

Cost of Quality-Applicability in Clinical Laboratories, Particularly in Resource-Limited Countries: A Survey of the Literature

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Abstract Healthcare providers rely on laboratory results to make medical decisions daily. Laboratories must adhere to specified requirements to ensure that the service provided is reliable and safe. The service provided to patients and clinicians should therefore be customer-focused. Discussions on expenditure on continuous quality improvement activities have grown as more laboratories develop quality management systems. This discussion is even more relevant as laboratory managers try to balance their organization's productivity by reducing waste and unnecessary expenditure. Quality cost is the total cost of activities that prevent or mitigate errors in laboratory processes (cost of good quality), and failure cost is the cost resulting from flawed laboratory processes (cost of poor quality). There is extensive evidence on the application of CoQ in manufacturing and other non-health service industries, however there is limited information about its applicability in clinical laboratories. Furthermore, laboratories located in countries with scarce resources may face unique challenges in assessing quality costs, including the ease of data collection for cost inputs. This article examines the information presented in the literature on quality-related costs in clinical laboratories. Secondly, it provides a summary of various cost models. Finally, it explores the application of quality cost in clinical laboratories, particularly in resource-limited countries, and outlines the benefits and challenges.

Keywords Clinical Laboratory, Cost of Quality, Quality Management Systems, Resource-Limited Countries.

Introduction

The emphasis on quality management systems (QMS) has grown immensely popular in low- and middle-income countries. The implementation of such systems often requires laboratory managers to assess the balance between operating costs associated with implementing good clinical practices and the need to earn a profit. The principle of quality management centers on providing reliable, standardized service that meets users' needs. Managers must therefore consider delivering a high standard of service at the lowest possible cost. To quantify expenses for quality activities and those related to waste and retesting, laboratory staff need to understand the core principles of quality costs. These principles appear seemingly complex to laboratorians, as much of the literature focuses on the application of cost of quality (CoQ) to manufacturing and non-health service industries [1-5].

The CoQ is described as the sum of the cost incurred from preventing or mitigating laboratory errors (sum of conformances) and the cost associated with service failures or errors (sum of non-conformances) [6, 7]. A practical framework is important to guide managers on measuring quality-related expenses. Philip Crosby emphasized that organizations should measure quality cost to determine when they have achieved zero defects. He thought that the absence of defects or errors would eliminate the need for rework or repairs and consequently result in lower production cost [8]. The prevention-appraisal-failure model is commonly used in many industries, including clinical laboratories.

A CoQ approach considers designing continuous improvement activities, which lowers the overall cost and fulfils customer requirements. Expenses on quality assurance activities are viewed as wise investment, which later yields a return in reduced failures. Managers, therefore, have to create a balance in expenses on such activities and their benefits to

the organization. As knowledge of quality management increases among laboratorians, managers continue to seek appropriate quality tools to improve laboratory processes and reduce errors. Although the literature offers extensive evidence on the application of CoQ in manufacturing and other service industries, there is little information on the use of these models in clinical laboratories. Furthermore, laboratories in resource-limited countries may face unique challenges in measuring or reporting quality costs due to several factors, such as ease of data collection for cost inputs. This article examines the information presented in the literature on quality-related costs clinical laboratories. Secondly, it provides a summary of various cost models. Finally, it explores the application of quality cost in clinical laboratories, particularly in resource-limited countries, and outlines the benefits and challenges of its application.

Demystifying Quality Costs

Quality costs are expenses incurred by a product or service in meeting a set of standards. These standards are outlined in terms of agreements with a company and its customers [10]. Quality cost has been classified into four distinct categories: prevention, appraisal, internal failure, and external failure costs (Table 1). Prevention and appraisal costs are associated with 'good quality'. These expenses are related to activities that reduce laboratory errors. Prevention costs are allocated to exercises that avoid errors. Appraisal costs are associated with evaluating, assessing, or auditing products to ensure that they conform to specific requirements [6, 7, 11, 12].

Internal and External costs, 'bad quality, are related to failures which occurs in a system. Internal failures are costs incurred to resolve errors which are detected by the laboratory before it gets to the physician. On the other hand, external failure costs consider expenses to correct errors which are identified outside the laboratory's control [6, 7, 11, 12]. Zahar and his

colleagues argued that some failure costs are hidden, this is likened to the ‘submerged section of an iceberg’ [11]. Managers therefore need to appreciate the interconnections among systems

within their processes to recognize hidden costs and account for their contributions to cost models.

