This Presentation Will Address

- History of Quality Costs
- Definitions
- Quality Cost Scales in the Medical Laboratory
- Poor Quality Examples from the Medical Laboratory
- Summary and Conclusion.

History of Cost of Poor Quality

Many Authors
- Joseph Juran
- Phillip Crosby
- James Harrington
- Jack Campanella
- Douglas C. Wood

Many Titles
- COQ
  Cost of Quality
- PQC
  Poor Quality Costs
- CPQ
  Cost of Poor Quality

Total Quality Costs

The Juran Model

- The sum of all costs for all activities associated with ensuring an accurate and timely product or service:
  - Prevention Costs
  - Appraisal Costs
  - Costs associated with Internal Failure
  - Costs associated with External Failure

Definitions of Quality Costs

- Prevention Costs:
  Costs for activities designed to prevent poor quality in products or services.
- Appraisal Costs:
  Costs for activities associated with measuring, evaluating, or auditing to assure conformance to quality standards.
- Failure Costs:
  - Internal – costs associated with detection of error before product or service reaches the customer.
  - External – costs associated with detection of error after the product or service reaches the customer.
Quality Costs

**PREVENTION**
- Product Needs Team
- Product Review
- Supplier Review
- Product Evaluation
- Quality Awareness
- Supplies, materials
- Confirmation retest

**APPRAISAL**
- Quality Control - receipt
- Calibration
- In-process inspection
- Final inspection
- Proficiency Testing

**INTERNAL FAIL**
- Scrap
- Rework
- Re-inspection
- Retesting
- Corrective Actions
- Downgrading
- Near miss time loss

**EXTERNAL FAIL**
- Customer complaint
- Customer Returns
- Warranty Claims
- Product Recalls
- Corrective Actions
- Remedial Notification
- Remedial Testing

**LIABILITY COSTS**

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**Juran:**

The Quality Economic Model
Percent conformance and Costs

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**Crosby:**

The cost of nonconformance

"Take everything that would not have to be done if everything were done right the first time and count that as the price of nonconformance."

Quality Without Tears: The Art of Hassle-free Management 1984

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**Crosby and the four absolutes**

The Measurement of Quality is the price of nonconformance.
- Cost of quality has two components – cost of conformance and the cost of nonconformance, where the cost of nonconformance is the sum of all expenses in doing things wrong.
- Cost of nonconformance can be 10X cost of conformance.
- Identifying cost of conformance is easy. 3-4% of operating cost.

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**Cost Ratios**
Costs of Quality
Prevention is ALWAYS cheaper

Costs of Poor Quality
• More than what meets the eye!

Different Folks cause Different Costs
The pen is messier than the soldering iron
• Phillip Crosby

Different Folks cause Different Costs
White Collar Error Costs
• Meetings that start late.
• Prolonged meetings.
• Computer down-time.
• Recording errors.
• Communication errors.
• Delayed sign-offs.
• Supply chain errors.
• In-house training.
• Dismissals for poor performance.
• Non-business phone calls.
• Missed commitments.
• H. J. Harrington
Cost of Poor Quality is *NOT* an Accounting Tool

Douglas Wood
ASQ

Management's View
Yesterday and Today

1984 2009

Why Industry and Medical Laboratory CPQ are different

Industry
1. Largely Private sector
2. Customer choice
3. Life choices
4. Warranty
5. Money common denominator

Medical Laboratory
1. Largely Public sector
2. Customers less choice
3. Life saving
4. Liability
5. Money and Time are separable issues.

Dimensions of Poor Quality in the Medical Laboratory

- Money
- Time
- Patient time and inconvenience
- Productivity
- Turn around Time
- Reputation
- Liability

Dimensions of Poor Quality in the Medical Laboratory

*In the Medical Laboratory, time and money are not the same.*

- Different professional groups within the laboratory do different things, and are paid on different scales, but all their tasks are essential to laboratory operation.
- Clinicians are integral to the laboratory, but are not part of the financial structure.
- Patients are integral to the laboratory, but are not part of the financial structure.

When is “time” not “time”

- Time
  - When it can’t be used widely.
  - When it can’t be equated to money
Time Sharing only within its own Group

Impacts of Time Wasting

In the blink of an eye

A few non-retrievable seconds slip by and translate into minutes, hours, days of consumed consequence.

CPQ and the Laboratory Cycle

Proposed revisit to CPQ for the medical laboratory

- **Money**  
  Prevention + Appraisal + Failure supplies
- **Staff time**  
  Investigation, Remediation, Correction
- **Clinician time**  
  Notification, rework, re-interpretation
- **Patient time**  
  Revisit, remediation, risk, liability

A physician called to have patient information changed. Report indicates mother was tested, but he was sure it was the child. Investigation indicates (a) requisition made out for mother, (b) person tested was mother, (c) report made out for mother.

