UNDERSTANDING AND APPLYING QUALITY COSTS IN YOUR LABORATORY

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Learning Objectives

■ Discuss each of the 4 types of quality costs with relevant laboratory examples

■ Calculate the cost of poor quality for a defined laboratory problem

■ Link current laboratory quality indicators to the costs of poor quality
Truth

“Companies (laboratories) that adopt a cost of quality concept are successful in reducing failure cost and improving quality for patients and other customers.”

Types of Quality Costs

- Prevention
- Appraisal
- Failure
  - Internal
  - External
Always Remember...

It costs far less to do the job right the first time than to recover from an error.

Prevention Costs

- When the laboratory specifically designs its processes to prevent poor quality results and services.

- For laboratory activities that prevent problems, errors, or waste from occurring in the first place.

- But not costs incurred to keep a problem or error that has already occurred from recurring!
Examples of Laboratory Prevention Costs

- **Preventive maintenance**
  Maintain laboratory instruments and equipment according to the manufacturer’s schedule ensures reliable performance

- **Quality planning**
  “Prior planning prevents poor performance!”

- **Work Process Training**
  Effective new employee training program can prevent downstream errors

- **Initial competence assessment**
  Ensures new/changed work is performed competently

- **Quality improvement projects**
  Time spent in quality education, meetings, and projects is labor well spent

Appraisal Costs

- For evaluating quality of work after it has been performed

- For measuring, evaluating, and auditing to ensure conformance to requirements

- To “catch and correct” problems and errors before harm to laboratory users and patients
### Examples of Laboratory *Appraisal* Costs

- **Ongoing competence assessment**
  Ensures personnel maintain their competence in assigned job tasks

- **Calibrations**
  Ensures accuracy of measuring equipment and instruments

- **Inspections of specimens and reagents before testing**
  Ensures quality of inputs to testing methods

- **Quality Control**
  Ensures that testing methods are working and results are valid

- **Proficiency testing**
  Ensures your laboratory’s method performance compares to that of peer laboratories

- **External accreditations (e.g., ISO 15189)**
  Ensures laboratory performance to minimum standards

### Failure Costs

- **Services that do not meet quality requirements the first time usually need rework or correction**

- **Internal failure costs**
  - *Caught and corrected inside the laboratory before delivery of results or reports*

- **External failure costs**
  - *Detected outside the laboratory by users who receive faulty results, reports, or other services*
Poor Quality is NOT Free!

Every time work is redone, the cost of quality increases!

Examples of Laboratory Internal Failure Costs

- **Specimen problems**
  Received specimens do not meet acceptance criteria and need recollection

- **Invalid instrument runs**
  QC or calibration is out of control and examination results cannot be released

- **Incomplete examination runs**
  Technical problem so that examinations cannot be completed

- **Expired reagents or materials**
  Are not to be used in phlebotomy or examinations

- **Anything that causes delays in turnaround time**
  - Rework
  - Retesting
  - Repair
  - Downtime
Examples of Laboratory External Failure Costs

- **Customer complaints**
  Dissatisfaction reported by any laboratory customer, user, client, or patient

- **Report recalls**
  Erroneous results are corrected with resulting consequences

- **Misdiagnoses**
  The cost of not receiving needed treatment and also the cost of receiving treatment erroneously – not including patient distress

- **Lawsuits**
  Uncommon, but very costly for whatever reason

Comparative Cost of Quality

- **Prevention**
  Defect prevention efforts

- **Appraisal**
  Inspection and testing to catch and correct defects

- **Failure**
  Customer finds defects or is dissatisfied with services

\[
\begin{align*}
\text{Prevention} & \quad \text{10} \\
\text{Appraisal} & \quad \text{100} \\
\text{Failure} & \quad \text{1000}
\end{align*}
\]
Understanding Failure Cost Elements

<table>
<thead>
<tr>
<th>Common Activities</th>
<th>Done Correctly, the First Time</th>
<th>Additional Work Due to Process Failure</th>
<th>Possible Additional Work for the Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discovery of failure (NCE)</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Immediate action</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preexamination</td>
<td>X</td>
<td>Depends on failure</td>
<td></td>
</tr>
<tr>
<td>Examination</td>
<td>X</td>
<td>Depends on failure</td>
<td></td>
</tr>
<tr>
<td>Postexamination</td>
<td>X</td>
<td>Depends on failure</td>
<td></td>
</tr>
<tr>
<td>Investigation</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Root cause analysis</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrective action</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report completion</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: NCE; nonconforming event.

