The cost of quality: What can your institution afford?

Donna D. Castellone

MS, MASCP, MT(ASCP)SH

New York Presbyterian- Columbia Medical Center

Laboratory Consultant

Learning Objectives:

1

1. Identify good and poor costs associated with quality.

2

2. Discuss the importance of a quality management system and quality indicators.

3

3. Enhance problem solving skills related to the costs associated with quality.

What are important quality questions:

- Who is responsible for quality?
- What is the return on investment?
- When do you justify additional investment in quality?
- Where are the biggest challenges is the return on investment?
- Why do you measure quality?

Goal of Laboratory Medicine:

- To improve health by providing laboratory results that support medical decisions
- The quality of laboratory medicine has influence on the quality and affordability of patient care.
- Errors have consequences in patient care and health care costs.
- The most likely errors rates are between 1 in 164 to 1 in 330 events in the laboratory

- Am J Clin Pathol 2012 347-354

Why should the laboratory get involved

- 70% of medical decisions are influenced by laboratory results
- Data analytic platforms can provide insight to ordering patterns
- Drill down information and analyze outcomes
- What can labs do with this information:

    1. Compare results ordered by different physicians for the same diagnosis and identify best practices
    2. Identify tests that are no longer clinically relevant or ordered accidentally
    3. Define when testing is ordered in appropriately

- Kuruvilla, T., Advance for Laboratory, 1/2016.

Why measure the cost of quality?

- Quantify the amount of expenditures as a result of process failures
- Prioritize improvement efforts based on the data
- Track performance improvements

- CLSI QMS20-R, Understanding the Cost of Quality in the Laboratory, 2014

Accountable Care Organizations

- Healthcare organizations will be paid for keeping people healthy
- Effective in providing prompt and accurate diagnosis
- Proactively monitoring and managing high-cost disease
- If laboratories are not paid per test- must function efficiently and effectively

Cost of quality

- **US is the top spender in health care**
- **However it is ranked as 36th in quality**
- **Quality is free**
- **What costs money is to do things right the first time**
- **If costs a laboratory a $1 investment in prevention- $10 in appraisal costs- it is $100 for a failure**

Ali, E, Counting the Cost of Quality , ASCP 10/29/15

Statistics

- **14 billion laboratory tests are performed annually**
- **Over 260,000 CLIA certified laboratories**
- **Comprise 2.3% of US health care expenditures**
- **2% of Medicare expenditures**

- www.cdc.gov 2024

Errors:

251,000 deaths per year occur because of errors in medical care.

This makes medical errors the third leading cause of death, only after heart disease and cancer.

Medical error as "an act of omission or commission in planning or execution that contributes or could contribute to an unintended result."

By this definition, failures in laboratory tests certainly qualify. Lab test failures contribute to delayed or wrong diagnoses and unnecessary costs and care.

BMJ 2016;353:i2139

Statistics:

A study estimated that diagnostic errors happen about 12 million times per year in U.S. outpatients.

This represents 1 in 20 adults

Institute of Medicine found that most people will experience at least one diagnostic error in their life.

Singh H, et al. BMJ Qual Saf 2014;23:727–731.

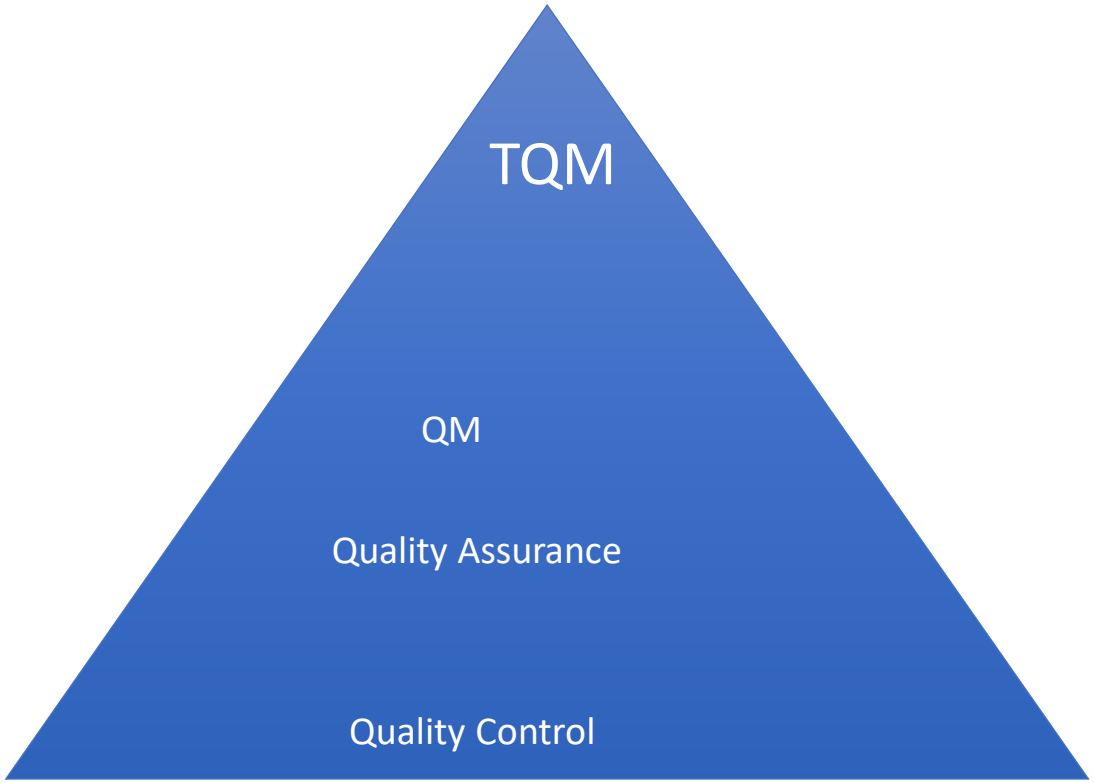
Laboratories are challenged to:

Maintain or increase quality- while lowering costs- how do we do this?

