Acta Scientific MICROBIOLOGY (ISSN: 2581-3226)

Volume 4 Issue 11 November 2021

Short Communication

Understanding Cost of Quality in the Laboratory

Ashok Rattan*

Advisor, Pathkind Labs, CAREC, Pan American Health Organization, World Health Organization, ex Professor, All India Institute of Medical Sciences, ex Laboratory Director, India

***Corresponding Author:** Ashok Rattan, Advisor, Pathkind Labs, CAREC, Pan American Health Organization, World Health Organization, ex Professor, All India Institute of Medical Sciences, ex Laboratory Director, India.

Received: September 06, 2021

Published: October 09, 2021

Clinical Laboratory costs account for less than 3% of the total healthcare cost yet it is estimated that 70% of medical decisions are influenced by these tests. These include diagnosis, prognosis and risk assessment, preventive and screening for illnesses and monitoring and management of treatment. In addition, aggregate test results data are used for public health surveillance, health care performance measurement and quality improvement. Data derived from clinical trials provides new knowledge for innovation, evidence based medicine and improved clinical practice guidelines all of which drives clinical laboratory testing [1].

The quality of laboratory testing thus has great influence on the quality and cost of patient care. Defects or errors in the laboratory medicine can have potentially serious consequences in the care of patients as well as the costs to the health care system Laboratory results, therefore must be accurate, reliable, timely and interpretable and consistently meet the needs and requirements of its customers by providing clinical value at the decision points within the health care system [2].

Conventional wisdom has it that quality is expensive and it is often felt that "you get what you pay for" implying that if you want services of higher quality, you should be prepared to pay more. Fortunately, in laboratory medicine, because of automation and use of high end no touch instruments together with bidirectional interphase, variations of the analytical process has been significantly reduced and so has the chances of error. Pre examination is the area where most variations and errors occur and it is essential that written policies and processes are shared with all concerned in the form of a "sample collection manual" which lays down what are the patient preparation requirements, sample collection volume and tube to be used and the temperature under which the sample needs to be transported as to ensure stability of the analyte being analysed each sample must be a companied by a test requisition form which has at least two unique patient identifiers and all relevant information. It is essential that any deviation from the standard operating procedure be identified and corrected as soon as possible and as early as possible near the root cause of the problem, to have the least impact on the results [3].

In the past it was assumed that mistakes occur because of " bad apples" who spoil the system and much efforts were spent on identifying them, blaming them, shaming them and removing them from the system. Deeming Red Bead experiments clearly demonstrated that quality issues are usually due to inefficient or flawed laboratory processes, and high failure costs are rarely the fault of lab staff.

Why quality principles are so essential

Customers, clinicians, and patients should always be the first priority for a healthcare business. It takes both effort and financial investment to produce high quality services, but it is far more costly to deal with the failures that arise from neglecting quality. High quality efforts reduce waste and help the laboratory maintain a more strategic and effective budget [4].

What are the costs of quality?

First, to understand how quality costs affect the lab, it is important to recognize that there are both good and poor quality costs.

Figure 1

Good quality costs are divided into two categories

- Prevention costs—spent on quality activities intended to proactively prevent problems from occurring, and
- Appraisal costs—spent on quality activities intended to identify current issues and prevent them from happening again.

Poor quality costs attempt to deal with the consequences of quality failures (also called non-conforming events) which can be very expensive. Poor quality costs are also divided into two categories:

- Internal failure costs—spent on resolving errors before they leave the lab's control, and
- External failure costs—spent on resolving errors after they have left the lab's control. These are the highest quality costs.

While good quality costs are usually easy to identify in a lab budget, poor quality costs are not always as straightforward; failure costs don't have their own category and are often folded into the rest of the budget.

Types of quality cost

Prevention costs prevent problems from happening in the first place. Examples include:

- Quality management system
- Quality planning
- Quality improvement activities
- Quality education
- Validation of lab processes before they are implemented
- Initial staff competency assessments
- Preventive maintenance

Appraisal costs assess service and product quality. Examples include:

- Ongoing competency assessments
- Tracking quality indicators
- Internal audit programs
- External accreditations
- Instrument calibration
- Sample and reagent inspections
- Quality control (QC) materials and data evaluation
- Proficiency testing

Internal failure costs resolve failures while they are still under laboratory control. Examples include:

- Pre-examination issues (insufficient/flawed/mislabeled samples, data entry errors, etc.)
- Invalid instrument runs
- Expired reagents/materials
- Rework, repairs, retesting
- Downtime

External failure costs resolve problems once they have left laboratory control. Examples include:

- Lost/erroneous reports
- Customer complaints
- Report recalls
- Misdiagnoses
- Damaged reputation
- Lost revenue
- Lawsuits

Activities we must budget for: Cost of good quality

Preventive acitivities

- **Quality planning:** Creating of plans for quality, reliability, operations, production and inspection
- **Training:** Development, preparation and maintenance of programs
- **Service requirements:** Establishment of specifications for incoming materials, processes and final reports

- **Quality Management System:** Creation and maintenance of quality sstem
- **Quality improvement activities:** To identify areas where variations occur and to focus activities to reduce variations.

Appraisal activities

- **Competency assessments**: After training, the competency of staff to deliver consistent work is assessed and documented at regular intervals
- **Verification:** Checking of incoming materials, process setup and results meeting specifications. Internally, this includes calibration of instruments and running internal quality controls. Externally this includes participation in proficiency testing
- **Quality audits:** Confirmation that the quality system is functioning satisfactorily. This includes both internal audits performed by the laboratory as well as certification and accreditation inspections conducted by external agencies.