Laboratory's budgets do not have a “Failure Costs” category – the expense is already included in the current operational performance.
Calculating Costs: The Basic Worksheet

- Costs calculated are only for the failed process.
- Do not include the cost of initially performing the process.
- Every time a process is repeated, the available funds for “doing it right the first time” are depleted, which results in higher expenses than budgeted.

The worksheet can be used to:
- Calculate the cost of a failure or group of failures
- Estimate the cost of a failure or group of failures
- Communicate the financial effect of a failure or a group of failures

Calculating Reagents and Material Costs Example:
Failed Instrument Examination (manually loaded test)

<table>
<thead>
<tr>
<th>Reagents and Materials Description</th>
<th>Item Cost (per Item)</th>
<th>Quantity Used</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibrators per batch</td>
<td>$0.33</td>
<td>3</td>
<td>$0.99</td>
</tr>
<tr>
<td>QC per batch</td>
<td>$2.30</td>
<td>3</td>
<td>$6.90</td>
</tr>
<tr>
<td>Reagents for 106 tests (100 pts)</td>
<td>$1.02</td>
<td>106</td>
<td>$108.12</td>
</tr>
<tr>
<td>Pipette tips</td>
<td>$0.10</td>
<td>106</td>
<td>$10.60</td>
</tr>
<tr>
<td>Transfer test tubes</td>
<td>$0.06</td>
<td>106</td>
<td>$6.36</td>
</tr>
</tbody>
</table>

**Reagents and Materials Subtotal**: $132.97

**NOTE**: This example is not meant to be all-inclusive or representative of any specific laboratory; it is meant only as an illustration of how a failed instrument examination calculation could be derived.

- **Reagents and Materials**: List (individually when possible) the various reagents and materials (e.g., reagents, controls, disposables,) used for repeating the failed process.
- **Item Cost**: List the cost of each reagent and material.
- **Quantity Used**: List the number of items used.
Calculating Labor Costs Example: Failed Instrument Examination

<table>
<thead>
<tr>
<th>Labor Item Description</th>
<th>Labor Cost (per Hour)</th>
<th>Portion of Hour in Tenths</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing personnel - basic troubleshooting</td>
<td>$30.00</td>
<td>0.5</td>
<td>$15.00</td>
</tr>
<tr>
<td>Supervisor - additional troubleshooting and documentation of resolution</td>
<td>$40.00</td>
<td>0.3</td>
<td>$12.00</td>
</tr>
<tr>
<td>Testing personnel - hands-on time to repeat 100 specimens, 3 controls and 3 calibrators</td>
<td>$30.00</td>
<td>0.2</td>
<td>$6.00</td>
</tr>
<tr>
<td>Supervisor reviews actions before releasing results</td>
<td>$40.00</td>
<td>0.1</td>
<td>$4.00</td>
</tr>
<tr>
<td>Labor Subtotal</td>
<td></td>
<td></td>
<td>$37.00</td>
</tr>
</tbody>
</table>

- **Labor**: List individual job titles involved in the failed process. Include anyone involved in the initial discovery, investigation, repeated process, and follow-up of the failure.
- **Labor Cost**: List the individual's wage per hour, or an average wage per hour, for that job classification. Benefit costs are excluded - it is up to the laboratory to decide whether or not to include them.
- **Portion of Hour in Tenths**: List the amount of time spent in tenths of an hour—six minutes equals 0.1 hour.

Calculating Total Cost Example: Failed Instrument Examination

<table>
<thead>
<tr>
<th>Total Costs</th>
<th>Cost Description</th>
<th>Additional Applied Factor</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Basic Failure Cost</td>
<td>$169.97</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lost Revenue Cost</td>
<td>Estimated Cost: $100.00</td>
<td>$100.00</td>
</tr>
<tr>
<td></td>
<td>Lost Opportunity Cost</td>
<td>Estimated Cost: $169.97</td>
<td>$169.97</td>
</tr>
<tr>
<td></td>
<td>Total Failure Cost</td>
<td></td>
<td>$439.94</td>
</tr>
</tbody>
</table>

- **Lost Revenue Cost**: The net revenue (profit) per test not received = amount received (vs amount charged) minus direct costs
- **Lost Opportunity Cost**: The Basic Failure Cost (materials and labor) expended from the budget not available for other activity
The Failure Cost Worksheet for a Failed Examination Run

Costs calculated are only for the failed process.