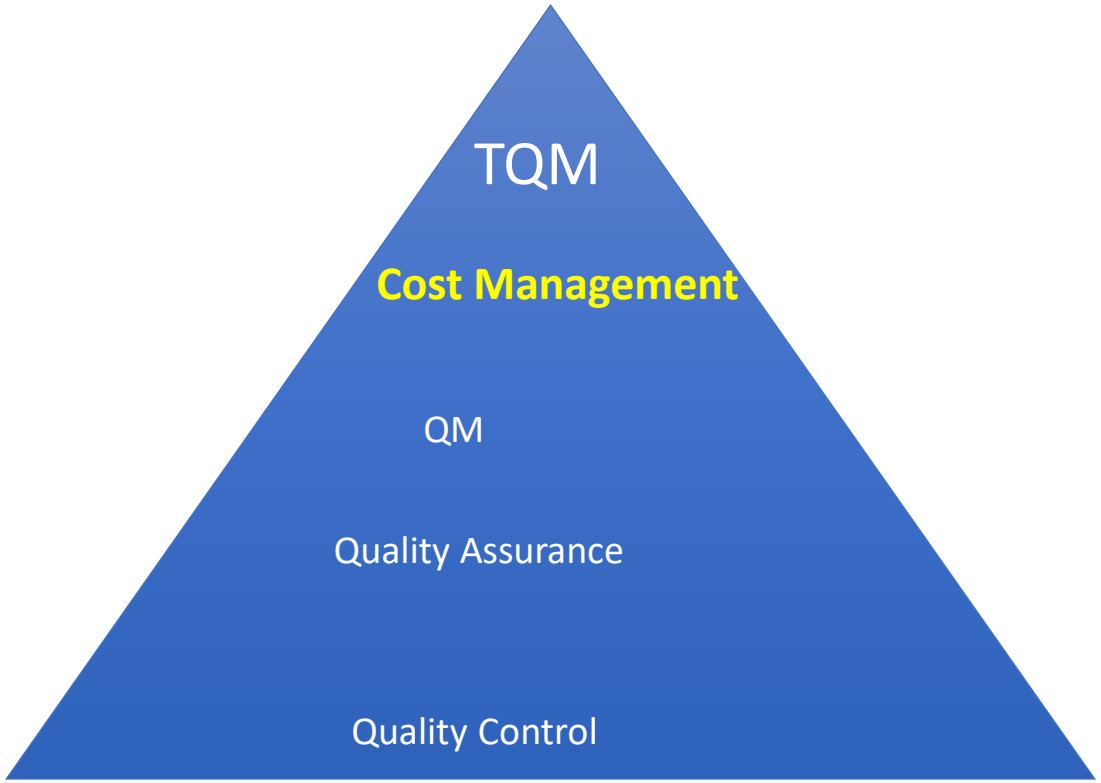
1. **We tell people to work harder and be more careful**
2. **We use the band-aid approach**
3. **Get new “stuff”, more OT, use consultants**

Stages of Quality:

OLD



NEW



Where are the costs?

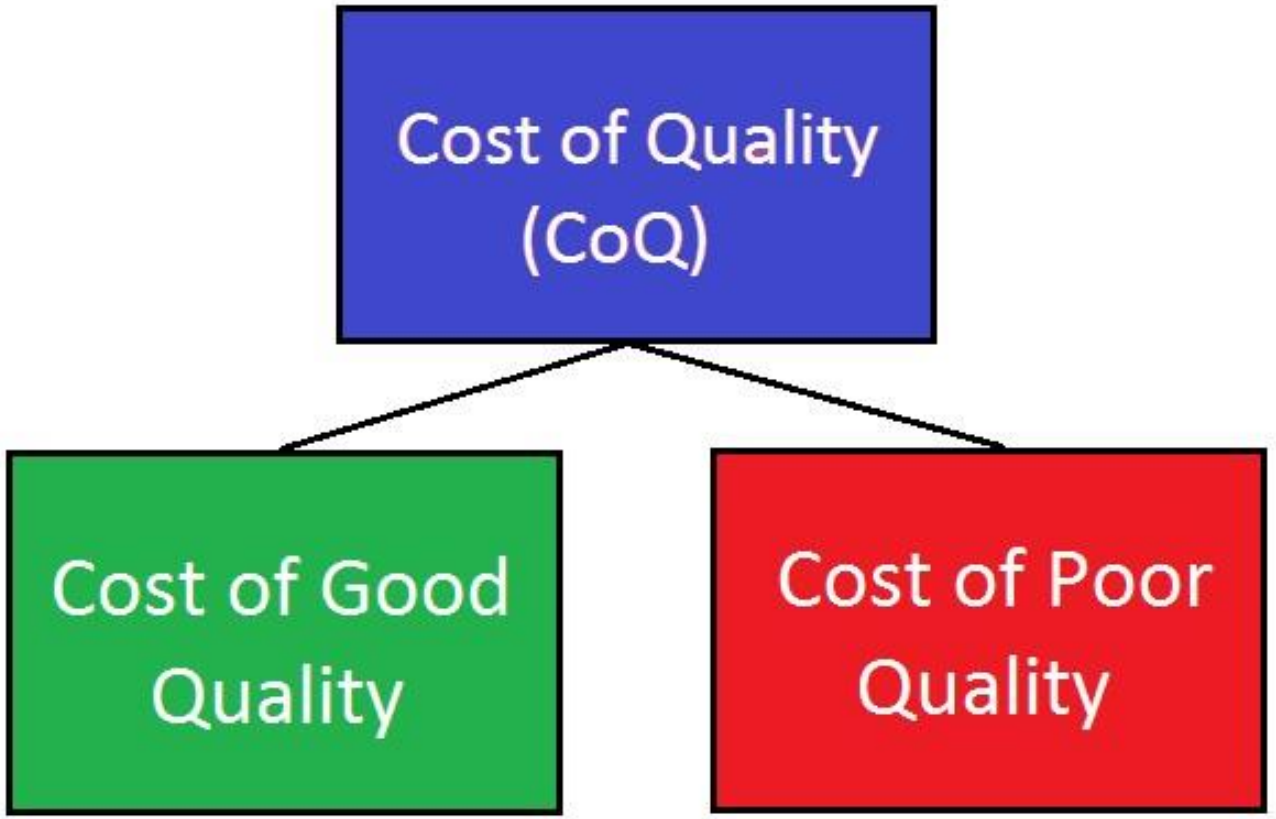
- ***Every time that work is redone the cost of laboratory services increase and therefore the cost of quality increases***

Philip Crosby said:

"Quality is free- not a gift but free-

Unquality costs money"

