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# Assessing Cost of Quality in a Medical Device Division of a Training Hospital: A Case Study in Iran

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***ABSTRACT***

**Background:** Cost of Quality is an approach that helps organizations evaluate the extent to which their resources are used to prevent poor quality activities, assess the quality of provided services, or evaluate the number of resources that are wasted due to the internal and external failures occurring in a system. The research objective was to measure the Cost of Quality(CoQ) in a medical device division of a hospital in Qazvin, Iran.

**Methods:** We performed a qualitative study in the medical device division in a public hospital affiliated with Qazvin University of Medical Sciences, Iran in 2020. To measure and report the (CoQ) in the division, the Prevention-Appraisal-Failure (PAF) model was used. Data were collected through document review, semi-structured interview, and group discussion, which were entered into the Excel software to calculate their distribution and frequencies using the descriptive statistics method.

**Results:** Among different cost categories, the highest amount of expenditures belonged to internal and external failure costs. Results also revealed that several factors were responsible for the failures, including lack of knowledge of personnel about the proper use of medical devices; failure to periodically perform calibration on due dates; lack of adequate supervision; stress and work pressure among employees; and lack of managerial commitment toward the importance of preventive maintenance.

**Conclusion:** In order to decrease the number of failures occurring in a working system, it is required to increase personnel's knowledge about the proper use of medical devices, perform calibration of devices on due dates, increase managerial commitment toward preventive and quality appraisal activities and apply systematic supervision.

**Key words:** Cost of quality, Medical device division, Prevention, Appraisal, Failure.

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## Introduction

Nowadays, one of the key missions of healthcare organizations is adopting appropriate strategies to improve the quality of diagnostic, treatment, and care services to achieve the highest standards of care provided to patients (1, 2). In the health delivery system, quality has three main dimensions, namely technical, process-based, and structural aspects. Technical quality means compliance with professional clinical standards and the provision of proper diagnostic, treatment, and care services. Process quality is related to how health care services are delivered and the degree of adherence to practice guidelines and plans that direct service delivery. Finally, the structural dimension is evaluated based on the availability of input structures through which services must be delivered (3).

Despite the importance of considering quality in health care organizations, more attention is yet needed to be paid to the issue of quality costs in such settings. In a study conducted among 393 quality managers, less than 35 % of them reported that they continuously tracked the figures of quality costs. COQ is defined as an approach that helps an organization to evaluate the extent to which its resources are used to prevent poor quality activities, assess the quality of provided services, or examine the resources that are wasted due to internal and external failures. Such information allows organizations to gain considerable savings due to the improvement of work processes (4). Juran and Crosby (5) believed that with an increase in the application of quality improvement and defect prevention strategies in an organization, the cost of the amendment and doing unnecessary tasks decrease significantly

There are four main types of cost categorized as prevention, appraisal, internal, and external failure costs (6). Feigenbaum (7) developed the Prevention-Appraisal-Failure (PAF) model, which gained worldwide acceptance to determine whether costs are quality-related or imposed due to the lack of quality. In the PAF model, costs due to poor quality are divided into three areas of prevention, appraisal, and failure. Prevention costs are the expenditures spent for defining indicators for continuous system monitoring and developing forward-looking operational plans to prevent system inconsistencies and failures. Appraisal costs are spent to achieve quality requirements in all stages of production, purchase, transportation, distribution, and after-sales services such as calibration and product audit costs. The group of costs imposed on the system before the product/ service delivery is categorized as internal failure costs, while the external failure expenditures are related to the costs imposed on the system due to non-compliance with quality standards after the product/ service is delivered to the customers. In this model, the goal is to spend more money on prevention and appraisal processes compared to internal and external failures in order to reduce the cost of defective product/ service. Generally, quality costs identification is a fundamental way to control costs and maintain desired quality in healthcare institutions (5, 8-10).

It is noteworthy to mention that the increasing technological developments that health systems are facing provide access to advanced medical equipment. Approximately 45 % of the budget in hospital settings is assigned to the purchase, repair, and maintenance of medical equipment (11, 12). Proper use of medical equipment not only facilitates diagnosis and treatment but also prevents inefficiencies due to the waste of resources (13). Thus, establishing a quality management system in the supply chain of hospitals' medical equipment has been highlighted in recent years to ensure the proper maintenance of such devices and consequently the continuation of providing high-quality services to patients (12). Although quality control services cost money for healthcare organizations, such expenditures can greatly help them in future financial savings (14, 15).

Based on our knowledge, limited studies have been conducted regarding the quality cost of medical equipment division, which emphasizes the importance of investigating this issue in hospitals due to the necessity for cost management and



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ensuring the continuation of quality services. As a result, the current study aims to determine the cost of quality in a medical device division of a training hospital in Qazvin, Iran. Such information would ultimately act as a measure to assess the degree to which the hospital puts an effort in improving quality services with a preventive and promotional perspective.

