two types of comparisons can be employed in the AHP: absolute and relative measurements. Absolute measurement is applied to rank the alternatives in terms of the criteria independent of other alternatives; however in relative measurement the priority of an alternative depends also on other alternatives.

In absolute comparison, alternatives are compared with a standard in one's memory that has been developed through experience. In relative measurement, alternatives are compared in pairs according to a common attribute. As a result, in absolute measurement, the rank of alternatives does not reverse when new alternatives are introduced, or the old ones are deleted; however, the priority of alternatives may change by altering the existing set of alternatives (Saaty, 1986, 1988).

AHP has been widely applied to many applications involving decision making (Vaidya and Kumar, 2006; Ho, 2008), and is often used for prioritizing alternatives when multiple criteria must be considered (Modarres, 2006). Fong and Choi (2000) and Mahdi *et al* (2002) utilize AHP for selecting contractors. Ramadhan *et al* (1999) use AHP to determine the rational weights of pavement priority ranking factors, and Bevilacqua and Barglia (2000) utilize it for maintenance strategy selection in an Italian Oil refinery. Lalib *et al* (1998) propose a model to help take a maintenance decision using AHP. Simpson and Cochran (1987) use AHP to prioritize construction projects to assure that most needed projects receive funding when the budget is limited. Al Harbi (2001) presents the AHP as a potential decision making method for use in project management.

This paper proposes a MCDM model to prioritize medical devices according to their criticality. The proposed criticality assessment model is described in detail in the next section and a numerical example illustrates how it can be used. We also discuss classification of medical devices according to their total criticality score values and explain how individual score values for each criterion can be used to establish guidelines for selecting appropriate maintenance strategies for different classes of devices. The last section of the paper provides our conclusions.

Proposed criticality assessment model for medical equipment

We consider criticality prioritization of medical devices as a MCDM problem and use AHP to solve it. The objective is to identify and include the more critical devices in the equipment management program of a hospital, and investigate in details the reasons of having such high criticality scores to take appropriate actions, such as 'preventive maintenance', 'user training', 'redesigning the device', etc when reducing the criticality score is applicable and manageable.

The first step in applying AHP is to construct the hierarchy structure of the goal, namely, prioritization of medical devices. All required criteria for assessment of devices must be identified and placed at the appropriate level of the hierarchy (Saaty, 2008). Figure 2 shows a decision hierarchy for prioritization of medical devices.

The assessment criteria lie at the second level of the hierarchy structure. Relative measurement method is used for pairwise comparison of the assessment criteria and for determining their relative importance or weights with respect to the goal. In other words, the weight of each criterion is determined by comparing its relative contribution to the goal (prioritization of medical devices) with other assessment criteria. Therefore, if a new criterion is added or an existing one is deleted from the hierarchy, all criteria should be reassessed to find their new weights.

The alternatives or medical devices compose the third level of the hierarchy. The objective is to assign a criticality score for every single device participating in the model. However, the large number of alternatives (devices) makes their pairwise comparison with respect to all criteria almost impossible. Moreover, medical devices are dynamic, that is devices are added to or removed from the inventory over time, so we suggest an absolute measurement technique for ranking alternatives. Therefore, each device is assessed with respect to each criterion and is given the most descriptive grade without comparing it with other devices. Thus, our proposed model uses both relative and absolute measurement in the application of AHP.

To be able to assess a device with respect to a criterion, the criterion's grades and their associated intensities should be defined in advance. The grades are possible categories or classes of a criterion. For example, 'old', 'average', and 'new' can be considered as three classes of a device's age. The definition of each class should be decided and concurred by the decision makers. The decision makers may consider a device as new when its actual age is 25% of its expected life span. In this paper, the grades and their descriptions are either obtained from the available

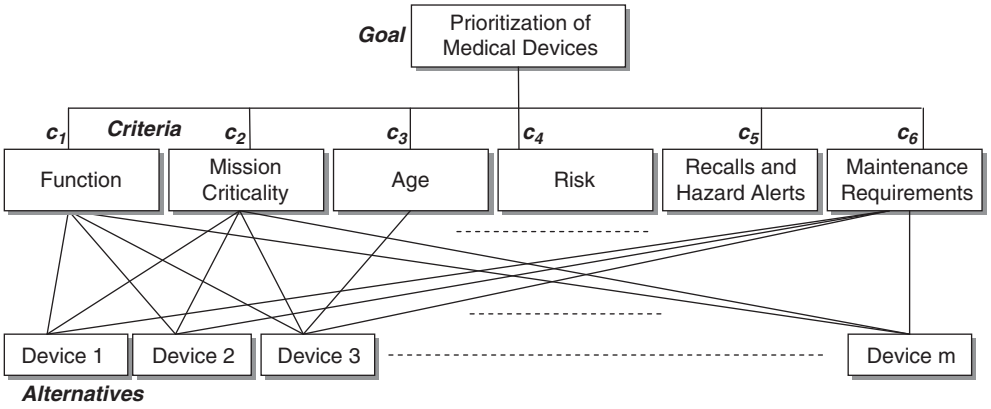

Figure 2 Decision hierarchy for prioritization of medical devices.

standards and literature, or proposed by the authors and approved by the clinical engineers.

Since the grades are subjective, each should be assigned an intensity value indicating its score or importance with respect to the criterion. Quantifying the grades is a necessary step, because when a device is assessed with respect to a criterion and is assigned the most descriptive grade, then it is the assigned grade's intensity which participates in the prioritization model. In order to determine more accurate intensity values for the grades, we propose to use the relative measurement method to pairwise compare the grades with respect to their criterion. Employing this method let us avoid assigning arbitrary intensities for the grades and having more consistent score values for them.

After defining the grades and intensities for all criteria, the model is ready to be used to assess the devices. Each device is compared with respect to each criterion and is assigned the most descriptive grade.

The proposed model can be summarized as the following steps:

- Identify all sufficient, efficient and independent criteria and sub-criteria for criticality assessment of devices.
- Determine weighting values for all criteria and sub-criteria using relative measurement method.
- Set up grades and determine intensities for each criterion using relative measurement method.
- Evaluate alternatives (devices or failure modes) with respect to each criterion, and assign the most descriptive grades using absolute measurement method; the assigned grade's intensity for an alternative is called its score with respect to a criterion.
- Calculate the criticality score for each device i as follows:

$$CS_i = \sum_{j=1}^{n} w_j s_{ij} \tag{3}$$

  $i = 1, \ldots, m$ where m is the maximum device number, $j = 1, \ldots, n$ where n is the maximum criteria, w_j is the weight of the jth criterion, S_{ij} is the score of the ith device with respect to the jth criterion, $\Sigma_{j=1}^{n} w_j = 1$.
- Order devices according to their criticality scores.

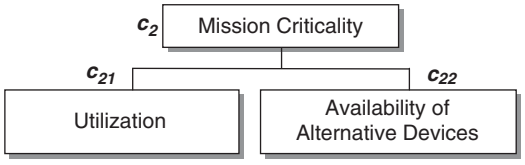

Figure 3 Hierarchy for mission criticality.

In our proposed model (Figure 2), six criteria are identified at the top level. Some of these should be divided into sub-criteria; we divide 'Mission criticality' into 'Utilization' and 'Availability of alternative devices'. Figures 3 and 4 show associated 'Mission criticality' and 'Risk' sub-criteria.

