Implementation of Reliability Centred Maintenance in Maintaining Medical Equipment in Hospital

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Abstract

Maintenance services are performed to ensure the equipment is operating according to manufacturer standard and maintained at desired level of quality. The implementation of properly scheduled of maintenance services may prevent unexpected breakdown and disruption of operational in a hospital. However, in some cases, series of breakdown occurred with the maintenance services in-place. This raised the doubts on the reliability and effectiveness of the maintenance services that being exercised. In general, there are many types of maintenance services nonetheless which suit best for medical equipment need to be identified. This paper is to identify the right maintenance services for medical equipment in hospital using Reliability Centred Maintenance (RCM). The equipment was selected based on the criticality and the breakdown history. Failure factors of breakdown were identified and based on this data, a right maintenance services were recommended for the further action.

Keywords: maintenance, medical equipment, reliability-centred maintenance

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INTRODUCTION

Medical equipment is one of a huge interest these days as health is becoming a great concern and creates increasing of expenditures and greater attention to healthcare. Hospital institutions creates wide markets especially in construction of new hospitals and clinics, and establishment of public health insurance as well as the global demand for medical equipment (Desphande,2002). Absence or failure of medical equipment could significantly pull down the medical industry and become detrimental to the lives of billions of people worldwide. Medical equipment in hospital need to be well maintained by with maintenance program in-place. Equipment shall operates as intended as per designed safe to be used on patient. The main purpose of maintenance program is to improve and sustain the equipment function and services using a systematic system and standard regulations set by the local authorities or the hospital institutions (Shohet,2003). Maintenance is important to reach the intended life-time of technical equipment whereby the function is to keep a system in or restore it to the condition deemed necessary for it's to function as intended (Bloom,2006).

In general, the type of maintenance services in hospital are usually recommended by manufacturer or expert with operational experiences rather than it is being optimized according to the need of the organization (Rausand, 2003). As a result, hospital might perform inaccurate maintenance program and pay unnecessary cost in maintaining the equipment. Most of hospitals in United State have started adopting their own maintenance program. They applied the maintenance resources to the most needed since 2004 when Joint Commission on Accreditation of Healthcare Organization (JCAHO) introduced standard EC.6.10 (JACAHO, 2004). This standard allows hospitals not to have the maintenance services for the medical equipment if it is not needed and necessary for safe and reliable operation [6]. Improper implementation of maintenance program in hospital may lead to equipment recurrent breakdown and unnecessary spending on maintaining the equipment. Maintenance capabilities are suggested to be studied during the initial state of deciding to acquire equipment to avoid an excessive maintenance program in the future (Jia and Christer, 2002). Equipment breakdown will reduce the uptime therefore will affecting the productive capability of equipment by reducing output, increasing operating costs and interfering with customer service. Consequently, in order to assist the hospital management as well as the engineering team to efficiently maintain the medical equipment, we are proposing Reliability-Centered Maintenance (RCM) method to identify the right maintenance program to be implemented in hospital by identifying the cause of the breakdown.

RCM is one of the most effective maintenance approaches that are capable to reduce the maintenance activities and their related costs without affecting the overall performance, quality, safety and environmental integrity of the equipment (Backlund and Akersten, 2003). It has been widely and successfully used in vast industries especially in industries with complex system (Saniuk e.al, 2015). such as military, navy, nuclear power plant, electrical power generation and several other sectors (Rausand, 1998). RCM is practical to be used in this study as it focuses on the functional failures of systems and components (Mostafa, 2014). Equipment breakdown can be resolved through a thorough investigation employed to the system by go in depth into the components of the equipment (Desphande and Modak, 2002). RCM process able to determine the optimal maintenance and operational strategies based on the probability and consequences of the analysis failure modes (Ronda, 2008) It always been used as a new strategic framework for ensuring that any asset continues to perform, as its users want it to perform (Kelly, 1998).

Introducing RCM in healthcare industry will enhance the quality of maintenance implementation and thus increase the reliability of medical equipment in service (Tsang, 1995). It consists of principles that are to ensure the effectiveness of maintenance approach that are function oriented, systems focused, acknowledge design limitations, driven by safety and economics, and define failure as any unsatisfactory condition and uses logic tree to screen maintenance tasks [16]. At the end of the day, hospital may decide on which maintenance program best to exercise in maintaining medical equipment. Type of maintenance program is varies depending on the direction and finding of the respective hospital based on their review and audit on the medical equipment (International Atomic Energy Agency, 2007).

