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Preventive Maintenance Prioritization Index of Medical Equipment Using Quality Function Deployment / Saleh, N.; Sharawi, A.; Elwahed, M.; Petti, A.; Puppato, D.; Balestra, Gabriella. - In: IEEE JOURNAL OF BIOMEDICAL AND HEALTH INFORMATICS. - ISSN 2168-2194. - STAMPA. - 19:3(2015), pp. 1029-1035. [10.1109/JBHI.2014.2337895]

Availability:

This version is available at: 11583/2574342 since: 2016-07-14T16:38:24Z

Publisher:

IEEE - INST ELECTRICAL ELECTRONICS ENGINEERS INC

Published

DOI:10.1109/JBHI.2014.2337895

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Preventive Maintenance Prioritization Index of Medical Equipment Using Quality Function Deployment

N. Saleh¹, A. Sharawi², M. Abd Elwahed², A. Petti³, D. Puppato⁴ and G. Balestra¹

Abstract— Preventive maintenance is a core function of clinical engineering and it is essential to guarantee the correct functioning of the equipment. The management and control of maintenance activities are equally important to perform maintenance. As the variety of medical equipment increases, accordingly the size of maintenance activities increases, the need for better management and control become essential. This article aims to develop a new model for preventive maintenance priority of medical equipment using quality function deployment (QFD) as a new concept in maintenance of medical equipment. We developed a 3 domain framework model consisting of requirement, function, and concept. The requirement domain is the house of quality matrix (HOQ). The second domain is the design matrix. Finally, the concept domain generates a prioritization index for preventive maintenance considering the weights of critical criteria. According to the final scores of those criteria, the prioritization action of medical equipment is carried out. Our model proposes 5 levels of priority for preventive maintenance. The model was tested on 200 pieces of medical equipment belonging to 17 different departments of 2 hospitals in Piedmont province, Italy. The data set includes 70 different types of equipment. The results show a high correlation between risk - based criteria and the prioritization list.

Index Terms—Medical Equipment, Preventive Maintenance, Prioritization, Quality Function Deployment

I. INTRODUCTION

PREVENTIVE maintenance (PM) is a core function of clinical engineering, having as objectives the assurance of ongoing safety and performance of medical devices and the preservation of the investment in the equipment through improved longevity [1]. PM is mainly a risk based approach and considered as a core function of clinical engineering department [2]. Despite its core role, the design and

management of an effective PM program is not a simple matter. Adequate administrative support is a requirement for an effective PM program. The two key issues for PM are the procedures to be executed and execution frequencies [1]-[3]. The procedures indicate the necessary steps that are required to assure the performance of the device, whereas, the second key is the frequency at which the set of procedures should be done.

Maintenance prioritization is a crucial task in management systems, especially when there are more maintenance work orders than available people or resources that can handle those devices [4]. The literature is rich with different prioritization approaches for medical equipment. In [5], *Josegh et al* have developed a model for preventive maintenance index considering Risk Level Coefficient (RLC) of the instrument. Risk level coefficient was calculated through five different classified factors related to the medical equipment electrical risk. The factors are static risk, degree and quality of safety arrangements, insulation, physical risk, and equipment contact with the patient.

In another work [6], the authors developed SISMA (System of Information Technology and Support System for Maintenance Actions) system. The system considers two aspects for PM evaluation; technical and economic needs to assess PM plan for medical equipment. Analytical Hierarchy Process (AHP) was used in [7] as a multi-criteria decision making tool to develop a maintenance priority index for medical equipment.

II. BACKGROUND

Quality Function Deployment (QFD) is one of the total quality management (TQM) quantitative tools and techniques that could be used to translate customer requirements and specifications into appropriate technical or service requirements [8]. QFD was conceived in Japan at the end of 60's by Yoji Akao. The first usage of QFD was implemented by Mizuno in 1972 to Mitsubishi's Kobe shipyard site [9].

QFD uses visual matrices that link customer requirements, design requirements, target values, and competitive performance into one chart [8]. Therefore, QFD is considered a quantitative tool that facilitates evaluation of customer's satisfaction. Typically, a QFD system can be broken into four inter-linked phases to fully deploy the customer needs phase by phase [10]. The four-phase model consists of house of quality

Manuscript received on November 19, 2013.

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matrix (HOQ), design matrix, process planning matrix, and finally production matrix [10] - [11].

