Resolving Every Lab's Internal-External Conundrum: Recognizing the Recurring Cost of "Bad" Quality in the Lab as a Necessary Step to Delivering More Value to Physicians

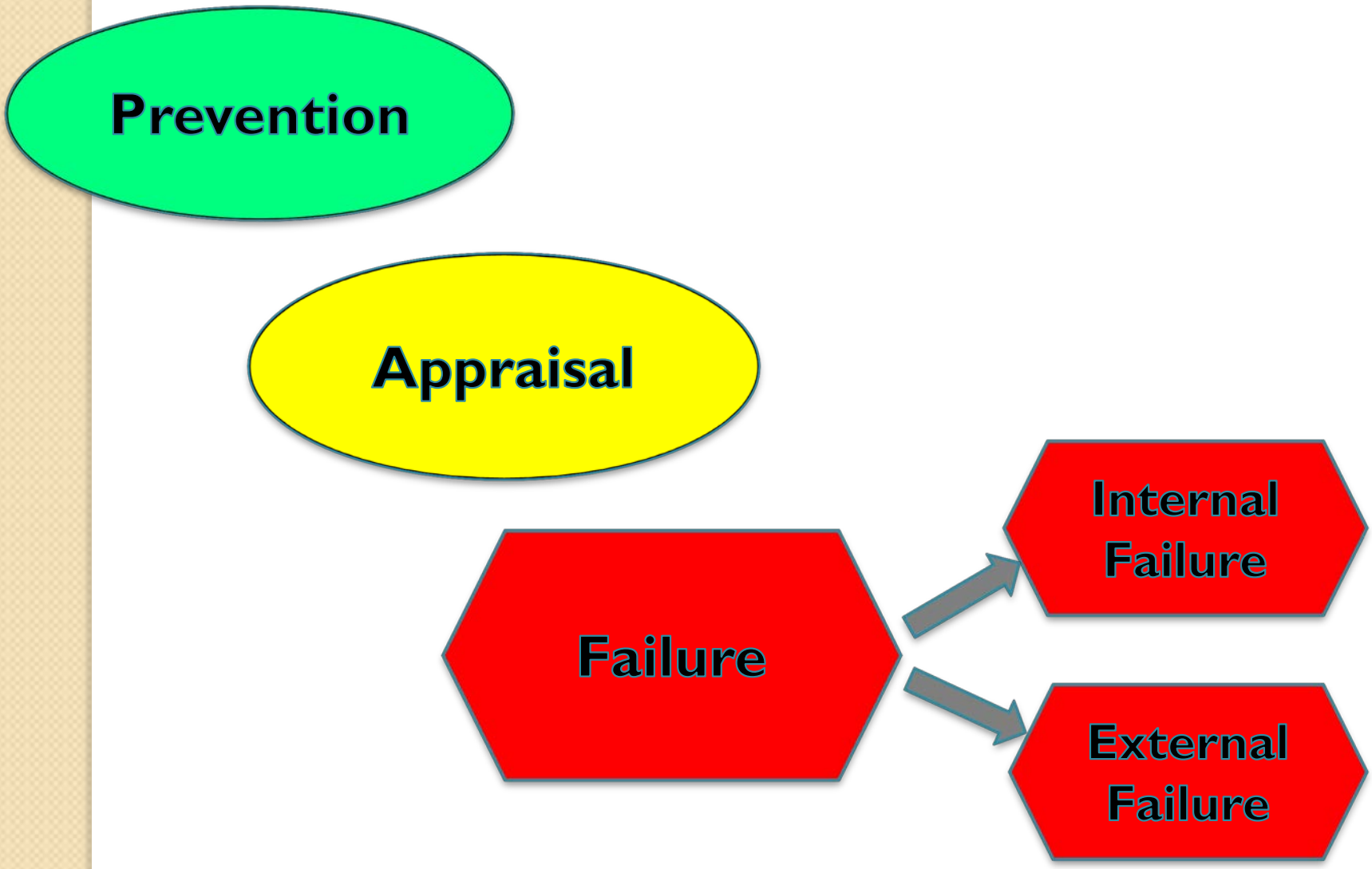
Lucia Berte

President, *LABORATORIES MADE BETTER! P.C.*

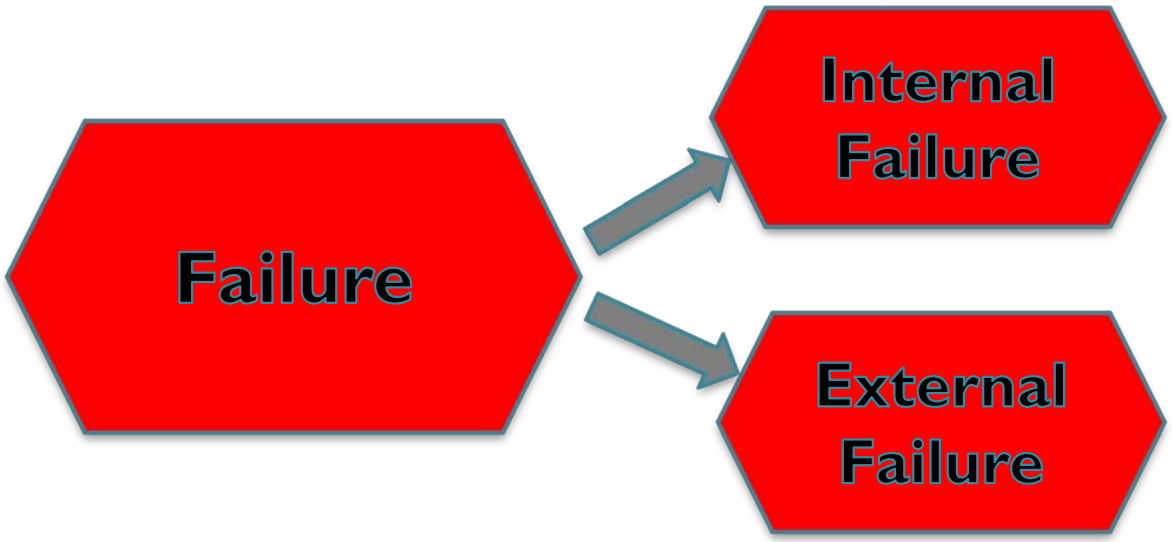
Objectives

- Identify sources of "bad" quality in the lab
- Measure the recurring cost of "bad" quality
- Link the different types of quality costs to value-added laboratory initiatives

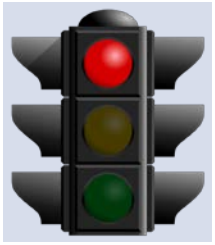
Refresher: Types of Quality Costs



Recurring Cost of "Bad" Quality

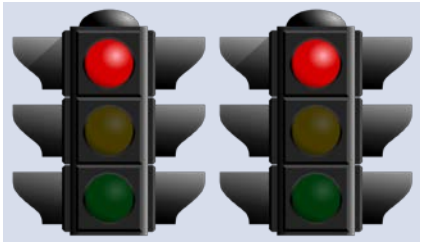


Failure Costs – Internal (Before Delivery of Results)



- Sample problems in the preexamination phase
- Insufficient or expired reagents or supplies
- Rework, repair, retesting, reinspection
- Wasted blood and blood components
- Downtime
  - Computer
  - General unavailability of services
- Any NCE caught and corrected before customer receipt

Failure Costs - External (After Customer Receipt)



- Lost reports
- Lost samples after testing
- Reporting errors
- Customer complaints
- Other NCEs, post receipt
- Misdiagnoses
- Lawsuits

Identifying Sources of "Bad" Lab Quality

- Nonconforming events sorted by
  - Process where occurred
  - Process where detected
- Customer complaints sorted by process involved
- Accreditation deficiencies sorted by workflow process and management process
- Internal audit finding sorted by process involved
- Process measured by a quality indicator outside acceptable threshold
- Examination method QC and PT outliers

“Bad” Quality in Your Lab?

