



# Laboratory Quality Management System

## Module 17: Process improvement

Venue:

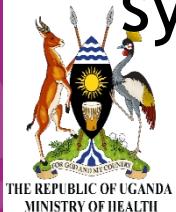
Presenter:

Date:

# Introduction

Continual improvement concept.

- Process improvement, establishes a program for helping to assure continual improvement in the laboratory quality over time.
- This continual improvement of the laboratory processes is essential in a quality management system.



# Learning Objectives

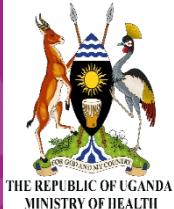
At the end of this activity, participants should be able to:

- Relate the historical perspective of process improvement.
- Describe the importance of process improvement in maintaining quality.
- Explain the need for tools to monitor laboratory processes.



# Module Content

- Tools for process improvement
- Quality Indicators
- Selecting Quality Indicators
- Implementing process improvement



# Activity 17-1

## Purpose:

To provide participants with useful information to improve laboratory processes.

Suggested time: 10 minutes

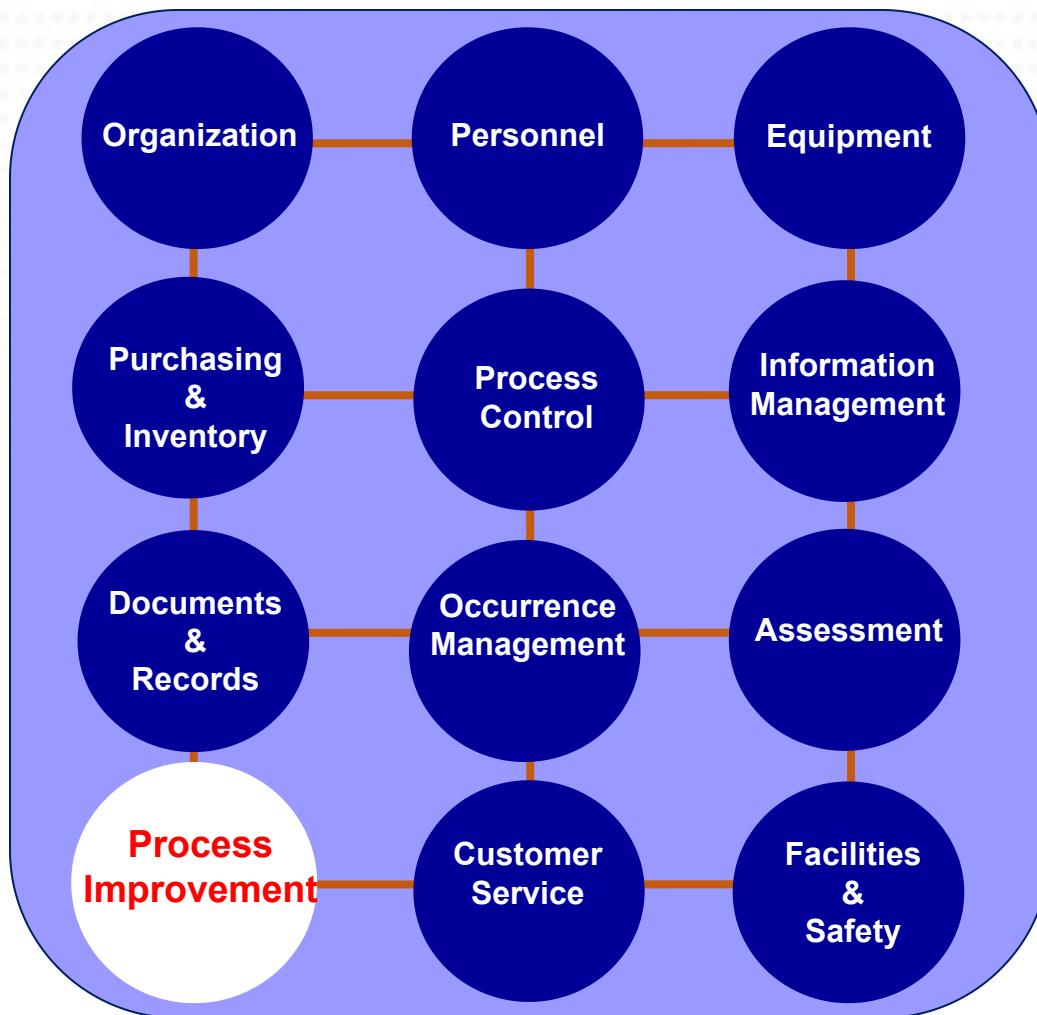


# Scenario

You have implemented Xpert technology in the laboratory. Staff are trained and comfortable using it. It has been validated, test results are being reported and it “seems” to be working well. How do you know that the test is working well and will continue to work well in the future?