Among the various matrices, the house of quality (HOQ) is commonly used in the different applications. The HOQ matrix displays the voice of customers (VOC) or customer requirements that are known as WHATs against the technical requirements or voice of engineers (VOE) that are known as HOWs [8] - [11].

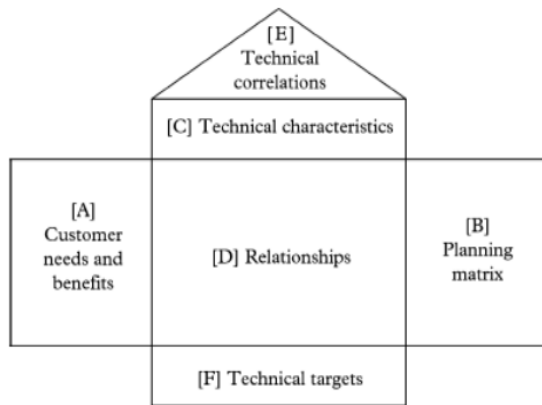


Fig. 1 The house of quality of function deployment [12]

In Fig. 1, a simplified matrix of HOQ is presented depicting the main parts of the matrix. The order suggested by letters A to F is normally followed during the process. Room "A" contains a list of customer needs, each of which is assessed against competitors and the results, which are absolute and relative weights for customer needs prioritization are reported in to room "B". Room "C" has the information necessary to transform the customer expectations into technical characteristics and the correlation between each customer requirements and technical response is put into "D". The roof, room "E", considers the extent to which the technical responses support each other. The prioritization of the technical characteristics, information on the competition and technical targets weights all go into "F" [12].

The most important parts in HOQ are "B" and "F" respectively, more details can be found in [12]. The planning matrix "B" is calculated based on a comparison between the intended service within a hospital and other hospitals. In this matrix, the importance of customer requirements is evaluated, and the actual evaluations of the customer requirements are assigned. The goal is the expected value for each requirement, and then the improvement ratio is calculated by dividing the goal to the evaluation of the intended requirements. The absolute weight is calculated by multiplication of goal and importance ratio, while the relative weight is the normalization of the absolute weight. Technical targets, room "F", are prioritized through calculating the absolute weight of HOWs as given in (1) and then normalizing it to determine the relative weight [13].

$$\text{Absolute weight} = \sum \text{id WHAT} \times \text{RWH} \quad (1)$$

where id WHAT is the importance degree of WHAT and RWH is the relationship value between WHAT and HOW.

According to the characteristics of QFD technique, our objective is to employ QFD as a new approach in medical equipment management to solve the problem of preventive maintenance prioritization of medical equipment considering a set of influential criteria.

III. METHODOLOGY

By using QFD, we proposed a 3 domains framework for preventive maintenance priority, as illustrated in Fig. 3; requirement domain, function domain, and concept domain.

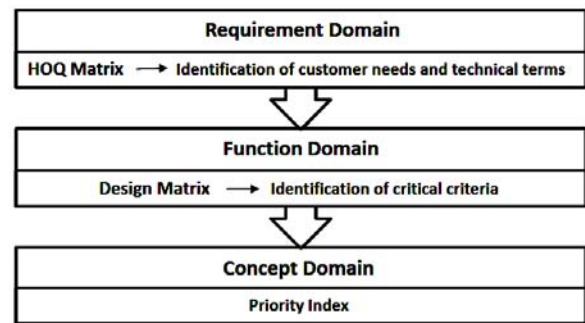


Fig. 2 The proposed 3 domains framework for preventive maintenance of medical equipment prioritization

The first domain considers the customer requirements and the technical characteristics that meet the customer requirements, i.e. HOQ of the model. The second domain is the function domain in which, the top technical criteria that resulted in first domain will be measured through new criteria to identify the critical criteria for preventive maintenance prioritization, i.e. top HOWs of the first domain becomes the new WHATs of the second domain. In last domain, the concept domain, a priority score index is generated considering the weights of critical criteria in order to determine PM priority of medical equipment.

A. Requirement Domain

The HOQ of PM prioritization model is the requirement domain of this framework. First, customer needs and technical characteristics should be identified. In general, the customers of medical equipment in hospitals include all customers that have a direct interface with medical equipment and who expect a range of services. In particular, the patients and clinical staff are considered the customers (WHATs) of medical equipment, whereas, the clinical engineering department is considered the one who is responsible to satisfy those requirements (HOWs).