The criteria suggested in this paper include some proposed criteria in the literature for MEMP inclusion of medical devices. For example, 'Function', 'Physical Risk', and 'Maintenance requirements' are suggested by Fennigkoh and Smith (1989). To assess the failure consequences of a device' failure modes we include in our model 'Physical Risk' as 'Safety and environment' criterion. Wang and Levenson (2000) suggest replacing 'Function' by 'Mission Critical' in the Fennigkoh and

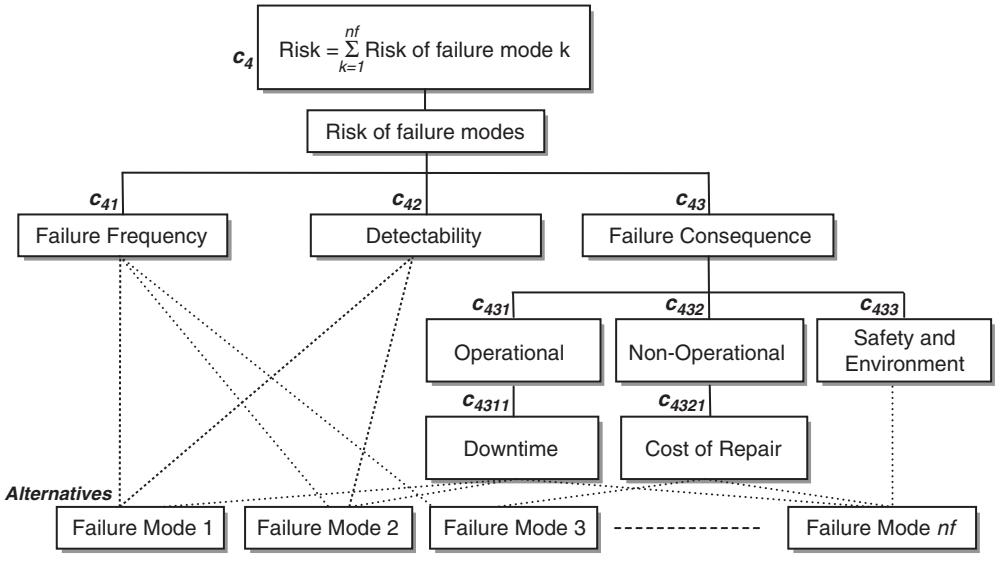

Figure 4 Hierarchy for risk assessment of a device.

Smith's model, and also taking into consideration the 'Utilization' rate of each piece of equipment. In this paper, we consider 'Utilization' and 'Availability of alternative devices' as sub-criteria of 'Mission criticality'.

Descriptions of criteria and sub-criteria

C_1—*Function*

The function of a device is the main purpose for which it is to be used. The *Medical Devices Bureau of Health Canada* recognizes four classes of medical devices based on how the device is represented for use by the manufacturer (Health Canada, 1998). Class I devices present the lowest potential risk and Class IV present the highest. This classification implicitly represents the function of a device. For example, a life support device such as a defibrillator is considered as a Class IV device with high risk of failure (death of a patient) if the device fails. However, this classification does not explicitly describe the function of a device. Moreover, risk or consequence of a device failure should not be confused with its function, thus we propose in our model 'Life support', 'Therapeutic', 'Patient diagnostic', 'Analytical', and 'Miscellaneous' as function categories. The proposed categories are an adaptation of Fennigkoh and Smith (1989) and Dhillion's (2000) classifications.

C_2—*Mission criticality*

Mission criticality or operational impact describes the extent to which a device is crucial to the care delivery process of a hospital (Wang *et al*, 2006). For example, Magnetic Resonance Imaging equipment might be extremely significant according to the mission of a hospital but less critical in terms of its function or potential risk through use. Wang suggests classification of devices in three groups (Critical, Important, and Necessary) according to their mission criticality (Atles, 2008). In our paper, mission criticality depends on utilization and availability of similar or alternative devices.

C_{21}—*Utilization*

Utilization shows the total hours a device is used on average in a hospital (hours per day or days per week or weeks per year). In this model, we consider the 'average hours a device is used per week' as the utilization criterion. To intensify the criticality of devices which directly or indirectly deliver a service to patients, 'Utilization' can be defined as a function of average usage and the number of patients served per unit time. Obviously, incorporating the 'Number of patients' into the model makes calculation of 'Utilization' more complicated.

C_{22}—*Availability of alternative devices*

Although not always true, with decreased backup and fewer similar devices at hand, the situation of a device in the care delivery process becomes more critical, especially when it is in high demand and there is only one such device in the hospital.

It should be noted that having several similar devices does not always mean high availability of alternative devices: the demand per unit time of these devices is also important. If there are several similar devices in a hospital but all are highly utilized, if either fails, there is less chance that others can be used as substitutes. Therefore, 'Availability of alternative devices' can be considered as a function of the number of similar or backup devices and their demand per unit time.

C_3—*Age*

Age score is based on the actual age of a device and its predictable life span. The life span for a group of similar devices can be obtained from the literature. In general, 10 years is the average life span of a medical device (Taylor, 2005).

C_4—*Risk*

Risk is one of the most important criteria in criticality assessment of a device but cannot be simply considered as a single number assigned to a device. Rather, the risk of a device should be an aggregate of all risk values estimated from the actual failures which have occurred in the device. All failure modes and their associated frequencies, consequences, and detectabilities should be extracted or estimated from history data and device maintenance work orders. The risk value can then be estimated as a function of frequency, consequence, and detectability for each failure mode. In short, the risk of the device is the total risk of all its failure modes.

C_{41}—*Failure frequency*

Failure frequency is the likelihood of a failure occurrence. The *VA National Center for Patient Safety* has designed 'Healthcare Failure Modes and Effects Analysis (HFMEA)' specifically for healthcare (DeRosier *et al*, 2002). Their suggested 'Failure Frequency' rating scales are shown in Table A7.

C_{42}—*Detectability*

Failure detectability is the ability to detect a failure when it occurs. In the proposed model, we use the detectability levels described in Table A8.

C_{43}—Failure consequence

To find the total consequences of each failure mode, its operational, non-operational, and safety and environment impacts should be assessed. These three categories are the conventional failures consequences used in the RCM terminology (Moubray, 1997), so we keep this level although both operational and non-operational criteria have only one related sub-criteria in our model as follows.

C_{431}—Operational

Operational consequence of a failure is its impact on the care delivery process of a hospital.

C_{4311}—Downtime

Downtime is generally the average time that a device is out of service. However, for medical devices it is also important to consider the number of patients who have to wait while the device is down. We therefore suggest the average of the total waiting time of all patients as 'Downtime' sub-criteria, considering both the number of patients and the length of time they wait due to device failure.

C_{432}—Non-operational

Non-operational consequence of a failure is its direct inspection and repair cost, including 'Man power' and 'Spare part(s)'.

C_{4321}—Cost of repair

Cost of repair is the sum of man power and spare part(s) costs incurred by fixing a failure or defect. Grade classification (ie high, medium, and low) for cost of repair depends on the budget of a hospital and the purchase price of devices.

C_{433}—Safety and environment

Safety and environment consequences of a failure are critical impacts that should be taken into account. These are described in Table A11 (Fennigkoh and Smith, 1989).

C_5—Recalls and hazard alerts

The number and class of recalls and the number of hazard alerts that may occur for a device are important criteria in prioritization of medical devices. US Food and Drug Administration guidelines categorize recalls into three classes according to the level of hazard involved (Meados, 2006).

C_6—Maintenance requirements

According to Fennigkoh and Smith (1989), equipment that is predominantly mechanical, pneumatic, or fluidic often requires the most extensive maintenance. A device is considered to have an average maintenance requirement if it requires only performance verification and safety testing. Equipment that receives only visual inspection, a basic performance check, and safety testing is classified as having minimal maintenance requirements.

Determining weighting values for criteria and sub-criteria

Once all criteria and sub-criteria have been identified, their relative importance can be determined with respect to their goal or their upper-lever criterion using Saaty's eigenvector technique (Saaty, 1980, 1990, 2008). In other words, relative AHP is employed to determine criteria and sub-criteria weighting values. Table 1 shows the weighting values calculated for all criteria and sub-criteria in the model. The values given here represent expert opinion; results may differ with the participation of a different group of experts.

