

Reality Check on the True Cost of Recurring Bad Quality in Your Lab...

- How to Find It
- How to Fix It
- How to Sustain the Cost Savings

Lucia M. Berte
www.LaboratoriesMadeBetter.com

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.

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Fact:

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

Philip Crosby

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A lab that didn’t “get it”...

Baltimore Sun, August 13, 2004

Lab workers warned Md. General 2 years ago
“Laboratory workers at Maryland General Hospital warned top hospital administrators and state officials in writing nearly two years ago of serious and long-standing testing problems that put patients and employees at risk...”

...and you know the rest of that multi-million dollar fix-it story...

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Daily
CLINICAL LABORATORY AND PATHOLOGY NEWS AND TRENDS

News, Analysis, Trends, Management
for **Clinical Laboratories and Pathology**
hosted by **Robert Michel**

When Cost-Cutting in the Clinical Pathology Laboratory Collides with Effective QA/QC: How Savvy Labs Sustain the Accuracy and Quality of their Lab Test Results

September 4, 2013

As medical laboratories struggle to reduce costs and squeeze their budgets, it is essential that the lab’s quality assurance/quality control program is run properly to protect and enhance the analytical integrity of lab test results


When does budget cutting in a clinical laboratory begin to undermine the accuracy and analytical integrity of the medical laboratory test results produced by the laboratory?

This question is apparently a subject of much discussion within some lab organizations where aggressive cost reduction programs are shrinking lab staff and reducing funds spent on controls and similar QA/QC resources.

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Example: Recollected samples

- **Paid** the direct cost for the rejected sample
 - 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



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What's the cost of quality in YOUR laboratory ?

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Four Types of Quality Costs

- Prevention
- Appraisal
- Failure
 - Internal
 - External



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Prevention Costs



- Quality planning
- Supplier capability
- Process capability
- Preventive maintenance
- Quality improvement
 - Meetings
 - Projects
 - Education
 - Training
- *Work process training*

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Appraisal Costs



- Inspections
 - Incoming
 - In-process
 - Final
- Internal Auditing
 - Sample tracing
 - Record tracing
- Competence assessment
- Equipment calibration
- Quality Control
- Proficiency testing
- Outside accreditations
- Method comparison testing

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

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Internal Failure Costs (before delivery)



- Path of workflow errors and problems
- Rework
- Reinspection
- Retesting
- Repair
- Expired reagents
- Nonconforming material review
- Downgrading

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External failure costs (after customer receipt) 

- Customer complaints
- Misdiagnoses
- Report recalls
- Lawsuits

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

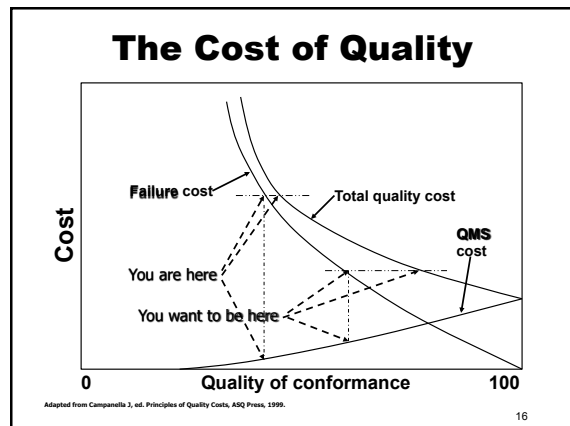
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Cost of Poor Quality

Sigma Level	Yield	DPM	COPQ
1	31%	690,000	Not competitive
2	69.1%	308,537	Not competitive
3	93.3%	66,807	24% to 40% of revenue
4	99.4%	6,210	15% to 25% of revenue
5	99.98%	233	5% to 15% of revenue
6	99.9997%	3.4	<1% of revenue

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.

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One Hospital System's Experience

- Goal of 50% reduction of specimen labeling errors over 18 months, through...
 - education
 - data collection and analysis
 - interhospital collaboration
- [Every mislabeled sample needed recollection – hence, failure cost incurred]

Reducing errors in blood specimen labeling: A multihospital initiative. Pennsylvania Patient Safety Advisory, 2011 Jun; 8(2):47-52.