For patient's requirements, no doubt that safety and availability of medical equipment are essential needs. Clinical

staff requirements were chosen based upon literature [14] and experience. Table I depicts proposed customer's requirements and technical characteristics. Prioritization of customer's requirements is performed considering a comparison between Italian hospital and Jordanian hospital [14].

TABLE I
 CUSTOMER REQUIREMENTS AND TECHNICAL CHARACTERISTICS
 OF HOQ OF PROPOSED FRAMEWORK

Customer Requirements	Technical Requirements	
	Criteria	Sub Criteria
Safety of medical equipment. Efficiency. Durability.	Risk	Physical risk Function Maintenance requirements
Quick response of technical team. Back up availability. Check the device after maintenance. Regular monitoring of the devices. Priority based on importance. Obvious operating instructions.		Mission criticality Function verification Age Labeling Electrical safety Parts replacement Regular inspection
Knowledge of maintained devices. Existence of a contact person 24h. Avoiding suspension of services.	User Competence	Qualification of technicians Complexity of devices Equipped workshop Test equipment availability Service manual availability Activities recording
		Updating or loan Spare parts availability Service provider type
	Costs	
	Standards	Meet standards

Table I shows that, customer's requirements are met by addressing five technical characteristics: *risk*, *performance assurance*, *user competence*, *costs*, and *standard compliance*, which are presented with its sub criteria in this table. The requirement domain (HOQ) is shown in Fig. 3.

The matrix is organized referring to Fig. 1; the left column contains customer requirements (VOC), whereas the main part of the matrix contains the technical characteristics (VOE) segmented into five columns and the relationship matrix. The right column is the planning matrix of HOQ. The bottom room is the technical target matrix. The relationships between WHATs and HOWs are indicated by scores 9 for strong relation, 3 for medium relation, 1 for low relation, and blank for

no relation [11]-[13].

In order to demonstrate how customer needs are prioritized, consider "safety" requirement as an example, by using 5 point scale, we evaluate 5 for importance, 3 for Italian hospital, 5 for Jordanian hospital, and 5 for goal. Regarding our perspective to Italian hospital, the improvement ratio is calculated by dividing the goal to Italian hospital, i.e., 5/3. The absolute weight is calculated through multiplication of improvement ratio by importance, i.e. 1.7×5 ; meanwhile, the relative weight is obtained by normalizing the absolute weight, i.e. $(8.3/91.5) \times 100$. As such for technical targets, to explain how technical criteria priority is identified, we consider "physical risk" as an example. Utilizing formula (1), the absolute weight of "physical risk" equals $9 \times 9.1 + 9 \times 7.3 + 9 \times 4.4 + 3 \times 8.7 = 213.3$, and the relative weight is calculated also by normalization to become 5.03.

B. Function Domain

The next stage of our proposed model is to identify the critical criteria among the technical criteria for preventive maintenance priority. We selected the *top 11 criteria of technical terms* based upon their weights and importance to become the inputs (WHATs) of the second matrix as illustrated in Fig. 4. The design matrix is constructed with the same way that is followed in building HOQ in Fig.3, except the planning matrix; it is the top 11 output relative weights of HOQ.

For better representation of five addressing criteria dimensions, we propose all sub criteria with relative weight greater than 4.5 % to be selected as *top criteria* in order to cover a wide range of criteria ranging from risk criteria with its clear impact in PM to a regular inspection since it is not regularly followed by a lot of hospitals especially in developing countries. The criteria are function, mission criticality, service provider type, standards compliance, maintenance requirements, age, functional verifications, team qualification, device complexity, physical risk, and regular inspection.

We classified the critical criteria into 3 categories for HOWs of the second matrix; *risk-based* criteria including function, physical risk, and maintenance requirements; *mission-based* criteria including utilization level, area criticality, and device criticality; and finally *maintenance-based* criteria incorporating, failure rate, useful life ratio, device complexity, number of missed maintenance, and downtime ratio. The criteria were selected based upon literature [3]-[5]-[6]-[7]-[14], in addition to the authors experience.

The matrix roof depicts the relations among HOWs [15]. Strong relation is indicated by ●, medium by ▼, and low by ○. The relationships are proposed according to author's experience. As shown in Fig. 4, the planning part of design matrix (importance of WHATs) is the resultant relative weight of top 11 criteria of first domain. The critical targets of the technical criteria are considered based upon the proposed thresholds as presented in Table II. On the other hand, the technical targets; i.e. the absolute weight and relative weight of the technical criteria are calculated as the same for requirement domain. In fact, the resultant ranking of most critical criteria for PM prioritization point to risk-based criteria is topping the list of criteria (44.9%) that it is logical with previous survey, followed by mission-based and maintenance-based.

