

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

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Truth

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

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Types of Quality Costs

Prevention

Appraisal



Failure

Internal

External

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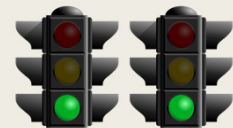
Always Remember...

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

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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!



Prevention

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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



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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



Appraisal

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Examples of Laboratory *Appraisal* Costs

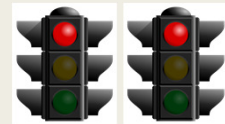
- **Ongoing competence assessment**
Ensures personnel maintain their competence in assigned job tasks
- **Quality Control**
Ensures that testing methods are working and results are valid
- **Calibrations**
Ensures accuracy of measuring equipment and instruments
- **Proficiency testing**
Ensures your laboratory's method performance compares to that of peer laboratories
- **Inspections of specimens and reagents before testing**
Ensures quality of inputs to testing methods
- **External accreditations (eg, ISO 15189)**
Ensures laboratory performance to minimum standards



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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*



Failure

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Poor Quality is NOT Free!

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



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Examples of Laboratory **Internal Failure Costs**

- **Specimen problems**
Received specimens do not meet acceptance criteria and need recollection
- **Expired reagents or materials**
Are not to be used in phlebotomy or examinations
- **Invalid instrument runs**
QC or calibration is out of control and examination results cannot be released
- **Anything that causes delays in turnaround time**
 - Rework
 - Retesting
 - Repair
 - Downtime
- **Incomplete examination runs**
Technical problem so that examinations cannot be completed



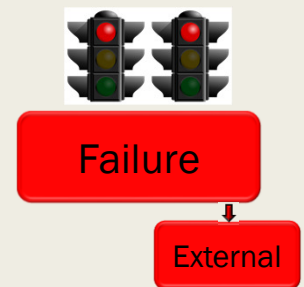
Failure

Internal

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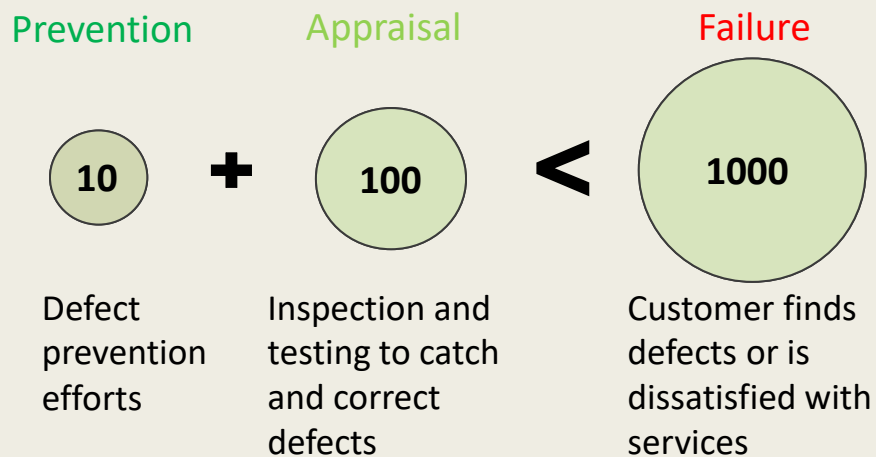
Examples of Laboratory External Failure Costs

- **Customer complaints**
Dissatisfaction reported by any laboratory customer, user, client, or patient
- **Misdiagnoses**
The cost of not receiving needed treatment and also the cost of receiving treatment erroneously – not including patient distress
- **Report recalls**
Erroneous results are corrected with resulting consequences
- **Lawsuits**
Uncommon, but very costly for whatever reason



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Comparative Cost of Quality



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What is the cost of quality in YOUR laboratory?



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Understanding Failure Cost Elements

Abbreviation: NCE: nonconforming event.

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

Laboratory's budgets do not have a "Failure Costs" category - the expense is already included in the current operational performance.

