Arab American University-Jenin

Faculty of Graduate Studies

The Cost of Quality and its effects on operational performance: A case study of Medical Laboratories in the West Bank

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This thesis was submitted in partial fulfillment of the requirements for the master's degree in

Quality Management

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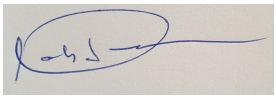
2. Dr. Nasir Abdul Karim, Internal Examiner	
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The Cost of Quality and its effects on operational performance: A case study of Medical Laboratories in the West Bank

Declaration

I hereby declare that this present master's thesis has been written by myself and is my work. All formulas and concepts utilized in this work were quoted according to the good science practice law; either it was taken literally from printed, non-printed contents or the internet. Also, this work has not been submitted, in whole or in part, for any otherdegree or professional qualification.

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Abstract

Many firms place a high value on quality as a marketing component to remain competitive; consequently, companies invest substantially in quality and continuous improvement projects to stay competitive. Organizations use management systems to ensure that their products and services meet their consumers' expectations, leading to various quality costs. Medical laboratories must find a way to strike a balance between price and quality without sacrificing the quality of their services. This research investigates the COQ practices and their effect on operational performance in Palestinian Medical Laboratories. A descriptive-analytical research design approach was used to investigate the COQ at 235 medical laboratories in the West Bank and Jerusalem. A validated questionnaire was used to collect data from labs licensed in the West Bank, and the data were analyzed using SPSS software to determine the COQ. Data analysis techniques such as exploratory and confirmatory factor analysis, descriptive statistics, correlation analysis, and multiple regression are used to analyze and organize the data. According to the study's findings, the level of implementation of quality cost systems in Palestinian medical labs was 52.8 percent on average for all four dimensions of quality costs, while the level of performance of medical laboratories was 60.2 percent (moderate level). The results show a strong positive relationship between COQ

practices and laboratory operation performance. Also, laboratories do not measure all costs of the quality items and use a model to calculate them. The lack of experience in calculating COQ is the first and most significant cause for laboratories not measuring COQ. Following that, there is a lack of knowledge in calculating it. This study is considered one of the first studies to analyze the impact of COQ practices on the operational performance of Palestinian medical laboratories. It will thus assist in enhancing the awareness of medical laboratory departments regarding the relevance of assessing quality costs. The level of awareness can be improved by developing training courses that will enhance the ability to calculate the dimensions of quality costs. The findings of this study assist decision-makers and managers in understanding the level of application of the COQ in laboratories and hence in developing quality-related plans and strategies.

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List of Abbreviations

ABC	Activity-Based Costing
AP	Appraisal Cost
AVE	Average Variance Extracted
CFA	Challenges Face Application of Cost of Quality (CFA)
COPQ	Cost of Poor Quality
COQ	Cost of Quality
CR	Composite Reliability
CV	Convergent Validity
Dem	Demographic
EFC	External Failure Cost
ERP	Enterprise Resource Planning
IFC	Internal Failure Cost
KMO	Kaiser-Meyer-Olkin
LP	Laboratory Performance
LIS	Laboratory Information System

MTA	Medical Technology Association
NCE	Non conformities
PAF model	Prevention Appraisal Failure Model
PC	Prevention Cost
PFIU	Palestinian Food Industries Union
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control
QM	Quality Management
TAT	Turned Around Time
VIF	Variance Inflation Factor

Chapter One: Introduction

1.1 Overview

Quality is a much more complicated term than it seems at first glance. In the case of quality, every quality expert appears to define it differently. There are multiple views to consider while defining quality, such as the consumer's perspective, the specification-based perspective, etc. A quality definition may be found in various places, and it can be associated with either objective facts or subjective feelings. For successful enterprises, quality must be improved in all aspects of operations, including products, services, systems, and procedures, to guarantee that the firm is fit and effective (Shiramizu & Singh, 2007). In one definition of quality, the product's characteristics are considered; in this situation, quality substantially impacts product price; another definition is a defect-free product or service. A third definition is the reduction of process waste. Conformance to requirements and the measurement of quality is the price of nonconformance, which, according to Philip Crosby (1979), is the definition of quality. Crosby also claims that quality is free (more sales that exceed the cost of quality would be produced by an improved quality that exceeds customer expectations; customers will search for the highest quality product). Deming's chain reaction stated that Quality improvement lowers costs because of less rework, fewer errors, fewer delays, better use of material and instruments, and promotes profitability by improving productivity (Deming, 1986).

Many companies take into account customer requirements when developing their products or services. Quality can be achieved by strict and precise adherence to such criteria to ensure product uniformity to meet unique consumer requirements. Quality involves providing the customer with a value that meets or exceeds customer

expectations. The central idea behind all quality concepts is customers' demand (Yang, 2017; Deming, 1986; Juran, 1975).

The discussion below elaborates on the cost of quality (COQ). More specifically, COQ is the cost of avoiding poor quality or the cost of poor quality, or the costs spent to decide the quality a product achieves (Ghunaim & Jaaron, 2021). Monitoring it and evaluating the degree of compliance between product specifications and customer expectations COQ can also be identified as costs incurred by the company to put goods and services in the consumer's hands under their requirements and desires (Djekic et al., 2014). Added to this is the cost of failures resulting from the product's lack of conformity to quality specifications, whether at the facility's internal or external level. Quality costs have historically been described as all expenses associated with ensuring that products comply with requirements or products that do not comply with specifications are produced (Ittner, 1996). Generally, the advantage of measuring and calculating the COQ is that COQ provides a valuable indicator to encourage and motivate management to apply it and implement it on the ground (COQ translates quality issues into the upper management "language," the language of money). Several other terms also know the word COQ, each defined by different authors; for example, quality cost, price of nonconformance, price of conformance, and cost of poor quality are all terms that have been used (Schiffauerova & Thomson,2006; Mahmood & Kureshi, 2015).

1.2 Research Problem

Medical laboratories work hard to deliver high-quality services to improve customer satisfaction in today's competitive market. If high-quality processes are given little attention, failures will increase. A cost-of-quality mindset approach streamlines laboratory procedures, removes duplication, reduces unnecessary costs, and saves

inefficient quality procedures, ultimately reducing failure costs. It is important to note that inadequate or faulty laboratory procedures typically cause quality problems. Therefore, measuring the cost of quality should be considered a critical task for managers working in medical laboratories. However, after interviewing several managers working in laboratories, most of them do not understand how to measure the cost of quality within medical laboratories. Few studies have been carried out to investigate the perception level of the COQ within medical laboratories (Dimitrantzou et al., 2020; Schmidt & Pearson, 2019).

Moreover, there is no clear image of the COQ models; which model should be used, which activity should be measured, and how can be calculated in the Palestinian medical laboratories, so this study intends to investigate and understand how the cost of quality is defined, how it is accounted, analyzed and measured at a medical laboratory.

It is crucial to know the level of implementation and establish a clear COQ framework that all laboratories efficiently use. The results of this research will be the baseline to understand and calculate the COQ within laboratories.

1.3 Research Significance

This study investigates the reality of the cost of quality in medical laboratories. And will provides a basic understanding of quality costs in medical laboratories to reduce unnecessary activity costs. Currently, all Palestinian laboratories are operated without applying any cost of quality models, so their continuous improvement programs are not at the lowest possible cost. Therefore, this study aims to understand how the cost of quality is defined, how it is accounted for in laboratories, and investigate the impact of COQ practices on laboratory performance, so this study will help improve the performance of medical laboratories. Therefore, patients and physicians will be satisfied.

And this directly affects the health of patients, reduces customer dissatisfaction, and retains their customers so that management can make accurate decisions to reduce quality costs and improve profitability. This study will provide valuable information on calculating the cost of quality in Palestinian medical laboratories so that quality managers and policymakers can adopt a customized model in their labs.

1.4 Research Questions

1. What is the reality of the cost of quality and the element used in estimating the COQ-related activities in Palestinian medical laboratories?
2. What is the impact of COQ practices on laboratory operational performance?
3. What is the effect of the presence of a quality department, ISO certification, and lab workload on COQ application and lab operational performance?

1.5 Research Hypotheses

H1: There is a significant positive relationship between measuring prevention costs practices and medical laboratory performance.

H2: There is a significant positive relationship between measuring appraisal costs practices and medical laboratory performance.

H3: There is a positive relationship between measuring internal failure costs and medical laboratory performance.

H4: There is a positive relationship between measuring external failure costs and medical laboratory performance.

H5: Laboratory has ISO certification that affects the relationship between COQ application and lab performance.

H6: Laboratory size affects the relationship between COQ application and lab performance.

H7: The presence of a quality department affects COQ application and lab performance.

1.6 Research Objectives

Usually, when laboratory managers think about the cost of quality in medical laboratories, they think about accreditation fees, quality control, proficiency testing, and auditing costs. So. This study aims to achieve the following objectives:

1. To clarify the COQ by recognizing its reality inside the Palestinian medical laboratories in terms of the top management.
2. To investigate the elements used in measuring the cost of quality in medical laboratories.
3. To investigate the effect of COQ practices on laboratory operational performance.
4. To investigate the effect of the presence of a quality department, ISO certification, and lab workload on COQ application and lab operational performance.

1.7 Thesis Structure

The thesis is organized into six chapters. The first chapter is an introduction that provides an overview of COQ and its definition, including the research problem and the research significance and objectives. This chapter also addresses research issues that will assist in narrowing the gaps found in current COQ applications in medical laboratories. The second chapter presents the literature review, which defines and classifications of medical laboratories. This chapter also includes information on COQ categories and COQ structure. The concept of hidden quality cost is also included in this chapter and research

on COQ in medical laboratories. Also, the chapter consists of the COQ conceptual framework. The third chapter consists of the methodology. The methods used to address the research questions and assess the extent of COQ implementation is discussed in the fourth chapter. Also, a brief introduction to the uses of a questionnaire is included in this section. This chapter also explores whether a particular form of the questionnaire can be used and what benefits can be obtained. Finally, a thorough summary of what is being analyzed completes this part. The fourth chapter includes data analysis and results. The fifth chapter discusses the results of the methods used in this study. The conclusion and recommendation of this study and answers to study questions are provided in the sixth chapter. Finally, the study ends with a constraint and suggestions for future research.

1.8 Ethical Consideration

A proposal was submitted to the Faculty of Graduate Studies at Arab American University for discussion and approval to initiate this study. The Ministry of Health permitted the research to be conducted in governmental labs. Each participant was told of the study's purpose and aims. Respondents were notified in advance of the questionnaire's length, and the confidentiality of the information acquired. The researcher maintains the confidentiality of the data obtained. Additionally, no possible conflict of interest exists between this study and any other party.

Chapter Two: Literature Review

2.1 Overview

A medical laboratory is a facility where clinical tests are carried out to gather information about a patient's health to diagnose, treat, and prevent disease. Over the years, the importance of clinical laboratories as a component of the healthcare system has become widely recognized. More physicians have recognized the importance of laboratory testing to validate their diagnoses and assist their patients in monitoring their response to treatment. Other than serving a well-established role in the care of individual patients, the role of clinical laboratories has frequently been utilized in the tracking and control of diseases that are important to the general public's health (Bayot, Brannan & Naidoo, 2021).

Generally, clinical laboratories in Palestine can be classified as follows (Bayot et al., 2021):

• According to ownership - it can be government-owned (public) or can be a private laboratory or non-profit.

• According to function - maybe general clinical laboratories or perhaps specialized laboratories.

2.2 Theory of COQ

The identification and quantification of quality costs can be achieved by effectively implementing a known cost of the quality model. There have been several techniques of measuring COQ proposed by various researchers, and in this part, the model for calculating COQ is briefly examined.

This section discusses various COQ models in detail, including a review of available research. According to the research findings conducted by Sandoval-Chávez and Beruvides (1997), six primary theories were found: Juran's model, Lesser's classification, PAF model, the economics of quality, business management, and the COQ, and Juran's revised model. Several models for quality cost analysis have been developed over the years. Feigenbaum (1956) developed the COQ (PAF) model and classified quality costs into prevention, appraisal, and failure. In addition, Porter and Rayner (1992) also stated that the process cost is comprised of the total cost of conformance (COC) and the cost of nonconformance (CONC), respectively.

Previous Cost of Quality Models

The concept of quality costing was first introduced in the 1930s (Crocket, 1935; Miner, 1933), but it was not until the 1950s that it was systematically addressed because quality costs were viewed as being limited to scrapping, reworking, and the costs associated with running the quality department, among other things. To our knowledge, Feigenbaum (1956) was the first person to attempt to classify the cost of quality. The COQ models can be grouped into seven generic models, as shown in Table 1.

Table 1. The COQ models (Schiffauerova & Thomson, 2006).

Model	Activity	Publications
P-A-F models	Prevention/appraisal/failure	Chang et al. (1996); Feigenbaum (1956); Merino (1990); Purgslove and Dale (1995); Tatikonda and Tatikonda (1996)

Crosby's model	conformance + non-conformance	Denton and Kowalski (1988)
Opportunity or intangible cost models	Prevention/ appraisal/ failure/opportunity	Modarres and Ansari (1987); Sandoval-Chavez and Beruvides (1998)
Opportunity or intangible cost models	Conformance/non-conformance/opportunity	Malchi and McGurk (2001)
Opportunity or intangible cost models	Tangibles/intangibles	Juran et al. (1975)
Process cost models	Conformance/non-conformance	Crossfield and Dale (1990)
ABC models	value-added/non-value-added	Tsai (1998)

The PAF model and Juran's model are the COQ models that serve as the underpinning theory for this research. Also, the Deming chain reaction serves as the underpinning theory for the effect of COQ on organization performance.

PAF Model

The PAF model, the first of the quality cost models to be developed, was created by Feigenbaum (1956). It is one of the most well-known quality models among quality

practitioners, and it has been used in both the manufacturing and service industries with success. The British Standard Institution has adopted this standard (BSI) and the American Society for Quality Control (ASQC) (Hwang, 1996).

Costs of quality were divided into three major categories: prevention, appraisal, and failure (Feigenbaum, 1956; Chang et al., 1969). This classification is still widely used, and these categories are:

- **Prevention costs (PC):** include the cost of any intervention to evaluate, avoid, and reduce the risk of a defect. Quality training, assurance, and planning are typical examples of preventive costs.
- **Appraisal costs (AC):** include the cost of determining fulfillment of standard specifications, inspection cost, quality audits cost, and cost of verification is a typical example of appraisal costs.
- **Internal failure costs (IFC):** include the costs incurred within an organization because of nonconformities or defects. Reagent scrap, rework and retest a typical example of internal failure costs.
- **External failure costs (EFC):** include the costs arising from nonconformities or defects after distribution to a customer/user. Warranties and loss of sales are typical examples of external failure costs.

The advantage of employing the PAF model is as follows: (Castillo-Villar, 2012).

- The fact that it has universal acceptance.
- Different types of expenditures can be identified
- To help determine whether the costs are related to quality.

- Identify quality-related costs and represent each category in terms of percentages of the total cost.
- Both manufacturing and service companies can apply it.

The total cost of quality (as shown in Figure 1) is the sum of the cost of good quality (cost to achieve quality) and the cost of poor quality (cost to overcome poor quality).

Figure 1. The total quality cost equation

The costs associated with the four categories listed above are represented by a well-known model known as the (prevention, appraisal, and failure) PAF model. It is subject to the rule (1:10:100) in the link between costs of quality type (Omachonu & Ross, 2004). This rule states that if one dollar is invested in prevention, the appraisal and failure costs will be lowered by 10:100, respectively. Assume that the lab manager develops a method and implements it to avoid quality control faults from occurring early on, so it will save a significant amount of money. Let us now imagine that a QC error happens and is recognized before a patient test is done, in which case the lab will lose the QC test and nothing else. The lab may be lost both the QC test and the patient test if the QC issue is not recognized before the patient test is done. Let us imagine that the QC issue was not noticed and that the patient result is delivered to the customer with the incorrect result, resulting in a loss of hundreds of dollars.

One technique of lowering expenses without compromising quality and reliability is eliminating or reducing the number of unneeded procedures or variations in operations.

Achieving these objectives is feasible by applying various continuous development methodologies, such as Lean and Six Sigma. Six Sigma and lean are critical continuous improvement approaches that strive to eliminate variance and waste in a process. Six sigma has a failure rate of 3.4 out of every million attempts. The DMAIC tools of the six-sigma technique were utilized to eliminate variance in the process (Murumkar et al., 2018).

Laboratory work processes should be designed to meet the requirements of regulatory, accreditation, and consumer standards. Planning, controlling, assessing, tracking, and improving laboratory operations are all made feasible with the proper allocation of preventive and appraisal costs. Investment in prevention will increase prevention costs and decrease appraisal and failure activity costs. As shown below in Figure 2, the total cost will be reduced when investing more in prevention activities. Internal and external costs are the most reduced cost (Neyestani, 2017).

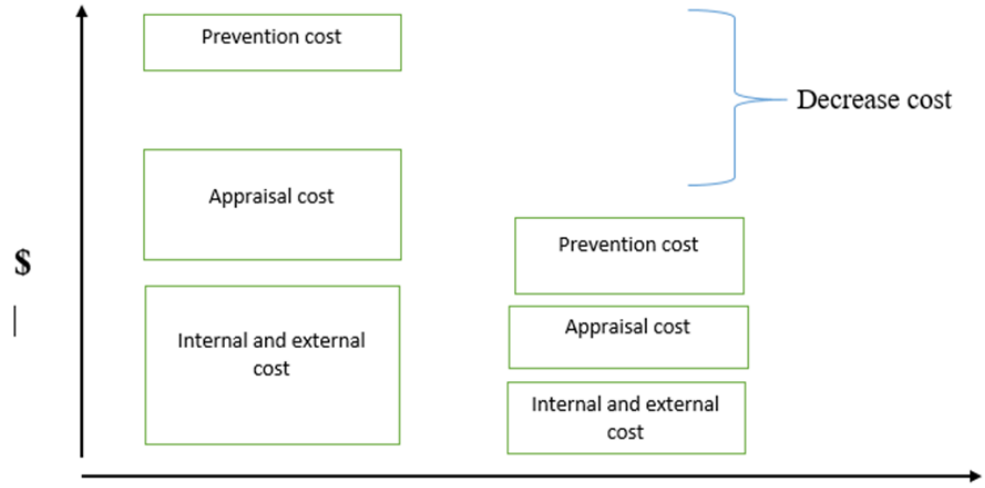

Figure 2. The effect of investment in prevention activities on other quality costs

Quality costs vary from 5% to 25 % of sales turnover depending on the type of market, business, or service (Williams et al., 1999). A study done by Murumkar et al. (2018)

shows that the company's COQ ranges from 10 to 40% of annual sales. So, companies must strive to keep them as low as possible. As shown in Figure 3, the cost of failure decreases as the levels of quality increase to perfection, while the cost of appraisal plus prevention increases. A target quality level is considered "ideal" because prevention, appraisal, and failure costs are kept to a bare minimum. Pursuing quality improvements that are greater than the ideal level would increase the total cost of quality (Juran and Gryna, 1988) and thus is referred to as the classical model of optimum quality costs, which is a more conservative approach. Juran then agreed that the classical model of optimum quality costs had a flaw, and he explained why.

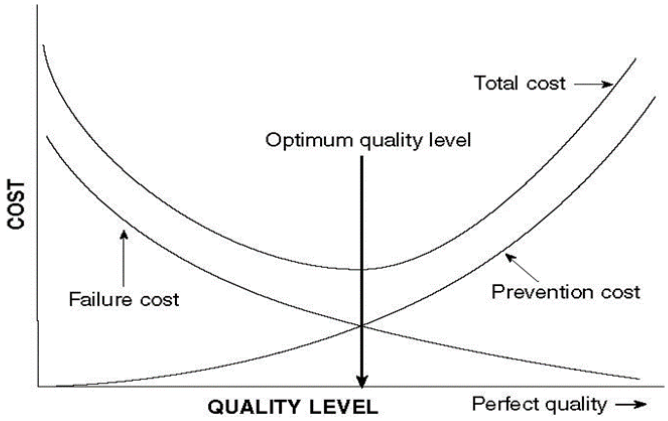

Figure 3. The classical model of optimum quality costs (Juran, 1988)

It is critical for companies to be successful in today's highly competitive industry that they provide excellent customer service. Consumer loyalty results in more sales and, consequently, increased income. The most significant components of quality costs are unsatisfied customers and the inability to obtain new customers due to poor advertising (Bhote, 1995). If organizations do not consider quality, they may incur direct and indirect costs due to rework or lost clients. As a result, organizations strive to lower quality costs

to improve profit and remain competitive, or at the very least to survive, in competitive marketplaces.

A COQ culture may be fostered by training employees at each step of the organization about the many types of quality costs, using instances drawn from their specific job processes as examples. Organizational leadership should understand that budget cutbacks will create the chance for increased failure costs by lowering the preventive and assessment programs. An increase in the cost of failure due to insufficient prevention activities may negatively affect the business and reputation.

Because good laboratory management demonstrates that quality investment eliminates, identifies, and decreases downstream errors, managers often seek reductions in quality investment to save operating expenses. The preparation of compelling reasons and supporting evidence by laboratories is essential for ensuring that funding for excellent service is maintained.

2.3 Types of Quality Cost in Medical Laboratories

Quality cost categories include costs associated with achieving and not achieving the desired quality level, cost of good quality (conformance), and poor quality (non-conformance).

2.3.1 Cost of Conformance

These costs include prevention costs and appraisal costs.

2.3.1.1 Prevention Cost: These costs are incurred due to any laboratory activities designed to prevent poor quality or lab mistakes. Preventing errors is usually less expensive than finding and rectifying mistakes that have the potential to degrade the

overall quality of laboratory services provided. Some examples of laboratory prevention activities are listed below.

- **Design or Modify Process Workflow:** The laboratory must establish and record the current workflow processes (pre-analytical, analytical, and post-analytical); figure 4 shows the typical laboratory workflow. The new and revised process workflow should be optimized, minimize non-value-added procedures, error-proofing, and reduce process variation to lower costs and fulfill the patient requirement with high-quality service. Employees who are already involved in the current process (the existing process) should analyze it to redesign it since they are the only ones who can speak to how it is done in practice. Root cause analysis is completed to determine the failure activity or nonconformities within a process. The new process should be documented as a draft for review and validation to ensure that the previous failure will not occur again. Once the new process is approved, the process should be documented, provide employee training and assessments should be conducted to ensure that the new process has been wholly comprehended and better understood. Figure 5 shows the steps for process redesign; the steps begin from analyzed current process steps.

