SPECIAL PAPER

Medical Imaging Devices Assessment at Public Health Sector of Greece. Risk-Based Maintenance: A Decision Support Model

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Abstract

Introduction: Medical imaging equipment such as ultrasound, X-ray, Computed Tomography and Magnetic Resonance Imaging systems are essential in modern hospital operation. They have the capacity to promote public health under the condition that they operate with high reliability and safety requirements.

Aim: The aforementioned prerequisites necessitate an efficient maintenance planning that could keep these devices in good condition at the minimum cost. The rare economic resources in Greece due to the recession have made this task rather difficult.

Methodology: A risk-based decision support model is introduced in this study towards the debate whether to maintain or not a medical imaging device. Several parameters and metrics have been utilized as input in the decision algorithm in order to produce optimum decision regarding the need to maintain a certain device. These include availability, key performance indicators, risk and economic factors. These metrics are capable of capturing all the information that is significant for each medical imaging device.

Results: A case study has been made in this study that utilized an x-ray imaging C-arm towards efficient decision making regarding maintenance that employed all the metrics of the last two years where the C-arm imaging device is without a preventive maintenance contract with the manufacturer.

Conclusions: The decision model introduced in this study could be of value for the hospital management and provide important information regarding the condition of each medical imaging device and possible future failures.

Keywords Medical Imaging Devices, risk-based maintenance, decision support system, cost-effectiveness

Introduction

A contemporary public hospital constitutes a place where state-of-the-art medical technology equipment is utilized from highly trained personnel so as to promote healthcare service performance. In particular, medical imaging equipment such as ultrasound (US), mammography, C-arm, Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) systems play a key-role in daily hospital operation (Bronzino, 1992). A fully functional and effective imaging device promotes the hospital's performance and subsequently public health. Moreover, their operation is under high reliability and safety requirements due to the complicated technology involved and possible direct and indirect hazardous consequences to patients in case of failures.

The complexity and high concentration of the aforementioned medical imaging devices necessitate a great amount of management effort towards efficient planning and control in order to avoid issues regarding functionality, performance, safety and operational costs. These devices must be kept in good condition and must be able to face the tough competition environment and complex health care system at the minimum cost. Maintenance activities generally consist of inspection, cleaning, adjustment, alignment, and/or replacement of sub-components that wear-out (Computerized maintenance management system 2011).

However, the majority of these devices suffers from deterioration with age combined with excessive use and may experience a failure at any time instant. On failure, the system may be replaced or repaired. Despite the complexity and high cost of medical devices, most hospitals do not utilize a proper management strategy which in turn lead to an increment at failure rate and finally to their rapid obsolescence. The economic crisis in Greece has resulted into rare economic resources for the public healthcare sector and at the same time an increased use of public health care services. As a result the management of a public hospital is continuously faced with the reduction of government funding combined with increment of demand. Most maintenance contracts in medical imaging devices have not been renewed, thus leaving them without regular maintenance. The majority of public hospital administrations have adopted a crisis management procedure in cases of operation break-down that mostly encounter the current damage. In particular, no preventive maintenance tasks are performed on a medical device. The only scheduled maintenance on each imaging device is corrective maintenance after it has suffered a failure, without considering additional parameters such as failure rate and equipment down-time that could provide important information regarding the real condition of each device. Consequently, the decision made by the management is to neglect the device, regardless of any signs of potential failure and to wait until the point at which functional failure occurs.

In this context, a maintenance strategy whereby the maintenance processes are planned based on failure risks, effects, and calculated costs of a specific imaging device in a public hospital can be an ideal solution despite the aforementioned problems. However, conflicting interests between hospital management and political strategies combined with social demands for better health and the interests of the suppliers create a complicated problem that cannot be addressed with simple guidelines towards an optimum solution. The decision to perform risk-based maintenance can be difficult and tricky for an imaging medical device. It is considered as a financial and technical analysis method that focuses on establishing the relative worth of maintenance. It defines opportunities for the elimination of maintenance decisions of low value and the introduction of decisions which have the capacity to address high risk areas regarding the equipment's availability and reliability combined with the financial loss prevention. Risk-based maintenance was originally developed as a means of reviewing existing maintenance programs, and in this mode it can perform adequately as a continuous improvement tool.