Costs =

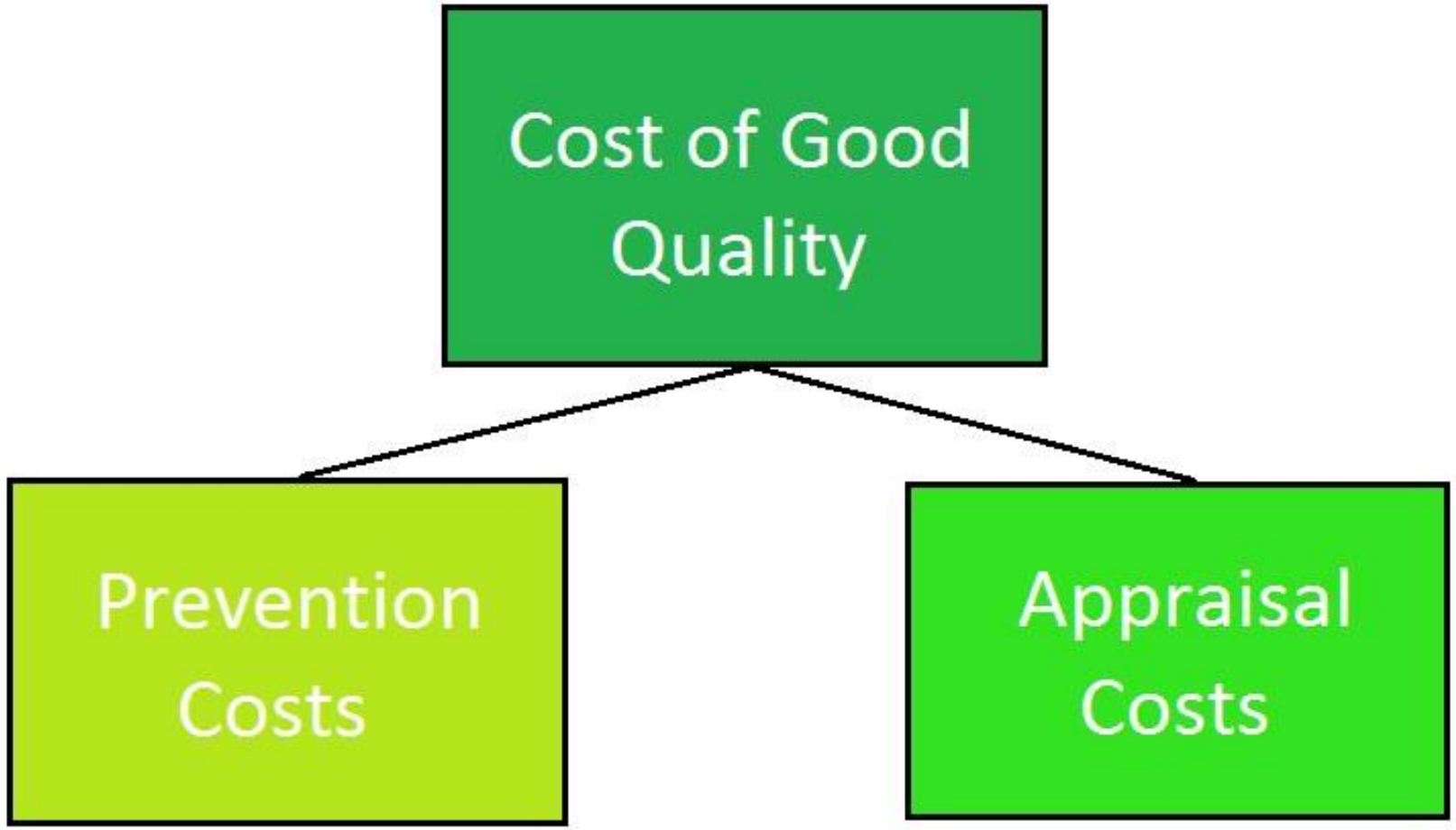

Cost of Quality (CoQ)
Cost of Good Quality
Cost of Poor Quality

Definitions

- **Return on Investment (ROI):** the benefit (or return) of an investment is divided by the cost of the investment, and the result is expressed as a percentage or a ratio

- **Cost Savings:** Actions that lower current spending, investment or debt levels.
- They result in a tangible financial benefit.

- **Cost Avoidance:** Any action that avoids costs in the future.
- They represent potential increases in costs that are averted through specific preemptive actions.


Cost of Good Quality
Prevention Costs
Appraisal Costs

Types of costs:

- ***Prevention Costs:*** Costs resulting from all activities that are designed to keep defects from ever occurring or that prevent poor quality from arising.

  cost of quality planning,

  Validation or verification of laboratory processes

  preventive maintenance,

  initial competency assessment.

- ***Appraisal Costs:*** Costs resulting from all activities that occur in evaluating the quality of work after it has been performed to identify deficiencies at any point and determine conformance to quality standards.

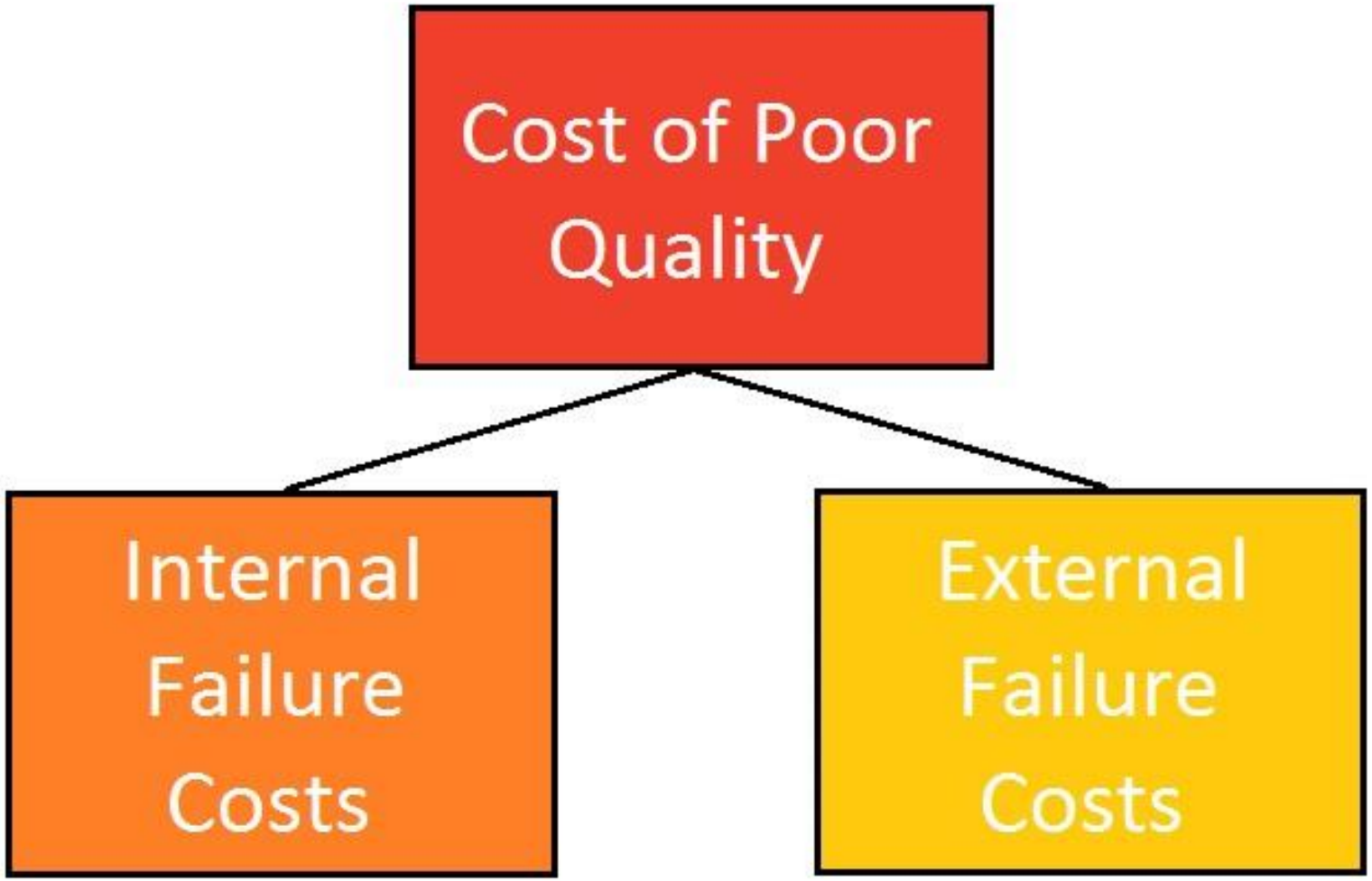
  cost of calibration of instruments,

  quality control,

  proficiency testing,

  on-going competency assessment,

  accreditation.


