

Understanding the Cost of Quality in the Laboratory



Lucia M. Berte
www.LaboratoriesMadeBetter.com

Program Objectives

After this program, you will be able to:

- Discuss the types of quality costs with laboratory examples
- Determine a means to identify and track laboratory failure costs
- Access resources for more learning on quality costs

2

Fact

“Companies rarely have a realistic idea of how much profit they are losing through poor quality.”

Schiffauerova A, Thompson T. A review of research on cost of quality models and best practices. *International Journal of Quality and Reliability Management*, Vol.23, No.4, 647-669, 2006.

3

Fact


“It’s cheaper to do the job right the first time than to recover from an error.”

Philip Crosby

4

Example: Recollected samples

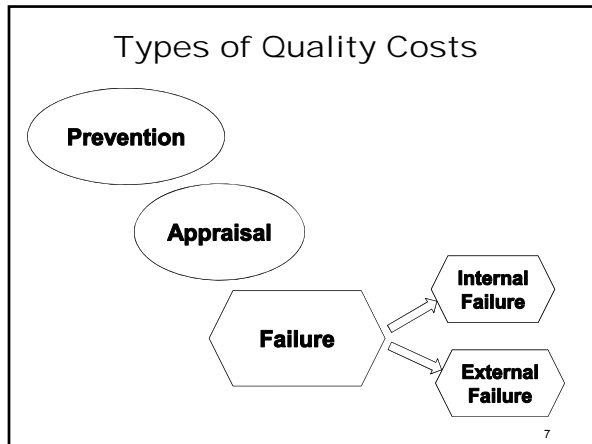
- **Paid** the direct cost for the rejected sample (expected business cost)
 - Labor
 - Supplies (collection, computer)
- **Lost** the margin from the first collection
- **Paid** direct cost for the second sample
- **Need** direct cost for the next sample



5

What’s the cost of quality in YOUR laboratory ?

6



Prevention Costs

- Quality planning
- Quality improvement
 - Meetings
 - Projects
 - Education
 - Training
- Supplier capability
- Preventive maintenance
- Process validation or verification
- Work process training
- Initial competence assessment

8

Prevention is Proactive

Your laboratory pays *only one time* for prevention –

but it *pays many times* to resolve recurring problems!

9

Appraisal Costs

- Surveying customers and users
- Ongoing competence assessment
- Calibrating measuring equipment
- Sample inspections at
 - Receipt
 - Examination
- Performing, reviewing QC
- Proficiency testing
- Measuring quality indicators
- Internal audit program
- External laboratory accreditation inspections

10


Can you identify prevention and appraisal costs on your operating budget?

11

Internal Failure Costs

Before delivery of results or report

- Preexamination sample problems
- Insufficient or expired reagents or supplies
- Rework, repair, retesting, reinspection
- Wasted blood and components
- Downtime
 - Computer systems
 - General unavailability of services



12

External failure costs

After receipt of results or services

- Lost reports
- Misdiagnoses
- Report recalls
- Lawsuits
- Customer or user complaints



13

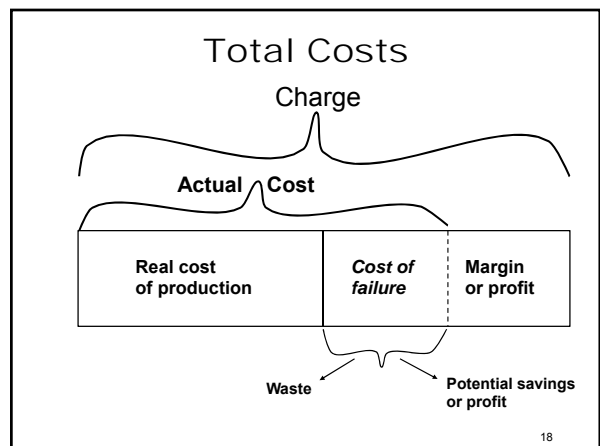
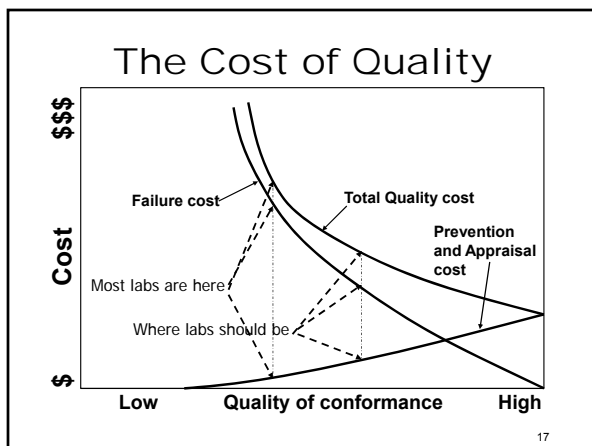
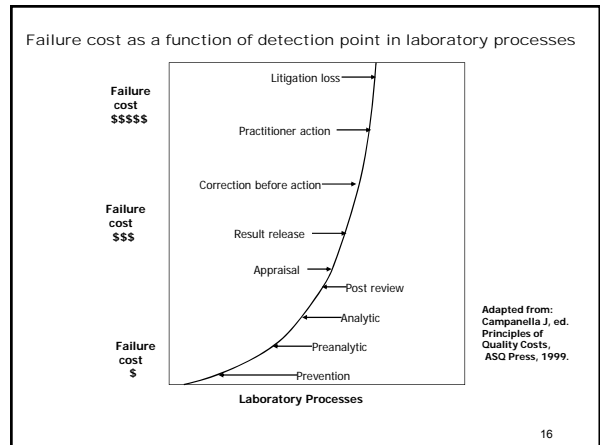
Can you identify internal and external failure costs on your operating budget?