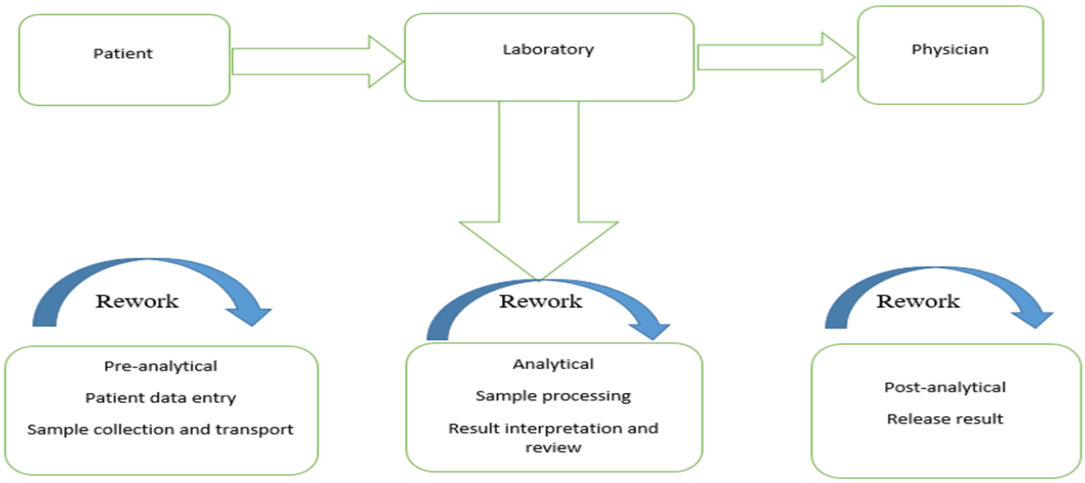

Figure 4. The typical laboratory workflow

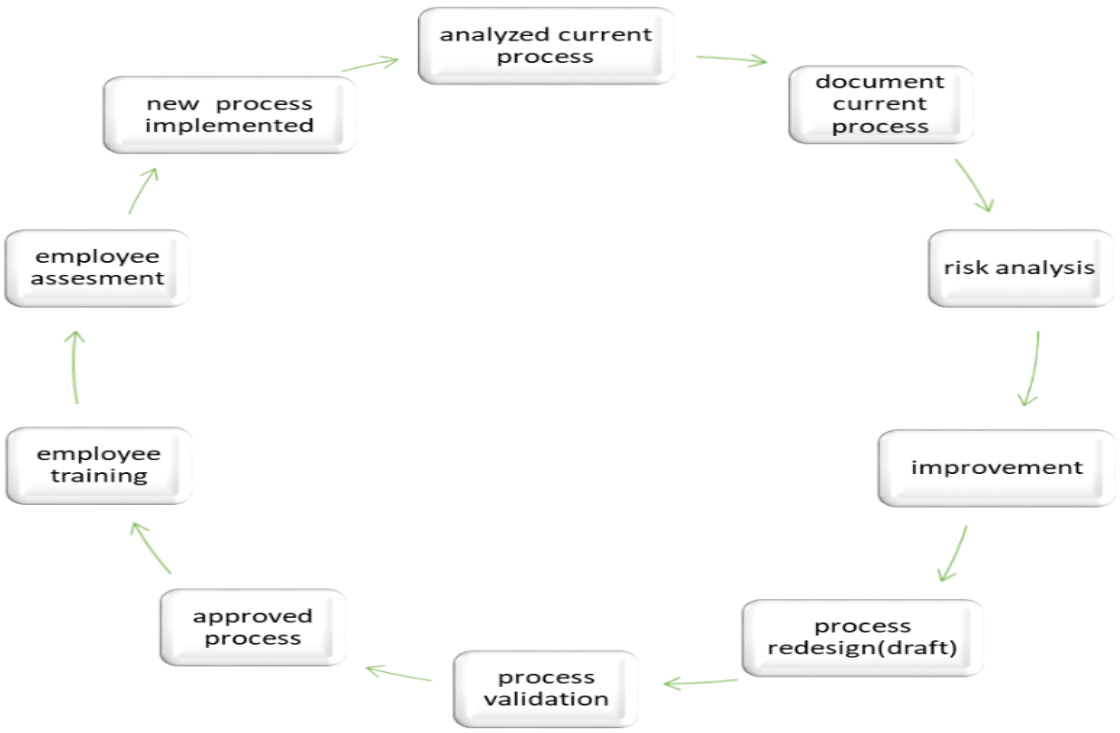

Figure 5. Steps for process redesign (CLSI. The Cost of Quality in Medical Laboratories)

- **Validation or Verification of New Laboratory Processes:** When a new process is implemented, the laboratory should verify the new process or validate the

process if it deviates from standard instructions; the cost and time result from validation or verification consider prevention cost to provide a result with high quality.

- **Standard Operation Procedure (SOP) preparation**: The laboratory should have a standard operating procedure (SOP) for all lab activities. The laboratory employs these examination procedures to give accurate test results or professional service. These procedures should be validated before being used it. The time and effort spent to create these sops consider prevention costs.
- **Preventive Maintenance:** is maintenance that is carried out on a laboratory instrument regularly to minimize the risk that it will malfunction. It is carried out when the machinery is still running so that it does not suddenly break down. Preventive maintenance is carried out frequently to ensure the correct functioning of the machines and ensure optimum efficiency, and this would add to laboratory costs, called preventive costs. However, it is still less than the cost of machine downtime since preventative maintenance is not done. For preventive maintenance, the laboratory should be planned very well to determine the time for each maintenance and minimize it to a minimum without affecting the machine's performance when the laboratory needs to reduce cost.
- **Laboratory Information System (LIS):** It is a software system for clinical laboratories that records, manages, and stores data used to prevent errors by minimizing personnel errors.
- **Planning for Quality:** a roadmap or several documents that define quality standards, procedures, resources, requirements, and the sequence of activities that apply to a particular product, service, project, or contract. Time spent identifying

quality targets that comply with the mission and strategic plan of the laboratory, as well as time spent on systematic analysis, debate, quality improvement, quality performance reporting, and modification of the observable quality goals of the laboratory. Also, time spent on quality education and training considers prevention costs.

- **Define Supplier Capability:** the laboratory should have a document to define supplier responsibilities and responsibilities when acting as a supplier to other laboratories. The lab needs to agree with a supplier and put clear criteria to evaluate supplier capabilities. The time and effort spent creating and putting precise supplier capability to avoid mistakes and inappropriate supplies consider prevention costs.
- **Reagent Specification Planning:** For purchasing, receiving, and storing reagents, the laboratory has a documented procedure. These procedures should define clearly, and planning the reagent specification, the time spent defining these specifications, and creating a procedure consider prevention costs.
- **Initial Competence Assessment and Work Process Training:** Laboratories should attempt to deliver reliable patient test results by combining methods that increased efficiency with technology appropriate for the lab goal and managed by personnel who are both qualified and competent to conduct the task. The laboratory evaluates each employee's ability to do assigned management or technical tasks, ensuring that all who operate equipment, run tests, review results, and sign test reports are competent. Personnel doing certain activities are qualified according to education, training, and experience requirements. To ensure that initial training was effective and that staff can do the given work processes

correctly and in line with laboratory policies, processes, and procedures, a competency evaluation should be conducted.

- ✓ **Internal Audit Planning:** quality cost to a gathering, analyzing, reviewing data to planning and creating internal audit program consider prevention cost. Also, the internal audit team salary considers prevention cost (cost from administrative auditing activity considers prevention cost).
- ✓ **Referral Laboratory Inspection:** Medical laboratories should have a documented procedure for choosing and assessing them to ensure that referral laboratories are qualified to perform lab tests. These activities and the cost resulting from laboratory inspection consider prevention costs.
- ✓ **Continuous Education:** laboratories should have a program to keep their employees up to date and efficiently operate within quality strategies. The time spent to create the plan and the cost of education should be seen as a cost of prevention.
- ✓ **Market Research:** The process of collecting, reviewing, and analyzing data about a market, service, or product decided to sell in that market and a better understanding of the expected customer and their needs. When a laboratory does research to determine which laboratory tests should be accessible to serve its customers and the optimum location, space, and design, based on the findings, the laboratory can determine which tests should be offered in the future if a doctor requests them. Marketing research provides knowledge on new and present customers, competitors, and the industry. Accurate and complete information is the basis of all success, and it enables company owners to assess the viability of an enterprise before investing significant resources in it.
- ✓ **Risk Assessment:** A risk assessment is a detailed examination of a workplace to discover those objects, circumstances, procedures, and other factors that might harm

people. After making the identification, you'll need to study and assess how severe and likely the danger is. After reaching this judgment, you may go on to decide what steps should be taken to remove or control the harm successfully. Risk assessments are essential because they assist in: raising awareness of dangers and risks, determining who could be in trouble, and determining if the current controls are adequate or if more should be done. Risk assessment should perform when Process workflow is modified to avoid unnecessarily disrupted services and patient damage. A matrix for assessing the risk that has been created. This makes it possible for the laboratory to recognize and prioritize numerous dangers. They just put up a show to gauge the probability of something occurring.

2.3.1.2 Appraisal cost: The quality of laboratory services and products is assessed, reviewed, and audited to ensure consistent compliance with the quality objectives, processes, and procedures of the laboratory, as well as regulatory, accreditation, organizational, and consumer requirements. Appraisal cost evaluates the quality level and recognizes and corrects errors before they adversely affect laboratory service. Some examples of laboratory appraisal activities are listed below.

- **Instrument Calibration:** One of the key processes used to ensure instrument accuracy is instrument calibration. Calibration is the method of configuring an instrument within an appropriate range to provide a result for a sample. A fundamental aspect of instrumentation design is removing or reducing factors that trigger incorrect measurements. The cost of calibration materials, such as reference materials, is a quality cost that ensures that tools and equipment have precise test results.

- **Quality Control:** A statistical process is used to track and analyze the analytical process that generates patient results in the medical laboratory. Quality control can be quantitative or qualitative; the results of QC are used to verify whether the instrument performs within pre-defined parameters, indicating that the results of the patient test are accurate. Patient results can then be used for diagnosis, prognosis, or recovery planning. Regular quality control result creates a QC database which the laboratory uses to validate the test system. This occurs by comparing daily QC outcomes with a range of QC values defined by the laboratory. This cost considers appraisal costs include quality control material, time-consuming to review quality results, and reviewing unacceptable results.
- **Proficiency Testing:** Also called inter-laboratory comparison, it measures the performance of particular tests or measurements by individual laboratories and is used to track the ongoing performance of laboratories. In proficiency, program material sends to a participant laboratory, and each lab measures a specific item and compares it with the reference range. Proficiency testing could be mandatory or voluntary. The cost includes the cost of material, time to run the sample and review the result, and the time to detect the causes of the unacceptable results.
- **Quality Indicator Evaluation:** Quality indicators are one of the methods of the QMS to track and regulate the efficacy of the system in pre-analytical, analytical, post-analytical processes, while the results obtained serve as a basis for the implementation of corrective measures and provide a signal to prevent the error from occurring. The quality indicator should be measured periodically.
- **Supplier Evaluation:** The method of quantitative and qualitative evaluation of approving suppliers. The aim is to ensure that suppliers of the best in class are

available for use. To assess and track their performance to minimize costs, mitigate risk and promote quality development.

- **Material Inspection:** the laboratory performs an inspection for material (incoming material inspection or source material inspection) to ensure it meets the accepted criteria. The cost result from this activity considers appraisal cost.
- **External Inspection:** when the laboratory participates either voluntarily or obligatory in external auditing, the cost result from this program considers appraisal cost. The benefit of this inspection is to find out nonconformities that can't find by internal auditing and then improve it to meet the minimum acceptable performance level. Example of external inspection (inspection from the ministry of health to get the certification, inspection by ISO or CAB team).
    - ✓ **ISO Certification:** ISO (International Organization for Standardization) is an independent, non-governmental that establishes standards to ensure the quality and efficiency of products, services, and systems. ISO certification verifies that a management system, manufacturing process, service, or documentation procedure satisfies all standardization requirements. ISO 15189 is the certification for medical laboratories. To be eligible to submit an accreditation application, you must be enrolled in the PT program for six months before requesting accreditation. The cycle for re-inspection is three years. Personnel involved in the program must achieve the requirements for proficiency in the roles and responsibilities they are assigned.
    - ✓ **CAB Certification:** The College of American Pathologists (CAP), the main association of board-certified pathologists, serves patients,

pathologists, and the public by developing and advocating excellence in the practice of pathology and laboratory medicine worldwide. To be eligible to submit an accreditation application, you must be enrolled in the CAP PT program for six months before requesting accreditation. The cycle for re-inspection is three years. Personnel involved in the program must achieve the requirements for proficiency in the roles and responsibilities they are assigned.

- **Customer Satisfaction Survey:** Customer satisfaction should be monitored regularly to ensure that your customers receive high-quality service and are pleased with labs results.
- **Operation Inspection and Review Test Result:** The lab director should review all laboratory procedures and activities, and a specimen should be checked. The test result should be reviewed and approved before the release result; the effort and cost result from these activities consider appraisal costs.
- **Internal Audit (Internal Inspection):** The laboratory should have a procedure for internal auditing. This procedure aims to provide instructions and assign responsibilities for the internal audits performed at the laboratory. The laboratory will ensure that an internal audit of the QMS is undertaken to continuously assess the state of conformance with approved quality system policies and procedures and that corrective and preventive action is taken. It helps a company achieve its objectives and meet customer requirements when necessary. A trained auditor should perform an internal audit with a clear checklist and well-defined responsibilities. Such operations are carried out autonomously, professionally, and systematically. This procedure applies to all processes and activities of the

QMS at the laboratory and all areas where the quality system has been implemented. This procedure covers the responsibilities, planning, execution, and reporting of internal audits and corrective action coordination for any observed non-conformance. Creating procedures and auditing planning consider prevention costs, while applying and performing activities consider appraisal costs.

- **Management Review:** During scheduled times, this approach aims to regularly evaluate the quality management system to ensure its suitability, efficiency, and effectiveness, identify opportunities for improvement, and address needs for progress in the system, policies, and priorities of the business, in addition to managing the process of creating and following up on quality objectives. The analysis should determine the need for improvements and record the steps taken. The time spends during management review considers appraisal cost.

On the lists of preventive and appraisal costs, basic items may have slight variations, as shown in Table (2) below:

Table 2. Prevention and Appraisal Costs Basic Items Variations

Activity	**Cost type**
Customer perception survey	Prevention
Internal audit program planning	Prevention
Quality management system planning	Prevention
Initial competence assessment	Prevention
Equipment preventive maintenance	Prevention
Supplier evaluation/review/rating planning	Prevention
Inspection for referral laboratory	Prevention
Customer satisfaction survey	Appraisal
Internal audit performing	Appraisal
Quality management system review	Appraisal
Ongoing competence assessment	Appraisal
Equipment calibration	Appraisal
Supplier evaluation /review / rating	Appraisal
Laboratory inspection(audit)	Appraisal

2.3.2 Cost of Nonconformance

They are fixing issues that influence the consistency of the laboratory results. Failure costs result from not first meeting quality standards and then requiring rework or correction. Internal and external failure costs are included in these costs.

2.3.2.1 Internal Failure Cost: Internal failures are detected and resolved inside the laboratory before patients or clients are adversely affected by the error. It is resolved before the examination report reaches a patient or other customer. Some examples of the laboratory internal failure activities are listed below.

- **Rejected Sample or recollection:** Often, if samples fall short of consistency, volume, or other eligibility requirements and are lost samples, tests cannot be conducted in the laboratory. In these cases, it might be necessary for the laboratory to reject the samples and not perform processing. The most rejected criteria are unlabeled specimens, samples lost during transportation, incorrectly labeled, incorrect container or preservative, an insufficient specimen for the procedure, and unsuitable specimens for a procedure. When a sample is rejected, the laboratory should recollect the sample, and this will increase the cost; the cost includes collection material, labor time, and the unsatisfied patient. Sometimes the sample cannot be recollected, and the error cannot be resolved like tissue biopsy, which will make significant losses for the laboratory.
- **Expired reagent, lost Reagent, and Lost Blood Component:** Before the expiry date, any reagent used in the laboratory should be used to provide an accurate result. To minimize this expense, the laboratory needs to have a robust inventory management system to ensure that reagents and other supplies necessary for scheduled work are stored and, the correct quantities are resupplied and that their

functionality is tested before use, all costs to deal with an expired reagent or lost reagent are known as internal failure costs. When the laboratory has a high inventory above lab necessary, this will lead to lost reagents and add extra cost. It is also essential to dispose of blood units that have not been used after preparation or have not been utilized before their expiration date in blood banks. So this will incur costs, including those associated with the collection, testing, preparation, and material used to obtain blood units.

- **Repeated Test, Repeated Inspection, Repeated QC, Repeated Calibration, and Rework:** If the laboratory result does not meet the acceptance range, the test should be repeated by the laboratory before releasing the patient result to provide an accurate result. The cost of repeated testing is regarded as the cost of internal failure. Any job (calibration, testing, inspection, QC, test comparison, etc.) that has not been adequately done for the first time and needs to be reworked will also produce costs perceived to be internal costs of failure.
- **Unscheduled Downtime:** Unplanned downtime occurs when equipment, LIS, or process is suddenly shut down or failed, or computer unavailability and lack of staff to conduct the test, interpretations of results, reporting of results. There are many failure costs, including costs for sending specimens to another laboratory, assurance of the system's proper functioning after the restoration of operation, and loss of customers during the downtime period.
- **Proficiency Testing Failure:** PT failure occurs when results fall outside the reference range; therefore, laboratories should investigate and identify the core reasons to avoid recurrence. The material and effort used to solve this failure consider internal failure costs.

2.3.2.2 External Failure Costs: are failures that doctors, patients, or other consumers who obtain unsatisfactory test results or services detect outside the laboratory. The most expensive quality costs may be external failure costs since they require costs to fix the issue and other costs when the failure adversely affects the patient or consumer. Some examples of the laboratory external failure activities are listed below.

- **The Wrong Result Reaches a Customer:** The laboratory is expected to examine and correct any finding of an incorrect result in a laboratory report. Wrong results may lead to misdiagnosis or inadequate therapy. The laboratory must issue updated reports and inform suitable practitioners of any mistakes and its correction. The time spends to correct the error result consider an external failure cost.
- **Lost Report:** missed patient report, causing patient care to be delayed. The time and effort to correct and find reports consider external failure costs.
- **Customer Compliant:** An expression of dissatisfaction with service received from the laboratory. Knowing your customer's problems and answering them is the best way to ensure your business growth. Investing in customer support can help laboratories recognize their complaints and strengthen their services and experience. The time spends to deal with a customer complaint and correcting the problem consider an external failure cost. Through designing and enforcing modified procedures and the necessary staff training and competence assessment, customer complaint costs can be reduced to a minimum.
- **Lost Patient/Lost Image of the Laboratory**: As a result of the incorrect results issued by the laboratories and not meeting the quality requirements leads to the loss of certain patients and damage to the credibility of the laboratory and the

confidence of doctors in its results; the laboratory has to do several things that would lead to increased costs to fix the defect and rebuild patients and doctors 'confidence in it. In addition, social media has a significant impact these days. When a lab makes a mistake with a patient's result, the news spreads quickly through social media, making patients lose confidence in the lab's quality, and the lab has to work hard to improve its image again.

- **Litigation due to Misdiagnosis:** As a result of a lab mistake, if an incorrect laboratory procedure leads to misdiagnosing a patient or receiving improper treatment, the patient will initiate laboratory litigation. Any costs resulting from this error and time spent fixing the issue may also pose concerns about the efficiency and reputation of the laboratory would be called external failure cost.

2.4 COQ Previous Studies:

The number of publications published on COQ has increased dramatically over the last decade, with the highest number of publications reported in 2018 (17 publications), followed by 2015 (14 publications) (14 articles). In 2010 and 2011, fewer publications were reported (6 papers each year), indicating that the field is becoming more competitive (Dimitrantzou et al., 2020). In fact, after reviewing articles about the cost of quality, it was found that most of them were about how to figure out and assess the cost of quality in the manufacturing sector, with only a few articles about medical labs and that none of these studies had been done in Palestine (Dimitrantzou et al., 2020). Figure 6 shows the distribution of the sample articles per sector.

Figure 6: the distribution of the sample articles per sector (Dimitrantzou et al., 2020).

Zahar et al. (2015) implemented the PAF model within Moroccan water laboratories. The data were collected during six months. It was found that about 77.9% of the overall quality costs were spent on "good quality" costs (prevention and appraisal), while 22.1% of the costs were spent on "poor quality" (internal and external failures). Also, prevention costs are the largest portion of the Total Cost of Quality.

Zahar et al. (2016) analyzed cost data to estimate the Cost of Quality (COQ) in a clinical laboratory located in Morocco, based on the four categories of cost data analyzed (preventive, appraisal, internal, and external cost). According to the findings of the study, 83% of total COQ was spent on costs of good quality, and 17% of total COQ was spent on costs of poor quality (41% of the COQ was prevention costs, 42%was appraisal costs, 11%internal failure costs and 6% external failure costs). Furthermore, the total COQ accounted for 30% of the total laboratory expenses. Upon further examination of each cost category, the studies found that the most preventive cost was the maintenance of

laboratory equipment. In contrast, the most appraisal cost was the cost of calibration and control reagent.

Additionally, reagent waste and expiration accounted for most internal failure costs, while customer compliance accounted for most external failure costs. To measure and assess the costs of quality-related operations at the Makerere University-Johns Hopkins Laboratory, Elbireer et al. (2010) found that healthcare policymakers misunderstand the costs associated with quality improvement efforts. This information is critical for managers because it allows them to make appropriate operational and budgetary considerations to provide high-quality services to patients. An estimated 90% to 94% (i.e., 24% for prevention and 70% for appraisal) of total COQ expenditures were spent on "good quality" expenses. Only 6% (4 percent for internal failures and 2% for external failures) were spent on "poor quality." COQ's budget has been set aside for prevention and appraisal activities. According to Schmidt and Pearson (2019), methods were established to estimate the COQ for laboratories due to errors in the analytical phase; measuring the COQ and utilizing that data to prioritize efforts for improvement can be difficult, but it is crucial for providing high-quality patient care. In the clinical laboratory literature, the concept of COQ has gotten relatively little attention, with only two investigations attempting to assess COQ in clinical laboratories so far (Schmidt & Pearson, 2019).

Kumar and Alsada (2019) published an article in which they analyzed current literature on the various costs of quality initiatives to acquire a better knowledge of quality costs and enable competitive advantage. The study's findings demonstrate that there is no standard explanation of quality costs in the scientific literature. The distinction between

quality costs and overall costs should be made by industrial organizations when it comes to enhancing productivity and achieving better financial results.

According to Mahmood et al. (2014), the influence of assessing the cost of poor quality on labor productivity and profitability in the manufacturing business was explored. Following the implementation of the COPQ measuring method, the results revealed that the COPQ decreased by approximately 24% throughout the 60-day study period, while labor productivity and profitability increased by around 17% and 11 %, respectively. Following the research findings, it is suggested that the COPQ framework may be utilized to encourage continuous improvement in construction projects, which is further supported by the study results.

Increasing numbers of businesses are taking on the responsibility of managing COQ, and it is widely recognized that COQ is vital to company success (Glogovac & Filipovic, 2018). A total of 186 enterprises were subjected to the study's findings (both manufacturing and service companies). These costs must be properly collected, analyzed, and used for continuous improvement. The results revealed that 42% of companies do not evaluate quality costs, that 28% of companies do evaluate quality costs but do not properly analyze them, and that 30% of companies reported that the level of COQ management is extremely high (Glogovac & Filipovic, 2018).