The majority of the medical imaging devices utilized in the Greek public hospitals considered as mid-life devices. The decision in minor low potential cost failures on new devices and major failures, in particularly aged devices, is considered as rather easy to make. The major dilemma of a manager is "when to perform a preventive maintenance based on risk metrics and over time to decide how much preventive or repairing costs of the imaging equipment is considered justified before start planning a replacement strategy?" There are often a number of technical issues involved, which the engineers often are competent to address, and provide a range of possible technically feasible solutions. But how the financial impacts of these solutions are assessed in order to arrive at a decision, particularly in terms of the hospital economics and future risk costs? For that reason, the need of a decision support model that can incorporate all the aforementioned comments be means of quantified risk metrics is considered to be of value in modern hospital management and can result in a significant reduction of operational costs.

Background

Very few studies have addressed the maintenance policy in medical devices throughout the past years. A medical equipment management program to prioritize medical devices based on their criticality proposed by (Taghipour, Banjevic & Jardine 2010). Different critical score values indicate different maintenance strategy. A fuzzy inference model is also proposed to identify the equipment to replace in order to achieve the goals of reducing expenditure in a hospital structure and to increase patient and medical staff satisfaction (Mummolo et al., 2007).

A new medical equipment maintenance and replacement score employing technical, conditional and safety rules has also been introduced in order to decide the possibility of maintenance or obsolescence (Taylor & Jackson 2005). Under the same framework (Dreiss, 2008) proposed a medical device replacement plan that utilized technical, financial and performance criteria. Also, an empirical algorithm model is introduced in order to rank medical devices towards replacement, safety testing, preventive or repair maintenance (Robson et al., 2005). Finally, (Chien, Huang & Chong 2010) implemented an efficient information system that could promote the managing performance of medical devices. Within the same context, (Chryssanthou et al., 2012) proposed a decision model whether to replace or maintain a Hospital Information System employing multiple technical, financial and organizational criteria. To the best of our knowledge no reports have been published so for regarding automatic decision-based maintenance strategy in medical imaging devices.

The paper is organized as follows: in the Material and Methodology section at first the performance indices followed by the decision model introduced in this study are presented. In the Results section the case study that employed an x-ray imaging C-arm towards efficient decision making regarding maintenance is presented. In the Discussion – Conclusion section the methods and results of the proposed decision model are discussed. Finally, at the Future Work section the questions the results of the study raised and future steps that could be more promising are showed.

Material & Methodology

The methodology for risk-based maintenance of medical imaging devices depends on the information that the hospital structure has. A lack of information on the real condition of equipment leads to choices based on the experiences of their operators or on the budget contingencies. This means that in some cases the device maintenance can be considered often as premature, unnecessary or even unsuitable or too late due to a lack of appropriate planning. On the contrary, when information is available from an adequate monitoring of devices, the tendency is to concentrate only on equipment which is broken without carrying out a comprehensive evaluation of the state of devices.

An accurate process of equipment state appraisal is required. In case of an increasing failure rate of medical devices the increment of both break-down maintenance costs and risk of unfavorable events are expected, whereas if devices are maintained too early an increase of maintenance costs will occur. The decision risk-based support model risk presented in the study addresses

Figure 1: Mathematical Equations

$$ASC = Maintenance\ Cost + (X-ray\ Tube\ Cost \cdot Probability\ of\ Failure) \quad (1)$$

$$MTBF = \frac{\Sigma(start\ of\ dowtime - start\ of\ uptime)}{number\ of\ failures} \quad (2)$$

$$AFR = 1 - e^{-\left(\frac{Annual\ Utilization\ Hours}{MTBF}\right)} \quad (3)$$

$$RC = Cost \cdot Probability\ of\ Failure \quad (4)$$

$$MCLR = \frac{Gross\ Annual\ Revenue}{Annual\ utilization\ hours} \cdot DownTime \quad (5)$$

$$V = MCLR + RC - ASC \quad (6)$$

$$F(t) = 1 - e^{-\lambda t} \quad (7)$$

the trade-offs in medical device costs and reliability for annual budgeting and maintenance scheduling.

The proposed model considers several parameters in order to produce optimum decision regarding the need to immediately maintain a medical imaging device. These parameters include availability (up-time vs. down time per year), key performance indicators (usage frequency rate, maintenance ratio, failure rate and probability of failure), risk factors (Reliability, condition) and economic factors (opportunity cost, Risk cost and maintenance cost). All these data are quantified with certain metrics that are capable of capturing all the information that is significant for each medical imaging device. The main performance factors or variables that may affect the final decision whether to perform maintenance or not in medical imaging devices are described as follows and are presented in Figure 1 (Ebeling & Charles 1997):

Actual Service cost (*ASC*): Regarding the imaging device, it is considered as the sum of the annual maintenance contract and the possible replacement of the x-ray tube which at most cases is not included in the maintenance contracts.The average life-cycle of an x-ray tube can reach up to 5 years, depending on the utilization hours (scan-seconds). The factor probability of failure represents the likelihood or probability of an event with unwanted consequences occurring such as tube failure (Mondro, 2002).