## Materials and Methods

We performed a qualitative study in the medical device division of a public hospital affiliated to Qazvin University of Medical Sciences, Iran. All data were collected through document review, interview, and group discussion in a period between April and June 2020. To identify the quality costs of the department, the PAF model was used. Following is the description of steps that were accordingly followed.

*Step 1: Classify quality costs into four groups, including prevention, appraisal, internal and external failure*

In order to ensure the correct classification of quality costs in the mentioned groups, researchers reviewed scientific texts and hospital accreditation documents, specifically those related to the medical equipment department. Moreover, some systematic interviews were conducted with study participants, i.e., hospital manager; staff working in the medical device division; head of the department; clinical supervisor; hospital matron; staff working in the accounting and financial department; and a nurse responsible for implementing quality improvement programs.

*Step 2: Gather financial information on four cost groups*

In this stage, researchers collected financial data related to the amount of money spent in each of the categories identified in the previous phase of the study. To meet this purpose, a data collection checklist was designed to facilitate the data gathering process based on the identified items. Next, the percentage of costs in each of the four groups was calculated to determine the cost share of each group compared to the total costs. It should be noted that the staff was asked to declare how much time they had spent on performing quality improvement activities derived from their subjective beliefs.

*Step 3: Analysis of collected data to determine major cost burden imposed on the system and influencing factors*

In this phase, first, the cost category, which brought the highest financial burden, was identified. Second, to determine influencing factors in creating quality costs, a Root Cause Analysis (RCA) method was applied through focus group discussions, and a fishbone diagram was implemented to determine all activities in connection with quality issues and prone to failure leading to costs that were taking place in the medical equipment department. These activities were identified by RCA team members through triangulation (one discussion session, one reflection session, and one documentation review), which ultimately highlighted the procedures where expenditures were at a high level. Using the fishbone diagram enabled the research team to effectively identify influencing factors causing costs in each of the four groups and the associated root causes.

*Step 4: Provision of effective solutions to improve the system status in terms of quality costs*

Finally, through brainstorming and cause and effect analysis, active and latent failures were recognized. This clarification helped the research team to provide a list of corrective actions to improve quality and reduce the financial burden due to identified failures. In this procedure, the initial draft of corrective actions sent to expert panel members via email. The participants were asked to score each of the proposed strategies based on the two factors, including the possibility of being implemented and the importance of the strategy according to the Likert scale. After receiving the comments of all members, data were entered into the Excel software to calculate their distribution and frequencies using the descriptive statistics method. Eventually, independently reviewing the strategies by each of the experts, a group meeting was held in order to reach a



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consensus on the final strategies. Before coordinating the expert panel meetings and following the required explanation was given to the experts regarding the study objectives, written consent form was signed by each of the participants.

This research has been approved by the ethical committee of the research deputy of Qazvin University of Medical Sciences (ethical code number IR.QUMS.REC.1397.246).

## Results

First, all costly activities performed in the medical equipment department were extracted and classified based on the PAF model, as shown in Table 1. In addition to reviewing job descriptions of the department staff and investigating the documents and financial records, this information was obtained through interviews with the staff and considering the activities that are done by the mentioned departments in terms of quality improvement according to Iran hospital accreditation metrics notified by the Ministry of Health and Medical Education (MOHME).

Next, the time required to perform each of the activities and related personnel costs were extracted (Table 2). For this purpose, various methods such as document review, interview, and direct observation were used.

As revealed in Table 2, the staff working in the medical equipment department spent approximately 15 hours a month on training activities, which influenced their salary. Performing such activities costs $ 11.89. In fact, in terms of personnel costs, the highest expenditure is related to internal failure costs and the lowest to the decommissioning of medical devices.

Besides, since part of the activities related to repairs, calibration, and maintenance of medical devices were performed by external companies annually or every 6 months, it was further necessary to extract the mentioned items' cost information. Data obtained from the hospital accounting unit for repairs, calibration, and maintenance costs were 5,221,000, 195.21, and 1,572,000 dollars, respectively. Moreover, as failure or breakdown of medical devices was an important factor in imposing a significant burden of cost on the hospital, the related revenue loss due to a temporary cessation of service delivery to patients was additionally calculated for 12 months.

As displayed in Table 3, revenue loss due to endoscopy failure for 53 days was considerably high, while the least revenue loss belonged to echocardiography with 8 days of device failure. Finally, in order to compare four groups of costs based on the PAF model, all calculated expenses were aggregated into a single figure. Among different cost categories, the highest amount of expenditures belonged to internal and external failure costs with approximately 20,111,000 and 5,229,000 dollars accordingly.