Key Word is *PROCESS*

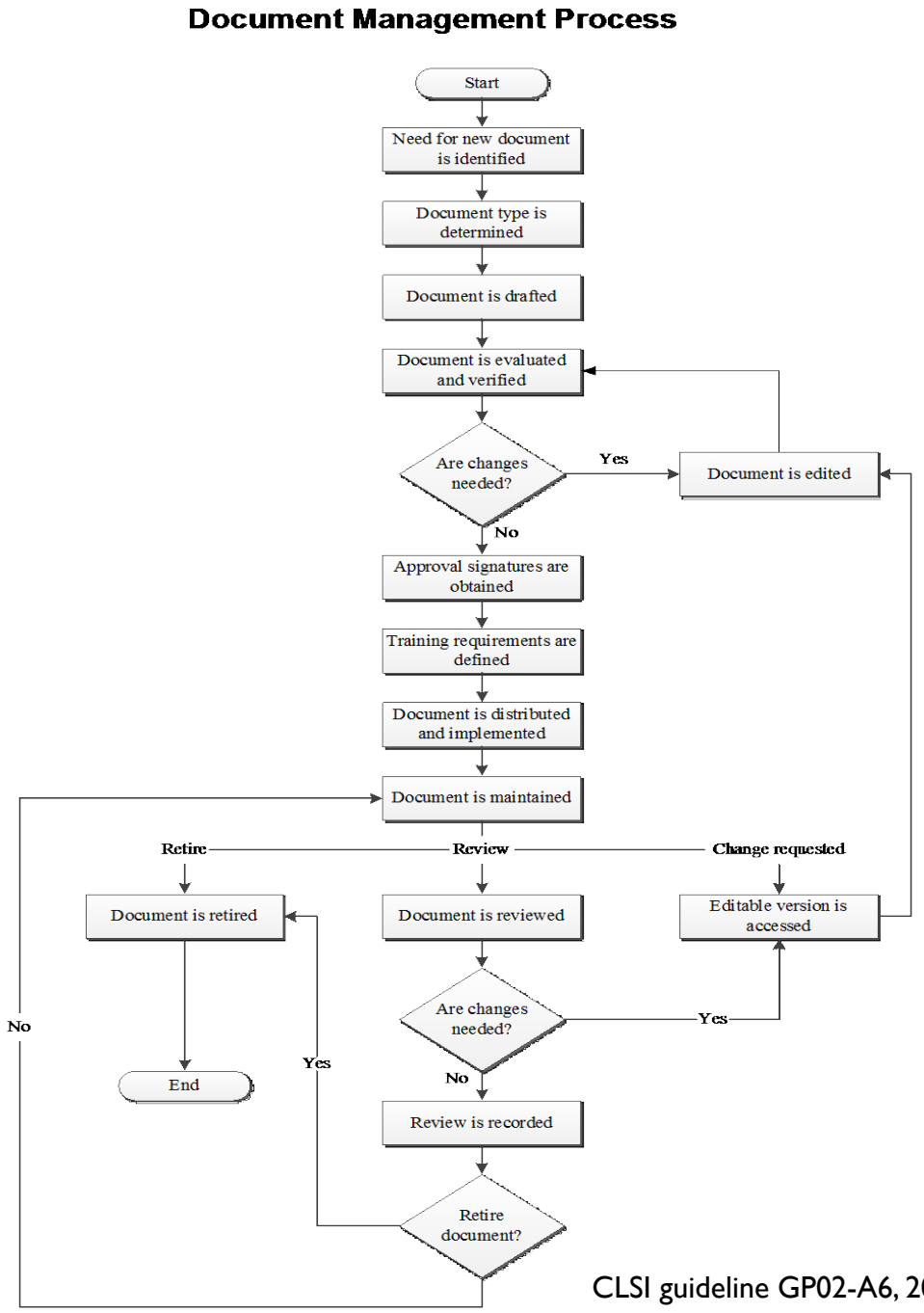
- All work is a ***process***
- ISO 9001 and CLSI QSE are management and workflow ***process***-based QMS
- Lean:
  Reduce waste from the selected ***process***
- Six Sigma:
  Reduce ***process*** variation
- Engaging with physicians:
  Test ordering and results interpretation ***processes***
- Change leadership:
  Process and cost thinking

Process

Sequence of activities that transforms inputs into outputs

Process ≠ "Lab SOP"

This is a Process



CLSI guideline GP02-A6, 2013

Weak D (D^u) Determination Procedure

Purpose

This procedure provides instructions for performing the weak D (D^u) determination.