Mean time between failures (MTBF) is the predicted elapsed time between inherent failures of a system during operation. MTBF can be calculated as the arithmetic mean time between failures of a system (Blanchard 1992). For each observation, the "down time" is the instantaneous time it went down, which is after (i.e. greater than) the moment it went up, the "up time". The difference ("down time" minus "up time") is the amount of time it was operating between these two events (Figure 2).

The certain metric integrates planned and unplanned downtime parameters which are essential regarding availability and reliability of the equipment.

Annualized failure rate (AFR): the certain metric gives the estimated probability that a device or component will fail during a full year of use. It is a relation between the mean time between failure (MTBF) and the hours that the medical imaging device is run per year (Evans, Hastings & Peacock 2011). The relationship between AFR and MTBF is:

The exponential term is used to characterize the reliability of a certain device. Reliability is the ability of a system or component to perform its required functions under stated conditions for a specified period of time. Consequently AFR represents the opposite of reliability (i.e., Probability of Failure).

Risk Cost (RC): This is the financial risk involved in letting the components function until their complete useful life is utilized (Samuelson & Marks 2003), **Mean Cost of Lost Revenue (MCLR)**: It is considered as the potential total cost of a device failure (Samuelson & Marks 2003) and the objective function was formulated for this decision problem and given in (6), where (MCLR) is average cost of lost revenue, (RC) is the financial risk cost, (ASC) is the actual service cost, and (V) is the decision output:

The value of V gives an indication of the decision, whether to perform the preventive maintenance on medical imaging device or not. In order to reach the final decision, at first the total losses if the component continues running until failure occur were evaluated (i.e., $MCLR + RC$ as in (6). Then, the Actual Service cost (ASC) was subtracted from the total losses in order to compare which is bigger, the total losses or the cost of a regular maintenance contract combined with the probability of x-ray tube failure.

If the objective function (V) yields a positive value, it will be represented by number one and the decision will be "perform Preventive maintenance on the device". Otherwise, if the value of V is negative, it will be represented by number zero, and the decision will be "do not perform maintenance on the device". In case of positive value from the objective function the total losses are considered bigger than the actual cost which implies that repairing the device in certain time table it would be better than perform the maintenance when it fails. Instead, in case of negative value from V the losses are smaller than the cost of remaining life and the decision is not to perform preventive maintenance for the time being.

Results

Risk-based maintenance: a case study

A sample application is provided to represent the type of input requirements and to illustrate the types of output and analysis provided by this proposed model. The device employed was a Siemens C-arm utilized for monitoring and assisting stent placement in patients with stenosis. Two types of data namely condition and event data were provided. Condition data indicates the state and health condition of the part whereas event data depicts cases and taken actions.

Condition Data

While medical imaging device operate, condition parameters, which are directly related with c-arm imaging device are recorded and employed for this study. The data provided for the years 2011 and 2012. The imaging device has been without maintenance contract (no scheduled maintenance strategy) throughout the past two years, and any malfunction was treated afterwards with corrective maintenance. The equipment has been purchased in 2009 and it is in its third year under operation. All surgical procedures take place three days per week for approximately 12 hours each day. The annual utilization hours were ~ 1900 . The two year segment that this research has studied had ~ 3800 utilization hours. Regarding the probability of failure of the x-ray tube it can be hierarchically defined for each year of operation (Table 1). The failure distribution has an exponential density that the tube will fail between $t=t_0$ and $t=t_1$.

Since the imaging system is utilized only three times a week the average x-ray tube life cycle will increase. For the purposes of this study, λ was set to 0.3.

Also the maintenance contract before 2011 was approximately 35.000 Euros (All parts and labor included except the x-ray tube which costs approximately 50.000 Euros).