To determine potential causes of failure costs and proposed corrective actions, Root Cause Analysis (RCA) was performed. Table 4 confirms that many factors were responsible for the failures, i.e., lack of personnel's knowledge about the proper use of medical devices; failure to perform calibration on due dates periodically; lack of adequate supervision; stress and work pressure among employees; and lack of managerial commitment toward the importance of preventive maintenance. Team members also suggested some corrective actions for reducing failure occurrence and increasing the ability to detect them properly and timely. Most of them emphasized the necessity to develop training programs; provide motivational mechanisms and practical strategies to decrease personnel stress and work pressure. Study results also affirmed that implementing quality improvement programs in the medical equipment department along with acknowledging employees about the importance of knowing how to work properly with medical devices were among the main actions to reduce potential failures.



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**Table 1.** Classification of the department costs

| Main costs | Cost subgroups | Related activities |
|---|---|---|
| Preventive costs | Design of quality | Quality planning<br>Design of quality<br>Process control<br>Staff training<br>Documentation<br>Evaluating educational effectiveness |
| | Calibration | Calibration of medical devices on due dates<br>Documentation of calibration records |
| | Maintenance and preventive repairs | System management<br>Requirement analysis<br>Preventive maintenance on due dates<br>Documentation of preventive maintenance records<br>Checking the devices' repairing requests<br>Doing the repairs<br>Documentation of repairing records |
| Appraisal costs | Initial evaluation of the medical devices | Inspection activities<br>Field testing<br>Usability testing |
| | Final evaluation of the product | Using the device after repair or installation to control its quality and efficiency<br>Quality audit |
| Internal failure costs | The cost of rework | Scrap<br>Rework<br>Replacement<br>Disposition<br>Troubleshooting<br>Late shipment |
| External failure costs | The cost of canceling service delivery | Loss of sales<br>Loss of hospital reputation resulting in the loss of expected revenue |
| | Customer complaints | Investigating the complaints in a timely manner and acknowledging the result<br>Perform corrective actions |
| | Warrantee costs | Recall and handling<br>Concessions<br>Litigation |
| Other costs | Decommissioning of medical equipment | Decommissioning medical devices<br>Disposal, donation, sale, refurbishing or reprocessing, trade-in, or internal reassignment based on risk and cost assessment |
| | Warehousing costs | Provide a suitable place in terms of humidity, temperature, and light to warehouse devices<br>Numbering/ coding the devices delivered to the warehouse<br>Managing incoming/ outgoing orders and the inventory |



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**Table 2.** Extracted time and costs in terms of quality activities

| Main costs | Cost subgroups | Time (hours per month) | Cost ($) |
|---|---|---|---|
| Preventive costs | Training | 15.0 | 11.8 |
| | Calibration | 8.8 | 6.9 |
| | Maintenance and preventive repairs | 154.8 | 122.7 |
| Appraisal costs | Initial evaluation of the medical devices | 1.6 | 1.2 |
| | Final evaluation of the product | 8.8 | 7.0 |
| Internal failure costs | The cost of rework | 180.6 | 143.1 |
| External failure costs | Customer complaints | 1.6 | 1.3 |
| | Warrantee costs | 5.0 | 3.9 |
| Other costs | Decommissioning of medical equipment | 1.0 | 0.7 |
| | Warehousing costs | 24.0 | 19.0 |

**Table 3.** Revenue loss due to medical devices failure

| Device name | Number of delivered services | Daily revenue ($) | Number of device failure days | Cost ($) |
|---|---|---|---|---|
| Echocardiography | 4621 | 55008 | 8 | 440000 |
| Endoscopy | 133878 | 313362 | 53 | 16608000 |
| Electrocardiogram | 26304 | 31340 | 34 | 1065000 |
| Electromyography | 398 | 8757 | 33 | 288993 |

**Table 4.** Potential causes and proposed corrective actions

| Internal failures | Probable causes | Corrective actions |
|---|---|---|
| | Failure to document their nonconforming product investigations sufficiently | Having good documentation to show how properly any nonconformity is controlled |
| | Untimely and discontinuous internal audits | Having a vigorous system to keep a continuous and timely internal audit |
| | Failure to do root cause analysis to find root causes of failures | Teach RCA method to internal audit group and necessitate them to follow the corresponding rules |
| Rework | Poorly defined corrective and preventive actions | Having a defined schedule for performing corrective and preventive actions |
| | Personal distractions including tiredness, stress, or anxiety due to work pressure | Reviewing the staff shifts and plan to reduce their work pressure |
| | Inadequate accessibility to the staff of medical equipment department to timely report them any nonconformity | Strengthening electronic automated systems to facilitate timely communication |
| Loss of sales | Untimely supplier responses to nonconforming inquiries | Having quality agreements with suppliers in which it is stipulated that within a specific period, they have to respond to nonconforming inquiries |