Cost of Poor Quality
Internal Failure Costs
External Failure Costs

Failure Costs:

- ***Internal failure costs:*** Costs that are caused by services that do not conform to the standards and are identified before the result leaves the laboratory.

  sample problems in the pre-examination phase

  cost of invalid instrument run,

  expired reagents

  anything that causes a delay in turnaround time

- ***External failure costs***: Costs caused by deficiencies found after the result leaves the laboratory and customer dissatisfaction.

  cost of complaints,

  patients' misdiagnosis,

  lost results,

  reporting errors

Other costs

- ***Time waste*:** time lost due to the investigation of the error, test rerun, and time consumed by the laboratory management in meetings and writing reports.
- ***Energy waste***: mental activity done by the staff. Spending time on repeated quality checks or phone calls can result in increased stress. These costs can be quite difficult to identify.
- ***Money waste***: actual financial loss appears insignificant, but increases when both direct and indirect costs are added.

What is a non-conforming event:

- **Something doesn't go as planned in the laboratory**
- **Accident, adverse event, error, event, incident, non-conformity, occurrence**
- **Failure to meet a requirement**
- **Regulatory requirement to track, record and resolve**

- Dawson, J, What is the Cost of Poor Quality? Calculating an ROI for your Lab's Quality program, 6/2017; Webinar Cardinal Health

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"

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

Why Medical Labs need Quality Management

- Medical Laboratories
  - Highly complex operations
  - Individuals doing complex tasks
  - Absolute need for Accuracy
  - Absolute need for Confidentiality
  - Absolute need for Time Effectiveness
  - Absolute need for Cost Effectiveness

Case: Where to start? How do you benefit from a Quality Management System?

- Initial quality system we had no less than 7 quality manuals
- Each laboratory had their own processes; and were not necessarily following what they had written
- We had different competency forms for each laboratory
- Employee files included jury duty forms between diplomas and leave requests next to continuing education
- Quality plans were written only for the automated laboratory
- We had no formal monthly review of quality, non conformance and improvement

TOP TEN CAP DEFICIENCIES: 2022

- GEN.55500 Competency Assessment Elements - Nonwaived Testing
- COM.04250 Comparability of Instruments and Methods - Nonwaived Testing
- COM.01200 Activity Menu
- COM.10000 Policy and Procedure Manual
- COM.01700 PT and Alternative Performance Assessment Result Evaluation
- COM.30600 Maintenance/Function Checks
- COM.04200 Instrument/Equipment Record Review
- COM.01400 PT Attestation Statement
- COM.30750 Temperature Checks
- GEN.20450 Correction of Laboratory Records

How did we get out of this?

- **Formed the CQI committee; it was chaired by the medical director; input from all stakeholders**
- **Goal was to standardize as many policies as possible; some will pertain to only certain sections; most were consensus documents; some were dictatorship**
- **Used a document management system**
- **We considered: best practices, reviewed forms versus on line documents, PT practices, competency became standardized**
- **Employee files were standardized**
- **We studied, participated in webinars**
- **Standardized, harmonized and unified**
- **We became a very boring laboratory- everything was the same**

Quality Management:

- Begins with *centralized oversight* from a quality leader.
- Without this organization around quality, people may be unsure of who's doing what and how to operate soundly. Things start to fall through the cracks. Risks multiply. Patient safety suffers.
- Decentralized quality programs are a recipe for disaster.

- A quality leader should be focused solely on quality management.
- **Trained in quality and familiar with all applicable regulatory requirements and where to find answers**
- Avoid conflicts of interest by having the quality leader report directly to administration
- Do not have the quality leader report to operations.

Quality Manual:

- Should be a guide, process-oriented and written simply.
- Staff members review and be able to access the manual
- They need to understand how they will contribute to providing quality lab services.

CSLI: QMS MANUAL

- 1. Documents and Records
- 2. Organization
- 3. Personnel
- 4. Equipment
- 5. Purchasing & Inventory
- 6. Process Control
- 7. Information Management
- 8. Occurrence Management
- 9. Assessment/Internal/External
- 10. Process Improvement
- 11. Customer Service and Satisfaction
- 12. Facilities & Safety

Quality Management Plan:

- There must be a document that describes the overall QM program.
- It can be a broad-rang plan can cover all of the CLIA Quality System re
- Should contain monitors of key indicators of quality
- No different than any other process
- Its purpose is to document meaningful processes that will improve outc laboratory
- Who will do what, when it is due, and what they are doing
- How are we doing? And can we do it better
- Can we do it more efficiently, more timely?

  Need a plan - this is a structured approach to evaluate current processes and improve systems How are we doing? And can we do it better?
  Can we do it more efficiently, more timely?

  Need a plan - this is a structured approach to evaluate current processes and improve systems
- Establish and monitor metrics and outcomes

- STRUCTURE; PROCESS and OUTCOMES

.

Outcome:

- Both CAP and NYS DOH inspections in 2017
- No process driven deficiencies
- Competency files, employee files, quality indicators, inventory
- All good

What did we get dinged on-

1. Our UV light policy was different in the safety manual, than what we were doing
2. An infectious disease fellow was noted texting on his phone at the microbiology bench

Cost Analysis:

- Meetings: 30/year – 20 managers/5 directors: cost of the meetings for the year: $70,500.00
- Additional workload: 5 hours/week : 5 QA managers =$19,200.00
- Committee costs: $89,700.00/year (conservative) for 2 years: $179,400.00
- Not have 3 strikes for a deficiency…….priceless

Case: How much did this cost?

- **Patient previous heart transplant (2004) presents with enlarged lymph nodes**
- **Toxoplasma IgG results as positive result; first positive for this patient ; concerned seroconversion in a chronically immunosuppressed patient**
- **Started on Bactrim**
- **13 days later has test repeated at an outside lab; test is negative**
- **6 days later requested the original sample be retested – results as negative**

Now what?

Original run results reviewed: only one positive patient- now repeated as negative

Now entire run was repeated, all results negative

Patient removed from Bactrim

NONCONFORMING EVENTS:

-incorrect result

Outcome

- Worse: Patient placed on an antibiotic unnecessarily
- Scenario took 20 days- clinician did not contact lab until 19 days later-

=Patient care impacted

=Quality compromised

=Time to retest, reagents used, technical time

=Loss of confidence

=Retraining, reviewing of testing and processes

Was there a missed positive?