Weak forms of the D antigen can be detected only after incubating the RBCs with the anti-D reagent and using the antiglobulin technique.

Sample

RBCs for examination can be either anticoagulated (eg, EDTA), or from a clot.

Materials

Reagents	Supplies	Equipment
• Isotonic saline • Anti-D reagent • IgG antiglobulin reagent • IgG sensitized RBCs	• 12 × 75-mm test tubes • Control drop pipettes • Test tube rack	• Calibrated centrifuge • Automatic cell washer

QC

Reagents must be evaluated each day of use with appropriate controls. Verify that reagent QC has been performed. If not, see Procedure XXX: "Daily Reagent Quality Control."

Procedure

NOTE: If the original direct examination with the anti-D was performed by tube method, the same tube may be used for the weak D examination, provided the manufacturer's directions so state. In this case, proceed directly to step 4, after recording the original anti-D tube examination as negative.

Step	Action
1	Place one drop of anti-D serum into a clean, labeled examination tube.
2	Place one drop of 6% albumin control reagent into a second labeled tube.
3	Add one drop of a 2% to 5% suspension in saline of the RBCs to be examined to each tube.
4	Mix and incubate both tubes for 15 minutes at 37°C.
5	Centrifuge for the saline spin time of the calibrated centrifuge.
6	Gently resuspend the cell button and examine for agglutination.

If the examination RBCs are:	Then:
strongly agglutinated in the anti-D tube but not in the control tube	• record the examination sample as D-positive. • do not proceed with the antiglobulin examination.
not agglutinated, or results are doubtful	proceed with step 7.

This is a Procedure

CLSI guideline GP02-A6, 2013

"…identify inefficiencies in the process and remove them. Integration of efforts is necessary to maximize quality and value."

Institute for Healthcare Improvement, 2006

Value will not be achieved until the laboratory adopts a process management perspective.

Measuring the Recurring Cost of "Bad" Quality

- Pick a process that has been involved in recurring NCEs, audit findings, complaints
- Develop a quality indicator to measure frequency of occurrence per specified time period
- Calculate the cost of "fixing" one instance
- Multiply that cost by the number of occurrences
- Sunk real labor and materials costs

Understanding Failure Cost Elements

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 budgets do not have a "Failure Costs" category—
the expense is added to the current operational performance.

Use Existing Quality Indicators

Calculate failure cost for highest frequency quality indicators

Provides a snapshot of portion of recurring "bad quality" – ie, failure - costs

VALUE: Quality vs Cost

Laboratories can have high quality at lowest reasonable cost.