You can build your laboratory’s worksheet in a spreadsheet program.

### Calculating Costs for a Failed Blood Collection

- Failure costs are primarily labor in different job titles.
- Unless a high recollection rate is lowered, there is no personnel reduction or significant budget effect.
- A lowered recollection rate allows for additional personnel production capacity.
Example of a Quality Report with Failure Costs

- Common laboratory failure costs
  - Recollected specimens
  - Repeated test runs
  - Corrected reports
- Calculate the best estimate of your laboratory’s failure cost for each
- Collect monthly occurrence data on these failures
- Create a spreadsheet of these failure cost totals by month
- Make this part of the laboratory’s quality report
- TAKE ACTION TO REDUCE FAILURE
- Track progress

### Quality Management System Laboratory Failure Cost Summary Report

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Month 1</th>
<th>Month 2</th>
<th>Month 3</th>
<th>Month 4</th>
<th>Month 5</th>
<th>Month 6</th>
<th>Month 7</th>
<th>Month 8</th>
<th>Month 9</th>
<th>Month 10</th>
<th>Month 11</th>
<th>Month 12</th>
<th>Monthly Average</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recollection Events</td>
<td>164</td>
<td>193</td>
<td>188</td>
<td>194</td>
<td>185</td>
<td>162</td>
<td>194</td>
<td>113</td>
<td>173</td>
<td>202</td>
<td>254</td>
<td>173</td>
<td>173</td>
<td>110</td>
</tr>
<tr>
<td>Estimated failure cost (Average = $5 30.00 per item)</td>
<td>$4,920</td>
<td>$5,250</td>
<td>$5,970</td>
<td>$5,670</td>
<td>$4,620</td>
<td>$4,650</td>
<td>$4,830</td>
<td>$4,020</td>
<td>$3,570</td>
<td>$5,190</td>
<td>$6,060</td>
<td>$7,620</td>
<td>$62,370</td>
<td></td>
</tr>
<tr>
<td>Examination</td>
<td>32</td>
<td>27</td>
<td>20</td>
<td>16</td>
<td>19</td>
<td>18</td>
<td>16</td>
<td>19</td>
<td>18</td>
<td>11</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Estimated failure cost (Average = $5 400.00 per item)</td>
<td>$12,800</td>
<td>$10,800</td>
<td>$8,000</td>
<td>$6,400</td>
<td>$7,600</td>
<td>$7,200</td>
<td>$6,400</td>
<td>$7,600</td>
<td>$7,200</td>
<td>$4,400</td>
<td>$5,200</td>
<td>$3,600</td>
<td>$85,200</td>
<td></td>
</tr>
<tr>
<td>Corrected Reports</td>
<td>120</td>
<td>68</td>
<td>60</td>
<td>86</td>
<td>100</td>
<td>72</td>
<td>40</td>
<td>59</td>
<td>100</td>
<td>66</td>
<td>57</td>
<td>59</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>Estimated failure cost (Average = $5 25.00 per corrected report)</td>
<td>$5,000</td>
<td>$3,750</td>
<td>$3,725</td>
<td>$2,150</td>
<td>$2,050</td>
<td>$1,800</td>
<td>$1,000</td>
<td>$1,475</td>
<td>$2,500</td>
<td>$1,650</td>
<td>$1,425</td>
<td>$1,475</td>
<td>$22,400</td>
<td></td>
</tr>
<tr>
<td>Total Failure Cost</td>
<td>$109,970</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

What Your Laboratory Can Do

- Build spreadsheets from the models shown here
- Find a recurring failure in your laboratory and calculate the failure cost
- Teach quality costs types to your laboratory’s personnel
Laboratory Cost of Quality Resource

- Clinical and Laboratory Standards Institute.  [www.clsi.org](http://www.clsi.org)
  - Guideline QMS20: The Cost of Quality in the Laboratory
  - Online learning course certificate program
- 2nd edition in November 2020
- More spreadsheets
- No commercial program available for medical laboratories

Thank You for Your Time and Attention!

Any Questions?