C. Concept Domain

The concept domain is the output of the design matrix. The output is a prioritization equation considering the eleven most critical factors with the resultant weights. Equation (2) generates the priority index of preventive maintenance that is presented as scores. Table II, illustrates a brief description of the critical criteria and their proposed scores.

$$PS = 11.7(FN) + 12.8(PR) + 20.4(MR) + 11(UL) + 6.5(AC) + 11.4(DC) + 8.3(FR) + 5.1(LR) + 6.3(CM) + 3.4(MM) + 3.1(DR) \quad (2)$$

- PS: priority score
- FN: function of equipment
- PR: physical risk
- MR: maintenance requirements
- UL: utilization level
- AC: area criticality
- DC: device criticality
- FR: failure rate
- LR: useful life ratio
- CM: device complexity
- MM: missed maintenance
- DR: downtime ratio

The complexity model [16] assesses the technical complexity of a device considering four factors; equipment maintainability, installation requirements, repair, and connectivity. The scores are given for each factor range from 0 to 2 for evaluation based upon the complexity level for each device in the list.

TABLE II

A BRIEF DESCRIPTION OF CRITICAL PARAMETERS AND THEIR PROPOSED SCORES

Parameter	Description	Thresholds	Scores
Function	Device function	Life support	5
		Therapeutic	4
		Diagnostic / monitoring	3
		Analytical	2
		Miscellaneous	1
Physical risk	Probable harms caused by equipment failure	Death	5
		Injury	4
		Misdiagnosis	3
		Equipment damage	2
		No risk	1
Maintenance requirements	Maintenance activities depending on equipment type	Extensive	5
		A above average	4
		Average	3
		Below average	2
		Minimal	1
Utilization level	Number of working days a week	>4 days	3
		3-4 days	2
		<3 days	1
Area criticality	Assessment of area criticality for patients	Urgent	5
		Intensity care units	4
		Diagnostic area	3
		Law intensity area	2
		Non clinical area	1
Device criticality	The importance level of equipment in serviced area	Critical	3
		Important	2
		Necessary	1
Failure Rate	Number of failures a year based on device criticality level	≥2 for critical, ≥4 for important, ≥5 for necessary	3
		1 for critical, 2-3 for important, 3-4 for necessary	2
		0 for critical, ≤1 for important, ≤2 for necessary	1
Useful life ratio	Ratio between age to expected life time of a device	Ratio > 80 %	3
		50% < Ratio <= 80%	2
		Ratio <= 50 %	1
Device complexity	Technical complexity based on a model	Score 6 - 8	3
		Score 3 - 5	2
		Score 0 - 2	1
Missed maintenance	Number of missed maintenance a year	≥ 2	3
		1	2
		0	1
Downtime ratio	Ratio between the duration of downtime in days to days a year	Ratio ≥ 20 %	3
		10% ≤ Ratio < 20%	2
		Ratio < 10 %	1

IV. RESULTS

For model verification, we utilized a data set of two hundreds medical equipment of two hospitals with one management system in Piedmont province; Italy. Seventy different types of equipment belonging to 17 different kinds of departments were analyzed along data collected for one year (2012). Table III, shows a sample data of various types

of investigated equipment along with priority scores based upon our proposed model.

The scores in Table III are obtained referring to the scores that are given in Table II. For instance, considering the "Ventilator" device; and according to concept domain "Function" is life support, "Physical Risk" is death, "Maintenance Requirements" is extensive, "Area Criticality" is urgent, "Device Criticality" is critical, meanwhile other parameters; "Failure Rate", "Useful Life", "Missed Maintenance", and "Downtime Ratio" are depending on the actual status of each device. Device complexity is calculated relied on complexity model [16]. Accordingly, by utilizing formula (2), the priority score for every device is calculated as shown in Table III.