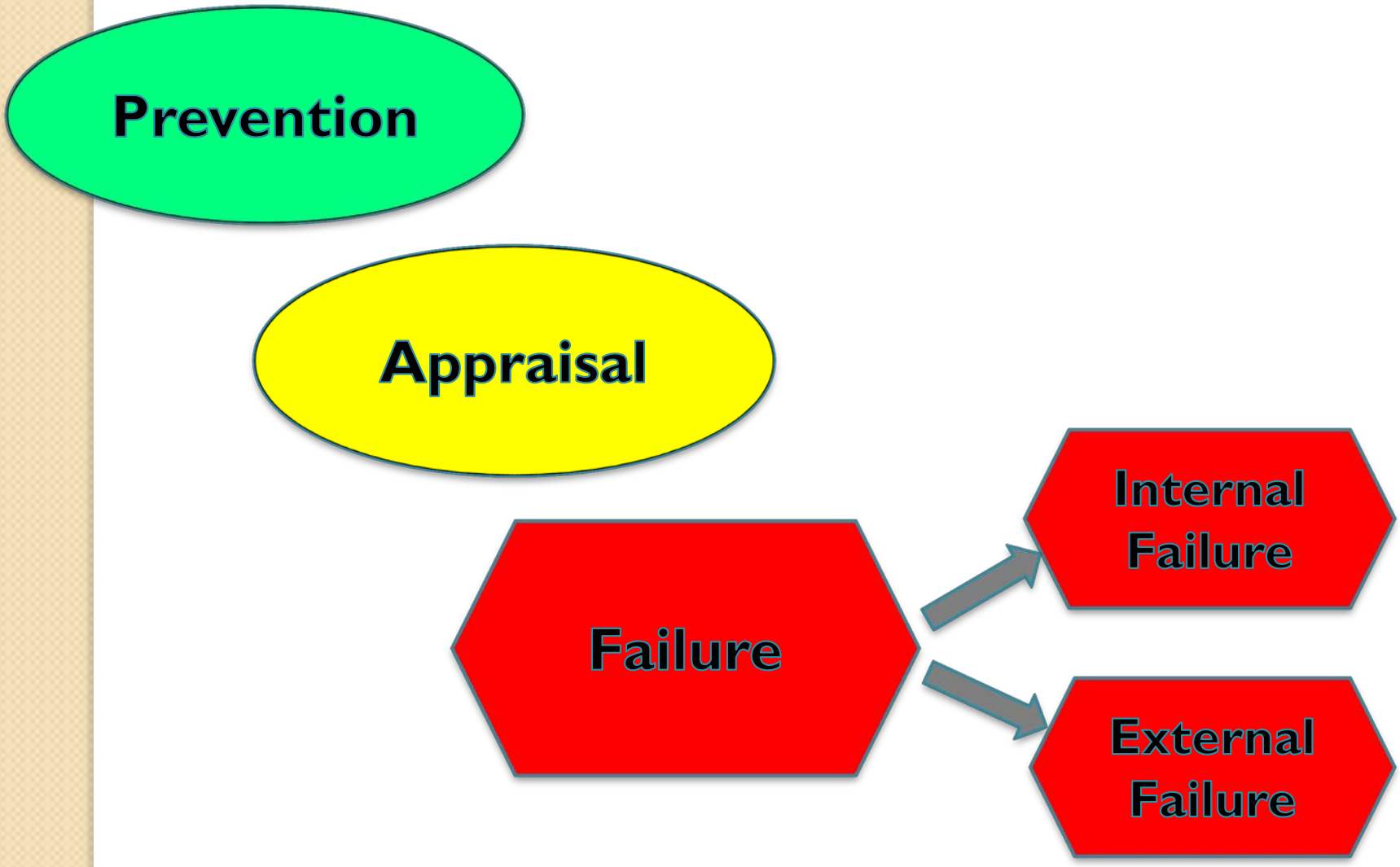
Low quality has low value and high failure cost.

Labs that deliver value to physicians…

Reduce or eliminate the cost of "bad" quality wherever it exists.

Deliver higher quality as well as lower cost.