# The Quality Management System



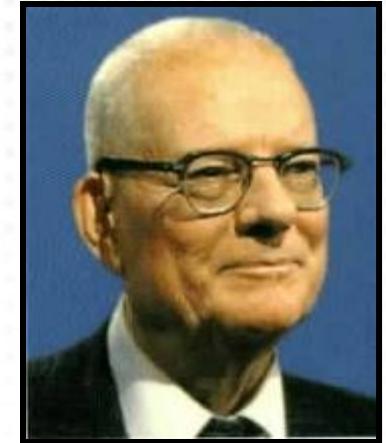
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## Historical basis

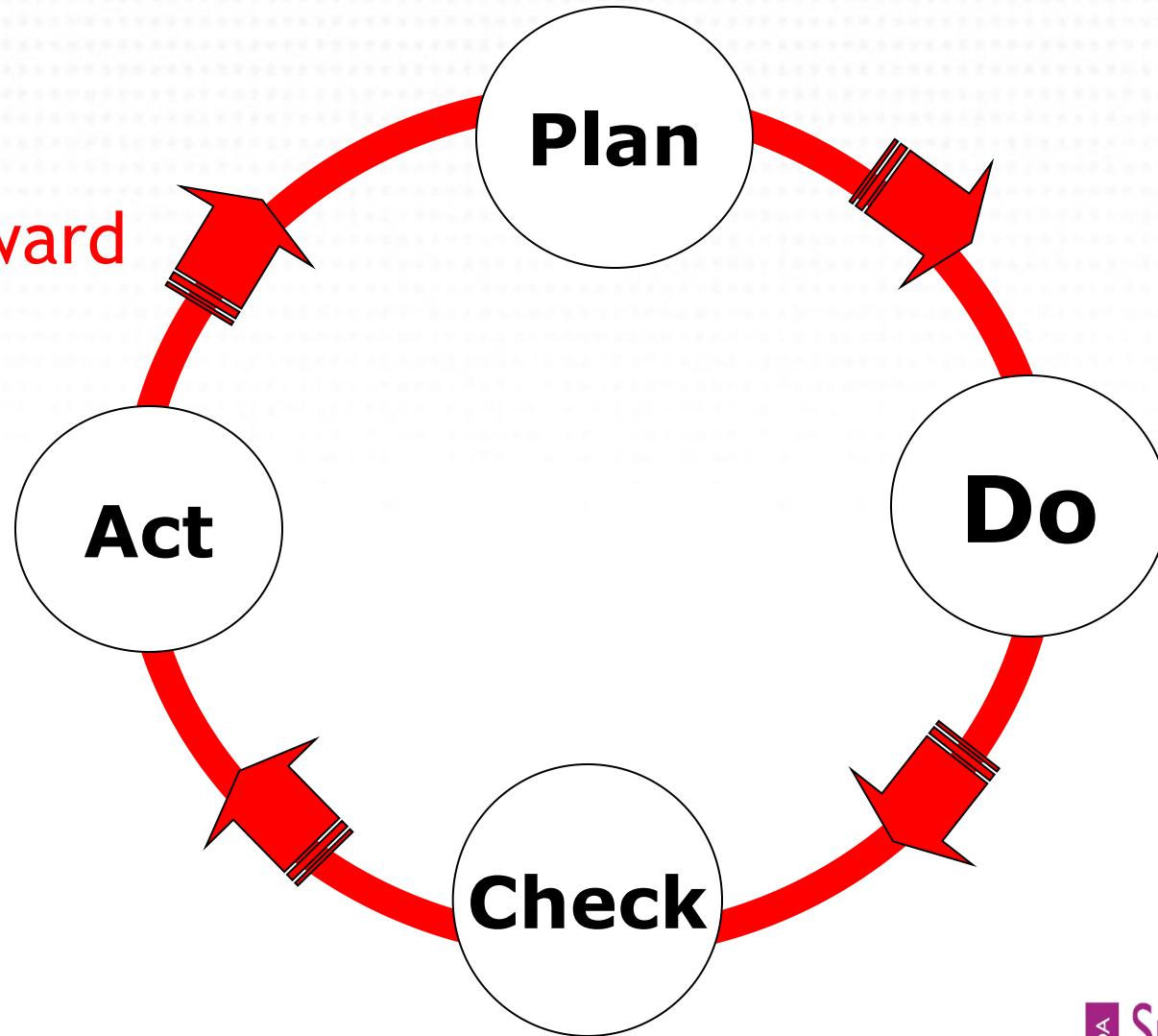
### W. Edwards Deming -



- **14 Points for Quality , and two points address continual improvement:**
  - create constancy of purpose for improvement
  - improve constantly and forever