Activities which soak up the budget and we should avoid: Cost of poor quality

Internal failure costs

- Performance of unnecessary work, instrument down time and inefficiencies
- Rework such as reruns, recovering missing specimens, redraws, correcting data entry errors and repairing equipments.
- Failure analysis: which is an activity required to establish the causes of internal failure. Time spent investigating nonconformities cost the organization money though it is better to perform root cause analysis and nip the problem in the bud than to apply "band aid" every time the same problem surfaces (indicating a weakness in the process).

External failure costs

- Complaints: All of the work and costs associated with handling and correcting issues arising from customer complaints.
- Misdiagnosis and any associated costs to the organization
- Harm to the patient
- Corrected reports: A physician calls and says" This result doesnot fit the clinical picture, can you check the results?"
- Malpractice and other lawsuits.

Understanding the cost of quality in practice

- Quality control (QC) materials are an example of a "key appraisal activity." If QC isn't run frequently enough, a laboratory might not realize an instrument is malfunctioning and producing invalid results.
- For example, let's assume QC that is typically run once per day is reduced to once per week. If something changes after the QC is performed, the laboratory will not know that the instrument is functioning incorrectly until the following week. The entire week's results will be called into question. Those results need to be re-evaluated, and if any affected information was submitted from the laboratory, it will need to be retracted. If the results leave the laboratory and reach the customer, those invalid results could negatively affect patient treatment, and have major economic consequences for that laboratory. Dealing with this QC failure quickly becomes much more costly than it would have been to simply run QC more frequently [5].

How to identify and track quality costs

- In order to implement strategic cost of quality procedures, the lab team first needs to understand how it is currently spending money on quality costs. From there, it can identify target areas with high failure rates and opportunities for more comprehensive prevention activities.
- It is a good practice to create a list of good quality costs and then ask the laboratory's budget administrator to help find those costs in the budget. While these costs are relatively easy to identify, it is worth noting that some good quality costs also require labor, which may not be captured. The lab should decide if the amount of labor is high enough relative to the hard costs to make it worthwhile to calculate; if not, they may choose to ignore it.

How to identify and calculate failure costs

- Tackling the identification and calculation of specific failure costs may seem somewhat overwhelming at first but doesn't have to be. A good place to start is with is Key Performance Indicators (KPIs) or Non-Conforming Events (NCEs). Most

laboratories will have statistics about the frequency of failures being tracked as KPIs or NCEs, which will make this first task significantly easier to manage.

- First, determine key non-conforming events. These incidents (i.e., lost reports, unacceptable samples, or any other instances of quality failures) can cost the laboratory a great deal of money. When focusing on high severity or non-conforming events, it can be helpful to prioritize those that have the greatest effect on patient care or those that occur the most often.
- Next, calculate the failure cost for each non-conforming event. These costs should include all materials needed to recover from the failure and, if necessary, to re-perform the tests. It should also include any labor costs needed to troubleshoot and fix the problem, including time documentation and supervision.
- Examine the budget and identify the relevant costs (labor, material, etc.) that were expended because of that non-conforming event. Add up these costs to get an estimate of how much money that specific quality failure cost the laboratory. Each time a non-conforming event occurs, the lab now has a pre-calculated estimate of how expensive that quality failure is.
- Last, track how much money each non-conforming event costs the laboratory. Achieve this by simply multipling the failure cost by how many times that event occurs over a certain period of time. This will estimate how much money this recurring quality failure is costing the laboratory over time [6].

How to reduce failure costs

- Laboratories can reduce failure costs through a combined system of prevention and appraisal activities that minimizes waste and variation in lab processes.
- It might seem logical to tackle each problem as it presents itself, but relying too heavily on retroactive problem solving can be expensive and inefficient, and makes for very high appraisal costs. Investing more money in advance will actually prevent most problems from occurring in the first place, while still effectively dealing with any issues.

Four strategies for reducing the cost of poor quality

- Begin by routinely identifying and tracking quality costs in the budget. This will allow the lab to understand how much is spent on quality and where those quality costs are used.
- Recognize key non-conforming events that affect patient safety, have negative trends, or result in large failure costs. Can these be reduced by prevention or appraisal activities?
- Start reporting Cost of Poor Quality (CoPQ) data, and include failure costs in lab quality reports or non-conforming incident reports. If failure costs are clearly displayed, they will draw attention to areas for improvement. Consistently reporting CoPQ data will also allow laboratories to track how failure costs are affected by various quality improvement efforts.
- Educate staff at every level about cost of quality principles, and share CoPQ data throughout the organization. When everyone understands why certain measures or approaches are implemented, they can work together towards a more cost-effective quality system. CoPQ data will also facilitate healthy conversations with lab administrators or finance departments on the value of quality programs [6].

Figure 2

Lowest total cost of quality

This diagram below visualizes the relationship between the cost of good quality, represented by the blue line, and the cost of poor quality, represented by the yellow line. The total cost of quality is represented by the red line. Majority of clinical labs I have encountered fall somewhere to the left of the sweet spot, which represents the lowest total cost of quality. If the lab falls to the left of the blue dot, it is likely that adequate resources have not yet been allocated to realize the lowest possible total cost of quality [6].

Figure 3

Conclusion

Instead of conducting limited quality activities and dealing with failures as they occur, it is more cost-effective to develop comprehensive preventive procedures and efficient problem-solving strategies. Integrating cost of quality principles into routine laboratory activities works to the advantage of the lab, the customers, and the budget. Devoting more attention to strategic quality processes can lower costs while making the lab more efficient and reliable thereby improving the quality [6].

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Volume 4 Issue 11 November 2021