Link Quality Costs to Value Added Laboratory Initiatives



Prevention

Adopt a process management perspective ASAP

Do a risk assessment of the process

Apply LEAN to design the most efficient and effective process

Appraisal

Adopt a process management perspective

Monitor quality indicators across the lab path of workflow

Calculate failure costs for key quality indicators

Calculate failure costs for QC and PT failures

Calculate cost of rectifying accreditation deficiencies

Report failure costs within the laboratory

Identify top 20% of processes that have failures

Flow chart current process

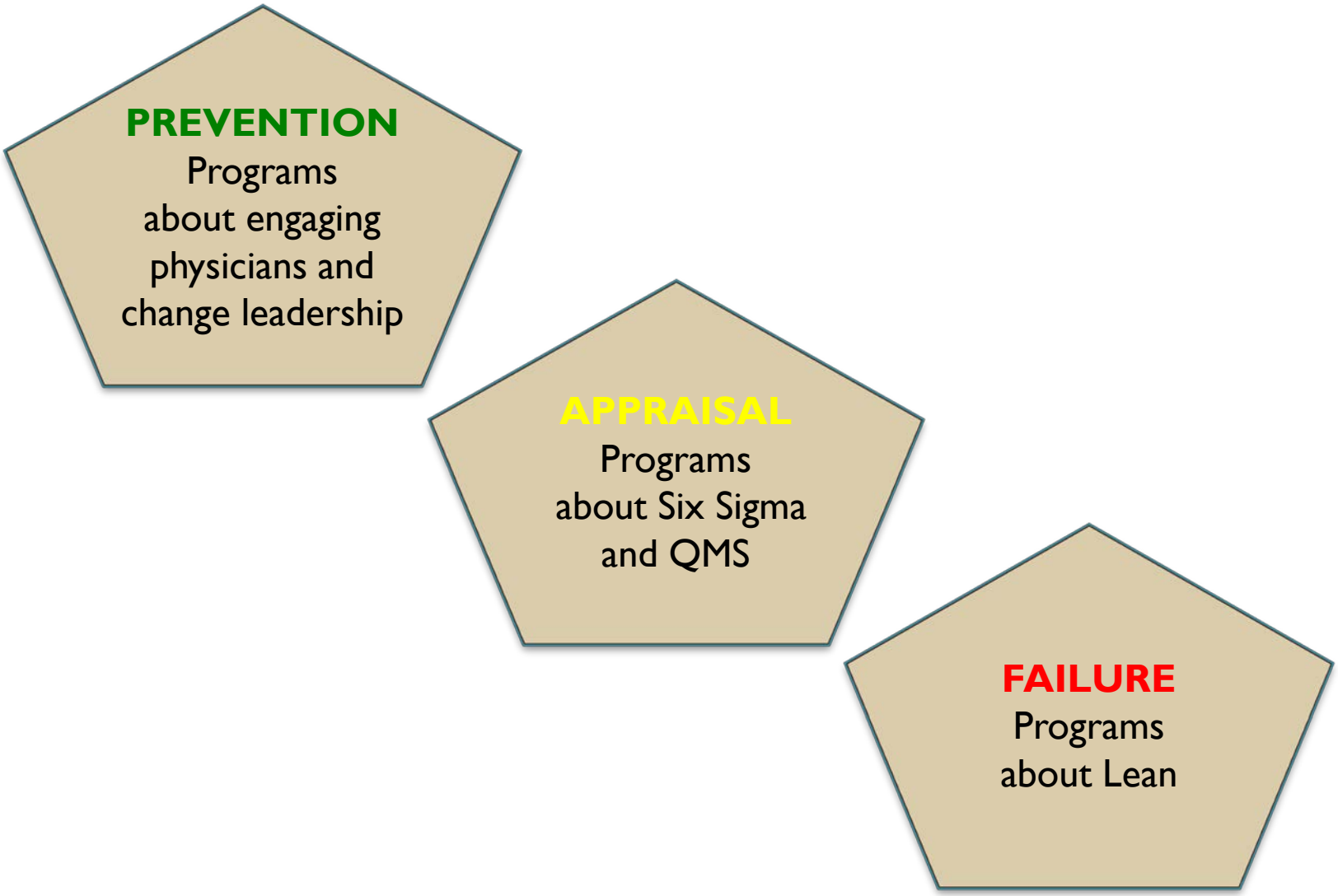
Identify waste

Identify risk

Design a Lean process

Continue to track failure costs

Confab-10 Programs, COQ, and VALUE



A Fact About the Recurring Cost of "Bad" Quality

"Companies that adopt a *cost of quality concept* are successful in reducing failure cost and improving quality for customers."

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, 2006.

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.
- *CLSI. QMS20: Understanding the Cost of Quality in the Laboratory. Wayne, PA: Clinical and Laboratory Standards Institute, 2014*
- Wood DC, mng ed. *Principles of Quality Costs, 4th ed.* Milw, WI: ASQ Quality Press, 2013.
- Wood DC. *The Executive Guide to Understanding and Implementing Quality Cost Programs*. Milw, WI: ASQ Quality Press, 2007.