# The Deming Cycle (PDCA)

By W. Edward  
Deming



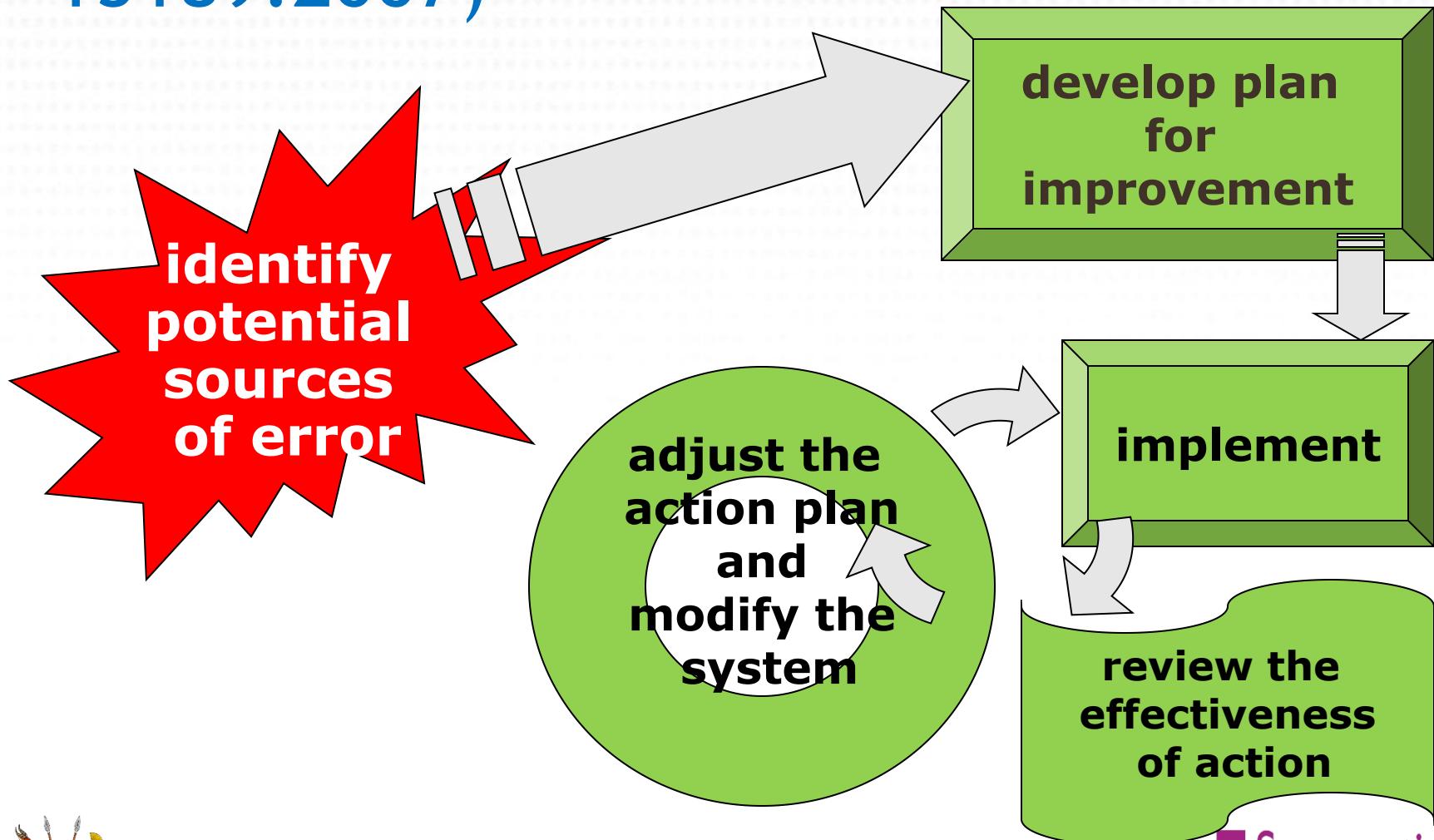
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# Continual Improvement (ISO 15189:2007)



# 1. Conventional Improvement Tools

- Internal audits
- External quality assessment
- External audit and accreditation
- Management review
- Opportunities for improvement
- Quality indicators