Monitoring for the Cost of Poor Quality

- Monitor trends by looking at certain point in time calculations
- Look at the average time of laboratory error

For example:

If you calculate your total time spent on errors/day on things like:

Patient demographics

Labelling

Retesting

Patient Recall for testing

Some are more time consuming than others- the average error is about 130 minutes

If you have 1040 error minutes/day= 17.3 hours/day or 2.3 FTE/average day

Noble, MA, Cost of Poor Quality in the Medical Laboratory, LifeLabs

Tracking the cost of bad quality: Internal costs

Internal Failures – Hard Costs				
Considerations	#	Units	Cost/Unit	Total
Wasted Tech Time	3	Hours	$35.00	$105.00
Wasted Reagents	2	kit	$181.00	$362.00
Process Redesign	3	Hours	$70.00	$210.00
Investigation	4	Hours	$80.00	$320.00
Director investigation	1	Hours	$120.00	$120.00
Keepsafe investigation	2	Hours	$80.00	$160.00
Rework -Failed Run	2	Runs	$90.00	$180.00
Competency	4	Hour	$95.00	$380.00
Phone calls	2	Hours	$35.00	$70.00
			Total	$1907.00

The Cost of Poor Quality in the Lab

Image courtesy of *Medical Lab Management*. Vol 2(5):8.

Evaluate Errors: ROOT CAUSE ANALYSIS

- Want to identify and evaluate errors, incidents and other problems that may interfere with patient care services. Can no longer say, I can't control that!
- Need a mechanism to capture internal and external sources such as complaints, including mistakes and near misses
- Conduct root cause analysis of occurrences, issues, errors and gaps in quality
- Measure quality indicators
- Outcome is to demonstrate risk reduction activities based on such root cause analyses – do not band-aid situations!


ROOT CAUSE METHODOLOGY
STEP 1 DEFINE PROBLEM
STEP 2 MAP CURRENT PROCESS
STEP 3 FIND ROOT CAUSE(S)
STEP 4 DEVELOP SOLUTION
STEP 5 IMPLEMENT SOLUTION
STEP 6 ASSESS EFFECTIVENESS

Three types of causes

Physical causes – Tangible, material items failed in some way (analyzer stopped working).

Human causes – People did something wrong, or did not do something that was needed. Human causes typically lead to physical causes (analyzer broke because no one emptied the waste).

Organizational causes – A system, process, or policy that people use to make decisions or do their work is faulty (no record of when waste was changed).

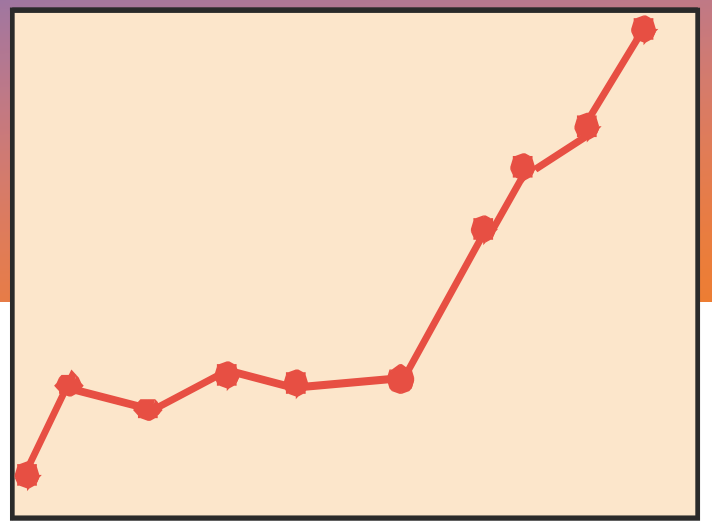
Walk the walk-

- Perceived processes- what we think is happening
- Reality processes- what the process actually is
- Ideal process- what the process could be or would like it to be.

INVESTIGATE- sometimes best done by someone who doesn’t have an emotional attachment

OUTCOME: Never found out what happened despite intensive investigation. Random, costly error.

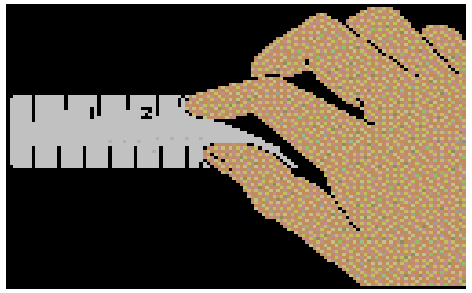
Benchmarks of performance?



Are key indicators of quality
monitored and evaluated for opportunities for improvement?

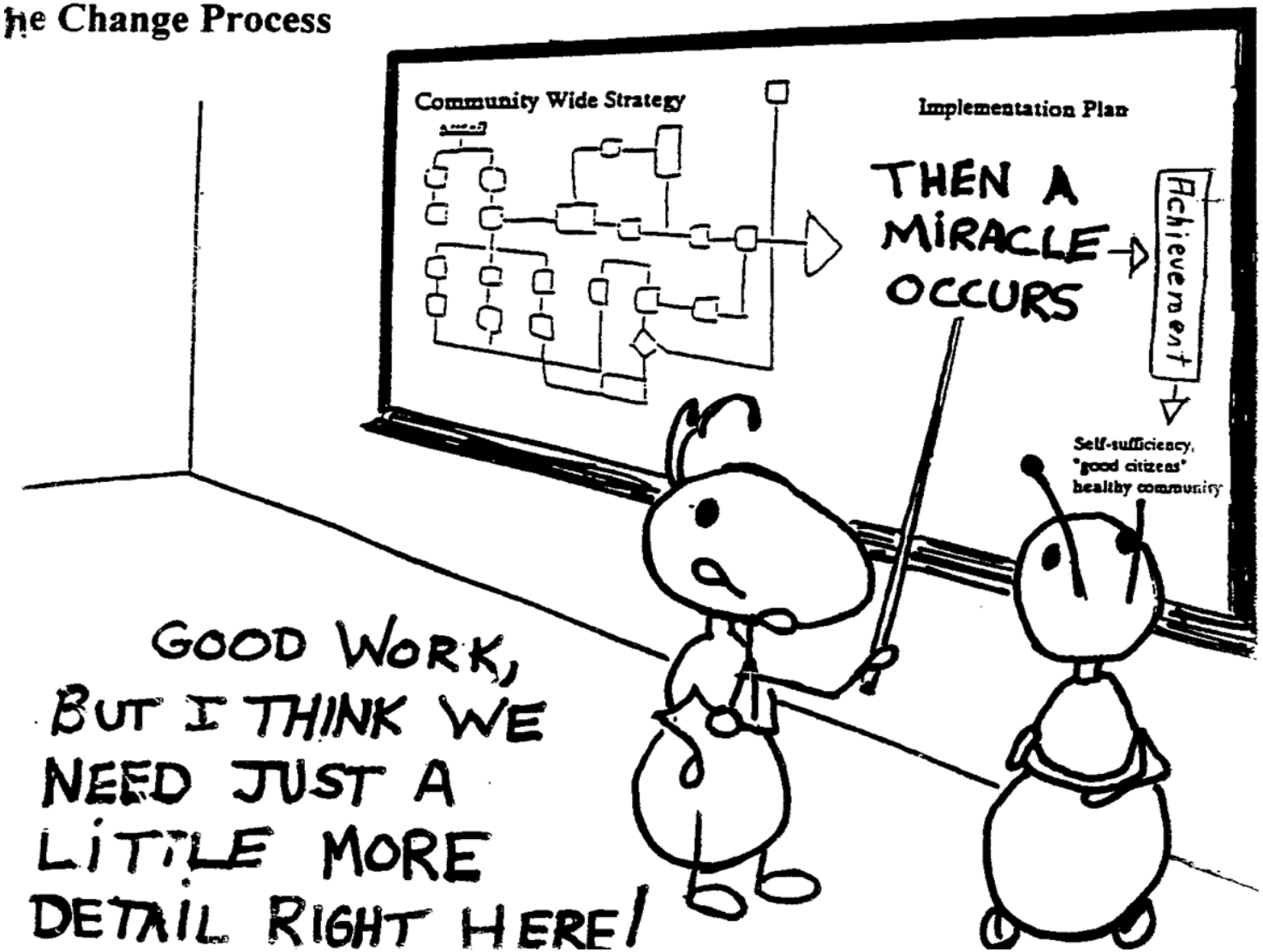
Are the chosen indicators being measured against a benchmark such as a practice guideline, Q-Probe data, published references, or trend analysis? Sufficient indicators for the laboratory's scope of care?