Setting up grades and intensities for each criterion

We suggest using the absolute measurement technique for ranking of medical devices due to their large number and dynamic nature. To employ absolute measurement, qualitative (descriptive) grades for each criterion are constructed. Then, to find grade intensities, the grades are pairwise compared according to their corresponding criterion. If a grade with highest intensity is assigned to a device with respect to a criterion, the criterion for this device should contribute with its full capacity (criteria's weight) to its upper-level criterion or goal. It means that this intensity should have value of 1. Therefore, the intensities should be divided by the maximum intensity that can be obtained for each criterion. Finally, using absolute AHP, each alternative is evaluated with respect to each criterion and is assigned an appropriate describing grade (Saaty, 1990, 2008).

The grades' intensities for the assessment criteria proposed by current classification models in the literature can be criticized, especially with respect to inconsistency in logical reasoning. For example, in the model proposed by Fennigkoh and Smith (1989), 'Death' and 'No significant risk' have score values of 5 and 2 as the major and minor failure consequences, respectively; however, this does not appropriately reveal their severities ratio. Therefore, in our model, we propose using AHP to find the intensities of the criteria's grades.

In the AHP hierarchy, the qualitative grades and intensities should be determined for criteria/sub-criteria

Table 1 Criteria/sub-criteria weighting values

Main criteria (weight)	*Sub-criteria (weight)*	*Sub-criteria (weight)*	*Sub-criteria (weight)*
C_1—Function (0.45)			
C_2—Mission criticality (0.10)	c_{21}—Utilization (0.70)		
	c_{22}—Availability of alternatives devices (0.30)		
C_3—Age (0.06)			
C_4—Total risk (0.16)	c_{41}—Failure frequency (0.30)		
	c_{42}—Detectability (0.24)		
	c_{43}—Failure consequence (0.46)	c_{431}—Operational (0.16)	c_{4311}—Downtime (1.00)
		c_{432}—Non-operational (0.08)	c_{4321}—Cost of repair (1.00)
		c_{433}—Safety and environment (0.76)	
C_5—Recalls and hazard alerts (0.16)			
C_6—Maintenance requirement (0.07)			

upon which the alternatives are directly evaluated (criteria with no sub-criteria). Appendix A describes the qualitative grades and intensities of criteria/sub-criteria taken from the literature or designed for this study. To demonstrate how the intensities can be calculated for a criterion, the required steps are explained for the criterion 'Function' in Appendix A.

Ranking medical devices

Our model is now ready to rank medical devices. Each device should be assessed with respect to every covering criterion; the lowest level criterion or sub-criterion connected to the alternatives (Saaty, 2008) and assigned an appropriate grade. The score of a device at a criterion which has sub-criteria is then the sum product of the sub-criteria's weights and their grades' intensities assigned to the device. This part of the AHP process is called 'synthesizing' (Saaty, 2008). Therefore, the total score for a device can be obtained as an absolute value from the weighted sum of the main criteria and their assigned intensities for the device. In order to easily prioritize and classify devices according to their score values, the absolute total score values should be normalized by dividing the total score values by the maximum of all devices' score values.

To estimate a device's 'Risk', its failure modes should first be assessed with respect to the risk criterion. In other words, alternatives in 'Risk' hierarchy (Figure 4) are the failure modes of a device. The 'Risk' for a device is the sum of risk values of all its failure modes, that is

$$RF = \sum_{k=1}^{nf} RF_k \tag{4}$$

The risk of a failure mode can be calculated using weighted sum of risk criteria, that is

$$RF_k = c_{41}G_{kFF} + c_{42}G_{kFD} + c_{43}G_{kFC} \tag{5}$$

where RF_k is the risk of failure mode k of the device, $k = 1, 2, \ldots, nf$ (the total number of devices' failure modes). G_{kFF}, G_{kFD}, and G_{kFC} are the intensities assigned to the failure mode k of the device with respect to 'Failure Frequency', 'Failure Detectability', and 'Failure Consequence'. c_{41}, c_{42}, and c_{43} are the weighting values of G_{kFF}, G_{kFD}, and G_{kFC}, respectively. The weighted sum allows us to take into account the magnitude of risk factors.

The grades' descriptions presented in Tables A7–A11 are used to assign appropriate grades to a failure mode. For example, if a particular failure mode of a device occurs once in 2–5 years, 'uncommon' grade is assigned to its failure frequency. The failure history of all possible failure modes of a device should be extracted from the *computerized maintenance management system* (CMMS) and analyzed to select appropriate grades. A module can be implemented in the CMMS to automatically extract and analyze the history of a failure mode. Tables A7–A11 are either adapted from the FMEA proposed for medical devices (DeRosier *et al*, 2002), or are designed based on the authors' experience from the other industries.

In order to compare the risk values of all devices, we need an upper bound for the risk criterion. After calculating the risk values for all devices, we divide them by the maximum existing risk value, so the device with the highest risk value will have a risk ratio of 1. Obviously, when the number of device is just one, the obtained risk value will be 1, but this method is intended to compare several devices.

Instead of the weighted sum, heuristic reasoning can be used to deduct the grade of a device/failure mode with respect to a criterion from its sub-criteria's grades assigned to that device/failure mode. A deterministic reasoning such as propositional logic or a non-deterministic reasoning such as fuzzy logic can be employed (Rzevsky, 1995). In this case, the rules of inference should be established before assessing the alternatives. Rules are knowledge expressions in the form of conditions and actions. A rule consists of an IF-statement and a THEN-statement. The IF-statement

contains a combination of conditions. If the IF-statement is satisfied, the THEN-statement can consequently be concluded. For example, the consequence of a failure mode can be deducted from the grades of its sub-criteria as follows:

IF *safety and environment consequence* is *death* AND
operational consequence is *low* AND
non-operational consequence is *high* THEN
failure consequence is *high*.

In general, rules represent the experts' knowledge, and a rule-based expert system (Durkin, 1994) is a system in which the knowledge is stored in the condition-action rules.

In our model, the criteria may be also considered as either static or dynamic. For example, function is a static feature of a device which does not change over time, while other criteria such as age or risk are dynamic. Therefore, the prioritization model should be applied to devices periodically to adjust their criticality scores according to changes in the score values of the dynamic criteria. For example, a recently purchased device may not have enough failures reported in the CMMS, but gradually some failure records will be added for it to the system. New failures contribute to more precise estimation of the total risk value of the device and they may eventually influence the total criticality score of the device.

Numerical example and discussion

We are currently testing the proposed model as a case study on the real data from a hospital. The CMMS of the pilot hospital has the information of about 11 365 non-imaging and 2241 imaging physical units (devices) and all of them should be prioritized. Thus, presenting our complete results would require much more space which is not possible in this paper. We therefore present a simplified example to illustrate the model's application in the prioritization of medical devices. We extracted information of 26 different medical devices from a hospital's CMMS. The selected devices are similar to the devices listed and discussed in (Fennigkoh and Smith, 1989) and (Wang and Levenson, 2000). We used the assessment given in these papers for the selected devices with respect to some of our proposed criteria such as 'Function', 'Mission', and 'Maintenance requirement'.

We extracted multiple failure modes for each device selected for the study, and assessed them with respect to the risk criteria. Tables 2–5 demonstrate the approach. As shown in Tables 2a–2b, Infant Incubator, Defibrillator, and Intra_aortic Ballon Pump have the highest normalized criticality score of 1.000, 0.964, and 0.943, respectively. For these devices, the main contribution to the critically score comes from their high score values with respect to 'Function', 'Mission', and 'Risk'. Infant Incubator is also assigned a 'Low' grade for 'Recalls' which is an important criterion with a weight of 0.16 in the prioritization hierarchy structure. Surgical and Exam Lights have the lowest criticality scores, so they can be excluded from the maintenance management program of the hospital. Additional comments on the results of the example are given in the following sections.