- Direct Cost impact – trivial
- Staff time - Review and remediation (9 hours)
- Clinician time – brief
- Patient time – 2 hours
- Patient risk – incalculable
- Reputation Damage and Liability Risk - incalculable
CPQ and the Laboratory (2)

Blood samples are drawn for multiple tests on the same analyzer, but an insufficient volume of blood is collected. Usually these are "near-misses" because a laboratory worker runs around and finds more blood from the patient drawn into a different tube. Retrieves sample and increases tube volume. Time to draw sample correctly: 30 seconds, Time to draw sample with reduced volume: 30 seconds.

- Direct Costs – Trivial
- Staff time – 3-4 hours per day.
- Clinician time – nil
- Patient time - nil

Direct Costs – Trivial
Staff time – 3-4 hours per day.
Clinician time – nil
Patient time - nil

CPQ and the Laboratory (3)

Improperly collected Blood Culture volumes (either too low or too great) result in false negative cultures – 10%. Time to collect properly 2 minutes. Time to collect improperly 2 minutes.

- Direct Costs – Nil
- Staff time – Trivial
- Clinician Time – Nil
- Patient Time – Nil
- Potential impact on reputation, liability, risk - substantial

CPQ and the Laboratory (4)

The patient goes to an laboratory for an ECG, but the ECG is performed incorrectly. Time to record ECG correctly – 10-15 minutes. Time to record ECG incorrectly – 10 - 15 minutes. One laboratory reports 3-5 per week.

- Direct Costs – Trivial
- Staff time – review, contact, recall, retest – 1 hour
- Clinical time – 1-2 hours
- Patient time – 3 hours
- Reputation, Liability, Risk - substantial

Direct Costs – Trivial
Staff time – review, contact, recall, retest – 1 hour
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Patient time – 3 hours
Reputation, Liability, Risk - substantial

CPQ and the Laboratory (5)

A laboratory is made aware by physician complaint of possible cross contamination of 100 tuberculosis samples within the laboratory testing process.

| Direct costs: | $20 per test |
| Staff time: | Review and Analysis 70 hours |
| | Contact 40 hours |
| | Rework 20 hours |
| | Corrective Actions 40 hours |
| | Additional Monitoring 7 hours each week |
| Clinician time | Patient recall and retests 100 hours |
| Patient time | Retest 100 hours |
| Reputation, Liability, and Risk | incalculable |

A large community laboratory changed its method for measuring vitamin D in order to save both time and money, but did not adjust its reference range to accommodate the new methodology. As a consequence, a massive recall (one million tests) of patients and retests was required.

- Direct costs: $3,000,000
- Staff time: New reference range – 5 days
  Time to recall patients - 60 days
  Time to retest patients - 120 days
- Clinician time: 1-2 days for each clinician
- Patient time: 1-3 hours for each patient
- Reputation, Liability, Risk: incalculable

Improperly tested and interpreted breast tumor markers result in false positive and negative information. Time to test and interpret properly 2 minutes, Time to test and interpret incorrectly 2 minutes.

- Direct Costs | $100 per test
- Staff time | Review – 6 months
- Clinician time | hours per patient
- Patient time | 2-4 hours each
- Reputation, Liability, Risk | $7,000,000 plus
Medical Laboratory Losses

Observations

1. Laboratory Errors result in time loss and costs throughout the laboratory testing cycle.
2. Laboratory Losses and costs involve all profession groups and all reasons.
3. Poor Quality Impacts are often felt downstream from the error and.
4. Poor Quality Impacts are usually borne by people who did not directly cause the problem.
5. Creating loss take trivial time compared to investigation, remediation, and correction.
6. Inconvenience, Reputational damage, Liability, and Risk are common consequences.

Impact of Error on CPQ Scales

Costs of Poor Quality

Spidergrams

How to monitor medical laboratory CPQ

- Index
  - Near-miss time
  - Sample repeat times
  - Patient complaints
  - Physician complaints
  - Opportunity For Improvement reports
  - Critical events reports
- Process
  - Investigate, capture time and finances losses
  - Compile
  - Internal targets until benchmarks become available.
  - Management Review leading to Action Plan.

About monitoring for medical laboratory CPQ

- It is probably unreasonable and inappropriate to try to capture all costs at all times.
- A sequence of point-in-time calculations can equally monitor trends.
Why Medical Laboratory Errors Happen

Process Failure
Distraction-Inattention
Training – Compliance – Competency
Equipment Failure
Knowledge - Interpretation

All errors cost
But, some errors cost more than others,
and some a lot more!

Recovering Poor Quality Costs

- Be aware
- Have an active OFI or continuous improvement program
- Develop and Measure a CPQ process
- Record
- Monitor
- Remediate and Correct

Costs of Poor Quality

Money
Time
Inconvenience
Reputation
Risk

Conclusion…

Regardless of one-scale or multi-scale
It is still easier, faster, and cheaper
to prevent errors
than to have to find them and fix them.