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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

Reagents & Materials Costs	Reagents and Materials	Item Cost	Quantity Used	Total
	Item Description	(per Item)		
	Item #1			\$0.00
	Item #2			\$0.00
	Item #3			\$0.00
	Item #4			\$0.00
	Item #5			\$0.00
	Item #6			\$0.00
Item #7			\$0.00	
etc			\$0.00	
Reagents and Materials Subtotal			\$0.00	

Labor Costs	Labor	Labor Cost	Portion of Hour	Total
	Item Description	(per Hour)	in Tenths	
	Job title #1 (Discover)			\$0.00
	Job title #2 (Investigate)			\$0.00
	Job title #3 (Repeat Process)			\$0.00
Job title #4 (Follow Up)			\$0.00	
etc			\$0.00	
Labor Subtotal			\$0.00	

Total Costs	Cost Description	Additional Applied Factor	Total
	Basic Failure Cost		\$0.00
	Lost Revenue Cost - Net profit per test	Estimated Cost:	\$0.00
	Lost Opportunity Cost - Budgeted funds used to pay for failure	Estimated Cost:	\$0.00
Total Failure Cost		\$0.00	

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

Reagents & Materials Costs	Reagents and Materials	Item Cost	Quantity Used	Total
	Item Description	(per item)		
	Calibrators per batch	\$ 0.33	3	\$0.99
	QC per batch	\$ 2.30	3	\$6.90
	Reagents for 106 tests (100 pts)	\$ 1.02	106	\$108.12
	Pipette tips	\$ 0.10	106	\$10.60
Transfer test tubes	\$ 0.06	106	\$6.36	
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 (eg, 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.

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Calculating Labor Costs Example: Failed Instrument Examination

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

- **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.

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Calculating Total Cost Example: Failed Instrument Examination

Total Costs	Cost Description	Additional Applied Factor	Total
	Basic Failure Cost		\$169.97
	Lost Revenue Cost	Estimated Cost: \$ 100.00	\$100.00
	Lost Opportunity Cost	Estimated Cost: \$ 169.97	\$169.97
Total Failure Cost			\$439.94

- **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

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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.

Reagents & Materials Costs	Reagents and Materials	Item Cost	Quantity Used	Total
	Item Description	(per item)		
	Calibrators per batch	\$ 0.33	3	\$0.99
	QC per batch	\$ 2.30	3	\$6.90
	Reagents for 106 tests (100 pts)	\$ 1.02	106	\$108.12
	Pipette tips	\$ 0.10	106	\$10.60
Transfer test tubes	\$ 0.06	106	\$6.36	
Reagents and Materials Subtotal				\$132.97

Labor Costs	Labor	Labor Cost	Portion of Hour in Tenths	Total
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Supervisor reviews actions before releasing results	\$ 40.00	0.1	\$4.00	
Labor Subtotal				\$37.00

Total Costs	Cost Description	Additional Applied Factor	Total
	Basic Failure Cost		\$169.97
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	Lost Opportunity Cost	Estimated Cost: \$ 169.97	\$169.97
Total Failure Cost			\$439.94

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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*.

Reagents & Materials Costs	Reagents and Materials	Item Cost	Quantity Used	Total
	Item Description	(per item)		
	Reprinted specimen label	\$ 0.25	1	\$ 0.25
	Specimen tube	\$ 0.50	3	\$ 1.50
	Needle	\$ 0.50	1	\$ 0.50
	Alcohol wipe	\$ 0.01	1	\$ 0.01
Bandage	\$ 0.01	1	\$ 0.01	
Reagents and Materials Subtotal				\$ 2.27