TABLE III
DATA SAMPLE OF INVESTIGATED EQUIPMENT FOR PM PRIORITY

Equipment	F N	P R	M R	U L	A C	D C	F R	L R	C M	M M	D R	PS	PS %
Ventilator	5	5	5	2	5	3	2	3	3	3	1	377	93
C-arm	3	3	4	2	5	3	3	3	3	2	2	316	78
Monitor	3	3	3	3	3	2	3	3	2	1	1	269	66
Centrifuge	2	3	3	3	2	2	1	3	1	1	1	228	56
Scale	1	1	1	1	3	1	1	2	1	2	1	121	30

By using the result of priority scores percentages, the preventive maintenance priority is classified into five categories as illustrated in Fig. 5. The first class is very high priority class and includes equipment that supposed to be maintained within two weeks with priority score percentage equal or greater than 80. In second class, high priority, preventive maintenance should be performed within one month if priority percentage in range 70 to 80. Class 3 is medium priority, contains all equipment that should be considered for preventive maintenance within 2 months in case of priority percentage in range 60 to 70.

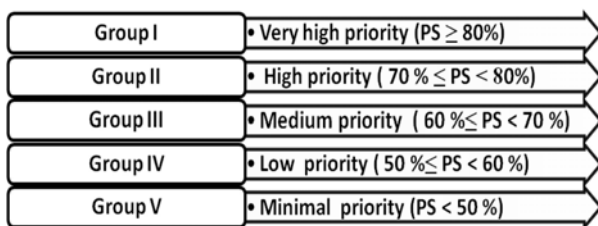


Fig. 5. The preventive maintenance priority index groups based on priority score (PS) value of the proposed QFD model

Class 4 is low priority, includes all equipment with priority percentage of 50 to 60, and in this case preventive maintenance should be performed within 3 months. Finally all equipment with priority percentage less than 50 could be visually inspected and considered for next preventive maintenance as minimal preventive maintenance.

In our data set of equipment and according to the proposed model and priority classification, the results indicate that 30

devices (15 %) needs very high priority preventive maintenance, 39 devices (19 %) should be included as high priority, 59 devices (30 %) should be considered for medium priority, 54 devices (27 %) for low priority and finally 18 devices (9 %) should be with minimal priority preventive maintenance. Fig. 6 presents data set output classification considering the QFD model.

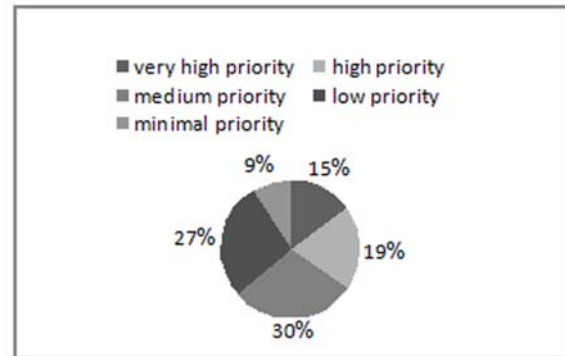


Fig. 6. The results of preventive maintenance prioritization index for investigated medical equipment.

By analyzing the results, very high priority class incorporates all equipment with high risk criteria, relatively high mission based criteria, and also with high complexity level. High priority class contains relatively high risk criteria and mission based criteria in addition to high missed maintenance. Medium priority class is considered for equipment with relatively high utilization level, area criticality, and old equipment. Low priority class contains old not risky devices. Relatively stable equipment doesn't need preventive maintenance. The results are consistent with the classification given by an experienced clinical engineer. In other words, the devices that pose risk for patients and users in case of PM omission, old devices, and complex devices such as radiology equipment are highly considered for PM, meanwhile low risk devices, reliable devices, and relatively new devices are modestly considered for PM. Moreover, as indicated in Fig. 5, the risk-based criteria contribute with approximately 45% of the weight of priority index. In fact, this contribution reflects high correlation existence between risk assessment and preventive maintenance management of medical equipment.

V. CONCLUSION

In this study, quality function deployment is presented for first time to solve the problem of preventive maintenance prioritization of medical equipment. The proposed model has proven its validity in real environment correctly separating equipment that needs preventive maintenance from those that do not need it. The model was tested based upon the periodical schedule of the hospitals. It is important to note that the classification is founded considering the requirements of patients and clinical staff. By analyzing the

results, we can state that the risk-based criteria have a great impact on preventive maintenance prioritization decision in addition to criticality and age of medical equipment. Also, the work highlights the importance of existence of a detailed history for every device that helps the decision makers to manage the medical equipment obviously. The model can be used every time a preventive maintenance is to be planned modifying only the instruments data. Moreover, the model development could be improved by addressing the customer requirements according to Kano's model to clarify the attitudes of customer satisfactions in medical equipment PM. In addition, the developed QFD model can be implemented in other stages of management of medical equipment such as acquisition and procurement of medical equipment. The model could be extended to maintenance agencies in order to organize their PM programs.

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