Table 1. Summary of Quality Cost Types & Cost Elements

Type of Cost	Examples of Cost Elements
Prevention	Development of Quality management system
	Continuous quality improvement activities
	Preventive maintenance & establishing service contracts
	Quality education
	Verification of laboratory processes before implementation
	Initial staff competency assessments
Appraisal	Monitoring quality indicators
	Ongoing staff competency assessments
	Instrument calibration
	Internal audit programs and external accreditation
	Sample & reagent inspections
Internal Failure	Errors occurring in the pre-examination phase such as mislabeled, insufficient or flawed samples, data entry errors, sample and reagent transport failures.
	Errors occurring in the examination phase such as calibration and quality control failures, invalid instrument runs, expired reagents, instrument downtime, retesting.
External Failure	Patient misdiagnosis
	Customer complaints
	Revised and recall reports
	Damage reputation and loss revenue
	Litigation

Cost of Quality Models

There is an extensive body of literature on cost of quality models, including various reviews that provide a comprehensive analysis on the subject. Cost models are frequently divided into four groups: the prevention-appraisal-failure (PAF) model, or Crosby model; opportunity cost models; process cost models; and activity-based (ABC) models [4, 13]. In addition to these frameworks, the Six Sigma approach was also another option for managing quality costs [14].

The most recent review of the subject matter by Foulad and colleagues [9] provided a

comprehensive overview of cost models, including newer models which address gaps in earlier work. These frameworks include tangible and intangible costs, opportunity costs, hidden costs, poor-quality costs and the Kélada model. The literature review in this section provides a description of both early and newer models.

The PAF model, which was developed by Feigebaum [15] is perhaps the most widely used across various organizations. In this structure quality related costs are divided into (i) expenditure on activities which promotes adherence to product standard (control) and

(ii) cost associated with defects (failure). Expenses related to controlling product standards are further subdivided into two groups: expenses to prevent nonconformances (prevention cost) and expenses for activities that maintain product standards. Failure outlays are also divided into two categories. These are (i) outlays related to failures which occur within the organization (such as spoilage or scrap) and (ii) outlays related to failures which take place when the product leaves the organization (such as customer complaints and product issues). It is the view that as prevention-related expenses increase within an organization, the costs allocated to failures and appraisal will ultimately decrease [15].

Crosby's description of cost categories closely mirrors Feigenbaum's, which is why authors refer to it as the PAF model [4]. Quality-related outlays can be quantified as total conformance and nonconformance expenses. Conformance outlays consist of activities that ensure things are done correctly the first time. These expenses include activities that hinder the production of defects (e.g preventive maintenance) and activities which prioritize the assessment of the quality of a product (e.g inspections). Expenses related to non-conformance are referred to as failure cost and include rework, redesign, or corrective actions after failure to conform to product requirements.

Industry leaders also frequently use the process cost model. The model considers continuous improvement in key processes, reflecting Kaizen & Deming's plan-do-study-act (PDSA) cycle [13]. Cost items are viewed as steps within a process than costs incurred in producing a product or service. The total quality cost is measured by allocating expenditure to activities which promotes (conformance) or deviates (nonconformance) from set standards at each stage of the process.

The Six Sigma methodology is similar to the use of continuous improvement activities in the process cost model. Six sigma is a data-driven

approach that seeks to eliminate defects or failures in business processes. The method uses a five-step project management technique: define, measure, analyze, improve and control (DMAIC). These steps are repeated in cycles and allow for continuous improvements in work processes. The method is largely supported by the lean approach, which emphasizes eliminating waste and inefficiencies [14].

Scholars proposed the Activity-Based Cost (ABC) method to address gaps identified in the earlier models. The method assigns costs to each activity, which allows accounting teams to collate cost elements, including overhead costs. This information is thought to help managers make strategic decisions [9, 13].