The proposed model in this paper incorporates all criteria suggested by clinical engineers (Fennigkoh and Smith, 1989; Wang and Levenson, 2000; Ridgway, 2001; Hyman, 2003; Wang *et al*, 2006) to assess the criticality of medical equipment. Moreover, the model gives a realistic estimate of the total risk of a device by taking into account its different failure modes and assessing their frequency, detectability and consequences. The failure modes are extracted from the device's failure history available in the CMMS of the hospital and are analyzed with respect to the risk's sub-criteria. AHP enables the model to accommodate multiple criteria and integrates scientific judgments with personal opinion in the evaluation of the alternatives (Herath and Prato, 2006). Calculating the consistency ratio (Saaty, 1990) in pairwise comparison of the criteria makes the model able to produce more precise and consistent criteria's weights compared to direct assignment of the weights. Furthermore, the intensities which are obtained for the criteria's grades are also more consistent due to applying the relative measurement method. One of the limitations of the proposed model is that it requires experts to be involved in the process of applying the model to medical devices and this process may be expert intensive. Moreover, the prioritization results may not always be acceptable by clinical engineers and requires reassigning the criteria's weights and/or grades' intensities. To apply the proposed model to the CMMS of a hospital and obtain accurate results, the CMMS should be up-to-date and should include the information required for assessment of devices.

Classification and maintenance strategies

As has been noted, the proposed model prioritizes devices according to their criticality. The normalized score value indicates the relative criticality of a device compared to other devices. Given such a model, hospitals could focus their maintenance efforts on more critical devices. Devices with lower criticality scores could be discarded from a maintenance management program, while devices with high score values could be monitored and supervised.

Normalized scores (eg, the values in the sixth column of Table 2b) can be used for prioritizing or ranking of devices. The normalized scores depend on the total number of devices involved in the model. However, total scores of devices (eg, the values in the fifth column of Table 2b) can be used as absolute measurements for classification. The total score is a metric which can be compared with

Table 2 (a) Assessment of the devices with respect to 'Function', 'Mission', 'Age' and 'Risk'; (b) Assessment of the devices with respect to 'Recalls' and 'Maintenance requirement', and total, normalized and transformed criticality scores

No	*Device name*	*Function*	*Mission*	*Age*	*Risk*
(a)					
1	Infant incubator	Life support (1.00)	0.760	Average (0.43)	1.000
2	Defibrillator	Life support (1.00)	1.000	Average (0.43)	0.790
3	Intra-aortic balloon pump	Life support (1.00)	1.000	Almost New (0.17)	0.784
4	External pacemaker	Life support (1.00)	0.802	Almost New (0.17)	0.854
5	Hematology slide stainer	Analytical (0.13)	0.802	New (0.12)	0.550
6	Treadmill	Therapeutic (0.21)	0.538	Old (1.00)	0.739
7	Gamma camera	Patient Diagnostic (0.16)	1.000	Average (0.43)	0.775
8	CT scanner	Patient Diagnostic (0.16)	0.802	Almost Old (0.67)	0.614
9	Infusion pump (B)	Therapeutic (0.21)	1.000	Old (1.00)	0.668
10	ECG physiological telemetry unit	Patient Diagnostic (0.16)	1.000	Almost Old (0.67)	0.760
11	Automatic X-ray processor	Patient Diagnostic (0.16)	1.000	Old (1.00)	0.269
12	Ultrasound machine	Patient Diagnostic (0.16)	0.802	Average (0.43)	0.576
13	Mobile hypo/hyperthermia unit	Therapeutic (0.21)	0.340	Average (0.43)	0.718
14	Infusion pump (A)	Therapeutic (0.21)	0.760	Almost New (0.17)	0.886
15	Multi-channel electrocardiograph	Patient Diagnostic (0.16)	0.538	Almost New (0.17)	0.695
16	Fetal monitor	Patient Diagnostic (0.16)	0.340	Old (1.00)	0.610
17	Centrifuge	Analytical (0.13)	0.340	Almost Old (0.67)	0.598
18	Cardiac cath harp	Therapeutic (0.21)	0.538	Almost New (0.17)	0.432
19	Scale for patient care	Miscellaneous (0.11)	0.165	Old (1.00)	0.817
20	Blood pressure modules	Patient Diagnostic (0.16)	0.340	Old (1.00)	0.328
21	Computer terminal	Analytical (0.13)	0.298	Almost Old (0.67)	0.737
22	Water bath circulator	Analytical (0.13)	0.207	Old (1.00)	0.524
23	Sterilizer	Miscellaneous (0.11)	0.760	New (0.12)	0.399
24	Ultrasound doppler	Patient Diagnostic (0.16)	0.298	Almost New (0.17)	0.792
25	Surgical lights	Therapeutic (0.21)	0.340	Almost Old (0.67)	0.432
26	Exam lights	Miscellaneous (0.11)	0.207	Average (0.43)	0.677

Table 2 *Continued*

No	*Device name*	*Recalls*	*Maintenance requirement*	*Total score*	*Normalized score*	*Transformed score (%)*
(b)						
1	Infant Incubator	Low (0.12)	High (1.00)	0.801	1.000	77.77
2	Defibrillator	Null (0.00)	High (1.00)	0.772	0.964	74.55
3	Intra-aortic Balloon Pump	Null (0.00)	High (1.00)	0.756	0.943	72.71
4	External pacemaker	Null (0.00)	High (1.00)	0.747	0.933	71.74
5	Hematology Slide Stainer	High (1.00)	High (1.00)	0.464	0.579	40.10
6	Treadmill	Null (0.00)	High (1.00)	0.397	0.495	32.58
7	Gamma Camera	Null (0.00)	High (1.00)	0.392	0.489	32.04
8	CT Scanner	Low (0.12)	High (1.00)	0.380	0.474	30.72
9	Infusion Pump (B)	Null (0.00)	Low (0.17)	0.373	0.466	29.97
10	ECG Physiological Telemetry Unit	Null (0.00)	Medium (0.50)	0.369	0.460	29.47
11	Automatic X-Ray Processor	Null (0.00)	High (1.00)	0.345	0.431	26.82
12	Ultrasound Machine	Null (0.00)	High (1.00)	0.340	0.425	26.27
13	Mobile Hypo/Hyperthermia Unit	Null (0.00)	High (1.00)	0.339	0.423	26.17
14	Infusion Pump (A)	Null (0.00)	Low (0.17)	0.334	0.417	25.63
15	Multi-channel Electrocardiograph	Null (0.00)	High (1.00)	0.317	0.396	23.71
16	Fetal Monitor	Null (0.00)	Medium (0.50)	0.299	0.373	21.63
17	Centrifuge	Null (0.00)	High (1.00)	0.298	0.372	21.60
18	Cardiac Cath Harp	Null (0.00)	High (1.00)	0.298	0.371	21.51
19	Scale for patient care	Low (0.12)	Low (0.17)	0.288	0.359	20.42
20	Blood Pressure Modules	Medium (0.21)	Medium (0.50)	0.287	0.358	20.35
21	Computer Terminal	Null (0.00)	Low (0.17)	0.258	0.322	17.12
22	Water Bath Circulator	Null (0.00)	Medium (0.50)	0.258	0.322	17.11
23	Sterilizer	Low (0.12)	Medium (0.50)	0.251	0.313	16.29
24	Ultrasound Doppler	Null (0.00)	Low (0.17)	0.251	0.313	16.26
25	Surgical Lights	Null (0.00)	Low (0.17)	0.250	0.312	16.18
26	Exam Lights	Null (0.00)	Low (0.17)	0.216	0.270	12.44

Table 3 Assessment of the devices with respect to 'Mission criticality' sub-criteria