External failure costs as a percentage of an organization’s total cost of quality have been observed to decrease due to improvements in a company’s quality system. A rise in the overall COQ has been seen as an organization goes from a low level of quality system maturity to a high level of quality system maturity. The most often mentioned cause for organizations failing to measure quality costs regularly was a lack of managerial support for the practice (Sower et al., 2007). Several researchers, including Lari and Asllani

(2013), have shown that the quality cost model may be utilized to evaluate the overall performance of an organization.

For their case study, Sanjay et al. (2016) looked into the workings of a rapidly expanding medium-sized manufacturing company that had numerous quality control systems in place but had not yet implemented a formal COQ program. According to the study's findings, the average total COQ is 3.48% of gross sales. The proportions of PC and AC are significantly lower than those found in the standard literature. Internal failure costs account for a significant portion of quality costs, and the enterprise resource planning (ERP) system contains approximately 80% of the information required. COQ can also be measured weekly or daily if a proper interface with the current ERP system is planned and maintained.

According to Abdelsalam and Gad (2009), a study was conducted on residential construction projects in Dubai using the PAF model to calculate the COQ and determine the level of quality that reduced the total COQ to the lowest possible level. These projects in Dubai have a COQ of 1.3% of the total civil work cost of the project, with an optimum COQ value of 1.34% of the total COQ calculated.

It is difficult to find a standardized model applied to various industries. Furthermore, applying the given model to a specific sector necessitates the use of specialized knowledge. It is clear from the literature that each industry must adapt the currently available models to meet its particular requirements and make them more user-friendly (Trehan et al., 2015). A dynamic model was developed to determine the relationship between product cost and product level (Kim & Nakhai, 2008). Some disagreements about a "typical" rate of quality costs (Roden & Dale, 2000). Approximately 25-30 % of

the COQ, according to Crosby (1979). On the other hand, Plunkett and Dale (1999) stated that the COQ percentage is between 5 and 25%.

Internal and external failures cost more than preventive and appraisal costs (Carr & Ponoemon, 1994). In addition, there is a statistically significant association between them and the level of quality. In the United States, the study was carried out over 48 months at pulp production plants, with 46 different papers being used. They looked at the link between the COQ components and discovered that the internal cost is the most expensive component, while prevention is the least costly. On the other hand, Porter and Rayner (1992) assumed that investing in the areas of an appraisal will minimize the likelihood of a failure cost. Concerning management, the COQ is an effective measure for determining the financial health of an organization.

The purpose of continuous improvement programs is not only to fulfill customer needs but also to do so at the lowest possible cost. As a result, when attempting to enhance quality, a company must consider the costs of attaining quality. In contrast, Total Quality Management (TQM) focuses on improving processes and removing all types of waste from the organization. Quality costs must be calculated sensibly before any TQM project can be considered successful (Vaxevanidis & Petropoulos, 2008).

In a manufacturing process, according to Tye et al. (2011), managers may discover opportunities for enhancing the quality and lowering waste while maintaining productivity by utilizing the COQ method. COQ can also be used to account for non-value-added expenditures that are not otherwise recognized. These researchers demonstrate how quality implementation costs affect Malaysian manufacturing enterprises and how to incentivize these businesses to use quality management systems (QMS). According to the findings of this study, customer complaints, rework costs, and

warranty expenditures have all decreased due to the implementation of quality costs in manufacturing enterprises. Meanwhile, sales volume has increased.

Several studies such (Cheah et al.,2011; Eldridge et al., 2006; Kumar & Alsada, 2019; Narasimhan, 2013; Psomas, 2018; Pires et al., 2017; Sower et al., 2007; Teli et al., 2017) have examined the reasons for and Challenges Face Application of Cost of Quality (CFA) this include:

- A lack of comprehension of the notion of the COQ
- Unable to monitor the COQ due to a lack of knowledge
- Obtaining COQ data is difficult.
- A lack of attention on the part of management in tracking COQ
- The inability to incur the necessary expenses for COQ measurement due to financial constraints
- Failure to perform effectively due to a lack of experienced personnel
- COQ is viewed negatively by management as an additional burden.
- Inadequate accounting and computer systems are needed to monitor COQ
- Organizations do not recognize the advantages of COQ.
- Lack of support from other departments.

Other studies (for example, Chopra & Garg, 2011; Psomas, 2018; Schiffauerova & Thomson, 2006; Uyar, 2008) have been conducted to determine the effects of COQ implementation. In other words, according to the literature, the following are the primary advantages of using the COQ system:

- A rise in revenue and profit
- An increase in the competitiveness of the firm

- Enhancing the quality of the goods and services
- Fewer complaints from customers
- Productivity increases
- Consumer and staff satisfaction will rise.
- An area that requires a lot of costs to fix
- A considerable decrease in costs
- The proper removal of all wastes

There is a cost usually not calculated or miscalculated by the organization, and it is referred to as the hidden cost of quality. Typically, companies fail to track the effect of hidden costs and have difficulty identifying and measuring them. These costs can be divided into two categories; intangible and tangible costs (Sandoval and Beruvides, 1998).

- Tangible hidden costs such as compliant investigation costs.
- Intangible hidden costs such as lost sales and a decrease in company reputation.

The cost of failure is like an iceberg. Some costs are easier to see and identify (for example, the visible piece of an iceberg). In contrast, others are more difficult to see and recognize (for example, the unseen section of an iceberg) (DeFeo, 2001). Failure costs are reduced when the laboratory does root cause research and improves procedures that have resulted in failures. Projects for quality improvement will minimize the need for hidden costs of quality. Failures that negatively influence the budget and cause money to be saved are eliminated if a project for process transformation successfully lowers or eliminates non-conformities. Literature related to the hidden cost of poor quality (COPQ)

from a historical perspective was reviewed (Mahmood & Kureshi, 2015). The study reviewed 42 articles carried out over 40 years from 1975 to 2014 and found that COPQ ranges from 16.91% to 26.90% of the company's revenue. Also, the study shows most of the studies were carried out within the manufacturing sector (40 of the studies focused on the manufacturing sector).

Giakatis et al. (2000) demonstrated that the COQ categories should include manufacturing and design losses. They also stated that the hidden costs are significant, even compared to the prevention, appraisal, and failure costs. They represent significant opportunities for cost reduction if they are taken into consideration. On the other hand, Sailaja et al. (2015a) analyzed and measured the hidden cost of quality in an electronic manufacturing equipment firm with ISO 9001:2008. The study shows that the cost of quality measured in the traditional systems is 8.89% of sales revenue, while the same is 34.02% in the improved system with hidden costs and opportunities included. The total hidden and opportunity costs are 25% of the sales revenue. Also, Giakatis et al. (2001) analyzed the hidden quality costs and showed the differences between quality loss and quality cost. The study stated that the PAF model addresses a significant part of the quality costs. Other costs or losses are considered if ignored, so it is essential to categorize manufacturing and design losses. They are more than three times the traditional quality costs. Sailaja et al. (2015b) prioritized hidden quality cost elements using Analytical Hierarchy Process (AHP) techniques in industry situations, and the study showed that the category of opportunity costs in the first stage has more effect on quality costs (86.5%) than the direct hidden costs (13.5%). In the second rank, internal failure costs are more important than the other sub-categories among the sub-categories of the direct hidden cost category.

Modhiya and Desai (2016) reviewed the COQ methodology and hidden costs in manufacturing industries. The study stated that companies that use COQ programs have been very effective in reducing COQ and improving customer service. The model most widely used in practice is the classical P-A-F approach; however, other categorizations of quality costs are recorded as being used successfully. Kim and Lia (1994) estimated hidden quality costs with quality loss functions. Jeffery (2003) identified several types of hidden quality losses. A study done by Krishnan (2006) implemented a simple formula, using three types of indicators that could be used to track the degree of poor-quality costs (PQC) to calculate total costs of failure by accumulating the values of both hidden and visible costs of failure. Jenoui and Abouabdellah (2017) estimated suppliers' hidden quality costs with the Taguchi quality loss function and topics method.

Rosenfeld (2009) stated that hidden costs could not be calculated easily; they also exist, cost, and hurt. Such hidden costs include, among other things, deterioration of the image of the company, loss of clients, project delays, increased overheads, and payment of liabilities. A company that cares about its performance and reputation in the long term must consider the hidden costs and measure them. He also noted that internal and external failures are followed by multiple hidden, unrecorded, indirect costs and consequential damages. Tannock and Saelem (2007) stated that the hidden cost of quality could be several times higher than the cost of visible quality; its determination is difficult and therefore damaged. This claim further supports the iceberg theory.

As demonstrated above, most studies agree that most businesses compute the visible failure cost while overlooking the hidden failure cost. Consequently, having a thorough understanding and in-depth knowledge of how to calculate hidden COQ allows a business to accurately determine the actual failure cost to save money by cutting down on

unneeded expenses. Specifically, this study aims to assess the level of perception held by top management about the cost of quality and hidden costs in medical laboratories. Additionally, it looks into the variables considered when calculating the cost of quality table 3 below shows some hidden costs based on previous studies about the hidden cost of quality.

Table 3: The laboratory measurable quality cost (visible) and the hidden quality cost (invisible).

Measurable quality cost(visible)	Hidden quality cost(invisible)
Inspection Maintenance Calibration Expired inventory Accreditation assessments QC Proficiency testing	Repeated training Extra communications Downtime TAT delays Reduced capacity Customer dissatisfaction Reduced results Lost customers Process redesign Slowed operations Billing error Excessive supply, expired reagent, Canceled test Overtime to solve a problem Excessive process Loos of reputation Discount lost Over quality failure to keep current clients liabilities in the future Losses new patient

Several articles examine the impact of COQ practices on organization performance within the manufacturing sector, and a few studies investigate it within the laboratory sector. Several studies examine the effect of the cost of a quality activity on organization performance. One of these studies done by Bayram et al. (2020) found that the prevention cost has a significant positive effect on organization performance by decreasing errors

and accidents and increasing employee satisfaction. Psomas et al. (2018) found that for an organization to be competitive, it should increase prevention and appraisal costs and decrease non-conformities costs. Also, the finding shows a strong correlation between internal and external failure and between prevention and appraisal costs. A positive correlation between COQ practices and organizational performance. According to Ayach et al. (2019), investing in preventative activities will minimize the total cost of quality by reducing customer dissatisfaction, rework, mistakes, and accident incidence. Ghunaim and Jaaron (2021) showed a positive correlation between COQ practices and organizational performance in the food industry. The study shows the manager should invest more in prevention activities to decrease internal and external failure costs. Akenbor (2014) stated a positive relationship between quality conformance cost and customer satisfaction, but a significant negative relationship between quality nonconformance cost and customer satisfaction.

Additionally, increasing quality conformance costs, such as preventive maintenance, will eliminate the customer's internal and external failure costs, resulting in improved customer satisfaction. Another study was conducted by Tye et al. (2011), who concluded that the implementation of quality costs in manufacturing enterprises has resulted in a reduction in customer complaints, rework, warranty expenditure, failure costs, and total quality costs, while sales volume has increased as a result of the implementation of quality costs. Virima et al. (2019) investigate the relationship between service quality factors and customer satisfaction.

Quality indicators were created in the lab to track and measure performance in pre-examination, examination, and post-examination. The indicators are monthly lab errors, number of lab accidents, number of unacceptable tests performed by external quality

control, number of rejected samples, customer satisfaction, employee satisfaction and loyalty, instrument downtime, employee training and education, number of tests per employee, and percentage of reports not sent to the patient. Using Quality Indicators (QIs) as a component of a laboratory improvement approach, which have been proved to be effective monitoring and improvement tools, is widely acknowledged as a technique for minimizing the probability of making an error when working in a laboratory environment. The purpose of quality improvement is to keep the risk of error at a low level to reduce the risk to the patients. To contribute to the advancement of Brazil's health systems, the Brazilian Laboratory Indicators Program, according to Shcolnik et al. (2012), gives considerable benefits to those who participate in it. According to Tsai et al. (2019), TAT, the timeliness of the response, and the cost per test are the most often utilized performance measures in the laboratory.

Moreover, the authors believe that by employing useful performance indicators, they will be able to identify areas for improvement and prospective adjustments in the workflow. According to Ricós et al. (2004), performance indicators (PIs) should be expressed numerically for the performance to be understood correctly. Despite the relevance of PIs, according to Cornes et al. (2016), a study done in the United Kingdom indicated that only a tiny number of laboratories gather pre-analytical error data on a regular and complete basis. However, Sciacovelli et al. (2017) stated that, even though many laboratory specialists believe that PIs are beneficial to the testing process, it is challenging to maintain personnel interest over the long term and continue to gather information consistently and systematically. In Appendix E and table 4, we summarized the most laboratory performance indicators based on previous laboratory indicator studies.

2.5 Conceptual Framework

This section links the activity element associated with the cost of quality categories in the medical laboratory (i.e., the conceptual framework components). These elements are classified under four COQ categories (prevention cost, appraisal cost, internal failure cost, external failure cost). According to the literature review and after reviewing COQ models, table 4 below shows the cost of quality activities in medical laboratories:

Table 4. COQ activities in medical laboratories and performance indicator

Cost Categories	**Activity**
Prevention Cost (PC)	Laboratory information system (LIS) Security of information Initial competence assessment Continuing education and training Preventive maintenance (PM) contracts for laboratory instrument Validation or verification of new laboratory processes Supplier quality planning Reagent specification planning Operations quality planning Operator quality education

	Operations process validation or verification Modify process workflow Work process training (QA) teams' salaries Marketing research Customer perception surveys Supplier reviews planning Supplier rating planning Facility design Internal audit program planning Inspection for referral laboratory Design error proofing process Risk management planning Quality performance reporting Quality improvement Quality program planning Quality education and training

	Office supply costs for quality-related preventive activities Lab safety program Labor time for personal done quality activity Quality management system
Appraisal Cost (AC)	Incoming material inspections Measurement equipment Source material inspection Specimen check Operation inspection Supplier evaluation Quality audits performing External inspection Quality control program Proficiency test program Accreditation assessment cost (ISO/CAP) Calibration cost Equipment function check

	Quality management system review Quality indicator review Comparison between lab Competency assessment The lab manager reviews test result Outside endorsements and certifications Evaluation of support department Temperature monitoring Office supply costs for quality-related appraisal activities Customer satisfaction survey
Internal Failure Cost (IFC)	Purchased material replacement costs Supplier corrective action Uncontrolled material losses Dealing with expired reagent Defective reagent Reagent shortage Cost of emergency purchasing order High inventory cost

	Repeated QC LIS downtime Repeated test Re-inspection Extra operations Instrument downtime Repeated sample collection Repeated calibration Sample lost during transportation Wrong order Wrong test Retraining of employee Correction of data entry errors Competency reassessment Rework/process rework Data entry error Pt. failure analysis time cost The material used after pt. failure

	Extra communication. Sop rework The material used to recollect the sample Employee safety accident cost Ineffective meeting Undocumented procedure Corrective actions on external assessment findings Corrective actions on internal audit findings Corrective actions due to not removing the root cause Office supply costs for internal failure cost Time lost due to the investigation of the error Unnecessary work Time lost due to recalibration Time lost due to test rerun Corrective action design

	Rework after redesigning corrective action Waste due to redesign
External Failure Cost (EFC)	Complaint investigation Litigation Lost report Lost customer Corrected report Penalties Lost revenue Recollect sample Report error recall Retest Sample transport Labor cost Price discount or free after error The cost of treating a patient as a result of giving wrong results Customer accident cost Incorrect billing

	Office supply costs for external failure cost Sending results to the wrong patient Cost due to process modification after error Cost due to retraining after error Delay sending results to the patient
Laboratory Performance Indicators	
Indicators	The average number of tests per employee Number of Lab errors Laboratory revenue or workload Number of Lab accidents Number of tests Repeated Employee training and education Employee loyalty External customer satisfaction Instrument downtime External quality control failure Reagent lost and expired before use Number of LIS used by laboratories

The literature review identified and summarized the COQ element of the framework, as shown below in Figures 7 and 8.

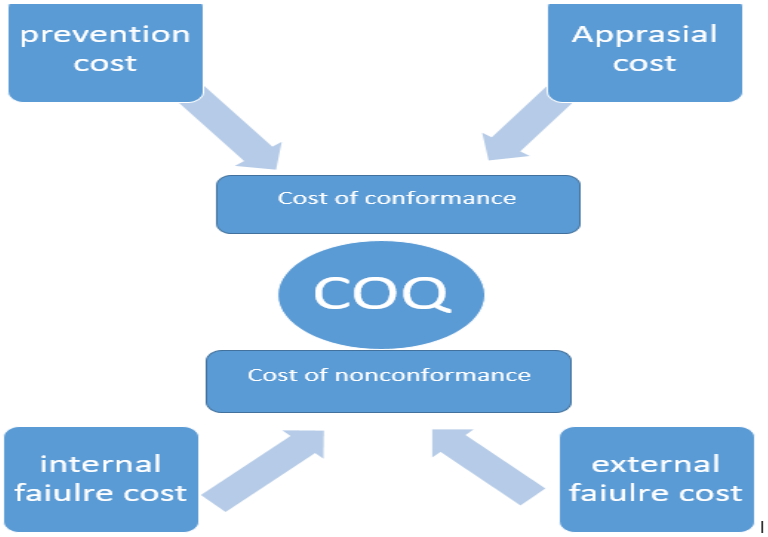

Figure 7. COQ categories conceptual framework

2.6 Study Variables

- Dependent variable: laboratory performance.
- Independent variable: prevention cost, appraisal cost, internal failure cost, external failure cost
- Moderator variable: lab workload, presence of quality department, ISO certification

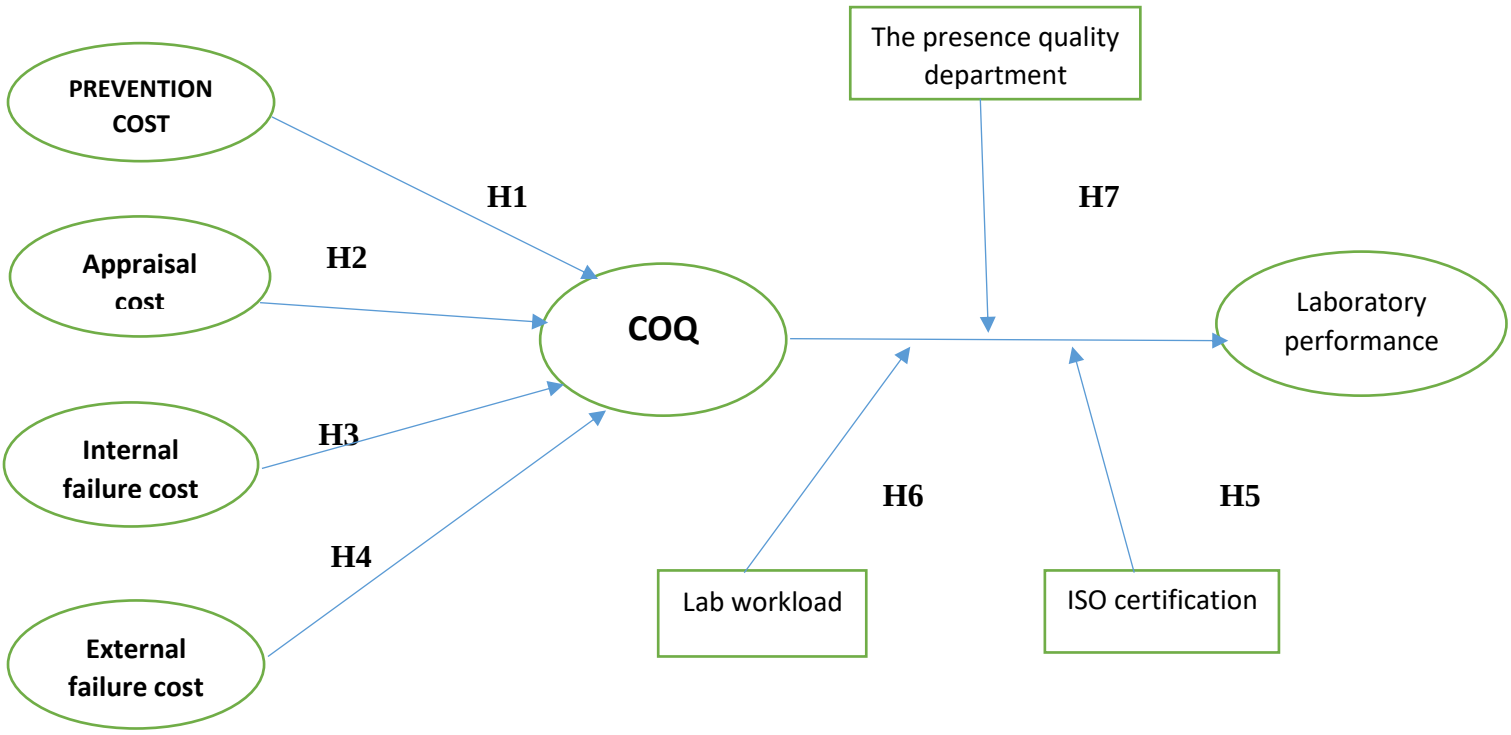

Figure 8. Laboratory performance a conceptual framework

Chapter 3: Research Methodology

3.1Overview

This study aims to provide a basic understanding of how quality costs in medical laboratories are collected, calculated, and measured to reduce unnecessary activity costs and understand the impact of COQ practices on laboratory performance. The study was carried out in medical laboratories in the West Bank. There are more than 700 laboratories in the West Bank since they are either private or governmental laboratories. The Medical Technology Association is also responsible for lab activity and coordination of audit laboratories.

A descriptive research approach was adopted to study the reality of the cost of quality in medical laboratories. This approach can investigate the issues of cost of quality in medical laboratories, and it describes the reality of the cost of quality by further analyzing it. First, COQ literature reviews help us determine how and what information is needed to complete this study and identify the COQ categories. Another critical source of data collection is the laboratory documentation and information management system, which considers one of the best sources of quality cost data. Second, several unstructured interviews with quality managers were conducted to ensure that all cost elements were identified and the elements used in measuring the cost of quality in medical laboratories were investigated. Third, a quantitative data collection method was adopted to collect the relevant data from various laboratories. A questionnaire is developed based on a literature review and distributed among managers and employees working in medical laboratories for this study. This study checked questionnaire reliability and validity through Cronbach's Alpha test and factor analysis. Fourth, the questionnaires were analyzed using SPSS software.