Labor Costs	Labor	Labor Cost	Portion of Hour in Tenths	Total
	Item Description	(per Hour)		
	Specimen processor identifies mislabeled specimen, initiates a nonconforming event (NCE) report, and notifies patient's nurse	\$ 15.00	0.3	\$ 4.50
	Specimen processor notifies phlebotomist to recollect specimens	\$ 15.00	0.1	\$ 1.50
	Phlebotomist recollects specimens	\$ 17.00	0.3	\$ 5.10
	Specimen processor reprocesses specimen	\$ 15.00	0.1	\$ 1.50
	Supervisor reviews NCE report	\$ 25.00	0.2	\$ 5.00
Supervisor investigates mislabeling event	\$ 25.00	0.5	\$12.50	
Labor Subtotal				\$ 30.10

Total Costs	Cost Description	Additional Applied Factor	Total
	Basic Failure Cost		\$ 32.37
	Lost Revenue Cost	Estimated Cost:	\$ -
	Lost Opportunity Cost	Estimated Cost:	\$ -
Total Failure Cost			\$ 32.37

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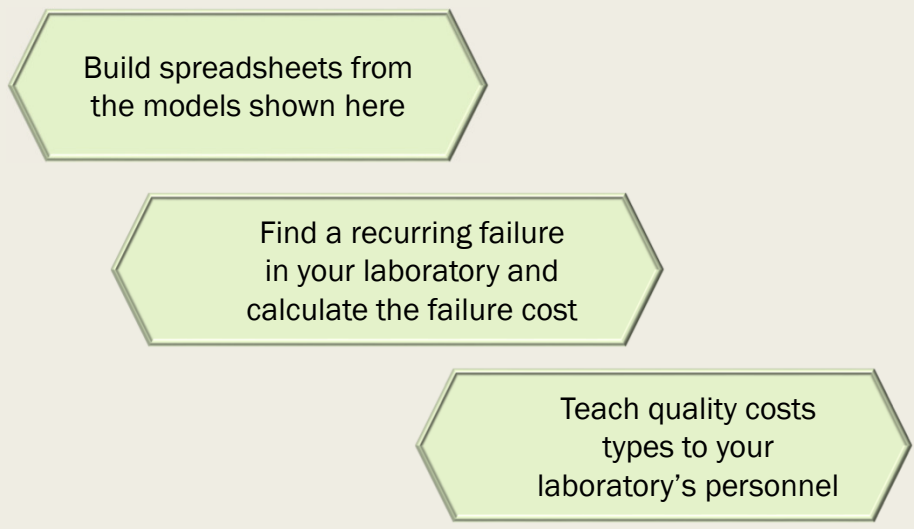
Example of a Quality Report with Failure Costs

- 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															
	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Monthly Average	Threshold	YTD Failure Cost
Preexamination															
Number of Specimen Recollection Events	164	175	199	189	154	155	161	134	119	173	202	254	173	≤ 150	
Estimated failure cost (Average = \$ 30.00 per collection)	\$4,920	\$5,250	\$5,970	\$5,670	\$4,620	\$4,650	\$4,830	\$4,020	\$3,570	\$5,190	\$6,060	\$7,620			\$62,370
Examination															
Number of Failed Instrument Runs	32	27	20	16	19	18	16	19	18	11	8	9	18	≤ 15	
Estimated failure cost (Average = \$ 400.00 per failed run of 100 tests)	\$12,800	\$10,800	\$8,000	\$6,400	\$7,600	\$7,200	\$6,400	\$7,600	\$7,200	\$4,400	\$3,200	\$3,600			\$85,200
Examination															
Number of Corrected Reports	120	68	69	86	100	72	40	59	100	66	57	59	75	≤ 75	
Estimated failure cost (Average = \$ 25.00 per corrected report)	\$3,000	\$1,700	\$1,725	\$2,150	\$2,500	\$1,800	\$1,000	\$1,475	\$2,500	\$1,650	\$1,425	\$1,475			\$22,400
Total Failure Cost															\$169,970

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What Your Laboratory Can Do



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Laboratory Cost of Quality Resource

- Clinical and Laboratory Standards Institute. 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



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Thank You for Your Time and Attention!

Any Questions?



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