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# Monitoring Quality

## Quality Plan



# New Trends-Improvement Tools

Lean

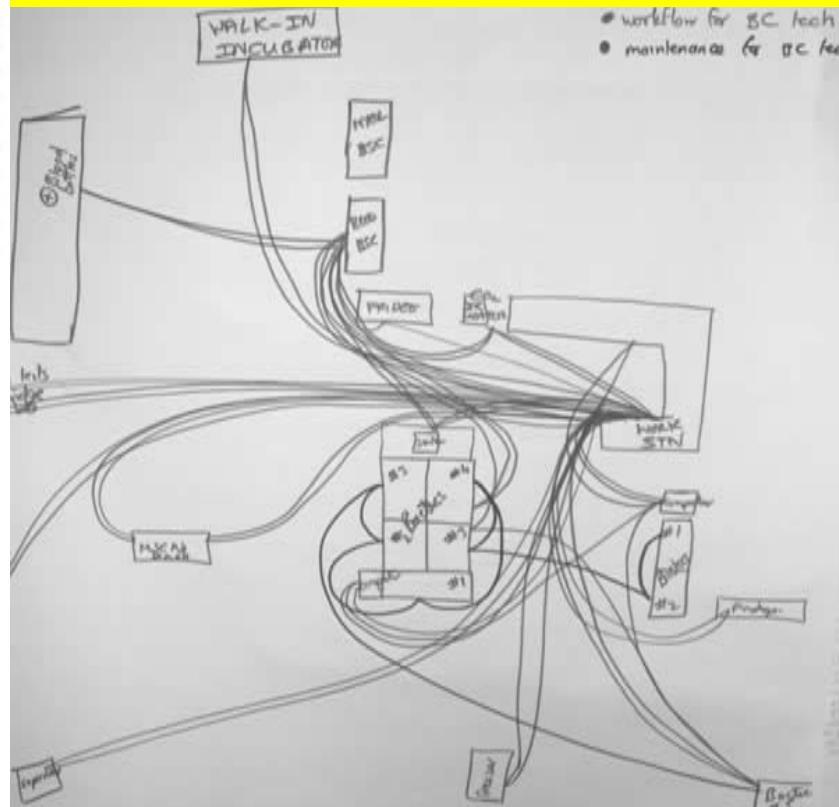


Optimizing **space**,  
**time**, and **activity** to  
improve the physical  
paths of workflow.