Unstructured interviewing, also known as non-directive interviewing, is an interview idea with no fixed style. Questions are not predetermined, allowing the interviewer to ask questions that spring to mind due to the absence of a structural question (Mueller & Segal, 2014). We used an unstructured interview in our research since we were unaware of what laboratories compute and whether there is knowledge and awareness of calculating the cost of quality. As a result, this type of interview was used to assist laboratory management in determining their existing situation. The interview was conducted with three lab managers from governmental sectors, two from non-profit sectors, and four from private sectors. The questions were open-ended, and the conversation was flexible and changed based on the respondent's answers. The questions asked during the interviews: Is the quality cost measured; do you know the quality cost categories; do you know the quality cost items; currently, how is your quality cost calculated and budgeted for the quality department. From the interview, we discovered most laboratory does not measure COQ, and there is a lack of knowledge about COQ. Also, from the interview, the most items measured within labs were quality control material cost, calibration cost, employee training cost, lab error cost, and customer compliant cost.

The direct costs associated with quality-related activities in the laboratory are allocated across various COQs cost categories. In the end, the conclusions, recommendations, and future studies are discussed.

The most commonly used tools for data collection for COQ research are questionnaires, interviews, observation, archives, and mixed methods (Dimitrantzou et al., 2020). Secondary and primary data were collected, the secondary data were derived from previous literature related to COQ, and the primary data were collected by questionnaires, interviews, and lab documents. A draft questionnaire was first evaluated by scholars and

experts and then subjected by a lab technician to a pilot test; the number of the pilot sample should be more than 50. Testing its reliability and ensuring the validity of the questionnaire construct were done (Connelly, 2008; Viechtbauer et al., 2015). The survey was considered sufficiently clear and had all items for each part.

A questionnaire is a set of questions written or typed in a specific order on a form to obtain responses from respondents. The final version of the questionnaire was reliable and valid and consisted of seven parts; the first part was related to the demographic data of the laboratories and contained 16 items. The second part was on the prevention cost practices and had ten items, the third part was on appraisal cost practices and contained ten items, and the fourth part was on internal failure cost practices and contained ten items. The fifth part was on external failure cost practices and had ten items. The sixth part was on the COQ practices' impact on laboratory performance and contained 13 items. Finally, the seventh part was on the challenges that face application of cost of quality and had ten items. Two versions of the questionnaire were created, one in Arabic and the second with English versions, as shown in Appendix A and B1. A 1-5 Likert scale was used for COQ and laboratory performance dimensions. The respondents were asked to reply to their observations on their laboratory practice that are most accurate. On the 5 Likert scales, the one response reflects “strong agree,” the two responses reflect “agree,” the three responses reflect “neutral,” and the four responses reflect “disagree.” The five responses reflect “strong disagree.”

The target population of this study is the medical laboratories in the West Bank and Jerusalem. More than 700 laboratories in the West Bank are based on the MTA list. Inclusion and exclusion criteria were applied when selecting the laboratories; the inclusion sample was the laboratories that have a license based on the MTA list (2021).

On the other hand, the exclusion sample was the laboratories that did not have a license and any lab having an age less than three years. After applying the inclusion and exclusion criteria, 500 laboratories matched the criteria.

By applying a Thompson (2012) equation shown below in equation (1) using a confidence interval of 95% and an error margin of 5%, the sample size should be 217 labs from the total population, but usually, not all labs would report a response to the questionnaire so to avoid the effect of low response rate, we distributed 344 questionnaires based on distribution rate equation.

Thompson equation:

$$n = \frac{N \times P \times (1 - P)}{\left[(N - 1) \times \left(\frac{d^2}{z^2}\right) + p \times (1 - p)\right]} \dots\dots\dots\dots\dots\dots\dots\dots (1)$$

Where N=Population size (which is 500)

n = Sample size (which is found to be 217)

p= probability (equals 0.5)

z= confidence level at 95 % (1.96)

d= error proportion (equals 0.05)

Distribution size = needed sample size/response rate (we use the response rate 57%).

An electronic questionnaire was used (see Appendix B2). The questionnaire was forwarded to the quality managers of these laboratories in the West Bank; all labs were allowed to answer the survey online using a Microsoft form delivered to all lab supervisors. The questionnaire was sent to medical laboratory quality managers by email, SMS, WhatsApp, and Facebook. To avoid missing data, we coded all questions as needed.

Over two months, the total number of collected questionnaires was 235, with a response rate of 68.3%.

The data collected by the questionnaire was analyzed by applying a statistical analysis technique provided in a computerized software system, SPSS, and AMOS. Firstly, we checked the outlier by using boxplot analysis, and there are no outliers within the COQ dimension. So, the analyzed data results help answer research questions and directly indicate the perceived level of laboratories' managers regarding COQ within medical laboratories.

Our research examines the effect of COQ practices on laboratory performance, as the performance of laboratories was measured through operational laboratory performance based on a managerial perspective only in this study. Also, the performance can be measured through financial performance, but most laboratories refused to provide us with the required information during this study, so we didn't measure it. This study didn't examine performance from a customer's perspective, but this may be done in future studies. We can use surveys, focus groups, online feedback forms, and any other method to learn what customers think about the services provided by laboratories. Operational performance refers to the measurable characteristics of the outputs of an organization's processes, such as reliability, production cycle time, and inventory turns. Operational success, in turn, affects company performance measurements such as market share and customer satisfaction (Kaydos, 2020). Our study used laboratory quality indicators from previous research to examine laboratory performance (LP), as shown in Appendix E and table 4.

3.2 Validity and Reliability

A pilot study was conducted to assess the validity and reliability of the questionnaire by collecting 83 samples from laboratories which were then excluded from the final data analysis.

We first assess the sampling adequacy by measuring KMO and P-value, which should be greater than 0.6 and less than 0.05, respectively, according to (Kaiser et al., 1974). Using SPSS, the results were 0.773 and 0.000 for KMO and P-value, respectively, indicating that the data is adequate and appropriate and can be used for analysis, as shown in Table 5.

Table 5. KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		0.773
Bartlett's Test of Sphericity	Approx. Chi-Square	6893.136
	df	1953
	Sig.(P-value)	0.000

The Cronbach's Alpha score was calculated to determine the reliability of the questionnaire used in the study. A Cronbach's Alpha score of 0.7 or higher indicates that the questionnaire is reliable (Kline, 1999). The study's overall Cronbach's Alpha score was 0.962, which is higher than the minimum criteria of 0.7. Also, the Cronbach's Alpha score for all constructs was between 0.94 and 0.97, which is also above 0.7, as shown in Table 6. As a result, the questionnaire used in the study was reliable.

Table 6. The Cronbach's Alpha score for all variables and questionnaire construct.

Dimension /variables	**Composite Reliability**	**Cronbach's Alpha**	**Number of items**	**Accepted Cronbach's Alpha**
All variable	***	0.962	63	Accepted
PC dimension	0.970	0.970	10	Accepted
AC dimension	0.967	0.966	10	Accepted
IFC dimension	0.961	0.961	10	Accepted
EFC dimension	0.956	0.969	10	Accepted

LP dimension	0.969	0.968	13	Accepted
CFA dimension	0.941	0.940	10	Accepted

According to a literature review, researchers and experts classified variables with similar loading under the same factor, referred to as face validity. Firstly, exploratory factor analysis was used to assess the validity of the questionnaire variable used in the study. To analyze the association between the variables and the factor, the factor loading is determined using SPSS. All variables are categorized into six factors if factor loading is greater than 0.6 (Hair et al., 2010 Table 3-2) and cross-loadings differ by more than 0.2. All variables in the table have a loading factor of more than 0.6, and there are no variables with cross-loading less than 0.2, so the questionnaire variables are valid. The six-factor named prevention cost dimension, appraisal cost dimension, internal failure cost dimension, external failure cost dimension, laboratory performance dimension, and challenges face application of cost of quality. The six-factor explained 76.4(eigenvalues) of the total variances.

Secondary confirmatory factor analysis (CFA) examined convergent and discriminant validity. The convergent validity is assessed by using Average Variance Extracted (AVE) and standardized factor loading. The AVE values above 0.5 are acceptable (Fornell and Larcker, 1981), and factor loading above 0.7 is acceptable (Hair et al., 2014). From Table ,7 all dimensions have AVE above 0.5 and outer loading for all items above 0.7, so the questionnaire is valid. The discriminant validity is assessed by using the Fornell-larcker criterion. The AVE of each construct can be compared to the squared inter-construct correlation, according to the Fornell-larcker criterion. From Table 8, the prevention cost AVE (0.767), so its square root (0.876) is above the inter-construct correlation values. All

of the other constructs in Table 8 show a similar pattern. As a result of the findings, discriminant validity appears to be well established.

Table 7. Confirmatory factor analysis

Variable	Construct	Loadings	AVE	CR
PC10	PC	0.857	0.767	0.971
PC9		0.867		
PC8		0.807		
PC7		0.877		
PC6		0.896		
PC5		0.898		
PC4		0.882		
PC3		0.953		
PC2		0.925		
PC1		0.787		
EFC1	EFC	0.988	0.707	0.959
EFC2		0.747		
EFC3		0.715		
EFC4		0.713		
EFC5		0.984		
EFC6		0.819		
EFC7		0.746		
EFC8		0.872		
EFC9		0.753		
EFC10		0.997		
AC10	AC	0.835	0.743	0.967
AC9		0.856		
AC8		0.872		
AC7		0.869		
AC6		0.761		
AC5		0.913		
AC4		0.862		
AC3		0.86		
AC2		0.861		
AC1		0.925		
LPI13	LP	0.835	0.704	0.968
LPI12		0.822		
LPI11		0.851		
LPI10		0.913		
LPI9		0.857		
LPI8		0.816		
LPI7		0.878		
LPI6		0.857		
LPI5		0.820		
LPI4		0.796		

LPI3		0.862		
LPI2		0.840		
LPI1		0.753		
CFA1	CFA	0.775	0.615	0.941
CFA2		0.828		
CFA3		0.859		
CFA4		0.713		
CFA5		0.789		
CFA6		0.803		
CFA7		0.754		
CFA8		0.775		
CFA9		0.774		
CFA10		0.763		
IFC10	IFC	0.943	0.713	0.961
IFC9		0.802		
IFC8		0.744		
IFC7		0.817		
IFC6		0.916		
IFC5		0.785		
IFC4		0.923		
IFC3		0.853		
IFC2		0.900		
IFC1		0.735		

Table 8. Fornell-Larcker's criterion result

	CFA	**PC**	**EFC**	**AC**	**LP**	**IFC**
CFA	**0.784**					
PC	0.177	**0.876**				
EFC	0.116	0.379	**0.841**			
AC	-0.128	0.235	0.387	**0.862**		
LP	-0.119	0.472	0.587	0.443	**0.839**	
IFC	-0.059	0.143	0.312	0.569	0.306	**0.845**

3.3Assessment of the Normality

Though parametric statistics can be applied to Likert data (Norman, 2010), an analysis of data normality is required for many statistical tests since normal data is an underlying assumption in parametric testing. There are two basic techniques for evaluating normality: graphically (Histogram or normal Q-Q Plot) and numerically (Shapiro–Wilk test, skewness, and kurtosis). In this study, we used skewness and kurtosis to check the normality of data (Groeneveld & Meeden, 1984). The normal skewness and kurtosis

statistic values are between + 1 and -1 (Hair et al., 2010) or can use the following criteria (Kim, 2013; Kline, 2016).

- For samples, less than 50 use the absolute z-scores for either skewness or kurtosis are larger than 1.96
- For samples, more than 50 and less than 300 use the absolute z-value over 3.29.
- For a sample of more than 300, use the absolute values of skewness and kurtosis without considering z-values. (Skewness +- 2 and kurtosis +-7).

George and Mallery (2020) stated that skewness and kurtosis values between ±1.0 are excellent for most psychometric purposes, but values between ±2.0 are in many cases also acceptable. From Table 9 and based on the above criteria, the data are normally distributed

Table 9. Normality test skewness and kurtosis.

	Skewness		**Kurtosis**	
	Statistic	Std. Error	Statistic	Std. Error
Prevention cost	0.389	0.159	-1.072	0.316
Appraisal cost	0.350	0.159	-0.864	0.316
Internal failure cost	0.292	0.159	-1.182	0.316
External failure cost	0.063	0.159	-0.237	0.316
Laboratory performance	0.614	0.159	-1.302	0.316

Chapter 4: Data Analysis and Results

4.1 Overview

Chapter four discusses our findings and their relation to our conceptual framework. As part of this chapter, we apply theories to our data to determine whether or not medical laboratories measure COQ. In addition, we investigate the relationship between COQ practices and laboratory performance. In addition, we examine the impact of laboratory size, ISO certification, and the presence of a quality department on COQ and laboratory performance, among other things.

4.2 Descriptive Statistics

In this study, we used descriptive statistics in the form of percentages to describe the demographics of the respondents, such as the age of labs, location, lab sector, number of an employee, etc. All these descriptive statistics are shown in Table 10.

From Table 10, about 81.7% of the laboratories do not measure COQ using the approved method. Also, 51.1% of the respondents stated that they don't know if the lab calculates COQ or not. In addition, about 63.8% of laboratories don't have a quality department. Also, about 51.1% of respondent laboratories are separated labs. Based on the number of patients per month, most of the laboratories participating in the study are small and medium-sized (77.4%). About 44.3% of responding laboratories are small (under 500 patients per month), 33.2 %are medium (501-1000), and 22.6% are large (above 1000). Also, a %of 83.8% of laboratories don't have ISO certification. Also, 94.5% of the laboratories don't have CAB certification. The findings suggest that the samples were obtained from medical labs from all governorates of the West Bank, where the biggest proportion was from the Hebron governorate (30.6%), followed by Ramallah (20 %) and Nablus (15.3%) governorates. Respondents who declared to have a COQ established were

asked to give information about the scale of quality costs at their laboratory. As mentioned by most medical labs, the magnitude of quality costs varies from 5 to 30% of sales revenues. The figures reveal that the respondents have work experience, that 38.7% have 11 to 15 experience while 27.2% have 6 to 10 years of experience.

The results also show that 28.1% of respondents reported the option 0-9 years of the lab age, 25.1% chose the option 10-19 years, 32.3% chose the option 20-29 years, 7.7% chose the option 30-39 years and 6.8%chose the option ≥ 40 years.

Table 10. Descriptive statistics analysis for demographic data

Code	Characteristic	Alternative	Percentage
Dem 1	Lab age (years)	0-9	28.1%
		10-19	25.1%
		20-29	32.3%
		30-39	7.7%
		≥ 40	6.8%
Dem 2	Lab sector	Private	57.9%
		Governmental	32.8%
		Non-Profit	9.4%
Dem 3	Number of employees	1-5	30.7%
		6-10	34%
		11-20	23%

		>20	12.3%
Dem 4	Lab apart from	Part from hospital Part from clinics separated lab	21.3% 27.7% 51.1%
Dem 5	Is the laboratory a part of a regulating business organization?	No Yes	82.6% 17.4%
Dem 6	Lab location	Bethlehem Jenin Tulkarem Jericho Jerusalem Nablus Ramallah Hebron Qalqilya Salfit Tubas Al-Eizariya	9.4% 6% 7.7% 1.7% 0.9% 15.3% 20% 30.6% 3.4% 0.9% 2.6% 1.7%

Dem 7	Lab workload	Small (0-500 patient/month) Medium (501-1000) Large (>1001)	44.3% 33.2% 22.6%
Dem 8	The lab has a branch	No Yes	78.7% 21.3%
Dem 9	The lab has a quality department	No Yes	63.8% 36.2%
Dem 10	The lab has an ISO 15189 certification	No Yes	83.8% 16.2%
Dem 11	Lab calculates COQ using an approved method	No Yes	81.7% 18.3%
Dem 12	Department responsible for calculating COQ	Quality department Financial department Purchasing department All departments Not calculated Quality and financial Quality and Purchasing	20.4% 4.3% 0.4% 6.8% 65.5% 1.3% 0.4%

		Financial and purchasing	0.9%
Dem 13	Percent of COQ from the total cost	5 %	2.6%
		10 %	4.3%
		15 %	2.1%
		20 %	0.4%
		30%	0.4%
		Not calculated	35.3%
		I don't know if the lab calculates it.	51.1%
		The financial department estimates it but doesn't give us the result.	3.8%
Dem 14	The lab has a CAB certification	No	94.5%
		Yes	5.5%
Dem 15	Job Title	General manager	2.1%
		Quality manager	11.5%
		Lab director	71.5%
		Lab technician	14.5%
		Other	0.4%

Dem 16	Work experiences	1-5	8.5%
		6-10	27.2%
		11-15	38.7%
		16-20	15.7%
		>20	9.4%

Finally, we evaluate the influence of moderating variables such as lab workload, ISO certification, and existent quality department on the relationship between COQ practices and laboratory performance by using multiple regression using SPSS also using SPSS AMOS to confirm the result.

To check the reality of COQ in medical laboratories, the COQ dimension was analyzed using descriptive statistics using the 5-point Likert scale range (Pimentel, 2010). The five point-Likert scales is considered an interval scale. The mean is very significant. From 1 to 1.79, it means strongly disagree. From 1.8 to 2.59, it means to disagree. From 2.60 to 3.39, it means neutral. From 3.40 to 4.19, it means to agree. From 4.20 to 5, it means strongly agree. Regarding implementation level, scores 1–2.339 are low, scores 2.34–3.669 are medium, and measures 3.67–5.00 are high.

Firstly, we calculate the mean for all items and dimensions. Table 11 shows descriptive statistics for prevention cost activity measuring within medical laboratories. From which we find that the respondents only agree to measure the activity cost of employee training (Mean 3.53, Std. Deviation 1.28) and cost of preventive maintenance (Mean 3.57, Std. Deviation 1.22). In addition, the respondent's answers for the remaining activity with disagree and neutral, as shown in Table 11. The weighted average of the prevention cost

dimension was 2.53,8 and Std. Deviation 0.898 indicates that the trend of the respondent is (Disagree, medium implementation).

Table 11. Descriptive statistics for prevention cost activity measuring within medical laboratories

Item	N	Mean	Std. Deviation	Implementation level
Your lab set a budget for employee training	235	3.530	1.285	medium
Your lab sets a budget to determine the material quality requirement	235	2.370	1.356	medium
Your lab sets a budget for process verification or validation	235	2.780	1.411	medium
Your lab set a budget for instrument preventive maintenance	235	3.570	1.229	medium
Your lab set a budget for risk management	235	1.870	1.276	low
Your lab set a budget for SOP preparation	235	2.200	1.455	low
Your lab set a budget for providing high-quality service	235	2.150	1.445	low
Your lab set a budget for the development of lab design	235	1.940	1.353	low

Your lab set a budget to prepare an internal audit program	235	2.410	1.422	medium
Your lab set a budget to modify process workflow	235	2.560	1.330	medium
Prevention Cost –Mean	**235**	**2.538**	**0.898**	**medium**

Table 12 shows descriptive statistics for appraisal cost activity measuring within medical laboratories. From which we find that the respondent only agrees to measure activity cost of calibration (Mean 3.51, Std. Deviation 1.347), cost of quality control (Mean 3.72, Std. Deviation 1.115), and costs for comparisons between labs (Mean 3.51, Std. Deviation 1.282). Also, the respondent answers the remaining activity with disagree, as shown in Table 12. The weighted average of appraisal cost dimension was 2.581, and Std. Deviation 0.745, which indicates medium implementation.

Table 12. Descriptive statistics for appraisal cost activity measuring within medical laboratories.

Items	**N**	**Mean**	**Std. Deviation**	**Implementation level**
Your lab determines costs for devices and equipment used in quality inspection	235	2.000	1.299	low
Your lab calculates the costs to test and inspect the purchased raw materials	235	2.220	1.114	low

Your lab calculates the cost of performing an internal audit	235	2.040	1.265	low
Your lab set a budget to get external certification (ISO/CAB)	235	2.170	1.276	low
Your lab calculates costs for supervision of the inspection staff	235	2.310	1.314	low
Your lab calculates costs for comparisons between labs.	235	3.510	1.282	medium
Your lab calculates the cost of performing an external audit	235	2.170	1.242	low
Your lab calculates the cost of performing material and instrument calibration	235	3.510	1.347	medium
Your lab calculates the cost of performing an internal audit on the supportive department	235	2.170	1.205	low
Your lab calculates costs for internal quality control	235	3.720	1.115	high
Appraisal Cost-Mean	**235**	**2.581**	**0.745**	**medium**

Table 13 shows descriptive statistics for internal failure cost activity measured within medical laboratories. from which we find that the respondent only agrees to measure the

activity cost of test rerun (Mean 3.49, Std. Deviation 1.424), costs of QC rerun (Mean 3.66, Std. Deviation 1.347), and the costs of the instrument and material recalibration. (Mean 3.53, Std. Deviation 1.255). Furthermore, the respondents answered for the remaining activity disagree and neutral, as shown in Table 13. The weighted average of the internal failure cost dimension was 2.9, and Std. Deviation 0.961 indicates medium implementation.

Table 13. Descriptive statistics for internal failure cost activity measuring within medical laboratories.

Items	N	Mean	Std. Deviation	Implementation level
Your lab calculates costs for returning materials that did not meet the quality requirement	235	2.430	1.317	medium
Your lab calculates the costs of lost material	235	2.880	1.256	medium
Your lab calculates the costs of test rerun	235	3.490	1.424	medium
Your lab calculates the costs of QC rerun	235	3.660	1.347	medium
Your lab calculates the costs of the instrument and material recalibration.	235	3.530	1.255	medium

Your lab calculates the costs of patient data reentry	235	2.600	1.245	medium
Your lab calculates the costs of sample recollection	235	2.480	1.262	medium
Your lab calculates the costs of lab incident	235	2.670	1.271	medium
Your lab calculates the costs of samples lost	235	2.600	1.324	medium
Your lab calculates the costs of taking corrective action	235	2.670	1.307	medium
Internal Failure Cost-Mean	**235**	**2.900**	**0.961**	**medium**

Table 14 shows descriptive statistics for external failure cost activity measured within medical laboratories. From which we find that the respondent only agrees to measure activity cost of handling customer compliant (Mean 3.41, Std. Deviation 1.382), costs of lab error reached to the patient (Mean 3.54, Std. Deviation 1.403), cost of conducting free examinations for the patient with whom the lab error occurred (Mean 3.46, Std. Deviation 1.369) and the cost of repeated tests issued to patients with an error (Mean 3.4, Std. Deviation 1.375). Moreover, the respondents answered for the remaining activity disagree, as shown in Table 14. The weighted average of the internal failure cost dimension was 2.555, and Std. Deviation 0.680 indicates medium implementation.