No	*Device name*	*Utilization*	*Alternative devices*	*Mission*
1	Automatic X-ray processor	High (1.00)	Low (1.00)	1
2	Blood pressure modules	Medium (0.34)	Medium (0.34)	0.34
3	Cardiac cath harp	Medium (0.34)	Low (1.00)	0.538
4	Centrifuge	Medium (0.34)	Medium (0.34)	0.34
5	Computer terminal	Medium (0.34)	High (0.20)	0.298
6	CT scanner	High (1.00)	Medium (0.34)	0.802
7	Defibrillator	High (1.00)	Low (1.00)	1
8	ECG physiological Telemetry unit	High (1.00)	Low (1.00)	1
9	Exam lights	Low (0.15)	Medium (0.34)	0.207
10	External pacemaker	High (1.00)	Medium (0.34)	0.802
11	Fetal monitor	Medium (0.34)	Medium (0.34)	0.34
12	Gamma camera	High (1.00)	Low (1.00)	1
13	Hematology slide stainer	High (1.00)	Medium (0.34)	0.802
14	Infant incubator	High (1.00)	High (0.20)	0.76
15	Infusion pump (A)	High (1.00)	High (0.20)	0.76
16	Infusion pump (B)	High (1.00)	Low (1.00)	1
17	Intra-aortic balloon pump	High (1.00)	Low (1.00)	1
18	Mobile hypo/hyperthermia unit	Medium (0.34)	Medium (0.34)	0.34
19	Multi-channel electrocardiograph	Medium (0.34)	Low (1.00)	0.538
20	Scale for patient care	Low (0.15)	High (0.20)	0.165
21	Sterilizer	High (1.00)	High (0.20)	0.76
22	Surgical lights	Medium (0.34)	Medium (0.34)	0.34
23	Treadmill	Medium (0.34)	Low (1.00)	0.538
24	Ultrasound doppler	Medium (0.34)	High (0.20)	0.298
25	Ultrasound machine	High (1.00)	Medium (0.34)	0.802
26	Water bath circulator	Low (0.15)	Medium (0.34)	0.207

predefined thresholds to decide to which category the device belongs. In our proposed model, devices can have a total score between 0.1050 and 1.0. Score 1.0 is for a device which gets the highest intensity when assessed against every single criterion, and 0.1050 is obtained when the device gets the lowest intensity from all criteria (see Appendix B for this calculation). So, the score in the proposed model is always between 0.1050 and 1. The total score can then be mapped to 0, 100% using the following equation:

$$\begin{aligned}\text{Transfomed score value} &= \text{TSV} \\ &= \frac{\text{score value} - \min}{\max - \min}\% \\ &= \frac{\text{score value} - 0.1050}{0.8950}\% \end{aligned} \quad (6)$$

We suggest the classification of thresholds and maintenance strategies as given in Table 6.

The thresholds in Table 6 are based on the score values obtained for the devices given in the numerical example. In general, the thresholds can be adjusted after applying the model to the inventory of a hospital and investigating the obtained transformed score values. The thresholds can be adjusted, depending on the minimum and maximum of these values. Different type of devices with different transformed score values should participate in the model to decide how the budget should be allocated for management of devices and which maintenance strategies should be applied. Participation of all devices is normally expected when the prioritization module is integrated into the CMMS of a hospital. Otherwise, the output decisions might be inaccurate. For example, if the prioritization model is just applied for a group of devices in a hospital and not all devices, the managers may allocate the budget only to this group and decide to apply predictive maintenance for all of them which is not necessarily required.

Therefore, thresholds should always be established according to both the characteristics of participant devices and their estimated transformed score values. Moreover, the number of classes and established maintenance strategies depend on available resources (budget, personnel, etc) in the hospital.

In general, maintenance strategies can be classified according to their required resources (cost, labor, and special equipment) and their impact on maintaining a piece of equipment (Mobley, 2002). In corrective maintenance, a device is just run until it breaks. This strategy does not require any staff or money to be applied; however, unplanned downtime and inefficient use of the staff to repair the device can even be more costly. In time-based maintenance the device is periodically checked and preventive maintenance is performed if necessary. This strategy is easy to implement and can reduce the failure rate of a device. However, it requires some resources such

Table 4 Risk assessment of the failure modes

Device name	*Frequency*	*Detectability*	*Consequence*	*Failure mode risk score*	*Total risk*	*Device risk = Total risk/max*
Automatic X-ray processor					0.4048	0.2688
Unit does not power up	Frequent	High	0.16	0.4048		
Blood pressure modules					0.4941	0.3281
Module receptacle was damaged	Occasional	Very low	0.3372	0.4941		
Cardiac cath harp					0.6500	0.4316
CRA/CAU bearing noise	Frequent	High	0.284	0.4618		
Low contrast resolution loss after previous HARP test	Occasional	High	0.126	0.1882		
Centrifuge					0.9005	0.5979
Broken speed control knob	Frequent	Moderate	0.2172	0.4479		
Centrifuge intermittently drops in speed while running	Occasional	Moderate	0.2172	0.2469		
Machine turns on but motor does not run	Occasional	High	0.164	0.2056		
Computer terminal					1.1095	0.7367
Mouse locked up	Frequent	High	0.1044	0.3792		
Overflow errors caused data to be missed in analysis	Occasional	Low	0.2796	0.3068		
Tape speed errors	Frequent	Moderate	0.164	0.4234		
CT scanner					0.9255	0.6145
CT cable loose	Occasional	Moderate	0.1044	0.1950		
System could not recognize a scan as raw data	Occasional	Moderate	0.284	0.2776		
Wire harness for CT dislodged	Frequent	Low	0.16	0.4528		
Defibrillator					1.1902	0.7903
Cable constructed	Occasional	Moderate	0.1424	0.2125		
Cable tie on paddle handle	Frequent	Moderate	0.164	0.4234		
Intermittent break in power cord	Occasional	Low	0.8176	0.5543		
ECG physiological telemetry unit					1.1441	0.7597
Broken terminal connection	Occasional	Low	0.164	0.2536		
Soot water damage from fire	Uncommon	High	0.284	0.2218		
Telemetry does not detect lead off	Frequent	Very Low	0.2796	0.6686		
Exam lights					1.0203	0.6775
Bulb broken inside socket	Frequent	High	0.1044	0.3792		
Lamp holder broken	Frequent	Moderate	0.1044	0.3960		
Loosed swivel head	Occasional	Moderate	0.2132	0.2451		
External pacemaker					1.2864	0.8542
Broken clip	Frequent	Moderate	0.1424	0.4135		
Pace lights visible only when pacemaker is lying down	Occasional	High	0.312	0.2737		
Pulse generator failure	Uncommon	Low	1.000	0.5992		