Pre-analytical, analytical, post-analytical?



All QI improvements are driven by collection of data driven information
In God we trust, all others require data!
You need metrics that have quality driven outcomes
BUT do not be unrealistic- or you will fail-

he Change Process



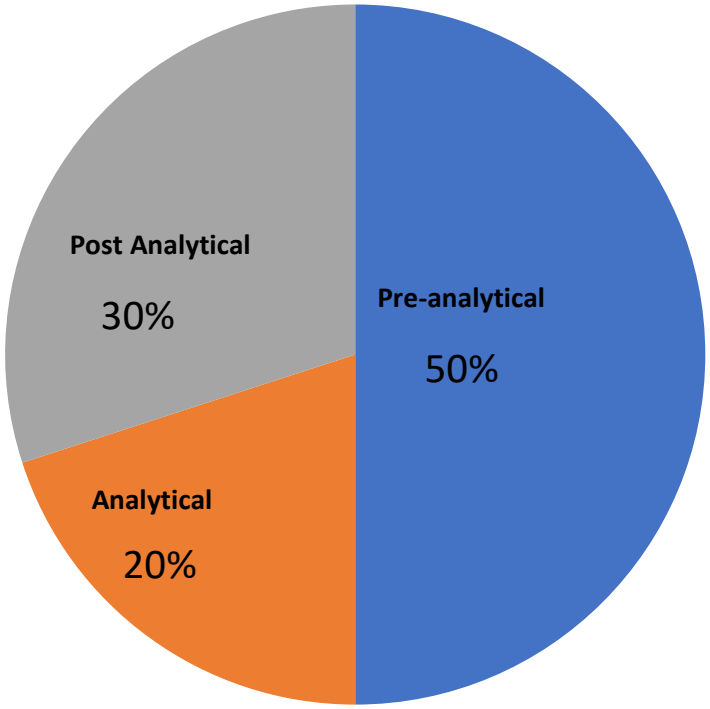
Controlling Error:

- Usually caused by bad processes
  - 80% caused by systems
  - 20% caused by acquired behaviors
- Need a culture-based organization
- Diagnosis the problem:

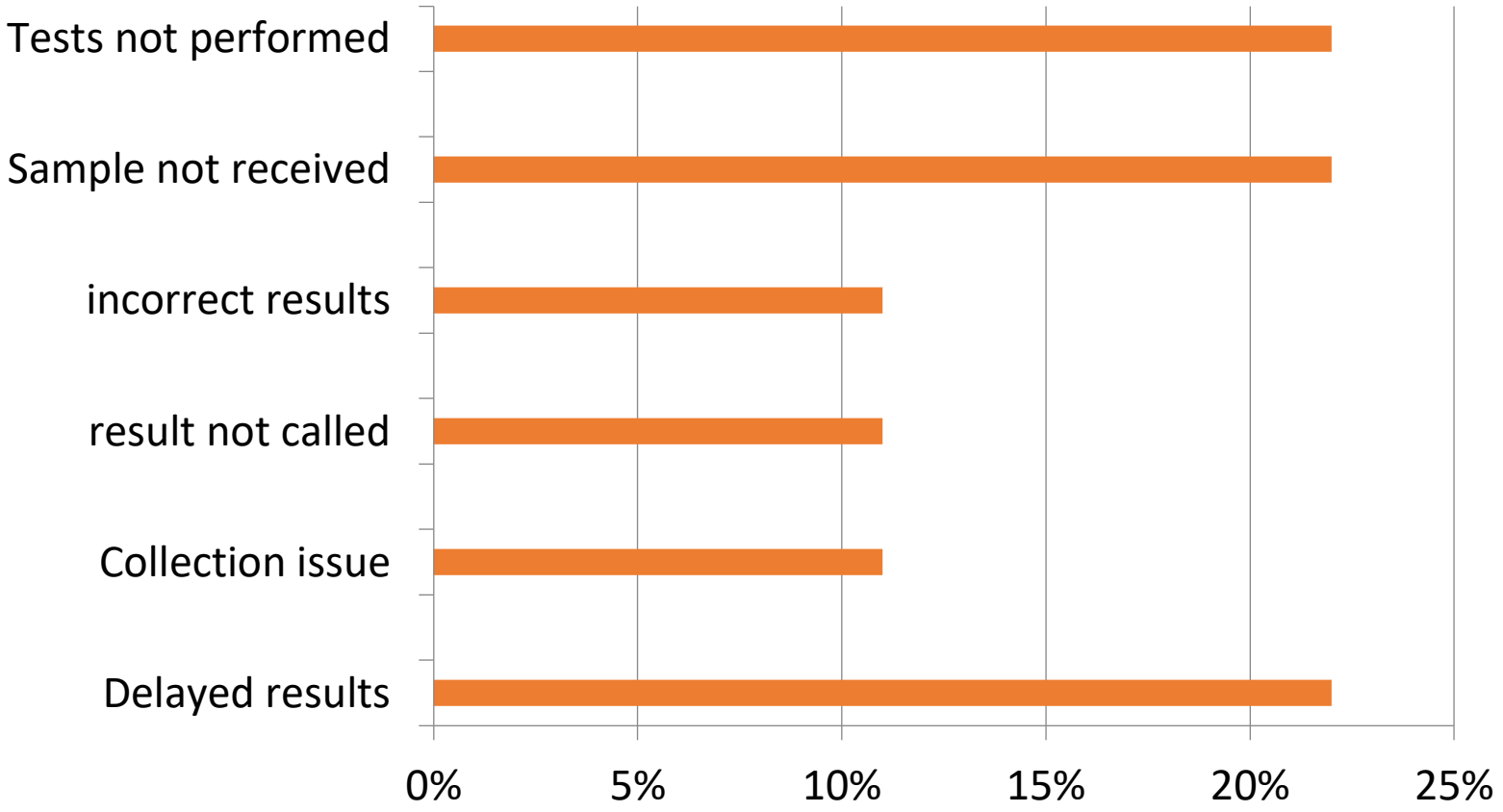
We don't know what we don't know.