Table 14. Descriptive statistics for external failure cost activity measuring within medical laboratories.

items	N	Mean	Std. Deviation	Implementation level
Your lab calculates the costs of handling customer compliant	235	3.410	1.382	medium
Your lab calculates the costs of lab error reached to patient	235	3.540	1.403	medium
Your lab calculates the costs of dealing with the courts as a result of lab errors	235	1.980	1.145	low
Your lab calculates the costs of treating the patient in case of complications as a result of the lab error	235	1.740	1.156	low
Your lab calculates the cost of conducting free examinations for the patient with whom the lab error occurred	235	3.460	1.369	medium
Your lab calculates the cost of the correction lab report reached to the patient with an error	235	2.070	1.319	low

Your lab calculates the cost of the penalty clause of contracts in the event of non-fulfillment	235	2.140	1.301	low
Your lab calculates the costs resulting from the loss of the market value of the laboratory as a result of lab errors	235	1.940	1.278	low
Your lab calculates the cost of repeated tests issued to patients with an error	235	3.400	1.375	medium
Your lab calculates the cost of customers losing	235	1.870	1.203	low
External Failure Cost-Mean	**235**	**2.550**	**0.680**	**medium**

Table 15 shows descriptive statistics for laboratory performance within medical laboratories. From which we find that the respondent only agrees with decreased instrument downtime (Mean 3.69, Std. Deviation 1.210), decreased the percentage of test reruns (Mean 3.75, Std. Deviation 1.198), the lab focuses on developing the employees' qualifications (Mean 3.66, Std. Deviation 1.262) and Patient satisfaction with service quality is increased (Mean 3.62, Std. Deviation 1.323). Also, the respondents answer for the remaining activity with Disagree and Neutral, as shown in Table 15. The weighted average of laboratory performance dimensions was 3.0124, and Std. Deviation 0.88512

Table 15. Descriptive statistics for laboratories performance within medical laboratories.

Items	N	Mean	Std. Deviation	Implementation level
Lab errors decrease	235	3.380	1.392	medium
Patient satisfaction with service quality is increased	235	3.620	1.323	medium
Material lost are decreased	235	2.490	1.379	medium
Lab workload is increased	235	3.030	1.394	medium
Employee satisfaction is increased	235	2.310	1.151	low
Your lab focuses on developing the employees' skills	235	3.660	1.262	medium
The percentage of test falling out of range in external quality control are decreased	235	2.830	1.355	medium
The percentage of test reruns is decreased	235	3.750	1.198	high
The average number of tests per employee is increased	235	2.940	1.434	medium
Lab incidents are decreased	235	2.380	1.352	medium
Instrument downtime is decreased	235	3.690	1.210	high
The percentage of lab errors did not send to the patient by he asked are decreased	235	2.650	1.273	medium
The number of the electronic program is increased to decrease lab errors	235	2.430	1.395	medium
Laboratory Performance-Mean	**235**	**3.012**	**0.885**	**medium**

The lack of experience in calculating COQ (Mean 3.3.66) is the first and most significant cause for laboratories not measuring COQ, as shown in Table 16. Following that, there is a lack of knowledge in calculating COQ (Mean 3.63. The remaining reasons for not measuring COQ are less significant. From Table 16, the most obstacles to estimating the cost of quality are the lack of a good accounting system for calculating the cost of quality, the difficulty of evaluating the cost of each activity, the difficulty of defining the activities that are used to calculate the cost of quality and increasing the paperwork with a mean value range between 3.81 and 3.61.

Table 16. Descriptive statistics for challenges facing the application of cost of Quality

Items	N	Mean	Std. Deviation	Implementation level
Ignoring the benefits of calculating the COQ is one of the reasons for not measuring it	235	3.390	1.257	medium
Lack of knowledge of how to calculate COQ is one of the reasons for not measuring it	235	3.630	1.043	medium
Lack of experience in how to calculate COQ is one of the reasons for not measuring it	235	3.660	1.129	medium

Lack of interest of top management is one of the reasons for not measuring COQ	235	3.220	1.095	medium
The inability to cover the expenses of calculating the cost of quality is one of the reasons for not measuring it	235	3.220	1.022	medium
Increasing the paperwork is one of the obstacles to calculating the cost of quality	235	3.610	1.173	medium
The difficulty of defining the activities that are used to calculate the cost of quality is one of the obstacles to calculating the cost of quality	235	3.610	1.236	medium
The difficulty of evaluating the cost of each activity is one of the obstacles to calculating the cost of quality	235	3.790	1.217	high
The difficulty of calculating the time that employees need for some activities is one of	235	3.190	1.082	medium

the obstacles to calculating the cost of quality				
The lack of a good accounting system for calculating the cost of quality is one of the obstacles to calculating the cost of quality	235	3.810	1.152	high
Challenges Face Application of Cost of Quality-Mean	**235**	**3.514**	**0.701**	**medium**

Table 17 presents the descriptive statistics for implementing COQ and laboratory performance amongst sectors. We discover that the implementation level between the private, governmental and nonprofit sectors is approximately similar.

Table 17. Descriptive statistics for implementation of COQ and laboratory performance between sectors

Item	**Sector**					
	Private sector		**Governmental sector**		**Nonprofit sector**	
	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean
Prevention cost mean	2.52	0.08	2.70	0.08	2.11	0.16

Appraisal cost mean	2.56	0.07	2.71	0.08	2.29	0.15
Internal failure cost mean	2.82	0.09	3.20	0.10	2.35	0.17
External failure cost mean	2.57	0.06	2.62	0.07	2.24	0.11
Laboratory performance mean	2.92	0.08	3.30	0.09	2.61	0.13

Table 18 presents ANOVA implementation COQ and laboratory performance amongst sectors. From ANOVA analysis, the significant value for prevention cost, internal failure cost, and laboratory performance are less than 0.05, so we conclude that there is a statistically significant difference between sectors also the significant value for appraisal cost and external failure cost more than 0.05 so we conclude that there is no a statistically significant difference between sectors.

Table 18. ANOVA analysis for implementation COQ and laboratory performance between sectors

ANOVA						
Item		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Prevention cost mean	Between Groups	6.020	2	3.010	3.822	0.023
	Within Groups	182.737	232	0.788		
	Total	188.758	234			
Appraisal cost mean	Between Groups	3.106	2	1.553	2.839	0.060
	Within Groups	126.886	232	0.547		
	Total	129.991	234			
Internal failure cost mean	Between Groups	14.230	2	7.115	8.165	0.000

	Within Groups	202.170	232	0.871		
	Total	216.400	234			
External failure cost mean	Between Groups	2.571	2	1.286	2.818	0.062
	Within Groups	105.848	232	0.456		
	Total	108.420	234			
Laboratory performance mean	Between Groups	11.056	2	5.528	7.445	0.001
	Within Groups	172.268	232	0.743		
	Total	183.325	234			

From the descriptive statistics presented in Table 19, we can see that the level of implementation within labs that have ISO certification is higher than the level of implementation within laboratories that do not have a certificate, which leads us to believe that labs with ISO certification are more effective than labs without certification but due to the sample labs that have ISO certification, we cannot generalized it. To confirm this, we do moderator analysis.

Table 19. Descriptive statistics for laboratories that have ISO certification or not.

Item	**Laboratory having ISO certification**			
	No		**Yes**	
	Mean	**Standard Error of Mean**	**Mean**	**Standard Error of Mean**
Prevention cost mean	2.31	0.06	3.72	0.07
Appraisal cost mean	2.38	0.04	3.62	0.06
Internal failure cost mean	2.66	0.06	4.15	0.07
External failure cost mean	2.39	0.04	3.39	0.08
Laboratory performance mean	2.83	0.06	3.98	0.07

From the ANOVA analysis presented in Table 20, the significance value for all dimensions is less than 0.05, so we conclude that there are statistically significant differences between labs that have or do not have ISO certification. We can see that the level of implementation within labs that have ISO certification is higher than the level of implementation within laboratories that do not have a certificate, which leads us to believe that labs with ISO certification are more effective than labs without certification but due to the sample labs that have ISO certification we cannot generalized it. To confirm this, we do moderator analysis.

Table 20. ANOVA analysis laboratories that have ISO certification or not.

ANOVA						
Item		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Prevention cost mean	Between Groups	63.367	1	63.367	117.748	0.000
	Within Groups	125.391	233	0.538		
	Total	188.758	234			
Appraisal cost mean	Between Groups	48.968	1	48.968	140.816	0.000
	Within Groups	81.024	233	0.348		
	Total	129.991	234			
Internal failure cost mean	Between Groups	70.828	1	70.828	113.366	0.000
	Within Groups	145.572	233	0.625		
	Total	216.400	234			
External failure cost mean	Between Groups	31.908	1	31.908	97.169	0.000
	Within Groups	76.512	233	0.328		
	Total	108.420	234			
	Between Groups	42.238	1	42.238	69.755	0.000

Laboratory performance mean	Within Groups	141.086	233	0.606		
	Total	183.325	234			

From the descriptive statistics presented in Table 21, we can see that the level of implementation within labs that have quality departments is higher than the level of implementation within laboratories that do not have a quality department, which leads us to believe that labs have quality department are more effective than labs without. To confirm this, we do moderator analysis.

Table 21. Descriptive statistics for laboratories that have a quality department or not.

Item	**The laboratory has a Quality department**			
	No		**Yes**	
	Mean	**Standard Error of Mean**	**Mean**	**Standard Error of Mean**
Prevention cost mean	2.03	0.05	3.44	0.06
Appraisal cost mean	2.17	0.04	3.30	0.06
Internal failure cost mean	2.34	0.05	3.89	0.06
External failure cost mean	2.21	0.04	3.17	0.06
Laboratory performance mean	2.55	0.06	3.83	0.05

From the ANOVA analysis presented in Table 22, the significance value for all dimensions is less than 0.05, so we conclude that there are statistically significant differences between labs that have a quality department or not. We can see that the

implementation level within labs with quality departments is higher than the level of implementation within laboratories that do not have a quality department, which leads us to believe that labs with quality departments are more effective than labs not have. To confirm this, we do moderator analysis.

Table 22. ANOVA analysis for laboratories that has a quality department or not.

ANOVA						
Item		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Prevention cost mean	Between Groups	109.020	1	109.020	318.566	0.000
	Within Groups	79.738	233	0.342		
	Total	188.758	234			
Appraisal cost mean	Between Groups	68.708	1	68.708	261.225	0.000
	Within Groups	61.284	233	0.263		
	Total	129.991	234			
Internal failure cost mean	Between Groups	130.052	1	130.052	350.929	0.000
	Within Groups	86.348	233	0.371		
	Total	216.400	234			

External failure cost mean	Between Groups	49.957	1	49.957	199.099	0.000
	Within Groups	58.463	233	0.251		
	Total	108.420	234			
Laboratory performance mean	Between Groups	87.998	1	87.998	215.085	0.000
	Within Groups	95.327	233	0.409		
	Total	183.325	234			

The descriptive statistics presented in Table 23 show that the implementation level within labs with large workloads is higher than the implementation level within laboratories with small and medium workloads. To confirm this, we do moderator analysis.

Table 23. Descriptive statistics for laboratories with different workloads.

Item	**Lab workload**					
	Small (0-500 patient/month)		**Medium (501-1000)**		**Large (>1001)**	
	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean
Prevention cost mean	1.99	0.06	2.53	0.08	3.64	0.07

Appraisal cost mean	2.11	0.04	2.60	0.07	3.49	0.06
Internal failure cost mean	2.28	0.06	2.94	0.09	4.06	0.08
External failure cost mean	2.20	0.05	2.49	0.06	3.36	0.08
Laboratory performance mean	2.47	0.07	3.10	0.09	3.93	0.06

From the ANOVA analysis presented in Table 24, the significance value for all dimensions is less than 0.05, so we conclude that there are statistically significant differences between lab workloads. We can see that the implementation level within labs with large workloads is higher than the level of implementation within laboratories with small and medium workloads. To confirm this, we do moderator analysis.

Table 24. ANOVA analysis for laboratories with different workload

ANOVA						
Item		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Prevention cost mean	Between Groups	96.065	2	48.032	120.219	0.000
	Within Groups	92.693	232	0.400		

	Total	188.758	234			
Appraisal cost mean	Between Groups	66.887	2	33.444	122.954	0.000
	Within Groups	63.104	232	0.272		
	Total	129.991	234			
Internal failure cost mean	Between Groups	111.299	2	55.649	122.840	0.000
	Within Groups	105.101	232	0.453		
	Total	216.400	234			
External failure cost mean	Between Groups	47.650	2	23.825	90.958	0.000
	Within Groups	60.769	232	0.262		
	Total	108.420	234			
Laboratory performance mean	Between Groups	75.640	2	37.820	81.482	0.000
	Within Groups	107.684	232	0.464		
	Total	183.325	234			

Table 25 presents the descriptive statistic for implementation COQ and laboratory performance amongst lab ages, from which we discover that the implementation level between labs age categories is approximately similar.

Table 25. Descriptive statistics for laboratories' age categories.

Item	**Lab age**									
	0-9		**10-19**		**20-29**		**30-39**		**>=40**	
	Mean	Std Error of Mean	Mean	Std Error of Mean	Mean	Std Error of Mean	Mean	Std Error of Mean	Mean	Std Error of Mean
Prevention cost mean	2.52	0.12	2.40	0.12	2.49	0.10	2.73	0.21	3.11	0.17
Appraisal cost mean	2.58	0.09	2.51	0.10	2.56	0.08	2.61	0.19	2.96	0.16
Internal failure cost mean	2.86	0.12	2.72	0.12	2.89	0.11	3.06	0.22	3.59	0.18
External failure cost mean	2.53	0.09	2.50	0.08	2.59	0.08	2.54	0.16	2.71	0.17
Laboratory performance mean	3.00	0.11	2.80	0.11	2.95	0.10	3.47	0.22	3.60	0.16

Table 26 presents ANOVA analysis and descriptive statistics for implementation of COQ and laboratory performance amongst lab age. The significance value for prevention, appraisal and external failure cost more than 0.05, so we conclude that there is no significant difference between lab ages. Furthermore, the significant value for internal failure cost and laboratory performance is less than 0.05, so we conclude that there is a significant difference between lab ages.

Table 26. ANOVA analysis for implementation COQ and laboratory performance between labs age categories.

ANOVA						
Item		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Prevention cost mean	Between Groups	7.174	4	1.793	2.272	0.062
	Within Groups	181.584	230	0.789		
	Total	188.758	234			
Appraisal cost mean	Between Groups	2.632	4	0.658	1.188	0.317
	Within Groups	127.359	230	0.554		
	Total	129.991	234			
Internal failure cost mean	Between Groups	10.088	4	2.522	2.812	0.026
	Within Groups	206.312	230	0.897		

	Total	216.400	234			
External failure cost mean	Between Groups	0.667	4	0.167	0.356	0.840
	Within Groups	107.753	230	0.468		
	Total	108.420	234			
Laboratory performance mean	Between Groups	12.192	4	3.048	4.097	0.003
	Within Groups	171.132	230	0.744		
	Total	183.325	234			

Table 27 presents the descriptive statistic for implementation COQ and laboratory performance amongst the number of employees, from which we discover that the implementation level between numbers of employee categories is approximately similar.

Table 27. Descriptive statistics for implementation COQ and laboratory performance between numbers of employee categories.

Item	**Number of employees**							
	1-5		**6-10**		**11-20**		**>20**	
	Mean	Std Error of Mean	Mean	Std Error of Mean	Mean	Std Error of Mean	Mean	Std Error of Mean

Prevention cost mean	2.94	0.12	2.08	0.08	2.55	0.11	2.79	0.13
Appraisal cost mean	2.82	0.09	2.28	0.07	2.62	0.11	2.75	0.10
Internal failure cost mean	3.20	0.11	2.45	0.09	2.93	0.14	3.33	0.11
External failure cost mean	2.77	0.09	2.33	0.06	2.65	0.10	2.47	0.09
Laboratory performance mean	3.30	0.10	2.58	0.09	2.98	0.12	3.55	0.11

Table 28 presents an ANOVA analysis of COQ implementation and laboratory performance amongst labs with different numbers of employees. From which the significance value for all dimensions is less than 0.05, so we conclude that there is a statistically significant difference between labs that have a different number of employees.

Table 28. ANOVA analysis for implementation COQ and laboratory performance between numbers of employee categories.

ANOVA					
Item	**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**

Prevention cost mean	Between Groups	30.434	3	10.145	14.801	0.000
	Within Groups	158.324	231	0.685		
	Total	188.758	234			
Appraisal cost mean	Between Groups	12.217	3	4.072	7.987	0.000
	Within Groups	117.775	231	0.510		
	Total	129.991	234			
Internal failure cost mean	Between Groups	28.038	3	9.346	11.462	0.000
	Within Groups	188.362	231	0.815		
	Total	216.400	234			
External failure cost mean	Between Groups	8.159	3	2.720	6.266	0.000
	Within Groups	100.261	231	0.434		
	Total	108.420	234			
Laboratory performance mean	Between Groups	29.167	3	9.722	14.569	0.000
	Within Groups	154.157	231	0.667		

	Total	183.325	234			

Table 29 presents the descriptive statistic for implementation of COQ and laboratory performance amongst labs part from the hospital, labs part from the clinic, and separated labs. We discover that the implementation level is approximately similar.

Table 29. Descriptive statistics for implementation of COQ and laboratory performance between labs type.

Item	**lab apart from**					
	Part from hospital		**Part from clinics**		**Independent lab**	
	Mean	**Standard Error of Mean**	**Mean**	**Standard Error of Mean**	**Mean**	**Standard Error of Mean**
Prevention cost mean	2.56	0.12	2.70	0.11	2.44	0.09
Appraisal cost mean	2.68	0.11	2.67	0.09	2.49	0.07
Internal failure cost mean	2.97	0.14	3.05	0.11	2.79	0.09
External failure cost mean	2.58	0.10	2.56	0.08	2.55	0.06
Laboratory performance mean	3.15	0.12	3.21	0.10	2.85	0.08

Table 30 presents an ANOVA analysis for the implementation of COQ and laboratory performance amongst labs part from the hospital, lab from the clinic, and separated labs from which the significance value for COQ dimensions is more than 0.05, so we conclude that there are no statistically significant differences also the significant value for laboratory performance less than 0.05 so we conclude that there is a statistically significant difference between lab from the hospital, lab from the clinic and separated. Furthermore, from descriptive statistics, we discover that the implementation level is approximately similar.

Table 30. ANOVA analysis for the implementation of COQ and laboratory performance between laboratories type

ANOVA						
Item		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Prevention cost mean	Between Groups	3.005	2	1.503	1.877	0.155
	Within Groups	185.752	232	0.801		
	Total	188.758	234			
Appraisal cost mean	Between Groups	2.030	2	1.015	1.840	0.161
	Within Groups	127.962	232	0.552		
	Total	129.991	234			
Internal failure cost mean	Between Groups	3.270	2	1.635	1.780	0.171
	Within Groups	213.130	232	0.919		
	Total	216.400	234			
External failure cost mean	Between Groups	0.030	2	0.015	.033	0.968
	Within Groups	108.389	232	0.467		
	Total	108.420	234			

Laboratory performance mean	Between Groups	6.900	2	3.450	4.537	0.012
	Within Groups	176.425	232	0.760		
	Total	183.325	234			

Descriptive data for the implementation of COQ and the performance of labs are included in Table 31 for laboratories a part of a regulating business organization or are independent. We discover that the level of implementation for labs that are a part of a regulating business organization is somewhat higher than the level of implementation for independent laboratories.

Table 31. Descriptive statistics for implementation of COQ and laboratory performance between laboratories a part of a regulating business organization, or is it independent

Item	**Is the laboratory a part of a regulating business organization?**			
	No		**Yes**	
	Mean	**Standard Error of Mean**	**Mean**	**Standard Error of Mean**
Prevention cost mean	2.35	0.06	3.44	0.10
Appraisal cost mean	2.47	0.05	3.11	0.08
Internal failure cost mean	2.71	0.07	3.78	0.10
External failure cost mean	2.45	0.05	3.07	0.10

Laboratory performance mean	2.85	0.06	3.78	0.07

From ANOVA analysis, the significance value for all dimensions is less than 0.05. As shown in Table 32, we conclude that there are statistically significant differences between labs a part of the company or not. Furthermore, the level of implementation for labs that are part of a company is somewhat higher than the level of implementation for laboratories that are not part of a company.

Table 32. ANOVA analysis for implementation COQ and laboratory performance between laboratories a part of a regulating business organization, or is it independent

ANOVA						
Item		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Prevention cost mean	Between Groups	40.256	1	40.256	63.161	0.000
	Within Groups	148.502	233	0.637		
	Total	188.758	234			
Appraisal cost mean	Between Groups	14.106	1	14.106	28.361	0.000
	Within Groups	115.886	233	0.497		
	Total	129.991	234			

Internal failure cost mean	Between Groups	38.503	1	38.503	50.429	0.000
	Within Groups	177.897	233	0.764		
	Total	216.400	234			
External failure cost mean	Between Groups	13.047	1	13.047	31.875	0.000
	Within Groups	95.372	233	0.409		
	Total	108.420	234			
Laboratory performance mean	Between Groups	29.441	1	29.441	44.577	0.000
	Within Groups	153.884	233	0.660		
	Total	183.325	234			

The descriptive statistics presented in Table 33 show that the implementation level within labs with branches is higher than the level of implementation within laboratories with no branch.

Table 33. Descriptive statistics for implementation of COQ and laboratory performance between labs have a branch or not.

Item	**The lab has a branch**	
	No	**Yes**

	Mean	Standard Error of Mean	Mean	Standard Error of Mean
Prevention cost mean	2.35	0.06	3.25	0.09
Appraisal cost mean	2.47	0.06	2.98	0.07
Internal failure cost mean	2.68	0.07	3.72	0.09
External failure cost mean	2.45	0.05	2.93	0.10
Laboratory performance mean	2.81	0.06	3.77	0.07

From the ANOVA analysis presented in Table 34, the significance value for all dimensions is less than 0.05, so we conclude that there are statistically significant differences between labs that have or do not have a branch. Furthermore, we can see that the implementation level within labs with branches is higher than the level of implementation within laboratories with no branch.

Table 34. ANOVA for implementation COQ and laboratory performance between labs have a branch or not.

Item	Sum of Squares	df	Mean Square	F	Sig.

Prevention cost mean	Between Groups	31.952	1	31.952	47.478	0.000
	Within Groups	156.806	233	0.673		
	Total	188.758	234			
Appraisal cost mean	Between Groups	10.279	1	10.279	20.007	0.000
	Within Groups	119.712	233	0.514		
	Total	129.991	234			
Internal failure cost mean	Between Groups	42.915	1	42.915	57.637	0.000
	Within Groups	173.485	233	0.745		
	Total	216.400	234			
External failure cost mean	Between Groups	8.991	1	8.991	21.071	0.000
	Within Groups	99.428	233	0.427		
	Total	108.420	234			
Laboratory performance mean	Between Groups	36.821	1	36.821	58.561	0.000
	Within Groups	146.503	233	0.629		

	Total	183.325	234			

From the ANOVA analysis and descriptive statistics presented in Tables 35 and 36, the significance value for all dimensions is less than 0.05, so we conclude that there are statistically significant differences between labs that have CAB certification or not. Furthermore, we can see that the implementation level within labs with CAB certification is higher than the level of implementation within laboratories with no accreditation.

Table 35. Descriptive statistics for implementation of COQ and laboratory performance between labs have CAB certification or not.