After developing the PAF model, scholars proposed CoQ frameworks to address its limitations. This has resulted in several variations of intangible and opportunity cost models. The intangible models emphasize the importance of hidden cost in assessing the true cost of quality. Juran argued that there were two groups of cost categories; costs that can be quantified (tangible factory costs and intangible sales costs) and those that are difficult to quantify directly (intangible cost) [16, 17]. Taguchi's hidden cost model also emphasizes the difficulties in quantifying intangible costs [14]. The cost framework is similar to the ideas presented. It was the view that the quality of a product is a 'loss' which is transferred to the clients [14]. Kelada's model builds on the ideas of Taguchi. In his framework cost categories are divided into five groups- direct, indirect, tangible, calculatable and intangible costs. While the four prior categories can be measured directly, intangible cost has to be estimated [9]. Sandoval-Chávez and Beruvides developed the opportunity cost model [18]. The framework accounts for potential losses in maximizing profits, such as underutilization of capacity, inadequate material handling, and poor delivery service [18].

Harrington had a different approach to defining the cost of quality. He proposed that

quality cost should be seen in terms of poor quality. This approach may have been intended to change managers' perception that producing quality products means higher costs. There are two main categories in this model, (i) Direct cost which includes categories prevention, appraisal, internal and external costs. These costs can be controlled by organizations (ii) Indirect cost- these costs are not measurable and include customer dissatisfaction, loss of reputation and lost opportunities [9].

Despite the extensive body of knowledge on CoQ frameworks, its application is limited across industries. Managers may have increased awareness that improving the quality of a service or product increases market competitiveness, however, there seems to be a lack of commitment to putting these tools in practice [4].

Application of Cost of Quality in Clinical Laboratories

Four articles were identified from the literature that demonstrated the use of CoQ models in clinical laboratories. Two articles used the principles of the PAF model. The third article was based on the process cost model, and the final article applied the six sigma and the lean concepts. The elements within the cost categories were largely consistent across laboratories, with deviations reflecting unique situations in each laboratory.

Menichino [19] was the first to explore the application of CoQ in a laboratory setting. The study applied the process cost model and classified cost categories as conformance or non-conformance within each process. Conformance costs included quality-related salaries, QC and calibration, normal specimen collection, testing, and results reporting. Cost of non-conformity included retesting, corrective action costs, instrument downtime, and associated repairs. The model enabled the laboratory to quickly identify areas of poor quality and excessive spending and subsequently target improvement activities

(Table 2).

Elbireer and his colleagues [9] analyzed cost data using the classical PAF model in a clinical laboratory located in a resource-limited country. In their study, prevention costs represent the cost of good quality, including personnel salaries related to quality assurance (QA), preventive maintenance programs, quality-related supplies, continuing education activities, and the laboratory information system (LIS). Appraisal costs elements included the External Quality Assessment (EQA) program for proficiency testing, quality control program, and process validation (i.e., method comparison). Cost of poor quality: internal failures were poor inventory practices, data entry errors, rework costs, quality control (QC) failures, calibration failures, retesting, and deviations from standard operating procedures. External failures included pre-analytical, analytical, and post-analytical errors. Similarly, Zahar and his companions [11] used the PAF model to determine CoQ. The authors also included the revised Juran's model to expand cost classifications. Similar cost elements were noted, with variations in internal and external failure costs, such as loss of results and aspiration failures (Table 2).

In the study [20], six sigma and lean approaches were used to quantify failure costs in a clinical laboratory. The authors evaluated quality costs using a series of calculations that accounted for defect costs throughout the test process. The authors divided cost categories into prevention, appraisal, internal failure, and external failure. Supplies and labor costs constituted prevention and appraisal costs, while internal and failure costs included the cost to correct the number of non-conformances recorded within one month (Table 2).

Similarities were observed in the base calculations for three articles, which were used to assign quality-related manpower hours, reagent wastage, and the retesting of controls or calibrators across the two articles where data were available. [7, 19]. Personnel salaries for

quality-related activities were calculated as the time per activity multiplied by the average personnel cost per hour. The cost of calibrators, QC testing, and rework was calculated based on usage and the price per test. In contrast, Carlson and his colleagues [20] use the cost per defect as the base calculation to quantify quality cost.