Table 4 *Continued*

Device name	*Frequency*	*Detectability*	*Consequence*	*Failure mode risk score*	*Total risk*	*Device risk = Total risk/max*
Fetal monitor					0.9182	0.6097
Monitor not powering-up	Occasional	High	0.164	0.2056		
Paper was not moving	Frequent	High	0.1044	0.3792		
The unit kept losing its configuration	Occasional	Low	0.3372	0.3333		
Gamma camera					1.1667	0.7747
Fatal timeout problems	Frequent	Low	0.2796	0.5078		
Peak shift	Uncommon	Very low	0.3372	0.4551		
System froze	Occasional	High	0.16	0.2038		
Hematology slide stainer					0.8279	0.5497
Power light did not light up after switching on	Occasional	High	0.1044	0.1782		
Unit is not auto indexing for different staining stations	Occasional	Low	0.164	0.2536		
Vertical movement cam loose on shaft	Frequent	Moderate	0.1044	0.3960		
Infant incubator					1.5061	1.0000
Audio alarms are not working	Frequent	Moderate	0.316	0.4934		
Missing access grommets	Frequent	Low	0.1424	0.4447		
Motor is stuck	Uncommon	Moderate	1.00	0.5680		
Infusion pump (A)					1.3348	0.8863
Dead battery	Uncommon	Low	0.8176	0.5153		
Problem with door clip	Frequent	Moderate	0.164	0.4234		
Screw missing on bottom left	Frequent	Moderate	0.1044	0.3960		
Infusion pump (B)					1.0058	0.6678
Dead battery	Uncommon	Low	0.9376	0.5705		
Screw missing on bottom left	Frequent	Low	0.122	0.4353		
Intra-aortic balloon pump					1.1815	0.7845
Broken ECG leads	Occasional	Moderate	0.164	0.2224		
Vacuumed performance failed	Frequent	Low	0.3996	0.5630		
Worn out ECG connector	Frequent	Moderate	0.1044	0.3960		
Mobile hypo/hyperthermia unit					1.0816	0.7182
Bad input jack	Frequent	Moderate	0.1044	0.3960		
Cool warning not working	Frequent	Moderate	0.1044	0.3960		
Pump had a noisy bearing	Occasional	High	0.3464	0.2895		
Multi-channel electrocardiograph					1.0467	0.6950
Computer locked up	Frequent	High	0.1044	0.3792		
Intermittent noise on all leads	Frequent	High	0.284	0.4618		
LCD display is intermittent	Occasional	High	0.164	0.2056		

Table 4 *Continued*

Device name	*Frequency*	*Detectability*	*Consequence*	*Failure mode risk score*	*Total risk*	*Device risk = Total risk/max*
Scale for patient care					1.2301	0.8168
Garbled display	Frequent	Moderate	0.2132	0.4461		
Scale will not zero	Frequent	High	0.1044	0.3792		
System does not go ready mode	Frequent	High	0.16	0.4048		
Sterilizer					0.6017	0.3995
Cassette jammed and punctured on plastic housing	Frequent	Moderate	0.164	0.4234		
Plaster is cracked	Occasional	High	0.1044	0.1782		
Surgical lights					0.6513	0.4324
Broken cover cat	Frequent	High	0.2172	0.4311		
Light drifting	Occasional	High	0.1956	0.2202		
Treadmill					1.1132	0.7392
CRT display tube goes blank	Frequent	Moderate	0.16	0.4216		
Does not indicate speed	Frequent	Moderate	0.2172	0.4479		
Poor contact in ECG lead connector block	Occasional	Low	0.1424	0.2437		
Ultrasound doppler					1.1921	0.7915
Damaged LCD leads	Frequent	High	0.2264	0.4353		
Loose battery contact	Frequent	Moderate	0.164	0.4234		
Not picking up the signal	Occasional	Low	0.3372	0.3333		
Ultrasound machine					0.8672	0.5758
Cable holder fell off	Frequent	Moderate	0.1044	0.3960		
Diagnostic software not working	Occasional	High	0.16	0.2038		
system locks up	Uncommon	Moderate	0.3464	0.2673		
Ventilator					0.5891	0.3911
Damaged power supply	Occasional	Moderate	0.16	0.2206		
Going to standby during use	Uncommon	Low	0.4984	0.3685		
Water bath circulator					0.7898	0.5244
Pump motor bearing failed	Occasional	High	0.3464	0.2895		
Relay no longer available	Occasional	Moderate	0.2172	0.2469		
Water bath not regulating temperature	Uncommon	Moderate	0.316	0.2534		

Table 5 Consequence assessment of the failure modes

Device name	*Operational (downtime)*	*Non-operational (repair cost)*	*Safety and environment*	*Consequence score*
Automatic X-ray processor				
Unit does not power up	Medium	Low	Delayed treatment	0.1600
Blood pressure modules				
Module receptacle was damaged	High	Medium	Inappropriate therapy	0.3372
Cardiac cath harp				
CRA/CAU bearing noise	High	Medium	Delayed treatment	0.2840
Low contrast resolution loss after previous HARP test	Medium	Medium	No consequence	0.1260
Centrifuge				
Broken speed control knob	Medium	Medium	Inappropriate therapy	0.2172
Centrifuge intermittently drops in speed while running	Medium	Medium	Inappropriate therapy	0.2172
Machine turns on but motor does not run	Medium	Medium	Delayed treatment	0.1640
Computer terminal				
Mouse locked up	Low	Low	No consequence	0.1044
Overflow errors caused data to be missed in analysis	Medium	High	Inappropriate therapy	0.2796
Tape speed errors	Medium	Medium	Delayed treatment	0.1640
CT scanner				
CT cable loose	Low	Low	No consequence	0.1044
System could not recognize a scan as raw data	High	Medium	Delayed treatment	0.2840
Wire harness for CT dislodged	Medium	Low	Delayed treatment	0.1600
Defibrillator				
Cable constructed	Low	Low	Delayed Treatment	0.1424
Cable tie on paddle handle	Medium	Medium	Delayed treatment	0.1640
Intermittent break in power cord	Medium	Medium	Death	0.8176
ECG physiological telemetry unit				
Broken terminal connection	Medium	Medium	Delayed treatment	0.1640
Soot water damage from fire	High	Medium	Delayed treatment	0.2840
Telemetry does not detect lead off	Medium	High	Inappropriate therapy	0.2796
Exam lights				
Bulb broken inside socket	Low	Low	No consequence	0.1044
Lamp holder broken	Low	Low	No consequence	0.1044
Loosed swivel head	Medium	Low	Inappropriate therapy	0.2132
External pacemaker				
Broken clip	Low	Low	Delayed treatment	0.1424
Pace lights visible only when pacemaker is lying down	Medium	Low	Injury	0.3120
Pulse generator failure	High	High	Death	1.0000
Fetal monitor				
Monitor not powering-up	Medium	Medium	Delayed treatment	0.1640
Paper was not moving	Low	Low	No consequence	0.1044
The unit kept losing its configuration	High	Medium	Inappropriate therapy	0.3372
Gamma camera				
Fatal timeout problems	Medium	High	Inappropriate therapy	0.2796
Peak shift	High	Medium	Inappropriate therapy	0.3372
System froze	Medium	Low	Delayed treatment	0.1600
Hematology slide stainer				
Power light did not light up after switching on	Low	Low	No consequence	0.1044
Unit is not auto indexing for different staining stations	Medium	Medium	Delayed treatment	0.1640
Vertical movement cam loose on shaft	Low	Low	No consequence	0.1044