Collazo, G., Controlling human Error, 8/8/17 Compliance 4all

Quality Assessment reporting events:



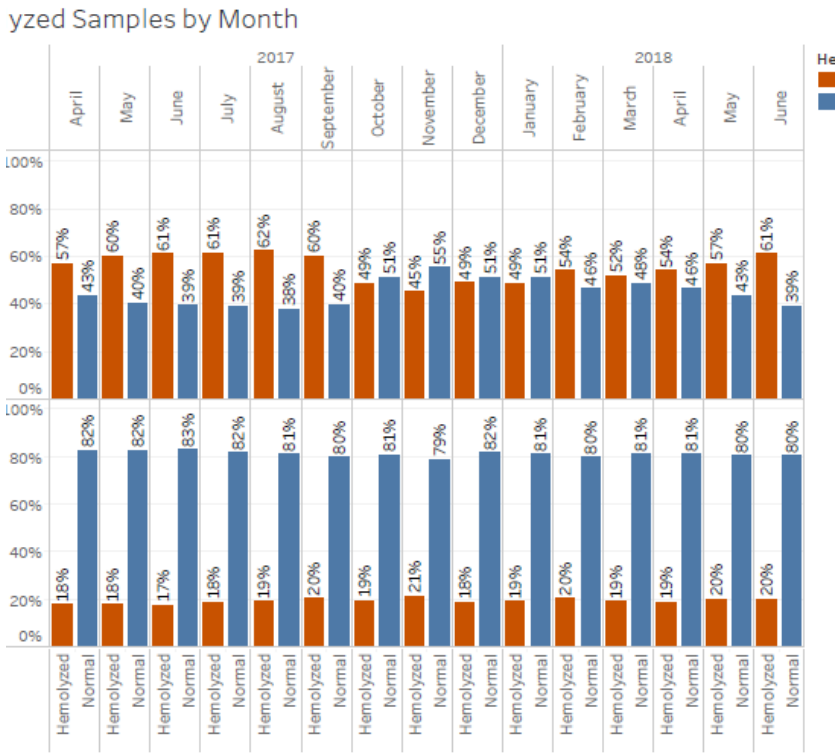
Quality Assessment Recorded issues:



Pre-analytic measures?

Do the chosen indicators include measures of pre-analytic variation appropriate to the laboratory's scope of care?

- erroneous request;
- error in patient identification;
- test order appropriateness;
- inadequate sample (hemolytic, lypemic, clotted etc.);
- missing sample (sample lost or not received)
- needle stick injuries
- transmission of physicians' orders
- requisition accuracy



Analytical measures

Do the chosen indicators include measures of analytic variation appropriate to the laboratory's scope of care?

Turn around times

external quality assurance results;

internal quality control results;

imprecision;

inaccuracy;

DAY 1	DAY 2	DAY 3	DAY 4
95	93	95	96
94	94	96	95
95	95	95	95
94	93	96	96
94	94	95	96

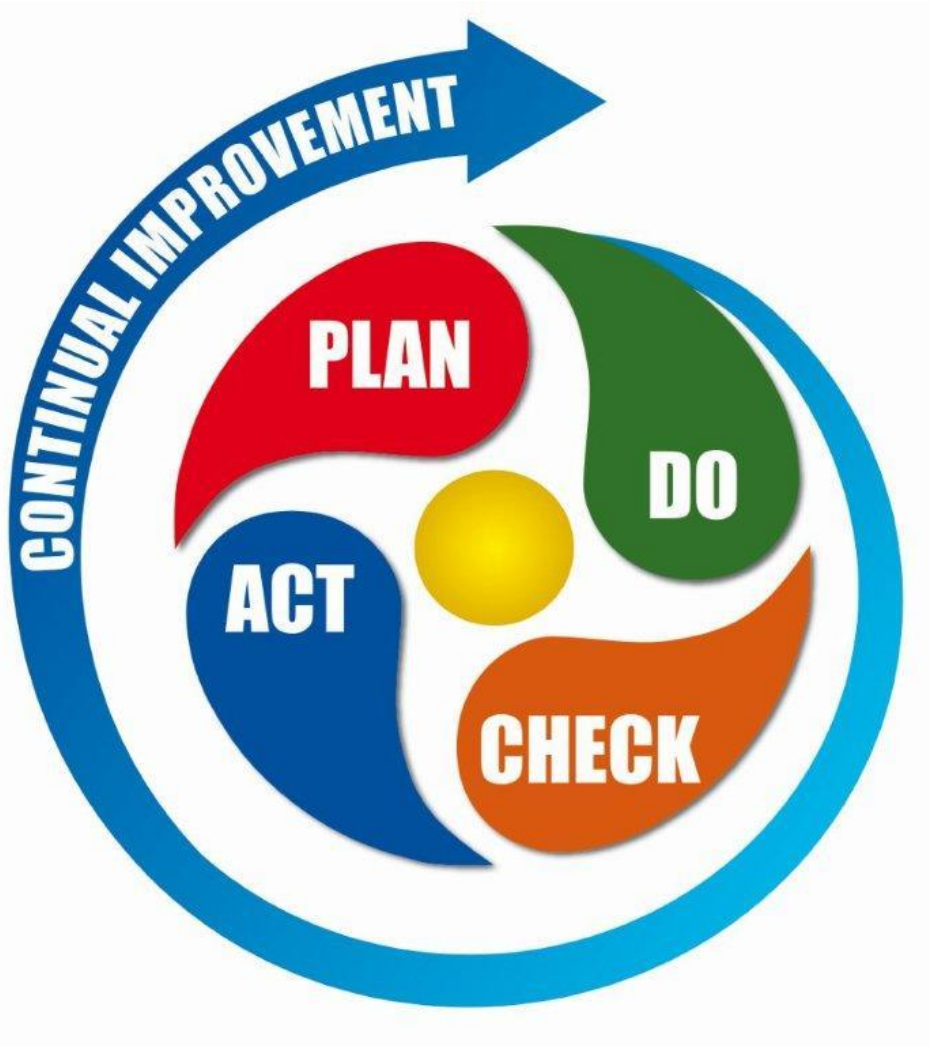
Ran control 20 times, over 4 days,

Mean 95 % - range 85-105

Manufacturers range: 80-120 sec.

Review of the first month:

- Mean 102%
- Out of 30 days- 10 days spent, re-running controls-
- Wasting time and reagents to get controls within range
- This was happening throughout all of the laboratories
- If you review the 20 control runs, looks like a precision run
- Using these ranges, we would spend a lot of time and money and effort in having techs re-run, re-calibrate and hold up the runs.
- Running 20 controls was not working.