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One Hospital System's Experience 2.

- Baseline rate = 0.1 to 4.1 errors per 1000 OFE
 - With 1.3 million OFE, a range of 130 – 5330 errors
- Applying slide 7 formula:
 - at \$15.00/hr direct phlebotomy labor cost. and rate of 5 phlebotomies per hour = \$3 per phlebotomy
 - at direct supplies of about \$10 per 1-tube collection
 - assuming a margin of \$1
- Failure costs of \$14 + \$13 + \$13 = \$40 each

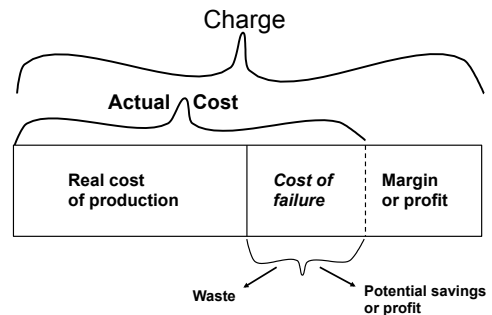
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One Hospital System's Experience 3.

- @ \$40 failure cost per error = \$5200 - \$213,200
- A 37% statistically significant decrease in errors in the collaborative over the 18 month period
- Post intervention error rate of 0.0 to 1.3 errors
- Failure cost reduced to \$0 for one hospital!

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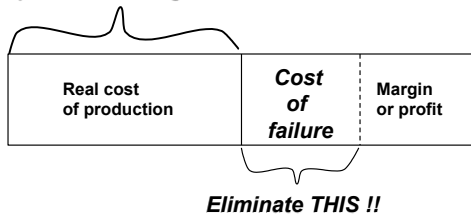
Total Costs



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Key to Your Lab's Survival

Reduce through better process management



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“Costs do not exist to be calculated.

Costs exist to be reduced.”

Taiichi Ohno

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Determining Failure Costs

- Use quality indicators
- Total the failure cost elements
 - direct variable costs for the failure
 - direct variable costs for the replacement
 - revenue margin foregone for the failure
 - direct variable costs used for the next sample
- Prepare failure cost reports



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Laboratory Path of Workflow Failure Costs 1.

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

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Laboratory Path of Workflow Failure Costs 2.

- Postanalytic
 - Result recalls
 - Reprinted reports
 - Redelivered reports
 - Remedial action on occurrences
 - Complaint resolution
 - Lawsuits

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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"

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Hidden Quality Costs

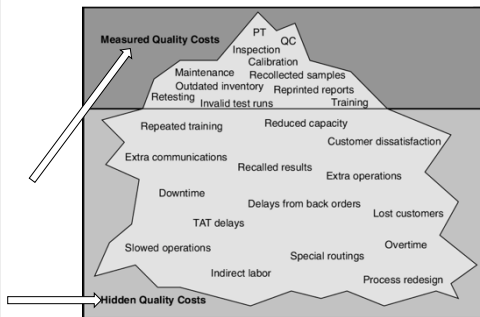


Fig. 13-3 with permission, from Harming's *Laboratory Management Principles and Processes*, 3rd ed., 2012. 27

Quality-Based Costing Identifies

- to be eliminated
- Waste caused by poor quality
- Areas where financial performance can be improved
- Cost justification for needed corrective actions



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Ways to Eliminate Failure Costs 1.

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

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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

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“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

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What's the cost of quality in YOUR laboratory?

Good quality ? **Bad quality**

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Take Home Message #1

For each failure there is a root cause.

Causes are preventable.

Prevention is always cheaper.

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Take Home Messages 2-8

- Know the 4 types of quality costs – P, A, IF, EF
- Identify P and A costs on your lab's budget.
- Calculate IF and EF costs and prepare reports
- Invest in P and A to ↓ IF + EF
- Use RCA and CI to further ↓ A
- The language of the C-Suite is \$\$\$\$\$\$

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Additional Resources

- 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.
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- Reducing errors in blood specimen labeling: A multihospital initiative. *Pennsylvania Patient Safety Advisory*, 2011 Jun; 8(2):47-52.

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