This method is highly recommendable for critical and high-end equipment such as imaging equipment (i.e., Magnetic Resonance Imaging, Computed Tomography etc.) and radiotherapy equipment (i.e. Positron Emission Tomography, Linear Accelerator) as the downtime will greatly impact the medical process in hospital.

2 RESEARCH METHOD

The objective of this method is to determine the type of maintenance for medical equipment after recurrent breakdown took place. The process started by identifying the importance and criticality of the medical equipment especially in case if it absents from being used. In this research, we chose ventilator machine as it is categorized as Class I equipment with high-risk effect to patient. The study conducted on 9 units of ventilators system in one of the selected hospitals. The breakdowns data were given by the biomedical engineering team with the consent from the hospital management for this research. The idea of the outcome of this research is a recommendation on the maintenance services to be exercised based on the findings. The effectiveness of the new recommended maintenance program can be validated by comparing the result with the previous used program.

2.1 Reliability-Centered Maintenance

The RCM analysis processes focus on the functions of equipment, the consequences of failure and measures to prevent or cope with functional failure. The process of RCM involves the step as follows:

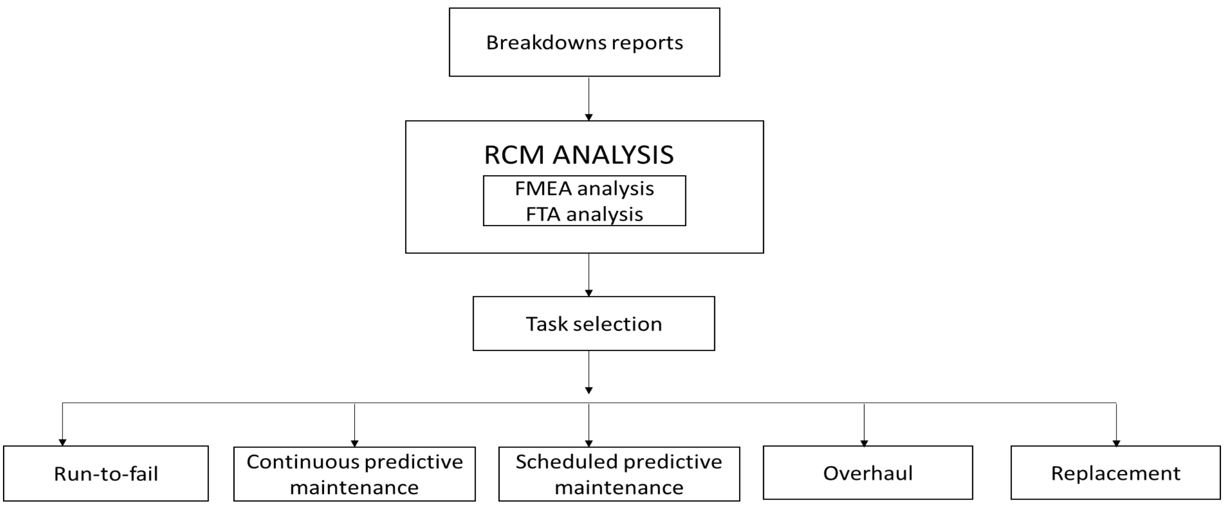

Figure 1. RCM process in maintaining medical equipment

Table 1. Reliability-Centred Maintenance Steps [18]

Reliability-Centred Maintenance Steps	**Description**
Step 1: Data preparation	▪ System selection ▪ Data collection ▪ System boundaries
Step 2: Analysis.	▪ Equipment identification ▪ Identification of system functions ▪ Failure mode effect analysis ▪ Determination of component criticality ▪ Logic tree diagram
Step 3: Task selection.	▪ Continuous predictive maintenance ▪ Scheduled predictive maintenance ▪ Overhaul ▪ Replacement ▪ Inspection and functional testing and Run-to-Failure
Step 4: Task comparison and review	▪ Recommendation of new task/ process selection comparing with the current practice ▪ Output of analysis to change maintenance program.