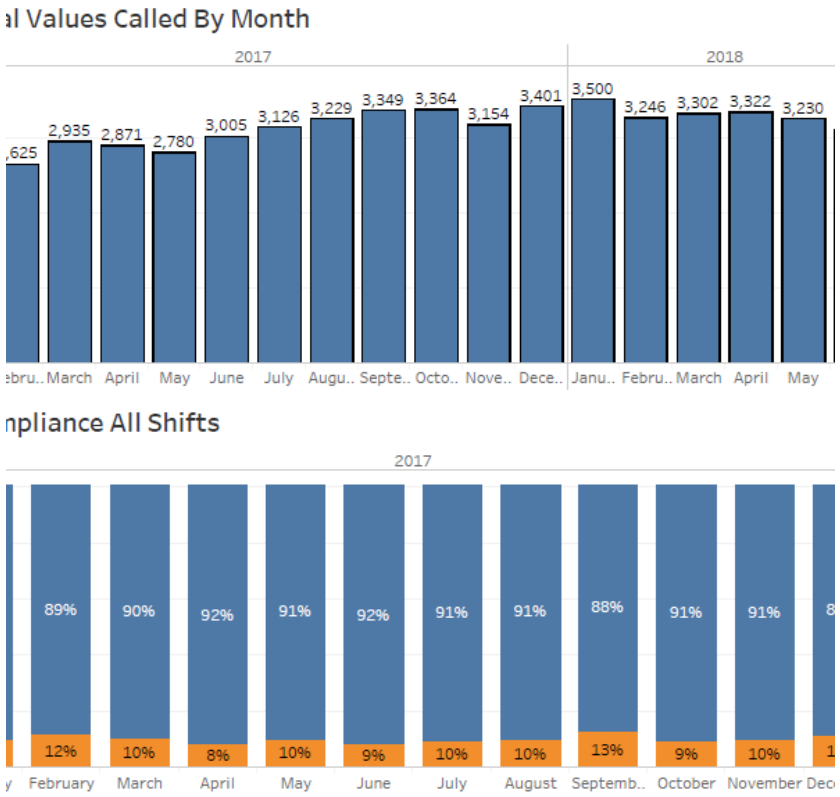

CONTINUAL IMPROVEMENT
PLAN
DO
CHECK
ACT

Continuous Improvement

- **Plan:** Implement a better process for QC review.
- **Do:** Look at how new controls are implemented within the departments.
- **Check:** The results of the 20 runs for the controls. Most look like precision studies. Ranges are too narrow, do not represent day to day runs. Techs spend a lot of time re-running, only to have the mean changed the following month.
- **Act:** We now do the 20 runs and verify the manufacturer's range. After a month, data from the 20 runs and the monthly QC provide a more realistic range which includes variability of reagent and technologists. Better range, less time with QC out of range, and having techs just re-run the same control repeatedly. A specific form now reflects changes across analyzers and LIS.

QI-6 Post Analytic
Critical Values Reporting

- Expected Goal: 100% compliance - Report CV with read back within 60 minutes of the result becoming available.
- Actual Compliance= 91%



Quantify the expected results:

- How many hours will be spared?
- How much money will be saved?
- What higher-value tasks can your team do in place of fixing the issue?
- **The way it's been vs. the way it should be**

removing barriers, inefficiencies and processes that increase risk. rather than consistently reacting to issues, empower your laboratorians to proactively solve them.

- By identifying and implementing quality initiatives, can deliver quality performance and help drive quality of care throughout their organization.

Changing Behaviors

Changing physician ordering behaviors is not easy.

Using targeted education, process maps, and algorithm development, however, pathologists can assist in reducing these costs overall.

informatics and clinical decision support utilization help play a role in controlling costs by allowing physicians to utilize more cost data upfront in the treatment or prior to ordering tests.

In a recent study in which a clinical decision support tool was used to block unnecessary duplicate test orders during computerized physician order entry (CPOE), significant cost savings were realized.

Over a 2 year period 11,790 unnecessary duplicate test orders were prevented, resulting in a cost savings of $183,586

From this test, there were no adverse effects reported.

Michael J. Misialek, MDhttp://costsofcare.org/the-cost-of-laboratory-testing

Overutilization of tests

- A recent study found that there is somewhere near a 30% overutilization rate for tests ordered and a similar underutilization rate.
- Granted most lab tests are inexpensive, however, consequences of inappropriate testing leads to significant cost and waste,

  increased length of hospital stay,

  increased procedures and visits.
- Although lab testing only accounts for 3-5% of medical costs, the downstream impact is much greater.
- Each test ordered could result in harm and unnecessary expense to the patient.

- Michael J. Misialek, MDhttp://costsofcare.org/the-cost-of-laboratory-testing

What about underutilization in testing?

- Vital testing delayed or missed
- Important to order the right test during the initial evaluation
- Leads to less errors and better care
- Missing a test could lead to preventable complications, lead to longer LOS and inappropriate treatment.

Focus on outcomes

- It is a false belief that implementing higher quality will result in higher costs.
- 80% of the cost are caused by 20% of the problems
- Laboratories need to use appraisal tools to identify and fix defects before results are delivered to physicians or patients.
- This approach will be of value in reducing the external failure costs, but it will also increase the appraisal cost.
- Aim is to emphasize the prevention of errors (spending money in prevention cost).
- Half of our quality cost directed to prevention

Cost of Poor Quality

Downstreaming:

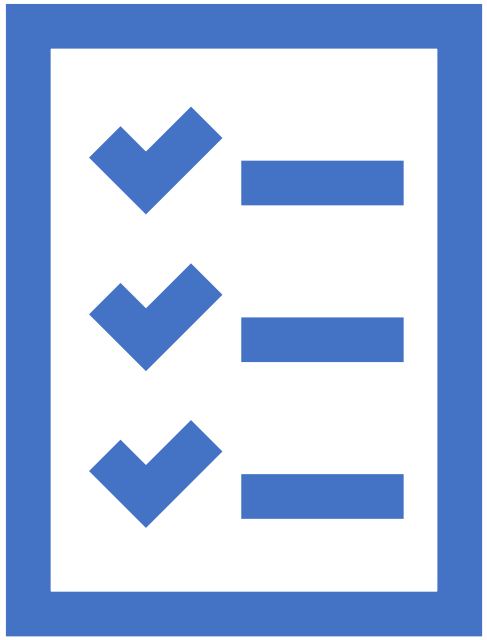
Errors that occur early- but are not detected until much later. Grows in size, complexity, cost

Upstreaming:

Examination or reporting errors that require a patient recall

The "don'ts" and "do's" for a more patient-centric lab

- Focus on systems, not individuals- 99% of people want to do the right thing!
- Think outside the bounds of the lab
- Form a quality committee
- Cost of quality-soft and hard costs
- We’re all in this together



How to start?

- **Start by looking for ways to quantify the issues**
- How often is the issue occurring?
- How many hours are spent fixing the repeat issue and what level of staff is assigned to the task?
- How much money is expended fixing the repeat issue?
- How are patients affected by these issues? Increased inpatient stay days? Wrong test at the wrong time leading to a missed diagnosis? Potential for patient harm?
- What can be done to proactively get ahead of the problem?
- ENGAGE PEOPLE!

Where to Focus

- *Track value-adding activities*
- *Decrease manual efforts*
- *Collaborate across all departments*
- *Decrease delayed communication*
- *Use the tools that you have*
- *Engage everyone from upper management to staff*
- *Sometimes you have to spend money to save money*

This is a sure bet

- Goal of the cost of **quality program** should be **3 – 5%** of total value.
- **non-quality** is estimated to be **12 – 20%** of total cost

- ***"The time to fix the roof is when the sun is shining" JFK***

"Quality is not a given, but it needs to be a practice; Patient care and test outcomes depend on it." DDC