Item	**The laboratory has CAB certification**			
	No		**Yes**	
	Mean	**Standard Error of Mean**	**Mean**	**Standard Error of Mean**
Prevention cost mean	2.50	0.06	3.22	0.18
Appraisal cost mean	2.55	0.05	3.11	0.14
Internal failure cost mean	2.84	0.06	3.85	0.15
External failure cost mean	2.53	0.05	2.98	0.19
Laboratory performance mean	2.96	0.06	3.90	0.12

Table 36. ANOVA analysis for implementation COQ and laboratory performance between labs have CAB certification or not.

ANOVA						
Item		**Sum of Squares**	**Df**	**Mean Square**	**F**	**Sig.**
Prevention cost mean	Between Groups	6.445	1	6.445	8.237	0.004
	Within Groups	182.313	233	0.782		
	Total	188.758	234			
Appraisal cost mean	Between Groups	3.807	1	3.807	7.030	0.009
	Within Groups	126.184	233	0.542		
	Total	129.991	234			
Internal failure cost mean	Between Groups	12.520	1	12.520	14.309	0.000
	Within Groups	203.880	233	0.875		
	Total	216.400	234			
External failure cost mean	Between Groups	2.441	1	2.441	5.367	0.021
	Within Groups	105.979	233	0.455		

	Total	108.420	234			
Laboratory performance mean	Between Groups	10.826	1	10.826	14.623	0.000
	Within Groups	172.498	233	0.740		
	Total	183.325	234			

From the ANOVA analysis presented in Table 37, the significance value for all dimensions is more than 0.05, so we conclude that there are no statistically significant differences between labs in different governorates.

Table 37. ANOVA analysis for implementation COQ and laboratory performance between labs in different governorates.

ANOVA						
Item		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Prevention cost mean	Between Groups	7.932	11	0.721	0.889	0.552
	Within Groups	180.826	223	0.811		
	Total	188.758	234			
Appraisal cost mean	Between Groups	4.951	11	0.450	0.803	0.637
	Within Groups	125.040	223	0.561		

	Total	129.991	234			
Internal failure cost mean	Between Groups	6.704	11	0.609	0.648	0.786
	Within Groups	209.696	223	0.940		
	Total	216.400	234			
External failure cost mean	Between Groups	3.142	11	0.286	0.605	0.824
	Within Groups	105.277	223	0.472		
	Total	108.420	234			
Laboratory performance mean	Between Groups	9.874	11	0.898	1.154	0.321
	Within Groups	173.450	223	0.778		
	Total	183.325	234			

4.2 Correlation Analysis

The findings of the correlation analysis of the COQ dimensions are shown in Table 38. (COQ, prevention cost, appraisal cost, internal failure cost, and external failure cost also include lab workload, ISO certification, and presence of a quality department). All of the relationships are statistically significant ($p<0.01$), using the strength of the correlation guide (Evans, 1996). According to the data, the strongest relationships are between internal failure cost and external failure cost (0.786) and between prevention cost and

appraisal cost (0.762). Also, the findings show a very strong positive relationship between COQ measuring and laboratory performance.

Furthermore, the findings show that the laboratory performance has the strongest relationship with measuring the prevention cost (0.767), appraisal cost (0.763), internal failure cost (0.836), and external failure cost (0.687). The relationship between the laboratory workload, the presence of the quality department, the laboratory's ISO certification, and the COQ dimension measurement is likewise moderately to strongly significant. Finally, the least significant relationship between the laboratory ISO certification and the external failure cost (0.542).

Table 38. Relationships among COQ dimensions, workload, ISO certification, laboratory performance, and presence of quality department.

Dimensions	Lab Workload	ISO certification	Quality department	PC	AC	IFC	EFC	COQ
Prevention cost (PC)	0.698**	0.579**	0.760**	1				
Appraisal cost (AC)	0.706**	0.614**	0.727**	0.762**	1			
Internal failure cost (IFC)	0.709**	0.572**	0.775**	0.794**	0.807**	1		
External failure cost (EFC)	0.633**	0.542**	0.679**	0.683**	0.694**	0.786**	1	

Laboratory performance (LP)	0.640**	0.480**	0.693**	0.767**	0.763**	0.836**	0.687**	0.849**
**Correlation is significant at the 0.01 level (2-tailed).								

4.3 Regression Analysis

Multiple regression is a statistical approach to investigating the relationship between a single dependent variable and numerous independent variables. The purpose of multiple regression analysis is to utilize the independent variables whose values are known to predict the value of the single dependent value (Cohen & Riegert, 2013; Berger, 2003; Hoyt et al., 2006).

Multiple regression analysis was used in the study to determine the effect relationship between the independent variable (COQ practices) and dependent variables (laboratory performance) also used to check the effect of the moderator variable (ISO certification, lab workload, and presence of quality department) on COQ practices and laboratory performance. A scatterplot showed that the relationship between dependent and independent variables was linear and didn't reveal an outlier. The regression model's result demonstrated a significant relationship between prevention cost, appraisal cost, internal failure cost, and laboratory performance. And this can be inferred from the t-value and its associated p-value, as shown in Table 39. The independent variable explains 73.7% of the variation in laboratory performance (R square 0.737). Table (37) shows that the strength of the relationship is strong by referring to the F-Value (161.045) and its p-value (0.000). It may be concluded that the study hypothesis is valid, and there is a correlation between laboratory performance and COQ dimensions. A multicollinearity

test was carried out to verify the existence of the mentioned relationship. The result revealed the VIF factor of the analysis was between 2.725 and 4.620. The maximum acceptable level is 5 (Ringle et al., 2015) or less than 10 (Hair et al., 1995). This indicates the non-existence of the multicollinearity problem.

From Table (39), the IFC dimension has the most significant effect (Std beta=0.508) on laboratory performance, followed by the PC dimension (Std beta=0.22), and the least is the AC dimension (Std beta=0.174). So medical laboratories should first determine their internal quality cost and conduct a continuous improvement program to remove or lower these internal costs. So this will eventually lead to the lowering of the total quality cost. Figure 9 shows the relationship between COQ practices and laboratory performance based on regression weight.

The constant beta is 0.52, and the unstandardized coefficients beta for prevention cost, appraisal cost, internal failure cost, and external failure cost are 0.217, 0.206, 0.468, and 0.021respectively.

Table 39. Multiple regression analysis results

Dependent variable	**Independent variable**	**R**	**R^2**	**F**	**p-value**	**Std Beta**	**Std Error**	**T-value**	**P-value**	**VIF**
Laboratory performance	PC Dimension	0.858	0.737	161.045	0.00	0.220	0.059	3.695	0.000	3.097
	AC dimension					0.174	0.073	2.832	0.005	3.282
	IFC Dimension					0.508	0.067	6.992	0.000	4.620

	EFC Dimension					0.016	0.073	0.290	0.772	2.725

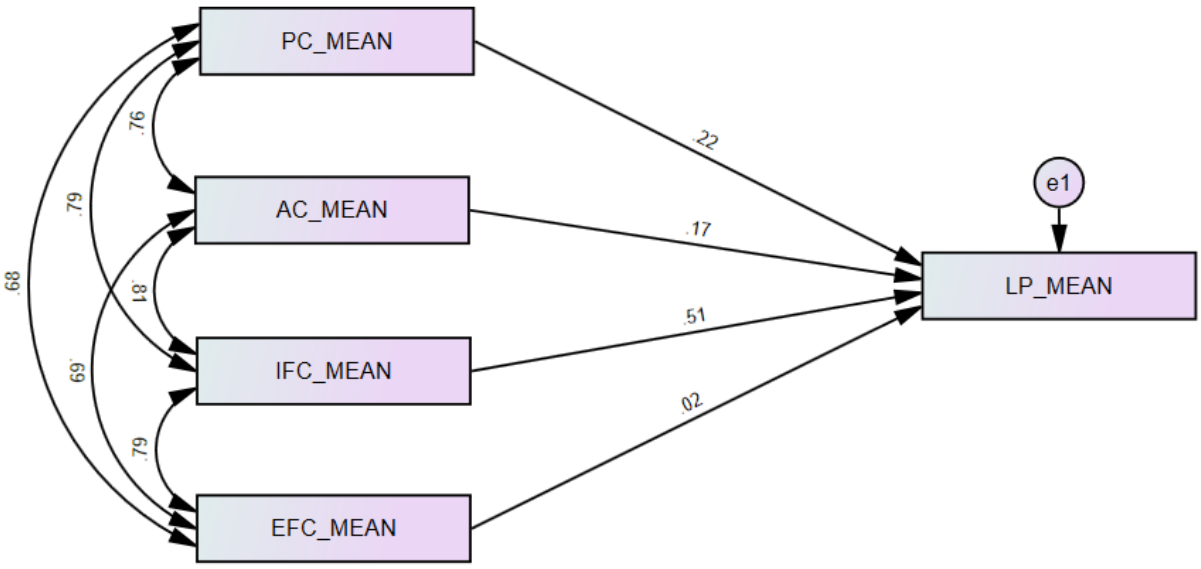

Figure 9. Model for the relationship between COQ and laboratory performance based on regression weight.

4.4 Moderator Variables Analysis

A moderator is a qualitative or quantitative variable that affects the direction and strength of the relationship between an independent and a dependent variable. When an interaction between an independent variable and a factor occurs, this is the moderator effect. (Baron & Kenny, 1986). In this study, the moderator variable was selected from demographic data; firstly, we checked the correlation between demographic data and COQ and laboratory performance. Secondly, only the demographic data with a moderate or above correlation strength with COQ and laboratory performance are selected as a moderator variable. Hence, in this study, the independent variables are COQ, the dependent variable is laboratory performance, and the moderator variables are lab workload, ISO certification, and the presence of a quality department. Moderation

analysis can be performed in various ways, including subgroup analysis, moderated regression analysis, and hierarchical regression analysis (Vij & Farooq, (2017).

Figure 10 and Figure 11 show the conceptual and statistical models for moderation interaction and should be clearly understood by the researcher before starting the analysis.

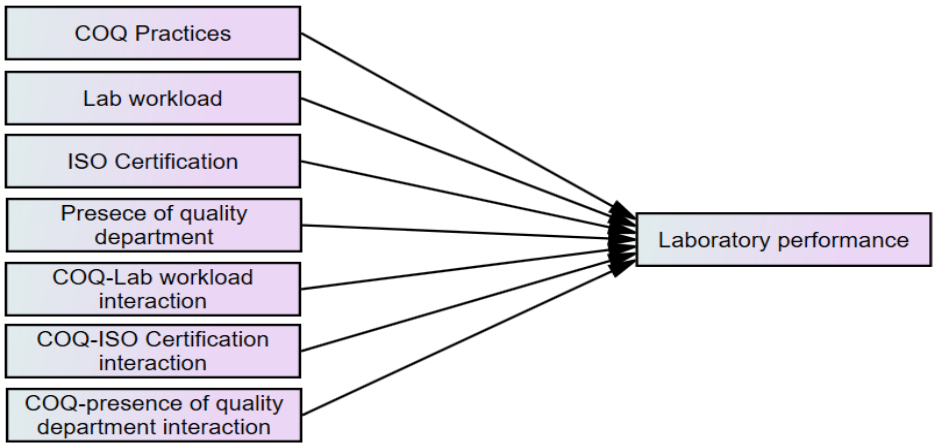

Figure 10. Statistical model for moderator variable

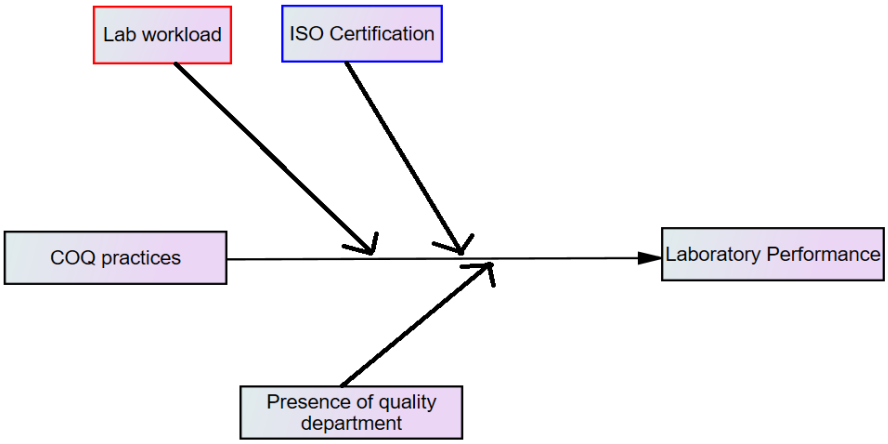

Figure 11. A conceptual model for moderator variable

A moderated multiple regression analysis was used in the study to check the effect of moderator variables (ISO certification, lab workload, and presence of quality department) on COQ practices and laboratory performance (Frazier et al., 2004; Hoyt et al., 2006;

Irwin & McClelland, 2001). An interaction term (lab workload*COQ) (presence of quality department*COQ) (ISO certification*COQ) was created. Before executing the linear regression model, we measure the mean-center for the COQ dimension to eliminate the probability of multicollinearity **(**Aiken & West, 1991). To examine the multicollinearity, we measured the variance inflation factors (VIF), and the result was between 1.851 and 4.484. The maximum acceptable level is 10 (Hair et al., 1995).

Firstly, we enter the COQ dimension, lab workload, ISO certification, and the presence of the quality department in model 1, and then we enter the interaction between COQ and moderator variable in model 2. The result of the regression model demonstrated that there was a significant relationship between the presence of quality department COQ practices and laboratory performance. And this can be inferred from the t-value and its associated p-value, as shown in Table 40. The independent and moderator variables explain 75.6% of the variation in laboratory performance (R square 0.756). Table 40 shows that the strength of the relationship is strong by referring to the F-Value (100.384) and its p-value (0.000). Also, the R square change between model 1 and model 2 was calculated. Also, to determine if the R square change is significant, we calculated the P-value for change. The results demonstrate that including the interaction in the hierarchical regression model resulted in a statistically significant increase in variance explanation ($p < 0.05$). The moderator variable explains laboratory performance variation's 2.9% (R square change). From Table 40, the study hypothesis five is rejected (P-value 0.828), and this means there is no moderation effect between ISO certification on COQ practices and laboratory performance. Study hypothesis six is rejected (P-value 0.689), and this means there is no moderation effect between lab workload on COQ practices and laboratory performance. Study hypothesis seven is accepted (P-value 0.001), which means there is a moderation

effect between the presence of a quality department on COQ practices and laboratory performance.

From Table 40, the COQ quality department interaction has the most considerable effect (Std beta=3.435) on COQ and laboratory performance. The constant beta is 2.653, and the unstandardized coefficients beta between COQ, lab workload, presence of quality department, ISO certification, COQ lab workload interaction, COQ_quality department interaction, and COQ_ISO certification interaction are 2.132, 0.05, 0.312, 0.085, 0.036, 0.78, and 0.063 respectively.

Table 40. Multiple regression analysis results for moderator variable

Dependent variable	**Independent variable Moderator variable**	**R**	**R^2**	**R^2 change**	**F**	**P-value**	**p-value F change**	**Std Beta**	**Std Error**	**T-value**	**P-value**
Laboratory performance	COQ	0.869	0.756	0.029	100.384	0.000	0.000	1.793	0.283	7.539	0.000
	Lab workload							0.129	0.242	0.597	0.551
	Quality department							1.292	0.704	3.375	0.001
	ISO certification							0.105	1.026	0.245	0.807
	COQ_lab workload interaction							0.141	0.089	-0.401	0.689
	COQ_quality department interaction							3.435	0.227	3.435	0.001

	COQ_ISO certification interaction							0.138	0.288	-0.217	0.828

Also, we confirm the result of the moderation effect by analyzing the data using the SPSS-AMOS program Abou-Moghli, (2019), as shown in Table 41. The finding reveals a significant effect of the COQ variable, quality department variable, and COQ-quality department interaction (P-value< 0.05). The other variables have no significant effect (P-value > 0.05), which is similar to what we obtain from regression analysis. Figure 12 shows the moderator variable relationship with COQ and laboratory performance based on regression weight generated by the SPSS AMOS program.

Table 41. Regression weight using SPSS AMOS

Dependent variable	**Independent variable**	**estimate**	**Std error**	**Critical ratio**	**P-value**
Laboratory performance	COQ	2.132	0.278	7.655	0.001
	Lab workload	0.145	0.238	0.607	0.544
	Quality department	2.375	0.693	3.427	0.001
	ISO certification	0.251	1.011	0.249	0.804
	COQ_lab workload interaction	0.036	0.088	0.407	0.684

	COQ_quality department interaction	0.780	0.224	3.487	0.001
	COQ_ISO certification interaction	0.063	0.284	0.221	0.825

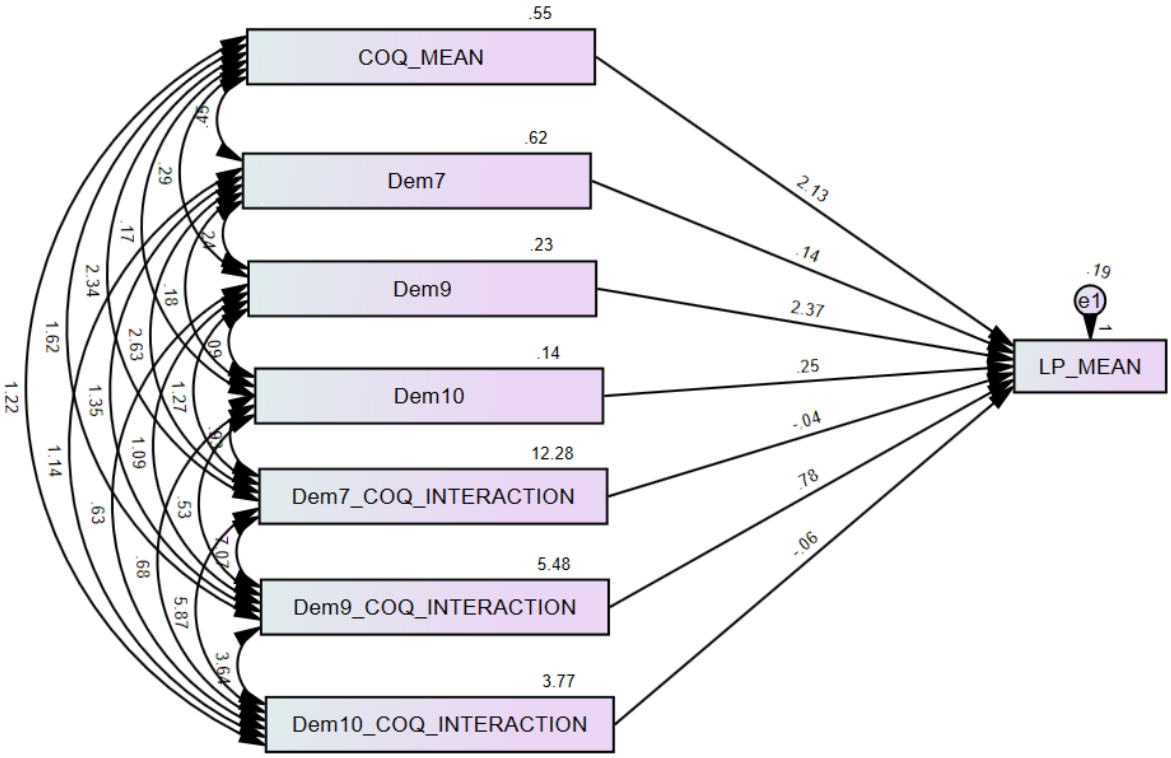

Figure 12. Model for moderator variable relationship with COQ and laboratory performance based on AMOS regression weight.

Chapter 5: Discussion

The main goal of this study is to investigate the level of implementation of COQ and the relationship between COQ practices and laboratories performance. The finding shows less level of implementation of COQ within medical laboratories and a positive correlation with laboratories performance. This research is the first to explore the impact

of COQ practices on laboratory performance in a medical laboratory in Palestine, thereby adding significant value to the existing body of knowledge.

5.1 Discussion of Demographic Data Analysis Results

Approximately 80% of the laboratories in this research are small to medium-sized, 57.9% of respondents are from the private sector, and 71.5% are lab directors. 63.8% of laboratories do not have a quality department, and 83.8% don't have ISO certification. As expected, because most laboratories are a personal investment, the volume of work is small to medium. There is no organizational structure, such as the presence of a quality department and an accounting department, resulting in predictable results. This study's findings contradict (Tye et al., 2011). The major respondent in this study stated that the measuring cost of quality under the responsibilities of the quality department, and the results were comparable to those found in Tye et al. (2011). In the vast majority of laboratories, COQ is not measured and evaluated.

5.2Discussion of COQ Dimension Analysis Results

According to the study's findings, the average degree of implementation of quality cost systems in Palestinian medical laboratories was 52.8 percent (2.642 out of 5; moderate level) across all four aspects of quality costs (preventive: 2.538; appraisal: 2.581; internal-failure: 2.900; external-failure: 2.550), while the level of performance of medical laboratories was 60.2 percent (3.012 out of 5; moderate level). We expected to get this result based on our knowledge of the laboratories and our laboratory management and workflow expertise. Furthermore, there is a significant relationship between the presence of a quality department, COQ practices, and laboratory performance. The findings of this research reveal no considerable link between labs that have ISO accreditation and laboratories that measure COQ activity.

As indicated by the survey results, most laboratories participating in this study do not evaluate the cost of quality. These findings are consistent with what was obtained from interviews with laboratory managers before the start of the study. According to our experience and observation, most COQ dimension items are not measured. The laboratory should spend more resources on prevention and appraisal operations to lower the cost of failure to the patient. This study's findings contradict (Miguel & Pontel 2004; Psomas 2018). According to Miguel and Pontel's study, around 65 percent of respondents measure COQ. Furthermore, Tye et al. (2011) show that 82.5% of respondents have implemented the COQ system.

5.3Discussion of Challenges Face Application of COQ

The most common reasons for laboratories not measuring COQ in this study are a lack of skills and knowledge, which is consistent with other studies (Psomas, 2018; Tye et al., 2011). So, employees must be trained, be involved in calculating the cost of quality, and be informed of the findings. However, the results from Psomas suggest that ignoring the benefits of calculating COQ is the most common reason for not measuring COQ. In contrast, the current study reveals that this reason is not as important. Also, following the results of Prickett and Rapley (2001), financial issues in paying the requisite expenditures are another typical reason for enterprises not monitoring COQ. However, the current research findings demonstrate that this is not a very important cause.

The lack of a good accounting system for calculating the cost of quality is one of the obstacles to estimating the cost of quality, and this is comparable to the finding of (Tye et al., 2011). In our opinion, there is no accounting system capable of providing laboratory managers with the necessary data to calculate the cost of quality. As a result, the laboratories are unwilling to calculate the cost of quality owing to a lack of required

information. As a result, laboratories must employ an accounting system to provide managers with the data they need precisely and straightforwardly. Furthermore, the respondent in this study for the item the lack of support from management was medium, and this is comparable to the finding of the Tye et al. The main challenges in not computing COQ in this study are the difficulty in identifying and evaluating the activities that are used to calculate the cost of quality. As a result, during this study, most COQ items were identified and clarified in a simplified manner, and an excel file for calculating them was established, making it easier for laboratory managers to compute and approve the cost of quality inside the laboratory. The absence of support from upper management, a lack of knowledge and comprehension of the quality cost calculation, and a lack of cooperation between departments and staff, in our opinion, are among the most significant challenges.