The laboratories reported variations in cost-of-quality data, even when the base calculations were similar. Data from a laboratory in Uganda showed that 94% of quality costs were attributed to good quality (24% spent on prevention activities and 70% on appraisal activities). Poor quality accounted for the remaining 6% of the cost (4% on internal quality costs and 2% on external quality costs) [7]. In contrast, quality costs in a hospital laboratory in the United States represented 35% of operating expenses (10% for good quality and 25% for poor quality [19]). Meanwhile, in a clinical laboratory in Morocco, good-quality costs accounted for 83% of the total quality cost (prevention and appraisal costs were shared equally). The cost of poor quality was reported as 17% (11% for internal failure and 6% external failure) [11]. In a study using sigma and lean approaches, good-quality costs accounted for 93% of quality costs (3% on prevention costs and 90% on appraisal costs). Bad quality costs accounted for 7% of the total quality cost (with all 7% spent on internal failure cost) [20]. These deviations were not uncommon and were also observed among organizations in the electronics or manufacturing industries [4].

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Table 2. Summary of Articles Demonstrating Application of CoQ Models

Country	Model	Cost Elements	Results	Publication
United States	Process Cost Model	Cost of Conformance salaries, QA activities, QC materials, activities related to normal specimen collection, testing and reporting	Cost of quality-35% of operating expense Cost of conformance-10% of operating expenses	Menichino T. 1992

		Cost of Nonconformance retesting, cost of corrections when things go wrong i.e. instrument down-time and repair cost (including manpower), delayed response, increase hospital length of stay	Cost of nonconformance- 25% of operating cost Impact- reduction of the cost of non-conformance decreased by 83% over 9 months due to continuous improvement	
Uganda	PAF	Prevention Cost personnel salaries QA related activities), preventive maintenance program, office supply quality-related cost, competence training and CE program, LIS	Good Quality Prevention cost-24% of total quality cost Appraisal cost- 70% of total quality cost	Elbireer A., et. al. 2010
		Appraisal Cost QC and calibration, annual accreditation and inspection, EQA PT, other process improvement activities, process validation (i.e external method comparison testing)		
		Internal Failure Cost poor inventory management (wasted reagents), QC and calibration failures/retesting, data entry errors and rework, processing and accessioning errors and rework, SOP violations/corrections/rework cost.	Poor Quality Internal failure cost- 4% of total quality cost External cost- 2% of total quality cost	
		External Failure Cost Total testing process Pre-analytical - delay specimen processing, data entry errors, specimen processing error, rejected sample not reported, other Analytical- wrong test performed, result error, test not performed, other Post-analytical - extended turnaround time, transcription error, storage status error, data download error, lab requisition form missing, other		

Morocco	PAF+ Revised Juran Model	Prevention Cost personnel salaries (QA related activities), preventive maintenance program, office supply quality-related costs, competence training, and CE program, LIS	Good Quality Prevention cost-41% of total quality cost Appraisal cost- 90 % of total quality cost	Zahar M., et. al. 2015
		Appraisal Cost QC & Calibration, annual accreditation and inspection, EQA PT, other process improvements and quality activities, process validation (i.e external method comparison testing)		
		Internal Failure Cost poor inventory management (wasted reagents), QC and calibration failures/retesting, data entry errors and rework, processing and accessioning errors and rework, SOP violations/corrections/rework cost.	Bad Quality Internal failure cost- 11% of total quality cost External cost- 6% of total quality cost	
		External Failure Cost Total testing process Pre-analytical - inappropriate sample, wrong anticoagulant, improper conservation method, inappropriate patient preparation, error in patient identification Analytical- expired reagents, control & calibrators, failure in aspiration system Post-analytical- mismatch sample and lab files, wrong result from analyzer sent to lab report, extended turnaround time, loss of result		
Not specified	Six Sigma Lean	Prevention cost supplies & labour	Good quality Prevention cost-3% of total quality cost Appraisal cost- 90 % of total quality cost	Carlson O.R., et. al. 2012
		Appraisal cost: supplies and labour		
		Internal Failure Cost - Cost to correct 45 internal errors	Poor Quality Internal failure cost- 7% of total	

		External Failure Cost - Cost to correct o external failures	quality cost External cost- 0% of total quality cost	
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Discussion

The literature search confirmed that laboratorians do not widely use the cost of quality as a quality tool. Laboratory Managers cannot effectively plan or improve processes without measuring the cost of poor quality. The studies presented data that emphasized the value of CoQ as a quality management tool. Menichino [19] identified several areas of waste within laboratory processes that increased poor-quality costs. One such issue was the receipt of unnecessary phone inquiries, which accounted for 6.6% of productive hours and 30% of the cost of all non-conformances. The installation of an automated phone distribution system reduced disruptions by two-thirds in the year. Similarly, the implementation of corrective actions led to a reduction in the number of canceled tobramycin tests. The corrective action reduced poor-quality costs by 83% within 8 months, resulting in savings of \$7,470 per year. These examples demonstrate that quality improvement efforts can lead to cost-reduction opportunities. The ultimate goal is to reduce failure cost to zero by continuously evaluating prevention efforts to achieve further improvements [10].