## Discussion

Extracting quality costs, especially in service organizations, has always been a challenging issue as such costs are not easily distinguishable from other types of costs. Based on the evidence, it is believed that quality costs overshadow a significant portion of hospital revenue. As a matter, investing in prevention and appraisal activities such as staff training and preventive maintenance of medical devices can reduce failure costs by a significant percentage. On the other hand, disregarding the need to allocate a larger share of costs to prevention and appraisal expenditures would lead to several problems, including loss of financial resources due to canceling service delivery or rework (16). With this approach, this study was conducted to identify and classify quality costs in four main groups of prevention, appraisal, internal and external failure.



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According to our knowledge, COQ has mainly been focused on the industries, and this is the first study to quantify quality costs in a hospital setting. Literature has affirmed that the PAF model necessitates organizations to invest in prevention and appraisal activities to reduce failure costs (6, 8). This model has been applied by most of the companies which use quality costing. Related findings suggest that failure costs exceed prevention and appraisal costs. Furthermore, many studies have found a statistically significant correlation between prevention costs and the level of quality in organizations, in addition to an inverse relationship between prevention costs and failure expenditures.

In a study conducted by Zarandi et al. (17), applying the PAF model recognized that 50 % of the total quality costs in the press hall were related to internal failure costs. According to the present study, the analysis revealed that prevention costs accounted for 11.33 %, appraisal costs 6.17 %, internal failure costs 65 %, and external failure costs 17.50 % of the total quality costs, emphasizing the necessity to apply appropriate strategies to reduce failure costs and allocate sufficient funds to preventive and appraisal activities. Indeed, hospitals should select and apply a uniform format of cost report which contains a comprehensive cost list of nonconformities to facilitate corrective actions. As emphasized by Crosby (5), quality costs are necessary to be measured not only to facilitate management control but also to develop quality thinking in any type of organization. Despite the importance of the issue, many companies ignore the amount of revenue they lose due to system errors or costs imposed upon them owing to poor quality. Consequently, many researchers began to focus on allocating a specific budget to preventive and appraisal costs to minimize failure costs. They also claim that organizations should continuously monitor quality costs, especially those that are not clearly identifiable such as lost sales or customer complaints. Planning to improve quality and modify organizational processes is an effective strategy to bring about a considerable reduction in an organization's failure costs (18, 19).

Quality improvement planning is especially important in health care organizations that are related to the issue of health and human life. Such provider institutions require very high levels of quality to obtain satisfying results from these programs. Applying quality cost strategy and its periodic reporting can be very helpful for managers and organizational authorities. Evidence regarding the successful use of COQ has been mentioned in several companies among both industrial and service provider types. In line with our findings, promoting the staff knowledge and skills, redesigning the work processes, and calibration were mentioned as significant examples of investment in prevention and appraisal activities, which consequently lead to a higher level of quality. As quality improves, a lower inspection level would be required, and thus a reduction in appraisal costs would appear. Ultimately the benefits of such investments would increase the company's revenue due to customer satisfaction and improvement of the organization's reputation in the community (20).

Besides, our study results found that most of the probable causes for failures were related to the inadequacy of knowledge and skills among staff working with medical devices. Several studies revealed similar results and emphasized the significant role of human errors and lack of effective communication highlighting the need to improve teamwork, facilitate communication, and provide training courses. Scheduling proper working shifts was another influencing factor that was mentioned to help mitigate the problems caused by fatigue and work pressures among personnel (21-26).

As observed in any other research work, the present study experiences certain drawbacks too. In this study, we used the snowball sampling method to find the participants which might result in missing some key informants. Another limitation was that we did not use a theoretical framework to categorize the gathered data and



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instead applied a vigorous step-by-step analysis to determine the themes.

## Conclusion

Among different cost categories, the highest amount of expenditures belonged to internal and external failure costs. To decrease the number of failures occurring in a working system, it was suggested to increase personnel's knowledge about the proper use of medical devices, perform calibration of devices on due dates, and increase managerial commitment toward preventive and quality appraisal activities, and apply systematic supervision. As a matter of fact, to manage the cost of quality in an efficient way, managers should put their most effort into shifting toward appraisal and prevention costs.

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## Conflict of interests

None declared.

## Authors' contributions

Rafiei S designed research; Jabarbeigi R conducted research; Kalhor R and Hashemi F analyzed data; and Rafiei S wrote the manuscript. All authors read and approved the final manuscript.

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