5.4 Discussion of Correlation Analysis Results

The findings of this study reveal a strong positive correlation between internal and external failure costs, implying that lowering internal failure costs will reduce external failure costs, resulting in fewer errors reaching the patient. Conversely, increasing internal failure costs will increase external failure costs, which were comparable to the finding (Chopra & Garg, 2011; Psomas, 2018). This study found a positive association between prevention and appraisal costs, which is similar to the findings of other studies (Chopra & Garg 2011; Sailaja et al. 2014a; Psomas 2018).

5.5 Discussion of the Hypothesis Testing Result

From the results shown in table (29), it can be noticed that majority of the independent variables had a statistically significant positive impact on laboratory performance. This result was comparable to the finding of Tye et al. (2011); the study shows that after implementing the COQ system, the firm's performance increased. In this manner, four

hypotheses were accepted, whereas three of the hypotheses were rejected. We summarized it in table 42. The study's first hypothesis (H1) was accepted (β =0.220; p = 0.000). Thereby indicating that prevention cost has a statistically significant positive impact on laboratory performance. This conclusion follows Ghunaim and Jaaron's (2021) findings, who discovered that prevention costs positively influenced organizational performance in food manufacturing enterprises. On the other hand, the second hypothesis (H2) in the study was accepted (β = 0.174; p =0.002). This conclusion is in opposite line with the finding by Ghunaim and Jaaron (2021), who discovered that appraisal cost did not influence organizational performance; on the other hand, this conclusion is in line with the finding by (Ayach et al.,2019; kerfai,2016). The third hypothesis (H3) in the study was accepted (β = 0.508; p= 0.000), implying that internal failure cost had a statistically significant influence on laboratory performance. This conclusion is in line with the finding by (Ghunaim & Jaaron, 2021; Akenbor, 2014; Kerfai et al., 2016). The fourth hypothesis (H4) was not supported in the study (β = 0.016; p = 0.772). In this vein, it was observed that external failure cost did not significantly influence laboratory performance. This conclusion contradicts Ghunaim and Jaaron's (2021) findings, which showed that external failure cost significantly influenced organizational performance. However, this contradiction in results might be explained by the fact that most labs are small to medium-sized businesses; therefore, they pay less attention to the impact of EFCs on laboratory performance. Also, most EFCs are hidden and hard to track by labs manager due to a lack of understanding of COQ, so their effect on laboratory performance cannot track. The fifth hypothesis (H5) in the research was rejected by the data (β = 0.138; p = 0.828). So this indicates that ISO certification does not have a moderating effect on COQ practices and laboratory performance. The findings did not accept the study's sixth hypothesis (H6) (β = 0.141; p = 0.689). So this suggests that the lab workload does not

have a moderating effect on COQ practices and laboratory performance. The findings accepted the seventh hypothesis (H7) in the study ($\beta = 3.435$; $p = 0.001$). So this suggests that the existing quality department does have a moderating effect on COQ practices and laboratory performance. According to Kerfai et al. (2016), COQ can assist managers in pushing practices that help an organization control expenses more effectively, boost profit, and improve performance more effectively. Also, this study found a positive correlation between appraisal costs and laboratory performance; therefore, this study's findings contradict those of Ghunaim and Jaaron (2021).

Table 42. Summary of hypothesis testing result

No	Hypotheses	T-value	P-value	Hypothesis Testing
H1	Prevention costs affect laboratory performance	4.548	0.000	Supported
H2	Appraisal cost affect laboratory performance	3.784	0.005	Supported
H3	Internal failure costs affect laboratory performance	3.17	0.000	Supported
H4	External failure costs affect laboratory performance	6.80	0.772	Not Supported
H5	Lab has ISO certification moderating COQ and laboratory performance	0.345	0.828	Not Supported

H6	Lab workload moderating COQ and laboratory performance	0.558	0.689	Not Supported
H7	Presence of a quality department moderating COQ and laboratory performance	0.339	0.001	Supported

Chapter 6: Conclusions and Recommendations

The majority of the findings of this study were predicted and were similar to those of previous worldwide studies. The study results demonstrate that the sample medical labs have not kept up with the international trend regarding COQ measurement. This study evaluates the implementation level of COQ and its effect on laboratory performance within west bank laboratories. The study used an electronic questionnaire to collect data from 235 labs on the west bank from different sectors. According to the finding, the lack of expertise and knowledge in labs is the most common cause of failure to measure the COQ, and this problem can be remedied. The majority of COQ dimension components are not computed in labs, and this may be explained because the labs do not have the necessary knowledge and experience to calculate it.

Furthermore, the finding shows no effect between EFC and laboratory performance. All hypotheses in this thesis were tested using the SPSS statistical program, and the results show that hypotheses 1, 2, 3, and 7 were supported, proving that there is a positive relationship between the application of quality cost and the performance of the laboratory and this similar to other research. Furthermore, the data reveal that hypotheses H4, H5, and H6 were not supported, suggesting that the lab workload and ISO certification did not affect the cost of quality and the performance of the laboratory; this study's findings contradict those of Ayach et al. (2019).

Quality procedures and laboratory expenses have a close relationship, according to research. If more money is invested in high-quality systems, it is possible to have fewer incidents and lower costs associated with recovery from failure. Failures (and the associated costs of poor quality) will grow if insufficient attention is devoted to high-quality process design and implementation. Medical laboratories will continue to produce

inaccurate results for the cost of quality unless a clear system is implemented and the activities that need to be measured to calculate the cost of quality are identified. The cost of quality was much greater than was seen in the accounting records. Money is the basic upper management language the transmission of such information to upper managers is without the cost figures of quality slower and less intense.

Traditionally, the quality cost calculation focuses on non-compliance, i.e., defects in the products or services; these are also called external and internal failure costs. Also, another critical cost is usually not calculated (this is called a "hidden cost" because it is not easily measured). Understanding, knowledge, and awareness of the cost of quality methods or models is the most critical factor that needs medical laboratories' attention to see the benefits of the cost of quality. To achieve the goals of the cost of quality, the medical laboratory should assess, effectively control and manage their cost of the quality method and provide training to their employees. The medical laboratory should invest in utilizing a cost of a quality known method of analysis; it was unfortunate to find out that its cost of quality is mismanaged. It has been proven in many sectors cost of quality is an eye-opener for businesses to make improvements and increase the efficiency of processes and people. Many known costs of quality methods are widely used in many sectors globally; however, they are not or are seldom used in the Palestinian medical laboratories, and not all quality cost categories are estimated.

It is better to spend more money on prevention than on remedial action once a problem has occurred. It is anticipated that by increasing the costs of prevention and appraisal, such as employee training, quality planning, SOP preparation, process workflow design, calibration, auditing, and quality control running, both internal and external failures, such as result error, QC failure, customer dissatisfaction, and employee injury, will be reduced.

This will then lead to labs improving their quality and competitiveness, which will, in turn, have a favorable impact on client satisfaction levels and ultimately lead to an increase in the performance of the laboratories. However, this result is consistent with the findings of Psomas et al. (2018) and Ayach et al. (2019). However, in today's healthcare economic climate, numerous laboratory management teams are finding that their resources are stretched to the limit, forcing them to make concerning cuts that may impact the quality of patient tests. One option that allows laboratories to make judgments while maintaining high-quality standards is to use quality cost measuring.

Medical laboratories are faced with a waste of laboratory resources on an annual basis, which is represented by the issuing of incorrect results to patients, the loss of examination materials, re-work, and re-examinations. As a result, patients and physicians become dissatisfied, and the profit margin of medical laboratories is reduced. Following the findings of the COQ measurement, medical laboratories may choose to increase their preventive and appraisal costs while simultaneously reducing their internal and external failure costs, thereby increasing their marketability and assisting laboratories during times of crisis, such as the current crisis (Corona pandemic).

6.1 Thesis Contributions

Much study has been done on COQ measurement and the relationships between the COQ dimensions. Specifically, this study in the West Bank was carried out to better evaluate the COQ measurement inside medical labs. Because it provides more in-depth insights regarding COQ assessment in medical labs, this work adds to the current body of knowledge as follows:

- After reviewing the previous research, we discovered that only a few of them were conducted in medical laboratories, and this study is considered to be one of the first studies to examine the effect of COQ practices on the performance of Palestinian medical laboratories. Quality managers and policymakers will benefit from this research since it will give vital information on how to assess the cost of quality in Palestinian medical laboratories, which will allow them to develop a customized model for use in their labs.
- An Excel file was also developed to assist laboratory managers in straightforwardly estimating the cost of quality and then identifying the areas that need to be focused on to assist labs and decision-makers in taking remedial action; these guidelines will ultimately aid in improving the overall quality of the service. This includes COQ categories based on the PAF model. We add the most item within each category so that the excel sheets will provide the cost for each category and the total cost of quality. The laboratories can easily add activities to the file without affecting the equation.
- Other sectors can use this Excel file after doing some modifications to an item presented within the file.
- After reviewing previous studies, we established the questionnaire that covers the essential item of COQ activities for assessing it in medical labs. We attempted to incorporate the questionnaire in elements of the study that had not been previously addressed by previous studies conducted in other industries.
- Our aim is that the findings of this research, in collaboration with the medical laboratory association, will lead to the adoption of a method for applying and

assessing the cost of quality. Consequently, medical labs may be encouraged to develop a reliable COQ measuring procedure that would accurately indicate the level of the COQ dimensions.

- General results from this research will help identify areas that must be followed up on and enhanced, which will lead to better performance and higher customer satisfaction in laboratories and increased profits, and more market competitiveness for those laboratories. It is possible to benefit from calculating the cost of quality when setting the prices of tests because reducing the cost of quality leads to conducting tests at lower prices so that the benefit returns to the customer and the laboratory profit increases.
- In this study, the reality of assessing quality costs, how it is done, and the elements that laboratories need to calculate the cost of quality effectively will be explored in more depth.

6.2 Thesis Recommendations

The strategic aim of all healthcare providers should be to deliver high-quality care to patients since this necessitates coordinated efforts from the top to the bottom of the pyramid within medical institutions and collaboration across medical institutions. Consequently, a defined procedure, controls, and rules must be established and enforced to support quality improvement activities. The following recommendation is based on the study conclusion and findings:

6.2.1 Recommendation for Medical Laboratories Owners

- From the study found, there is a moderation effect of the quality department on COQ practices, so we advise that laboratory managers establish a quality department within their facilities or, if this is not possible, delegate responsibility for quality to a qualified employee who will monitor quality

issues. The presence of a quality department aids in monitoring the laboratory's performance and identifying areas where some weaknesses and areas require improvement.

- We advise the owners and leaders of Medical Laboratories to assess the utilization and implementation of a known cost of the quality model. The COQ should be reported and evaluated regularly by the laboratory management since this will assist the manager in setting goals to minimize the total cost of quality.
- The laboratories manager should create a team to calculate the cost of quality and define the responsibilities of each team member. Employees who participate in inputs, work in processes, or benefit from process outcomes should all be part of the team.
- A quality culture should be developed from top management to middle management to the lowest level possible to achieve the lab goals.
- Labs managers must be aware that their team has sufficient time to evaluate the COQ items, so having an adequate number of lab technicians on hand is critical.
- Developing a motivating system for lab personnel based on their evaluations to encourage COQ implementation will give them a sense of pleasure for their efforts and participation in the program. The construction of an effective motivating system and their involvement in the decision-making process are necessary to provide lab employees with recognition from the lab manager and increase staff confidence in their work.

- The laboratory should spend on prevention costs by identifying improvement activities. If performed correctly, these improvement initiatives will decrease internal failure costs and reduce the appraisal cost.
- Cost of quality is not an improvement program. Instead, it is an eye-opener for management to visually look at facts to efficiently make appropriate judgments so the medical laboratory might utilize the PDCA cycle for continuous improvement and corrective and preventive action programs. The Pareto analysis can also be applied to find the 20% of activities responsible for 80% of the total cost of quality.
- A 5 years strategy and a ten years plan should be put together for implementation. Also, lab managers should note that some activity costs were not established, which requires follow-up and collection from employees so that they may be included as part of the cost of quality in the future.
- The COQ measurement system must be continuously implemented and considered part of the quality management system, and top management must provide support and assessment in this regard.

6.2.2 Recommendation for Policy-Makers

- According to the findings of this study and previous studies, the cost of quality implementation affects laboratory performance, and our proposal to policymakers to engage it inside laboratories. As a result, we recommend to decision-makers that the estimation of the cost of quality be included as one of the criteria for laboratories seeking to be licensed.
- We recommended that the medical technology association increase attention to COQ and teach laboratories how to compute COQ and implement COQ

models appropriate for their laboratory by conducting proper quid lines to implement COQ inside their laboratories.

- Conducting more extensive studies with a bigger sample size and incorporating a more significant number of hospitals and healthcare institutions.
- Our recommendations to Palestinian universities include establishing a quality course that educates students about quality cost and how it is calculated in medical laboratories.

6.3 Limitations

- This study was done in a few labs that have ISO certification, so the study's findings on the moderating impact of ISO certification may be erroneous or inaccurate.
- The most likely restriction on data collection is that some laboratories managers refused to provide us with appropriate data.
- The accessibility of the information is limited due to hospital regulations. Some laboratory managers consider the questions inappropriate and may refuse to answer some questions.
- Because of the Corona epidemic, we had trouble gathering data, which made the data collection procedure time-consuming and resulted in specific data not being accessible.
- Medical laboratories did not have any cost of the quality model. The cost of quality may be a part of the financial records under other categories, and some of the laboratory's activities are not measured.

- Compared to all the possibly identified COQ variables, the number of measurable variables included in the questionnaire is small.

6.4 Practical Implementation

According to our research findings, most laboratories do not understand how to assess the cost of quality. To benefit from the results of our study, laboratories must firstly develop guidelines for COQ collection and analysis and then teach and educate their staff on how to compute the cost of quality and the activities that must be calculated. As a result, an excel file (see appendix C1 to C19) was prepared to compute the cost of quality, as the file allows the laboratory to select the items to be measured. To successfully implement COQ, all departments should be educated and trained. Also, the commitment of the lab manager is critical for successful COQ implementation. According to the results, most laboratories have a small to medium workload. Some of them have only one or two employees, so we advise these laboratories to pick a few activities from each category and implement them as time passes. Their understanding of cost calculation improves; they can add additional activities based on measurement capability. According to the study's findings, IFC has the most impact on laboratory performance. Thus the laboratory should start there before moving on to the other categories. The laboratory can employ Pareto analysis to discover which activities have significant effects needed to be improved. Initially, applying the cost of quality will increase laboratory costs. Still, over time, the total cost of quality will reduce due to a reduction in internal and external failure costs. As a result, the advantage of implementing it will outweigh the expense of doing so.

Let's look at an example to understand how the cost of quality is reflected in real-world situations. Preventive maintenance is an example of a prevention cost by doing it

regularly to avoid a sudden shutdown. Choosing to decrease or remove maintenance might result in the equipment malfunctioning or producing inaccurate results, increasing the failure cost for the lab manager who made the decision.

Quality control reagents, used daily or weekly, are an example of appraisal costs. Assume that the quality control (QC) checks the functioning of the machine or reagent weekly. For cost-cutting purposes, if the manager chooses to run it once a month, the manager will have no way of knowing if the machine is working correctly until the next run. The instrument may provide inaccurate results, resulting in customer unhappiness. Working around this QC issue costs more money than just performing QC regularly.

To offer high-quality service, all employees must adhere to a specified procedure workflow that encompasses all steps of the service delivery process (pre-analytical, analytical, and post-analytical). The failure of management to design a process workflow might result in increased variation and inaccurate laboratory findings.

When phlebotomy-trained workers collect blood specimens, it is feasible to reduce or eliminate the costs associated with rectifying issues that arise from inadequate blood specimens collected by employees who have had just limited training or no training.

In the case of the inventory management system, while it will incur more costs if installed, it will save the laboratory money by reducing the cost of expired and surplus inventory, because of this, having such a system will raise the cost of prevention while simultaneously decreasing the cost of internal failure by a large margin.

6.5 Future Studies

- Conducting comparative studies to examine the implementation level of COQ within medical laboratories between limited resources countries and developed resources countries.
- Conducting comparative studies to examine the implementation level of COQ within medical laboratories between the West Bank, Gaza, and Jerusalem laboratories.
- Conducting comparative studies to check laboratory performance levels before and after COQ implementation.
- Comparative studies must be conducted to examine the effect of COQ practices on laboratories' performance for an extended period based on manager and customer perceptions.
- It is necessary to conduct evaluation studies to determine the factors that contribute to the effective implementation of COQ in labs.
- This study's findings were limited to laboratories in the West Bank. As a result, future research should try to collect data from all of Palestine's laboratories
- Extending the study to neighboring countries could be another area for future research.
- Future studies on the relationship between COQ practices and laboratory performance, including moderating variables other than lab workload, ISO certification, and the presence of a quality department, are required. These variables include financial capacity and a flexible account system, among others, to be investigated.

- Due to a limited number of laboratories that have ISO certification in Palestine, we need to conduct more research in the future to examine the moderating impact of ISO certification on COQ practices and laboratory performance utilizing a relatively large number of laboratories that have ISO certification.
- Conducting comparative studies to examine the implementation level of COQ between services and manufacturing companies.
- Conducting comparative method between using PAF model and ABC model.
- Conducting comparative studies to examine the implementation level of COQ within medical laboratories between labs have organizational structure or not?

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Appendices

Appendix A: Questionnaire (Arabic)

تكاليف الجودة وأثرها على الأداء التشغيلي: دراسة حالة للمختبرات الطبية في الضفة الغربية

عزيزي/عزيزتي:

يرجى تعبئة البيانات المطلوبة حيث ان هذا الاستبيان جزء من رسالة الماجستير في تخصص ادارة الجودة في الجامعة العربية الامريكية علما بان هذه البيانات ستستخدم لغرض البحث العلمي وستعامل بسريه تامة وستتطلب من وقتكم 10 دقائق تقريبا

أرجو مساعدتكم في توفير إجابات صادقة، ودقيقة، وموضوعية على الأسئلة الواردة في هذا الاستبيان والتي تعتمد على خبرتكم في اداره مختبراتكم وعليه يرجى منكم التعاون في تعبئة هذا الاستبيان مع مراعاة الدقة والأمانة العلمية بالإجابة.

القسم الاول: معلومات ديموغرافية (Demographic):

الرمز	السؤال
Dem1	عمر المختبر:
Dem2	القطاع : ☐ قطاع خاص ☐ قطاع حكومي ☐ قطاع غير ربحي
Dem3	عدد فنيي المختبر: ☐ 1-5 ☐ 6-10 ☐ 11-20 ☐ أكثر من 20
Dem4	طبيعة وجود المختبر: ☐ جزء من مستشفى ☐ جزء من عيادات ☐ منفصل
Dem5	المختبر جزء من شركة : ☐ نعم ☐ لا
Dem6	المدينة (موقع المختبر): .....
Dem7	حجم عمل المختبر: ☐ ضعيف ☐ متوسط ☐ كبير
Dem8	المختبر له فروع: ☐ نعم ☐ لا
Dem9	يوجد دائرة للجودة بالمختبر: ☐ نعم ☐ لا
Dem10	المختبر حاصل على شهادة الايزو ISO 15189: ☐ نعم ☐ لا
Dem11	يقوم المختبر بحساب تكلفة الجودة: ☐ نعم ☐ لا
Dem 12	الدائرة المسؤولة عن حساب تكلفة الجودة: ☐ دائرة الجودة ☐دائرة المالية ☐ دائرة المشتريات ☐ جميع الدوائر

Dem 13	ما هي نسبه تكلفة الجودة من حجم التكاليف التي يتم حسابتها بالمختبر حاليا: النسبة: ..... لا يتم حسابها
Dem14	المختبر حاصل على شهادة الاعتماد الكاب CAP: ☐ نعم ☐ لا
Dem15	المنصب الوظيفي: ☐ المدير العام ☐ مدير الجودة ☐ مدير المختبر ☐ فني المختبر ☐ غير ذلك .....
Dem16	عدد سنوات الخبرة: ☐ 5-0 ☐ 10-6 ☐ 15 -11 ☐ 20-16 ☐ اكثر من 20

القسم الثاني: تكلفة الجودة الوقائية Prevention Cost (PC)

الرمز	السؤال	اوافق بشده	اوافق	محايد	لا اوافق	لا اوافق بشدة
PC 1	تخصص إدارة المختبر موازنه لتدريب الموظفين على طرق عمل الفحوصات					
PC 2	تخصص إدارة المختبر موازنه لتحديد جوده المواد المراد شراؤها					
PC 3	تخصص إدارة المختبر موازنه للتحقق والتثبت من طرق عمل الفحوصات والاجهزة (Validation/verification)					
PC 4	تخصص إدارة المختبر موازنه للقيام بالصيانة الوقائية للأجهزة preventive maintenance					
PC 5	تخصص إدارة المختبر موازنه للتخطيط والعمل على تحديد الاخطار المحتملة risk management					
PC 6	تخصص إدارة المختبر موازنه لعمل طرق اجراء الفحوصات sop					
PC 7	تخصص إدارة المختبر موازنه لتحسين جودة الخدمات الصحية					
PC 8	تخصص إدارة المختبر موازنه لتطوير تصميم المختبر.					
PC 9	تخصص إدارة المختبر موازنه لعمل خطة للتدقيق الداخلي					
PC 10	تخصص إدارة المختبر موازنه لتعديل طرق عمل الفحوصات modify process workflow					

القسم الثالث: تكلفة جوده التقييم Appraisal Cost (AC)

AC 1	يقوم المختبر بحساب تكاليف الأجهزة والمعدات المستخدمة في التقييم					
AC 2	يقوم المختبر بحساب تكلفة عمل تقييم للمواد التي يتم شراؤها عند استقبالها بالمختبر					
AC 3	يقوم المختبر بحساب تكلفة المواد المستهلكة من خلال اجراء التدقيق الداخلي					
AC 4	تخصص إدارة المختبر موازنة للحصول على شهادات جودة عالميةISO/CAB					
AC 5	يقوم المختبر بحساب تكاليف اشراف طاقم الفحص					
AC 6	يقوم المختبر بحساب تكلفة اجراء فحوصات مقارنة بين المختبرات					
AC 7	يقوم المختبر بحساب تكلفة التدقيق الخارجي					
AC 8	يقوم المختبر بحساب تكلفة عملية معايره الاجهزة والمواد Calibration cost					
AC 9	يقوم المختبر بحساب تكلفة تقييم الدوائر الداعمة لأداء العمل					
AC 10	يقوم المختبر بحساب تكلفة برنامج الكونترول الداخلي					

القسم الرابع: تكلفة الاخفاق الداخلي Internal Failure Cost (IFC)