14

Premise

Laboratories are businesses; therefore, we should believe that adopting a cost of quality concept will help reduce waste and improve quality to patients and customers.

15



Laboratory Path of Workflow Failure Costs 1.

- Preexamination
 - Wrong orders
 - Wrong order entry
 - Unacceptable samples
 - Recollected samples
 - Accessioning, data entry, and processing errors
- Examination
 - Repeated tests
 - Incomplete test runs (instrument issue)
 - Invalid test runs (calibrator or control failures)

19

Laboratory Path of Workflow Failure Costs 2.

- Postexamination
 - Result recalls (reporting error)
 - Lost reports - reprinted or redelivered
 - Remedial and investigation action on nonconformances
 - Complaint resolution
 - Missed or incorrect diagnoses
 - Lawsuits

20

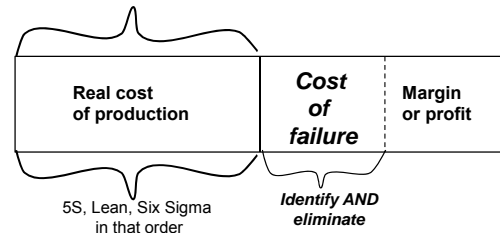
Management Infrastructure Failure Costs

- Forgone revenue from lost customers
- Lab safety accidents
- Staff turnover and replacement
- Expired reagents and supplies
- Overstock
- Equipment downtime
- LIS downtime
- TAT outliers
- Resolving document problems
- Confidentiality violations
- Resolving system interface issues
- Recurring NCE "corrective actions"

21

Key to Your Lab's Survival

Reduce through better process management



22

“Costs do not exist to be calculated.

Costs exist to be reduced.”

Taiichi Ohno

23

Ways to Eliminate Failure Costs 1.

- Streamline laboratory processes
 - Process analysis and flowcharting, using 5S and Lean
 - Automation, where possible
 - Six Sigma defect reduction
- Apply *prevention*
 - *Design* Failure Modes and Effects Analysis
 - Process validation – not only test methods!

24

Ways to Eliminate Failure Costs 2.

- Reduce turnover
 - Training programs for *all* staff
 - *Effective* training
 - *Effective* competence assessment
- Develop and use *effective* documents
 - Process-based
 - Flowcharts
 - Work instructions and job aids

25

“For organizations that do not have a formal effort to reduce chronic and sporadic problems, operations managers often *spend 30% of their time* on troubleshooting.

For the supervisors reporting to these managers, the time consumed *frequently exceeds 60%.*”

Joseph Juran



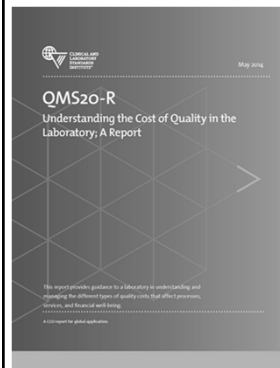
26

**How much money
does your laboratory
spend on...**

**...supporting good quality?
...resolving problems and errors?**

27

CLSI QMS20:2014 contains:



- Concept of quality costs
- Types of quality costs
- Effects on laboratory's budget
- Quality-based costing using laboratory failure costs
- *Worksheets for calculating quality costs*
- *Quality reports for management review*
- Action plan for transitioning to COQ culture
- www.clsi.org

28

Additional Resources

- Wood DC, mng ed. *Principles of Quality Costs*, 4th ed. Milw, WI: ASQ Quality Press, 2013.
- Wood DC. *The Executive Guide to Understanding and Implementing Quality Cost Programs*. Milw, WI: ASQ Quality Press, 2007.
- Schiffauerova A, Thompson T. A review of research on cost of quality models and best practices. *International Journal of Quality and Reliability Management*, Vol.23, No.4, 647-669, 2006.
- Berte LM. *The Cost of Quality*. In: *Harmening DM. Laboratory Management Principles and Processes*, 3rd ed. St. Pete, FL, DH Publishing and Consulting, Inc. 2012.

29

Last Words

**“If you always do
what you’ve always done,
you’ll always get
what you’ve already got!”**



30