Table 5 *Continued*

Infant incubator				
Audio alarms are not working	Medium	Medium	Injury	0.3160
Missing access grommets	Low	Low	Delayed treatment	0.1424
Motor is stuck	High	High	Death	1.0000
Infusion pump (A)				
Dead battery	Medium	Medium	Death	0.8176
Problem with door clip	Medium	Medium	Delayed treatment	0.1640
Screw missing on bottom left	Low	Low	No consequence	0.1044
Infusion pump (B)				
Dead battery	High	Medium	Death	0.9376
Screw missing on bottom left	Medium	Low	No consequence	0.1220
Intra-aortic balloon pump				
Broken ECG leads	Medium	Medium	Delayed treatment	0.1640
Vacuumed performance failed	High	High	Inappropriate therapy	0.3996
Worn out ECG connector	Low	Low	No consequence	0.1044
Mobile hypo/hyperthermia unit				
Bad input jack	Low	Low	No consequence	0.1044
Cool warning not working	Low	Low	No consequence	0.1044
Pump had a noisy bearing	High	High	Delayed treatment	0.3464
Multi-channel electrocardiograph				
Computer locked up	Low	Low	No consequence	0.1044
Intermittent noise on all leads	High	Medium	Delayed treatment	0.2840
LCD display is intermittent	Medium	Medium	Delayed treatment	0.1640
Scale for patient care				
Garbled display	Medium	Low	Inappropriate therapy	0.2132
Scale will not zero	Low	Low	No consequence	0.1044
System does not go ready mode	Medium	Low	Delayed treatment	0.1600
Sterilizer				
Cassette jammed and punctured on plastic housing	Medium	Medium	Delayed treatment	0.1640
Plaster is cracked	Low	Low	No consequence	0.1044
Surgical lights				
Broken cover cat	Medium	Medium	Inappropriate therapy	0.2172
Light drifting	Low	Low	Inappropriate therapy	0.1956
Treadmill				
CRT display tube goes blank	Medium	Low	Delayed Treatment	0.1600
Does not indicate speed	Medium	Medium	Inappropriate therapy	0.2172
Poor contact in ECG lead connector block	Low	Low	Delayed treatment	0.1424
Ultrasound doppler				
Damaged LCD leads	Medium	High	Delayed treatment	0.2264
Loose battery contact	Medium	Medium	Delayed treatment	0.1640
Not picking up the signal	High	Medium	Inappropriate therapy	0.3372
Ultrasound machine				
Cable holder fell off	Low	Low	No consequence	0.1044
Diagnostic software not working	Medium	Low	Delayed treatment	0.1600
system locks up	High	High	Delayed treatment	0.3464
Ventilator				
Damaged power supply	Medium	Low	Delayed treatment	0.1600
Going to standby during use	High	High	Injury	0.4984
Water bath circulator				
Pump motor bearing failed	High	High	Delayed treatment	0.3464
Relay no longer available	Medium	Medium	Inappropriate therapy	0.2172
Water bath not regulating temperature	Medium	Medium	Injury	0.3160

Table 6 Proposed classes and the thresholds

Criticality class	*Transformed score value*	*Maintenance strategy*
High	$40\% < TSV \leqslant 100\%$	Proactive, predictive, or time-based maintenance
Medium	$20\% < TSV \leqslant 40\%$	Proactive or time-based maintenance
Low	$0\% \leqslant TSV \leqslant 20\%$	Corrective maintenance

Table 7 Heuristic reasoning for maintenance decisions

Antecedent			*Consequent*
(Recalls ↑) or (Risk ↑)			Design-out maintenance
(Recalls ↓) and (Risk ↓)	(Function ↑) and (Failure consequence ↑)	(Utilization ↑)	Condition monitoring
		(Utilization ↓)	Inspections
		(Detectability ↑)	Failure-finding interval
	(Function ↓)	(Mission ↓)	Operate to failure
	(Function ↕)	(Utilization ↑)	Calendar-based maintenance
		(Utilization ↓)	Utilization-based maintenance

Symbols: ↑ high/critical ↓ low/non-critical ↕ medium/mid-critical.

as budget and labor to be implemented. Time-based maintenance may not always be optimal and a device may be over or under maintained when the preventive maintenance is carried out on a calendar based scheme. In predictive maintenance some variables such as the device vibration are measured to assess the device's physical status. The measured variables are used to predict failure of the device. This maintenance strategy requires some sensors or special equipment to measure the prediction variables. However, it can increase the operational life of the device and its availability.

Devices with low critically score can be excluded from the maintenance management program of a hospital and just get fixed whenever they break down (corrective maintenance). This group of medical devices more likely have a low score value with respect to the criteria possessing higher weights such as function, risk, and recalls and hazard alerts; so the asset management resources are better not to be spent on this group. Table 2b shows that corrective maintenance can be used for the last eight devices on the list starting with Scale for patient care and ending to Surgical and Exam lights. In other words, these devices are run to failure and just get fixed when they fail.

Proactive maintenance could potentially be applied to high critical devices. This type of maintenance employs monitoring and correction of failing root causes (Swanson, 2001) or in general, detection and elimination of root causes of such a high criticality score when it is applicable and manageable. If physical conditions such as vibration, noise, etc of a device with high criticality score can be measured, condition-based or predictive maintenance is recommended to avoid or reduce failure consequences; if not, time-based maintenance could be applied here as well. Time-based maintenance can be considered for devices with average criticality score. Unlike predictive maintenance, time-based maintenance is easier to implement, with no need to have any special sensor equipment. In Table 2b, devices such as Infant Incubator, Defibrillator, and Balloon Pump with transformed score of greater than 40% belong to the high criticality class.

To facilitate a risk reduction strategy, devices should be investigated periodically with respect to their dynamic criteria, and their current maintenance policies should be adjusted accordingly. For example, when the total risk score of a device is high, its root causes should be investigated and appropriate actions should be taken to reduce the risk. If risk is high due to the high frequency of failures, the root causes might be 'use error' or imperfect design. In this case, user training or redesigning the device if possible, could be effective risk reduction actions.

We also can use the score value obtained for a device with respect to each individual criterion to determine appropriate maintenance strategies for the device. Here, the decision factor is the score value of a device with respect to a criterion or a combination of criteria (antecedent or IF-statement) and the consequence (THEN-statement) is the most recommended maintenance strategy. This multi-criteria methodology introduced here is a method that requires more research and will not be further discussed, but some initial heuristic guidelines for selecting appropriate maintenance strategies are suggested in Table 7. For example, Table 7 recommends 'design-out maintenance' when a device has a high score value for either 'recalls' or 'risk', since the device more likely has an engineering design problem. When the score value of the device for both 'recalls' and 'risk' is low, and the device is

function-critical with significant failure consequence with low possibility of failure detection, failure-finding strategy is recommended to minimize the consequence of hidden failures.

Conclusions

This paper presents a multi-criteria decision-making model to prioritize medical devices according to their criticality. The model uses AHP to identify and include the more critical devices in the equipment management program of a hospital. The proposed hierarchy structure contains six criteria to assess criticality of the devices, 'Function', 'Mission criticality', 'Age', 'Risk', 'Recalls and hazard alerts', and 'Maintenance requirements'. The model gives a realistic estimate of the total risk of a device by taking into account its different failure modes and assessing their frequency, detectability and consequences. The proposed model uses both relative and absolute measurement in the application of AHP to determine weighting values for the criteria and their grades' intensities, and to evaluate the alternatives (devices). Calculating the consistency ratio in pairwise comparison of the criteria makes the model able to produce more precise and consistent criteria's weights compared to direct assignment of the weights. Furthermore, the intensities which are obtained for the criteria's grades are also more consistent due to applying the relative measurement method.

This model can be integrated as a module into the CMMS of a hospital to prioritize medical devices. Devices with lower criticality scores can be assigned a lower priority in a maintenance management program. However, those with higher scores should be investigated in detail to find the reasons of having such high criticality scores to take appropriate actions, such as 'preventive maintenance', 'user training', 'redesigning the device', etc when reducing the criticality score is applicable and manageable. Also, individual score values for each device with respect to a criterion or a combination of several criteria can be used to establish guidelines to select an appropriate maintenance strategy.

In our proposed model, the pairwise comparison matrices are constructed using Saaty's crisp 1–9 scales. Alternatively, *fuzzy analytic hierarchy process* (Kwong and Bai, 2002) can be used; in this case, scales are fuzzy numbers instead of crisp values to handle uncertainty in assigning the scale values.

Acknowledgements—We acknowledge the Natural Sciences and Engineering Research Council (NSERC) of Canada, the Ontario Centre of Excellence (OCE), and the C-MORE Consortium members for their financial support. We are thankful to the referees whose constructive criticism and comments have helped us to improve the presentation of the paper and to augment our literature review with new references. Specifically, the remarks concerning the demonstration of the proposed model were very helpful.

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Appendix A

Qualitative grades and intensities for criteria/sub-criteria

We explain how the intensities for grades of criterion 'Function' can be obtained; the intensities of other criteria's grades are obtained using the same method.

Step 1: Pairwise comparison matrix of the grades is constructed using expert opinion (α_{ij} for $i=1, \ldots, 5$, $j=1, \ldots, 5$). (Table A1).