IFC1	يقوم المختبر بحساب تكلفة اعادة المواد التي لم تطابق معايير الجودة الى الموردين					
IFC2	يقوم المختبر بحساب تكلفة المواد الفاقدة					
IFC3	يقوم المختبر بحساب تكلفة اعادة الفحوصات للمرضى					
IFC4	يقوم المختبر بحساب تكلفة اعادة فحوصات الكونترول					

IFC5	يقوم المختبر بحساب تكلفة اعادة معايره المواد والاجهزة					
IFC6	يقوم المختبر بحساب تكلفة اعادة ادخال بيانات ونتائج المرضى					
IFC7	يقوم المختبر بحساب تكلفة اعادة سحب العينات للمرضى					
IFC8	يقوم المختبر بحساب تكلفة اصابة الموظفين اثناء العمل					
IFC9	يقوم المختبر بحساب تكلفة فقدان العينات					
IFC10	يقوم المختبر بحساب تكلفة اتخاذ الاجراءات التصحيحية بالمختبر Corrective action					

القسم الخامس: تكلفة الاخفاق الخارجي External Failure Cost (EFC)

EFC1	تقوم إدارة المختبر بحساب تكاليف التعامل مع شكاوى المرضى					
EFC2	تقوم إدارة المختبر بحساب التكاليف المتعلقة بالأخطاء الطبية					
EFC3	تقوم اداره المختبر بحساب تكلفة التعامل مع المحاكم نتيجة الاخطاء الطبية					
EFC4	تقوم اداره المختبر بحساب تكلفة معالجة المريض في حاله حصول مضاعفات نتيجة الخطأ الطبي					
EFC5	تقوم اداره المختبر بحساب تكلفة عمل فحوصات مجانية للمريض الذي حصل معه الخطأ الطبي					
EFC6	تقوم اداره المختبر بحساب تكلفة تعديل تقارير المرضى التي يوجد بها خطا وصدرت للمرضى					
EFC7	تقوم اداره المختبر بحساب تكلفة الشرط الجزائي للتعاقدات في حاله عدم الوفاء بها					
EFC8	تقوم إدارة المختبر بحساب التكاليف المترتبة عن خسارة القيمة السوقية للمختبر نتيجة للأخطاء الطبية					

EFC9	تقوم اداره المختبر بحساب تكلفة اعادة الفحوصات التي صدرت للمرضى وبها خطأ					
EFC10	تقوم اداره المختبر بحساب تكلفة فقدان الزبائن نتيجة الاخطاء الطبية					

القسم السادس: مؤشر اداء المختبر (خلال السنتين الماضيتين) Laboratory Performance Indicator (LPI)

LPI 1	قلت أخطاء الفحوصات					
LPI 2	زادت درجة رضا الزبائن بخصوص جودة تقديم الخدمة					
LPI 3	قلت نسبة الفاقد في المواد المستخدمة في الفحوصات					
LPI 4	زاد حجم العمل					
LPI 5	زادت درجة رضا الموظفين بالعمل بالمختبر					
LPI 6	زاد اهتمام اداره المختبر بتطوير اداء الموظفين					
LPI 7	قلت نسبة الفحوصات التي تقع خارج المدى في برنامج الكونترول الخارجي					
LPI 8	قلت نسبة الفحوصات التي يتم اعادتها					
LPI 9	زاد معدل الفحوصات التي يقوم الموظف باجراها					
LPI 10	قلت حوادث اصابه الموظفين داخل المختبر					
LPI 11	قل معدل تعطل downtime الاجهزة بالمختبر					
LPI 12	قلت نسبة عدم ارسال نتائج الفحوصات للمرضى بالطريقة التي يريدونها (الهاتف/الايميل/ورقي/واتس اب)					
LPI 13	زاد الاعتماد على البرامج الالكترونية في العمل للتخفيف من الاخطاء الفردية					

القسم السابع: مؤشر صعوبات تطبيق تكلفة الجودة Challenges Face Application of Cost of Quality (CFA)

الرمز	السؤال	اوافق بشده	اوافق	محايد	لا اوافق	لا اوافق بشدة

CFA 1	تجاهل فوائد حساب تكلفة الجودة من اسباب عدم قياس تكلفة الجودة					
CFA 2	نقص المعرفة لحساب تكلفة الجودة من اسباب عدم قياس تكلفة الجودة					
CFA 3	نقص الخبرة لحساب تكلفة الجودة من اسباب عدم قياس تكلفة الجودة					
CFA 4	عدم رغبة مدير المختبر لحساب تكلفة الجودة من اسباب عدم قياس تكلفة الجودة					
CFA 5	عدم القدرة على تغطية تكاليف حساب تكلفة الجودة من اسباب عدم قياس تكلفة الجودة					
CFA 6	زيادة حجم الاعمال الورقية من معيقات حساب تكلفة الجودة					
CFA 7	صعوبة تحديد الانشطة التي تستخدم لحساب تكلفة الجودة من معيقات حساب تكلفة الجودة					
CFA 8	صعوبة تقييم كلفة كل نشاط من معيقات حساب تكلفة الجودة					
CFA 9	صعوبة حساب الوقت الذي يحتاجه الموظفين في بعض الانشطة من معيقات حساب تكلفة الجودة					
CFA 10	عدم وجود نظام محاسبي جيد لحساب تكلفه الجودة من معيقات حساب تكلفة الجودة					

Appendix B_1: Questionnaire (English)

The Costs of Quality and its effect on operation performance: A case study of Medical Laboratories in the West Bank

Dear:
Please fill in the following data as part of a master's thesis specializing in quality management at the Arab American University. This information will be used for scientific research and treated with complete confidentiality. This questionnaire will take approximately 10 minutes of your time.
I'm hoping for your assistance in providing honest, accurate, and impartial answers to the questions in this questionnaire, which are based on your laboratory management expertise

Part 1: Demographic Data (Dem)

Code	Questions
Dem1	Lab age: …….
Dem2	Lab sector: ☐ Private ☐ Governmental ☐ Non-Profit
Dem3	The number of employees: ☐ 1-5 ☐ 6-10 ☐ 11-20 ☐ more than 20
Dem4	Does your lab, apart from hospitals, clinics, and separated labs? ☐ Part from the hospital ☐ Part from clinics ☐ separated lab
Dem5	Is the laboratory a part of a regulating business organization? ☐Yes ☐ No
Dem6	Lab location: …….
Dem7	How do you classify your lab workload? ☐ Small (0-500 patient/month) ☐ Medium (501-1000) ☐ Large (>1001)
Dem8	Does your lab have a branch? ☐ Yes ☐ No

Dem9	Does your lab have a Quality department? ☐ Yes ☐ No
Dem10	Does your lab have an ISO 15189 certification? ☐ Yes ☐ No
Dem11	Does your lab calculate COQ using the approved method? ☐ Yes ☐ No
Dem12	Department responsible for calculating COQ: ☐ Quality department ☐ financial department ☐ purchasing department ☐ All departments.
Dem13	Please specify the percent of COQ from the total cost: ☐ ……% ☐ not calculated
Dem14	Does your lab have a CAB certification? ☐ Yes ☐ No
Dem15	the position you currently hold within your lab: ☐General manager ☐Quality manager ☐lab director ☐lab technician ☐ other, please specify ……
Dem16	the number of years that you have been in your current position: ☐0-5 years ☐6-10 ☐ 11-15 ☐ 16-20 ☐ more than 20 years

Part 2: Prevention Cost Indicator (PC)

Code	Question	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
PC1	Your lab set a budget for employee training					

PC2	Your lab sets a budget to determine the material quality requirement					
PC3	Your lab sets a budget for process verification or validation					
PC4	Your lab set a budget for instrument preventive maintenance					
PC5	Your lab set a budget for risk management					
PC6	Your lab set a budget for SOP preparation					
PC7	Your lab set a budget for providing high-quality service					
PC8	Your lab set a budget for the development of lab design					
PC9	Your lab set a budget to prepare an internal audit program					

PC10	Your lab set a budget to modify process workflow					

Part 3: Appraisal Cost Indicator (AC)

AC1	Your lab determines costs for devices and equipment used in quality inspection					
AC2	Your lab calculates the costs to test and inspect the purchased raw materials					
AC3	Your lab calculates the cost of performing an internal audit					
AC4	Your lab set a budget to get external certification (ISO/CAB)					
AC5	Your lab calculates costs for supervision of the inspection staff					
AC6	Your lab calculates costs for comparisons between labs.					
AC7	Your lab calculates the cost of performing an external audit					

AC8	Your lab calculates the cost of performing material and instrument calibration					
AC9	Your lab calculates the cost of performing an internal audit on the supportive department					
AC10	Your lab calculates costs for internal quality control					

Part 4: Internal Failure Cost Indicator (IFC)

IFC1	Your lab calculates costs for returning materials that did not meet the quality requirement					
IFC2	Your lab calculates the costs of lost material					
IFC3	Your lab calculates the costs of test rerun					
IFC4	Your lab calculates the costs of QC rerun					
IFC5	Your lab calculates the costs of the instrument and material recalibration.					

IFC6	Your lab calculates the costs of patient data reentry					
IFC7	Your lab calculates the costs of sample recollection					
IFC8	Your lab calculates the costs of lab incident					
IFC9	Your lab calculates the costs of samples lost					
IFC10	Your lab calculates the costs of taking corrective action					

Part 5: External Failure Cost Indicator (EFC)

EFC1	Your lab calculates the costs of handling customer compliant					
EFC2	Your lab calculates the costs of lab error reached to patient					
EFC3	Your lab calculates the costs of dealing with the courts as a result of lab errors					
EFC4	Your lab calculates the costs of treating the patient in case of complications as a result of the lab error					

EFC5	Your lab calculates the cost of conducting free examinations for the patient with whom the lab error occurred					
EFC6	Your lab calculates the cost of the correction lab report reached to the patient with an error					
EFC7	Your lab calculates the cost of the penalty clause of contracts in the event of non-fulfillment					
EFC8	Your lab calculates the costs resulting from the loss of the market value of the laboratory as a result of lab errors					
EFC9	Your lab calculates the cost of repeated tests issued to patients with an error					

EFC10	Your lab calculates the cost of customers losing					

Part 6: Laboratory Performance Indicator (LPI) for the last two years

LPI1	Lab errors decrease					
LPI2	Patient satisfaction with service quality is increased					
LPI3	Material lost is decreased					
LPI4	Lab workload is increased					
LPI5	Employee satisfaction is increased					
LPI6	Your lab focuses on developing the employees' skills					
LPI7	The percentage of test falling out of range in external quality control are decreased					
LPI8	the percentage of test reruns is decreased					
LPI9	The average number of tests per employee is increased					
LPI10	lab incidents are decreased					

LPI11	Instrument downtime is decreased					
LPI12	The percentage of lab errors did not send to the patient by he asked are decreased					
LPI13	The number of the electronic program is increased to decrease lab errors					

Part 7: Challenges Face Application of Cost of Quality (CFA)

CFA1	Ignoring the benefits of calculating the COQ is one of the reasons for not measuring it					
CFA2	Lack of knowledge of how to calculate COQ is one of the reasons for not measuring it					
CFA3	Lack of experience in how to calculate COQ is one of the reasons for not measuring it					
CFA4	Lack of interest of top management is one of the reasons for not measuring COQ					

CFA5	The inability to cover the expenses of calculating the cost of quality is one of the reasons for not measuring it					
CFA6	Increasing the paperwork is one of the obstacles to calculating the cost of quality					
CFA7	The difficulty of defining the activities that are used to calculate the cost of quality is one of the obstacles to calculating the cost of quality					
CFA8	The difficulty of evaluating the cost of each activity is one of the obstacles to calculating the cost of quality					
CFA9	The difficulty of calculating the time that employees need for some activities is one of the obstacles to calculating the cost of quality					
CFA10	The lack of a good accounting system for calculating the cost of quality is one of the					

	obstacles to calculating the cost of quality					

Appendix B2: Online Questionnaire Link

(https://forms.office.com/Pages/ResponsePage.aspx?id=QCZLJLdmJE2wq4P4IQt7N2UOToHRLhlFotqpMxZlb71UMVpaQlZNQlgxOURWQk5UTUNaUjBaSzlJMi4u&lang=ar.

Appendix C.1: Sample Recollection Calculator

Item	Cost/Item	Quantity Used	Cost/Min	Consumed Min	Total Cost
Print barcode(label)	*				
Sample tube	*				
Needle	*				
Syringe	*				
Alcohol	*				
Bandage	*				
Time to identify an inappropriate sample			*		
Time to recollect sample			*		
Time to transport a sample			*		
Total Cost					

Appendix C.2: Downtime Cost Calculator

Item	Cost/Hr.	Hr. Downtime	Total Cost
Instrument downtime			

Computer downtime			
LIS downtime			
The lab closed due to an accident			
Lack of labor to perform a test			
Total Cost			

Appendix C.3: Sample Check Calculator

Item	Cost/Min	Consumed Min	Total Cost
Check sample is correctly collected			
Check sample correctly transport			
Total Cost			

Appendix C.4: Calibration Cost Calculator (Appraisal Cost)

Item	Cost
Calibration material	
Calibration equipment	
Instrument reagent used for calibration	
Labor time to perform calibration	
Labor time to record calibration	
Labor time to review calibration data	
Total Cost	

Appendix C.5: Calibration Cost Calculator (Internal Failure Cost)

Item	Cost
Recalibration material	
Calibration equipment	
Instrument reagent used for calibration	
Labor time to perform recalibration	
Labor time to record recalibration	
Labor time to review recalibration data	
Total Cost	

Appendix C.6: Customer Satisfaction Cost Calculator

Item	Cost
Internal customer satisfaction	
External customer satisfaction	
Total Cost	0

Appendix C.7: Process Verification Cost Calculator

Item	Cost
The material used for verification or validation	
Labor time for verification or validation	
Machine used for verification or validation	
Total Cost	

Appendix C.8: Quality Improvement Cost Calculator

Item	Cost
Quality improvement team meeting	
The material used for quality improvement	
Labor time involved in quality improvement	
Total Cost	

Appendix C.9: Preventive Maintenance Cost Calculator

Item	Cost
Instrument preventive maintenance	
Facility preventive maintenance (facility safety)	
Total Cost	

Appendix C.10: LIS Cost Calculator

Item	Cost
QC program	
LIS Cost	
Form program /ISO program	
Data entry change program due to failure	
Total Cost	

Appendix C. 11: Expired Reagent Cost Calculator

Item	Cost/Item
Expired reagent	
Disposable of expired reagent	
Time cost to deal with expired reagent	
Total Cost	

Appendix C.12: Inspection Cost (Internal/ External) Calculator

Item	Cost
Inspection cost	
Accreditation fees cost	
Labor time cost	
Other costs	
Total Cost	

Appendix C.13: Reagent/Material Cost Calculator

Item	Cost Per Item	Quantity Used	Total Cost Per Item
Item 1			
Item 2			
Item 3			
Item 4			
Item 5			
Item 6			
Item 7			
Item 8			
Item 9			
Item 10			

Item 11			
Total Cost			

Appendix C.14: Labor Time Cost Calculator

job title	Labor Cost /Min	Labor Time	Job Cost
Title 1			
Title 2			
Title 3			
Title 4			
Title 5			
Title 6			
Title 7			
Title 8			
Title 9			
Title 10			
Title 11			
Total Cost			

Appendix C.15: Lost Patient Cost Calculator

NO	Total Spent Per Year
Patient 1	
Patient 2	
Patient 3	
Patient 4	
Patient 5	
Patient 6	
Total Cost	

Appendix C.16: Lost Revenue Calculator

Patient #	# Of Test Delete	Test Cost
Patient 1		
Patient 2		
Patient 3		
Patient 4		
Patient 5		
Patient 6		
Patient 7		
Patient 8		
Total Cost		

Appendix C.17: Pt (Appraisal Cost) Calculator

item	cost /item
Pt. material cost	
Pt. program cost	
Cost of test used for pt.	
Time cost to run pt. and enter data	
Time cost to review pt. result	
Total Cost	

Appendix C.18: Pt. (Internal Failure Cost) Calculator

item	cost /item
Time cost to analyze the failure causes	
Cost of test used after action taken	
Unplanned cost	
Total Cost	

Appendix C.19: QC Cost Calculator

Item	Cost/Item
QC material	
QC program	
Cost of test used to run QC	
Cost of instrument supply	
Cost of time to run QC and enter data	
Cost of time to review QC result	
Total Cost	

Appendix D: A letter for the Ministry of Health's Laboratories.

State of Palestine
Ministry of Health
General Directorate
of Paramedical Services

دولة فلسطين
وزارة الصحـــــة
الإدارة العامة
للخدمات الطبية المساندة

عطوفة الأخ الدكتور كمال الشخرة المحتـــــــــرم
الوكيل المساعد لشؤون الصحة العامة وصحة الاسرة
الأخ الدكتور أحمد البيتاوي المحتـــــــــرم
مـــــــــــدير مجمع فلسطين الطبـــي
الاخ الدكتور نجي نزال المحتـــــــــرم
ق.أ مـــــــــدير عام الادارة العامة للمستشفيات

GDPS. 917
17/10/2021

الموضوع: تسهيل مهمة

تحية طيبة وبعد,,,

نتوجه اليكم العمل على تسهيل مهمة طالب الماجستير رمزي صبارنة بتعبئة إستبيان وذلك لإجراء دراسة مسحية للمختبرات الطبية، حيث سيتم إرسال الإستبيان إلكترونيا عبر الايميل.

وتفضلوا بقبول فائق الاحترام,,,

أخوكم
اسامة النجار
مدير عـــــــام
الادارة العامة للخدمات الطبية المساندة

LANA

Ministry of Health – Ramallah
TelFax: 022964402: تلفاكس
e-mail :parmed@moh.ps
وزارة الصحة –رام الله
Ministry of Health - Nablus
TelFax: 09-2335821: تلفاكس
وزارة الصحة – نابلس

Appendix E: Laboratory Quality Indicator

Indicator	Process Workflow
Percentage of misidentification errors	Pre-examination
Percentage of test transcription errors	Pre-examination
Percentage of Incorrect sample type	Pre-examination
Percentage of Incorrect fill level	Pre-examination
Percentage of Unsuitable samples for transportation and storage problems	Pre-examination
Percentage of Contaminated samples	Pre-examination
Percentage of Sample hemolyzed	Pre-examination
Percentage of sample recollection	Pre-examination
Percentage of Samples clotted	Pre-examination
Percentage of Inappropriate test requests	Pre-examination
Percentage of Inappropriate time in sample collection	Pre-examination
Percentage of unintelligible requests	Pre-examination
Percentage of Inappropriate requests	Pre-examination
Percentage of LIS failure(downtime)	Pre-examination
Number of tests without IQC	Examination
Number of IQC results outside defined limits	Examination
Percentage of tests with Unacceptable performances in external quality control	Examination
Percentage of inaccurate results	Examination
Percentage of data transcription errors	Post-examination
Percentage of inappropriate turnaround times	Post-examination

Percentage of incorrect laboratory reports	Post-examination
Percentage of notification of critical values	Post-examination
Percentage of results with interpretative comments	Post-examination
Number of incorrect results for information system problems (automatic transfer data)	Post-examination
number of employee training events per year	Pre-examination
Customer satisfaction	Post examination
Number of Customers compliant	Post examination
Percentage of instrument downtime	Examination
Number of a lab accidents	Post examination
Percentage of nonconformities within each process	Examination
Number of tests done per patient	Examination
Number of tests done per instrument	Examination
Number of needle stick injury	Examination
Number of amended results	Post examination

الجـــامعـــــــة العربية الامريكية
كليـــــة الدراســـــــات العليـــــا

تكاليف الجودة وأثرها على الأداء التشغيلي: دراسة حالة للمختبرات الطبية في الضفة الغربية

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قدمت هذه الرسالة/الأطروحة استكمالا لمتطلبات الحصول على درجه الماجستير في إدارة الجودة، من كلية الدراسات العليا، في الجامعة العربية الامريكية، رام الله- فلسطين.

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الملخص

تضع العديد من المؤسسات الطبية قيمة عالية للجودة كأداة تسويقية من أجل الحفاظ على قدرتها التنافسية في السوق، لذلك تستثمر هذه المؤسسات بشكل كبير في مشاريع الجودة والتحسين المستمر من أجل الحفاظ على قدرتها التنافسية من خلال تطوير نموذج لحساب تكلفة الجودة. هدفت هذه الدراسة الى التعرف على نماذج تكلفة الجودة وكيفية تطبيقها داخل المختبرات الطبية والتعرف على النظام المستخدم حاليا وتحديدا قياس مستوى التطبيق ومعرفة مدى تأثير حساب تكلفة الجودة على اداء المختبرات الطبية حيث سيساعد ذلك على

تحسين جودة الخدمات المقدمة للمرضى وتقليل النفقات بالإضافة الى العديد من الفوائد الاخرى. ولتحقيق اهداف الدراسة، تم استخدام الأسلوب الوصفي التحليلي لتحديد مستوى تطبيق تكلفة الجودة وأثرها على أداء المختبرات داخل المختبرات الطبية في الضفة الغربية حيث شملت الدراسة 235 مختبر من القطاعات الخاصة والحكومية وغير الربحية. تم استخدام استبيان لجمع البيانات من المختبرات المرخصة من وزاره الصحة. ومن ثم ادخال البيانات وتحليلها باستخدام برنامج SPSS (Statistical Package for Social Science) الاحصائي حيث تم استخدام تحليل العوامل الاستكشافية والتأكيدية والإحصاءات الوصفية وتحليل الارتباط والانحدار المتعدد لتحليل البيانات وتنظيمها. اظهرت نتائج الدراسة ان مستوى تطبيق أنظمة تكاليف الجودة في المختبرات الطبية الفلسطينية بدرجة متوسطة بلغت 52.8% لجميع الابعاد الأربعة لتكاليف الجودة، وأن مستوى أداء المختبرات الطبية درجته متوسطة بلغت 60.2%, بالإضافة الى وجود علاقة قوية وموجبة بين ممارسات تكلفة الجودة واداء المختبرات الطبية. ايضا اظهرت الدراسة بان المختبرات الطبية لا تقوم بحساب جميع بنود تكلفة الجودة ولا تستخدم نظام واضح لذلك. بالإضافة الى ذلك اظهرت الدراسة بان السبب الرئيسي لعدم حساب تكلفة الجودة هو نقص المعرفة والخبرة بكيفية القيام بذلك. تعتبر هذه الدراسة من أولى الدراسات لتقييم تأثير ممارسات تكلفة الجودة في أداء المختبرات الطبية الفلسطينية وبالتالي ستساعد على رفع مستوى إدراك إدارات المختبرات الطبية لأهمية قياس تكاليف الجودة ويمكن رفع مستوى الادراك من خلال اعداد دورات تدريبية لزيادة القدرة على تحديد ابعاد تكاليف الجودة. نتائج هذه الدراسة تدعم أصحاب القرار والمدراء في معرفة مستوى تطبيق تكلفة الجودة في المختبرات وبالتالي وضع الخطط والاستراتيجيات المتعلقة بالجودة.