2.2.1 Step 1: Data Preparation

Data collection will be based on the system selection; type of equipment selected. The selection should be based on the how critical is the equipment to be available and functional. For example, Magnetic Resonance Imaging (MRI) is selected, as the absent of equipment will disturb the process in hospital, and the equipment availability of equipment is critically important when emergency and urgent scanning needed for critical cases. In the selection equipment for the data collection, system boundaries need to be defined for further analysis. System boundaries will define the necessary information to be added and what are to be omitted from the data analysis.

2.2.2 Step 2: Analysis

The analysis can be commenced once the system has been selected. The data must comprehensive collected from the point where the equipment being installed in the hospital until the current time where the analysis starts.

2.2.2.1 Equipment identification and its functions

Equipment that have been selected for the analysis must be profoundly understood especially their structure of equipment, the applications and functions. This is an initial step where we need to know the principle of the system and their function before any action or method can be implemented.

2.2.2.2 Failure mode effect analysis (FMEA)

Failure mode and effect analysis (FMEA) is a tool that examines potential product or process failures, evaluates risk priorities, and helps determine remedial actions to avoid identified problems. FMEA is one of the risk analysis techniques that have been widely used to identify potential failures (Ireson, Coombs and Moss,1995). It is a systematic process that highly recommended by international standards that able to identify possible failure causes so that the causes can be eliminate and to locate the failure's impacts, so the impacts can be reduced (Scipioni, 2002). An application of a FMEA follows a series of successive step: analysis of the process, product or system in every single part, listing of identified potential failures, evaluation of their frequency, severity and detection technique, global evaluation of the problem and identification of the corrective actions and control plans that could eliminate or reduce the chance of the potential failures (Zhao and Bai, 2010). A FMEA uses risk priority number (RPN) to assess risk in three categories (Fig. 2)

i. Occurrence (O) - the assessment of how frequently the specific failure cause is projected to occur,
ii. Severity (S) - the assessment of the seriousness of the effect of the potential failure to the system and
iii. Detection (D) - the assessment of the probability that the operating parameters monitoring system will detect a cause/mode of failure before the component/system is damaged and stopped.

$$RPN = O \times S \times D$$

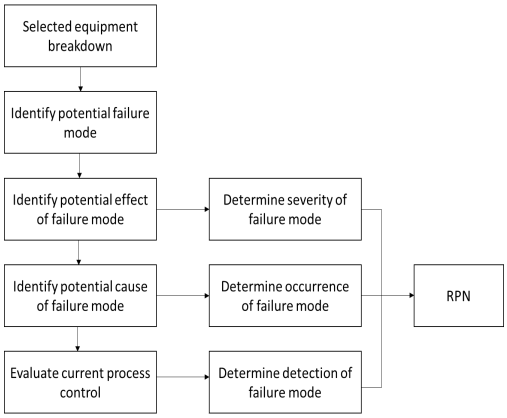

Figure 2: Process of FMEA method [23]

2.2.2.3 Determination of Component Criticality

A reliability centred maintenance approach requires identification of the critical components of the system. A component is defined as critical if the failure effects are massive to the equipment. For example, cold head is very important to MRI whereby faulty of the part will the affect the whole system from being functioning thus equipment cannot be operated. Medical equipment is usually composed of variety of electronic components which categorized into parts that are greatly impacting the equipment and parts that are less impacting the equipment. Hospital need to identify parts that are critically important based on recommendation by the manufacturer or authorized vendor/ distributors. This will help the monitoring process to be focused and narrowed down on the critical parts of equipment.

2.2.2.4 Logic tree diagram

RCM utilizes a decision logic tree to identify the maintenance requirements of equipment according to the safety and operational consequences of each failure and the degradation mechanism responsible for the failures (Zhao and Bai, 2015). The Logic Tree Analysis (LTA) process is used to determine the most applicable, cost-effective preventive maintenance tasks for component in equipment (Jasiulewicz-Kaczmarek, 2016). These recommended tasks are typically a function of component importance, design, utilization and service environment.