Event data

Event data shows taken actions related to failure of the C-arm. We do not have direct information about the part failure and the actual cost for each part. However, the machine failure time is known. The failure incidents for 2011 were 3 and for 2012 were 4. The corrective maintenance cost for 2011 and 2012 were 8.800 and 12.600 Euros respectively. The downtime was approximately 400 hours (three days per failure including the non-operational days). The MTFB was approximately 355 operational hours (~30 operational days). The annual gross revenue is calculated based on the Diagnostic Relates Groups (DRGs).

The decision criteria employed in the proposed risk-based decision model had the following values (in Euros):

$$MCLR \sim 8000\,,\, RC \sim 12000 \text{ and } ASC \sim 40000$$

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Subsequently from equation 6 the objective function outcome is approximately: -2.7 x 10^4. The negative sign of the objective function indicate the decision not to perform for the time being any maintenance.

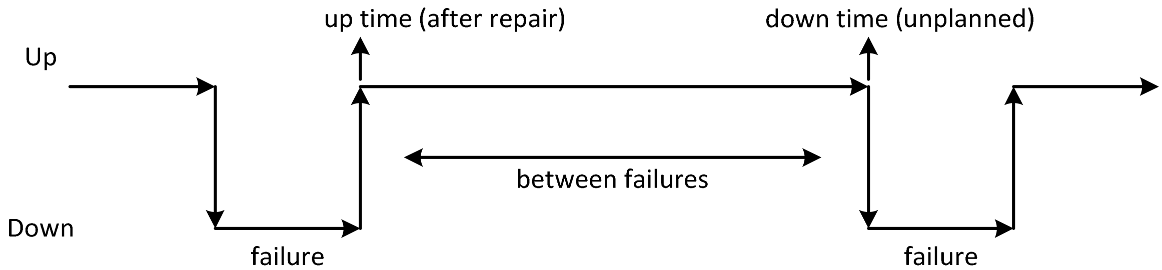

Figure 2: Schematic representation of the temporal sequence between downtime and runtime of a device.

Table 1 Correspondence between C-arm x-ray tube year of operation and probability of failure

Year of operation	1st	2nd	3rd	4th	5th	6th
Probability of failure (%)	0 (warranty)	25	45	59	69	77

Discussion – Conclusions

Imaging medical equipment has become an important component of modern health services. In addition to the traditional operation management, the patient safety, operation performance in cost/efficient analysis, and risk evaluation and control are the important issues for using medical equipment in hospital. But management or maintenance is particularly weak in the Greek public sector due to the rare economic resources. A decision support framework of medical imaging equipment maintenance management system has been proposed in the paper for assisting a hospital early to confront the potential risk and lack of resources. The significance of risk-based maintenance in fields like medical imaging has not been addressed in the modern literature. Unfortunately, there are numerous factors to be considered, while deciding on whether a particular device should be repaired or not when an opportunity arises.

All data collected from the public hospital are difficult to be precise. Especially regarding risk cost and reliability of the device. Depending on the type of product, manufacturers may have numerous definitions of failure. Manufacturers that are quality driven report all modes of failure for the purpose of process control which, among other benefits, drives out product defects. Therefore, additional questions are needed to accurately define a failure. What is a failure? What are the assumptions? Medical imaging devices fall on the high risk devices where even the slightest deviation from the manufacturer guidelines would lead to loss of quality that could deteriorate patient health. The importance of defining a failure should be evident and must be understood before attempting to interpret any metric such as the MTBF value. Assumptions were required to simplify the process of estimating MTBF. It would be nearly impossible to collect the data required to calculate an exact number. However, all assumptions were realistic.

The approach presented optimized the total cost of maintenance and gave an accurate indication about the economic of repairing or not a certain device under thorough risk-based maintenance strategy. The decision model provided the public hospital an alternative regarding the cost-effective distribution of economic resources. The lack of maintenance cost could benefit the hospital with some additional profits that could employ in the future so as to replace the x-ray tube under a close inspection policy regarding the reliability of the device.

Future work

Much work needs to be done in this area with more parameters involved, and numerous other relevant factors needs to be incorporated for a comprehensive study. This was just a preliminary research done to integrate the area of risk-based maintenance in medical imaging devices. The debate whether to maintain a medical imaging device or not and with what criteria, will be more pertinent than ever due to the funding problems raised by the economic crisis.

Various more sophisticated algorithms can be implemented such as neural networks that can predict the decision to maintain or not as long more data are available (i.e. certain parts with bigger failure rate) so as to train the model for optimizing the results. In addition, ranking could be attributed on the outcome of the objective function so as to produce an efficient scheduled maintenance plan that could be updated in certain interval towards the more cost-effective solution.

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