Step 2: The weight of each grade can be obtained as follows:

$$v_i = \frac{\left(\prod_{j=1}^{5} a_{ij}\right)^{\frac{1}{5}}}{\sum_{i=1}^{5}\left(\prod_{j=1}^{5} a_{ij}\right)^{\frac{1}{5}}},\ i = 1, ..., 5,\ j = 1, ..., 5$$

Step 3: The intensity of each grade can be obtained as follows:

$$\text{Intensity} = \frac{v_i}{\max(v_i)},\ i = 1, ..., 5$$

See Table A2.
The same method is employed for calculating the intensities of other criteria (Tables A3–A13).

Table A1 Pairwise comparison matrix for the grades of criterion 'Function'

	Life support	*Therapeutic*	*Patient diagnostic*	*Analytical*	*Miscellaneous*
Life support	1.00	5.00	6.00	8.00	9.00
Therapeutic	0.20	1.00	1.60	1.40	1.80
Patient Diagnostic	0.17	0.63	1.00	1.25	1.50
Analytical	0.13	0.71	0.80	1.00	1.29
Miscellaneous	0.11	0.56	0.67	0.78	1.00

Table A2 Calculating intensities for the grades of criterion 'Function'

	$\Pi_{j=1}^{5} a_{ij}$	$(\Pi_{j=1}^{5} a_{ij})^{1/5}$	$v_i = (\Pi_{j=1}^{5} a_{ij})^{1/5} / \Sigma_{i=1}^{5} (\Pi_{j=1}^{5} a_{ij})^{1/5}$	*Intensity* $v_i/max(v_i)$
Life support	2160.00	4.64	0.62	1.00
Therapeutic	0.81	0.96	0.13	0.21
Patient diagnostic	0.20	0.72	0.10	0.16
Analytical	0.09	0.62	0.08	0.13
Miscellaneous	0.03	0.50	0.07	0.11
		$\Sigma_{i=1}^{5} = 7.45$		

Table A3 Function grades and intensities

Function	
Grade	*Intensity*
Life support	1.00
Therapeutic	0.21
Patient diagnostic	0.16
Analytical	0.13
Miscellaneous	0.11

Table A4 Utilization grades and intensities

Utilization		
Grade	*Description*	*Intensity*
High	Usage hours per week $\geqslant$ 24	1.00
Medium	12 $\leqslant$ Usage hours per week $<$ 24	0.34
Low	0 $\leqslant$ Usage hours per week $<$ 12	0.15

Table A5 Availability of alternatives grades and intensities

Availability of alternative devices		
Grade	*Description*	*Intensity*
Low	No of available alternatives $\leqslant$ 1	1.00
Medium	1 $<$ No of available alternatives $\leqslant$ 4	0.34
High	No of available alternatives $>$ 4	0.20

Table A6 Age grades and intensities

Age		
Grade	*Description*	*Intensity*
Old	Actual life/Life span $>$ 1	1.00
Almost old	0.75 $<$ Actual life/life span $\leqslant$ 1	0.67
Average	0.5 $<$ Actual life/life span $\leqslant$ 0.75	0.43
Almost new	0.25 $<$ Actual life/life span $\leqslant$ 0.5	0.17
New	0 $\leqslant$ Actual life/life span $\leqslant$ 0.25	0.12

Table A7 Failure frequency grades and intensities

Failure frequency		
Grade	*Description*	*Intensity*
Frequent	Likely to occur (several occurrences in 1 year)	1.00
Occasional	Probably will occur (several occurrences in 1–2 years)	0.33
Uncommon	Possible to occur (one occurrence in 2–5 years)	0.20
Remote	Unlikely to occur (one occurrence in 5–30 year)	0.15

Table A8 Failure detectability grades and intensities

Failure detectability		
Grade	*Description*	*Intensity*
Very low	Not detected by regular inspection	1.00
Low	Detected by inspection	0.33
Moderate	Visible by naked eye	0.20
High	Self-announcing	0.13

Table A9 Downtime grades and intensities

Downtime		
Grade	*Description*	*Intensity*
High	Total waiting time$\geqslant$72 h per day	1.00
Medium	24$\leqslant$Total waiting time$<$72 h per day	0.25
Low	Total waiting time$<$24 h per day	0.14

Table A10 Cost of repair grades and intensities

Cost of repair		
Grade	*Description*	*Intensity*
High	Total repair cost$\geqslant$\$2500	1.00
Medium	\$500$\leqslant$Total repair cost$<$\$2500	0.22
Low	\$0$\leqslant$Total repair cost$<$\$500	0.17

Table A11 Safety and environment grades and intensities

Safety and environment	
Grade	*Intensity*
Death	1.00
Injury	0.34
Inappropriate therapy or misdiagnosis	0.21
Delayed treatment	0.14
No consequence	0.09

Table A12 Recalls and hazards grades and intensities

Recalls and hazard alerts		
Grade	*Description*	*Intensity*
High	Total number of class I or II recalls (in a year)$\geqslant$1 or Total number of hazard alerts (in a year)$\geqslant$4	1.00
Medium	2$\leqslant$Total number of hazard alerts (in a year)$<$4	0.21
Low	Total number of hazard alerts (in a year)$<$2	0.12
Null	Total number of hazard alerts (in a year)$=$0	0.00

Table A13 Maintenance requirements grades and intensities

Maintenance requirements		
Grade	*Description*	*Intensity*
High	Equipment that is predominantly mechanical, pneumatic or fluidics in nature often requires the most extensive maintenance.	1.00
Medium	A device is considered to have average maintenance requirements if it needs only performance verification and safety testing.	0.50
Low	Equipment that receives only visual inspection, a basic performance check, and safety testing is classified as having minimal maintenance requirements	0.17

Appendix B

Calculating the lower bound for the total score value

Table B1 shows how a score value of 0.1050 is obtained when a device gets the lowest intensity value with respect to all assessment criteria.

Thus, the minimum total score value is,

$$(0.45 \times 0.11) + (0.1 \times 0.165) + (0.06 \times 0.12) + (0.16 \times 0.124224) + (0.16 \times 0) + (0.07 \times 0.17) = 0.1050$$

Table B1 Calculating the minimum total score value

Main criteria (weight) assigned/calculated score		*Sub-criteria (weight) assigned/calculated score*		*Sub-criteria (weight) assigned/calculated score*		*Sub-criteria (weight) assigned/calculated score*	
c_1—Function **0.11**	(0.45)						
c_2—Mission criticality **0.165** $=0.7 \times 0.15$ $+0.3 \times 0.2$	(0.10)	c_{21}—Utilization **0.15**	(0.70)				
		c_{22}—Availability of alternatives devices **0.2**	(0.30)				
c_3—Age **0.12**	(0.06)						
c_4—Total risk **0.124224** $=0.30 \times 0.15$ $+0.24 \times 0.13$ $+0.46 \times 0.1044$	(0.16)	c_{41}—Failure frequency **0.15**	(0.30)				
		c_{42}—Detectability **0.13**	(0.24)				
		c_{43}—Failure consequence **0.1044** $=(0.16 \times 0.14)$ $+(0.08 \times 0.17)$ $+(0.76 \times 0.09)$	(0.46)	c_{431}—Operational **0.14** $=1 \times 0.14$	(0.16)	c_{4311}—Downtime **0.14**	(1.00)
				c_{432}—Non-operational **0.17** $=1 \times 0.17$	(0.08)	c_{4321}—Cost of repair **0.17**	(1.00)
				c_{433}—Safety and environment **0.09**	(0.76)		
c_5—Recalls and hazard alerts (0.16) **0**							
c_6—Maintenance requirement (0.07) **0.17**							

Calculated weights at every level are specified in bold.

Received May 2009;
accepted May 2010 after one revision