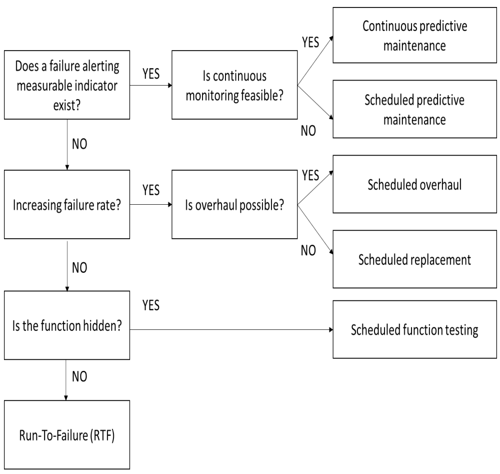

Figure 3: Example of RCM Logic Tree Analysis [26]

2.2.3 Step 3: Task Selection

Task selection need to be determined based on Logic Tree Analysis (Fig. 3). The tasks selected are influenced by the failure causes and appropriate to be implemented for the respective equipment. Medical equipment system can be very simple or complicated therefore the maintenance program for each of the system might vary. Task selection is much depending on the type of equipment and the availability of support given by the manufacturer. The cost of maintenances needs to be minimized without conceding with the reliability and availability of the medical equipment. The task selection must be made thoroughly as wrong selection of task might as increase the maintenance cost and reducing the reliability.

2.2.4 Step 4: Task comparison and review

The effectiveness of a task can only be accessed by comparing the results of before and after the implementation. The number of breakdowns with the current maintenance program in place need to be compared with the number of breakdowns after the new proposed maintenance program being implemented. The result of comparison can be reviewed and can determine whether the hospital made the right task selection or contrary. Further improvement may be addressed and introduced based on the review of the results.

3 EXAMPLE CASE STUDY

Following data are the example of the application of RCM to determine the right maintenance services for ventilator machine.

Step 1: Data Preparation

Description	Type of Equipment: Ventilator Quantity: 2 units Utilization: 24-hours for 7 days (24/7) Risk type: High risk

Step 2: Analysis

Description	Function: Blow air with extra oxygen into the airways and lungs through a breathing tube and carried out carbon dioxide out of the lungs.

Failure Mode Effect Analysis (FMEA)

Highest number of RPN indicates the priority of the equipment to be focused on. The severity, occurrence and detection table to calculate RPN shown as following

a) Severity (S):

Table 2: Severity rating scale for FMEA [27]

Rank of Severity	Description
1	Failure is such minor nature that the operator will probably not detect the failure
2-3	Failure will result in slight deterioration of part or system performance
4-6	Failure will result in operator dissatisfaction and/or deterioration of part or system performance
7-9	Failure will result in high degree of operator dissatisfaction and cause non-functionality of system

10	Failure will result in major operator dissatisfaction or major damage

b) Occurrence (O):

Table 3: Occurrence rating scale FMEA [27]

Rank of occurrence	Description
1	An unlikely probability of occurrence: probability of occurrence < 0.001
2-3	A remote probability of occurrence: 0.001< probability of occurrence < 0.01
4-6	An occasional probability of occurrence: 0.01 < probability of occurrence < 0.10
7-9	An occasional probability of occurrence: 0.10 < probability of occurrence < 0.20
10	A high probability of occurrence: 0.20 < probability of occurrence

c) Detection (D):

Table 4: Detection rating scale for FMEA [27]

Rank of detection	Description
1-2	Very high probability that the defect will be detected
3-4	High probability that the defect will be detected
5-7	Moderate probability that the defect will be detected
8-9	Low probability that the defect will be detected
10	Very low (on zero) probability that the defect will be detected

Table 5: FMEA for ventilator

Function	Potential Failure Mode(s)	Potential Cause(s)/ Mechanism(s) of Failure	Potential Effect(s) of Failure	Sev	Occu	Control(s)	Det	RPN
Power supply & Battery	Unit not power up	Blown/ incorrect/ missing A/C fuse	Machine cannot turn ON & use	7	6	Check/replace A/C fuses	3	**126**
	Decreased run time on battery (internal/external)	Power Driver PCB	Machine cannot running in battery	3	3	-Check connections -Replace Battery PCB -Check/replace battery	6	**54**
	Unit does not run on A/C	-Wiring disconnect -Defective Power Entry Module	Machine cannot be used for longer time	7	3	-Check all connections- especially by compressor -Replace Power Entry Module -Replace Power supply	2	**42**
	Excessive battery heat (internal only)	Battery PCB improperly wired Bad battery PCB	Over-heating & cannot turn ON	7	4	-Check wiring -Replace Battery PCB -Check/replace battery	6	**168**

RPN number are taken as criterion to determine the priority levels. The severity, occurrence and detection factors are typically ranging from 1 to 10. Highest number of RPN which goes beyond acceptable level need to be mitigated by available measures or else the risk event needs to be under monitoring.