Similarly, Carlson and his colleagues [20] demonstrated the usefulness of the sigma and lean approaches for identifying and preventing defects and failures in patient and clinician services. During this process, the laboratory eliminated testing waste, thereby reducing the cost of a good unit (service).

The studies among the laboratories demonstrated variations in quality costs. Comparisons among organizations may not yield valuable insights, as cost categories or denominators used in the base calculation, and the period of data collection for quality costs, may vary. The cost of poor quality in a clinical

laboratory in the United States was reported as 25% of operating expenditure [7], whereas in a clinical laboratory in Uganda, it was 6% of total quality expenditure [19]. Furthermore, costs within each category may differ based on the size and complexity of the organization, or on whether the organization is located in a resource-limited country. For example, the prevention cost for a clinical laboratory in Morocco was 41% of the cost of good quality. Equipment maintenance accounted for the largest share of prevention costs [11]. In contrast, prevention costs for a laboratory in Uganda were 24% of the cost of good quality. The largest share of this cost was salaries [19]. This variation was also observed in the two laboratories' cost allocations for appraisal. Appraisal cost in the former laboratory accounted for 42% of the total cost of good quality, with QC and calibration accounting for 50% of this expenditure. In contrast, in the laboratory in Uganda, appraisal costs represented 70% of the cost of good quality, with QC and calibrators comprising 89% of the category's total cost [11, 19].

The cost of good quality represented the largest allocation of the total quality cost [7, 11, 20]. Quality pioneers generally view investment in prevention costs as reducing failure costs. A reduction in failure costs will eventually justify fewer inspections, consequently reducing appraisal costs. Elbireer [7] argued that, from the perspective of patient care, it would be more prudent to invest in prevention and appraisal costs to reduce the likelihood of poor patient outcomes. An opposing perspective is that appraisal tools detect only a portion of existing failures, and resources must be allocated to their correction. As a result, appraisal activities will eventually increase quality costs. Appraisal activities must

therefore focus on the highest-risk areas [20].

Cost of quality models possesses several challenges [7, 9]. It may be difficult to collect or measure direct labor costs, particularly when staff are involved in diverse activities. Oftentimes, this cost category is not analyzed or underestimated due to a lack of data on how the time is allocated among diverse activities [21]. The accuracy of data collection is dependent on the quality of the preliminary data field. The classical PAF model relies on accounting systems to collect cost data, which may not always capture relevant or accurate data within cost categories. Furthermore, it is the practice that quality data includes the department name from which they originate. This poses the potential for under-reporting of quality failures and, in turn, the cost of poor quality. Additionally, the hidden costs of poor quality are often difficult to measure, such as loss of customer confidence and damage to reputation. It is, however, the view of Crosby that while attempts should be made to measure quality cost, they should not be treated as a performance measurement but as an indication of where corrective action will be profitable [8].

Foulad and colleagues [9] argued that CoQ models are designed primarily to reduce costs and maximize profits. He thought that existing models did not consider all stakeholders' interests, particularly environmental concerns and customers' losses. He proposed a 'paradigm shift' to integrate the needs of stakeholders into quality interests. There may be relevance to his ideas in the current challenges posed by climate change and environmental concerns about the disposal of laboratory waste.

Conclusion

Little literature exists on applying CoQ models in the clinical laboratory, particularly in

resource-limited settings. Existing publications demonstrated the value of these tools in identifying failures, preventing severe patient outcomes, and reducing costs. Tools such as the process model, six sigma, and the lean approach support continuous improvement in processes and the elimination of waste, which affect post-quality costs. Further research is, however, required to apply these models in resource-limited countries, where diverse challenges may arise. Additionally, consideration must be given to developing new models that capture the needs of all stakeholders.

Conflict of Interest

The author has no potential conflicts in the publication of this article.

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Ethical Approval

No ethical approval was required for this study. No data were collected from patients or the general public for this publication.

Data Availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' Contributions

DSW conceptualized the project ideas, drafted, and revised the manuscript.

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