Step 3: Task Selection

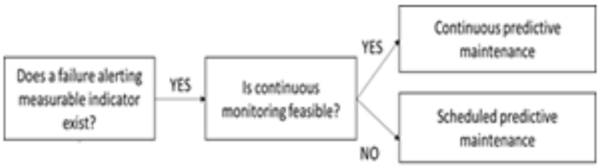

Figure 3: Logic Tree Analysis (LTA)

Task selection is determined based on the monitoring system of the equipment. If a continuous monitoring is available, continuous predictive maintenance will be best option. However, if continuous monitoring is not available, scheduled predictive maintenance is recommended.

Step 4: Task comparison and review
The implementation of scheduled predictive maintenance on the ventilator machine can be evaluated by comparing previous breakdown record with after-implementation recorded. The changes should be reviewed for future references.

4 DISCUSSION
There has been a long period of continuous debate about the shortcomings in efficiency and effectiveness of the traditional method to maintain medical equipment. Maintenance performance can impact the reliability of equipment either by improving the condition or prolong the lifespan of equipment (Tjenberg, Allan and Eriksson, 2005). Many maintenance services applied in the name of regulatory compliance provides little or no values in improving the safety of equipment (Ridgway, Clark, and Bettinardi, 2016). This paper may assist hospital as a guideline to select the right maintenance program for the medical equipment.
Ventilator machine selected as the sample equipment based on the criticality of the equipment to the patient in case of failure. According to general classification of medical device under Medical Device Classification Malaysia [30], ventilator is categorized under moderate-high risk level. In the first step of RCM on selection on the system, ventilator machine fits best in this research paper. FMEA method of RCM is commonly used in healthcare industry (Rosen, et.al., 2014), (DeRosier, et.al., 2001). The result showed “excessive battery heat (internal only) has the highest number of RPN followed closely by unit not power up. In the real practice, unit not power up indicates that the machine be turn ON therefore it cannot be used. In the sense of criticality, this situation affected most the end user as well patient. However, since the potential failure mechanism is easily can be figured out, this is somehow tolerable, but the real source of problem needs to be identified. Some equipment may encounter blown fuse quite common therefore another FMEA table needed to solve this issue, the sources of the breakdowns were identified, and the severity of each breakdown were rated. In the other hand, potential cause mechanism battery PCB improperly wired is more complicated. Thorough inspection needs to be done and possibility to find the source is harder. Monitoring on this problem can be performed based on the next step of RCM which is LTA. If real-time monitoring is existing to monitor the medical equipment in the hospital, continuous predictive maintenance will suit best the above-mentioned case. Scheduled predictive maintenance will be an option in vice-verse situation. Predictive maintenance applies based on the current condition of the equipment or called as condition-based maintenance. It can be performed based on data collected using real-time trend analysis if the system is available, or it can perform as scheduled maintenance based on the evidence of the breakdown (Niu, Yang and Pecht, 2010).

5 LIMITATION
RCM is widely accepted methodology that has been available in the industry for over 30 years and has proved to offer an efficient maintenance program (Desphande and Modak, 2001). However, many organizations failed to achieve their goal due to lack of data and gave up halfway as the process is longer and lengthy. The effectiveness of RCM can be obtained in a long run process where effort and time need to be spent lavishly to achieve the target. Some organizations lack expert especially in monitoring and analysing the data. For medical equipment industry specifically, some of the data need to be obtained from the Original Equipment Manufacturer (OEM) but not all have the data and even those who have the data might not want to share the data to the hospital.

6 CONCLUSIONS

Equipment breakdown due to parts or system failure is a common issue in hospital though most of hospitals are practicing well-developed maintenance program to ensure the stability and availability of equipment. This maintenance program is sometimes cost the hospital more the purchasing price itself especially when involves in major breakdown problems. Therefore, hospital sector needs to ensure that the money that they spent on the maintenance program in their hospital is worth the spending. Principle of RCM is doing right work at the right time based on equipment condition. The outcome of an RCM analysis may result in changes to existing maintenance tasks, where it will enhance the safety and reliability of the equipment and the optimization and maintenance activity.

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