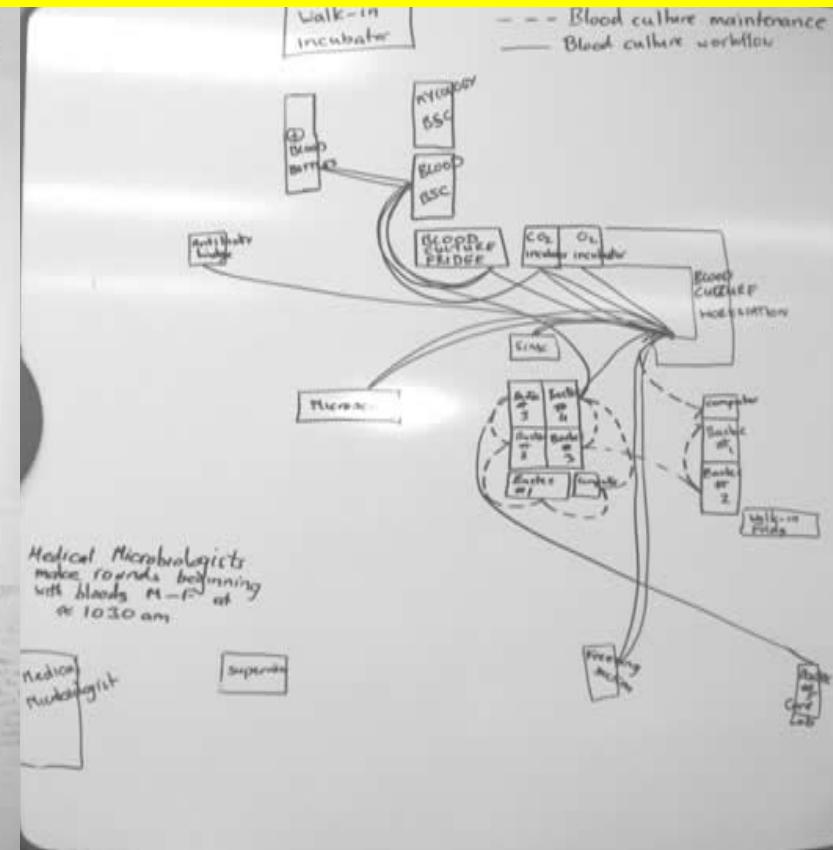


# Path of workflow and maintenance by blood culture technologist

## Pre Lean



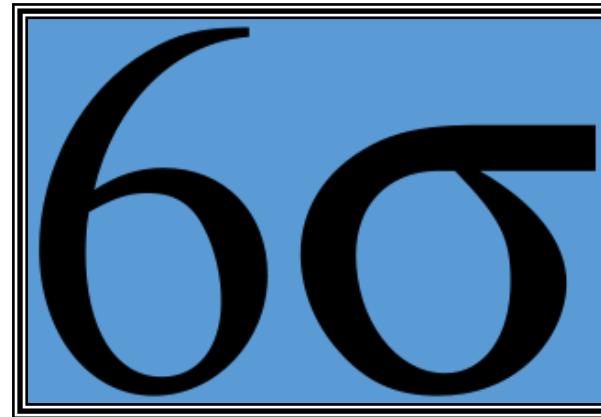
## Post Lean



# New Trends-Improvement Tools

## Six Sigma

A formal structure of project planning to implement change and improvement.



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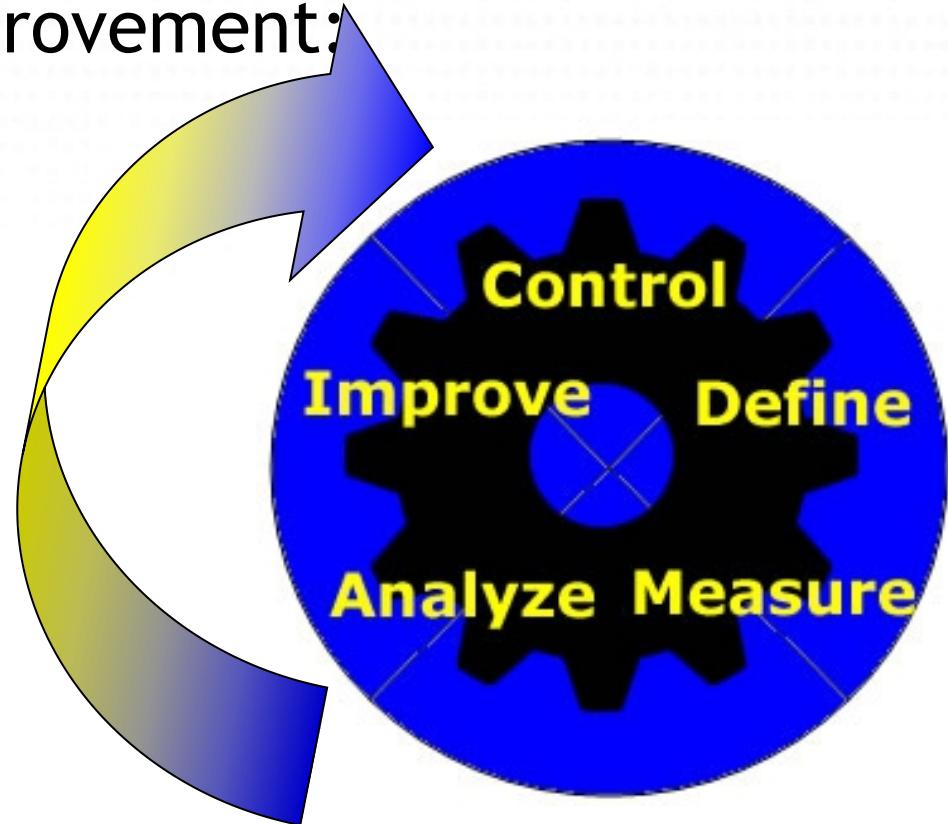
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# Structure in Six Sigma

Organized processes to assist in decision making  
for continual improvement:

- control
- define
- measure
- analyze
- improve



## 2. Quality Indicators

### What is Quality?

“Quality is defined as  
**conformance to requirements,**  
not as 'goodness' or 'elegance'.”



Philip Crosby

Four Absolutes of Quality  
Management

1979



# Quality Indicators Definition

Established measures used to determine how well an organization meets needs and operational and performance expectations.

ISO 9001

ISO 15189



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# Quality Indicators

- indicate performance
- determine quality
- highlight concerns
- identify areas needing further study
- track changes over time



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# 3. Selecting Quality Indicators

## General Guidelines

- Fewer quality indicators are better
- Link to factors needed for success
- Based on customer and stakeholder needs
- Start at the top flow down
- Change with changing environment and strategy
- Have targets or goals based on research rather than arbitrary values

Mark Graham Brown

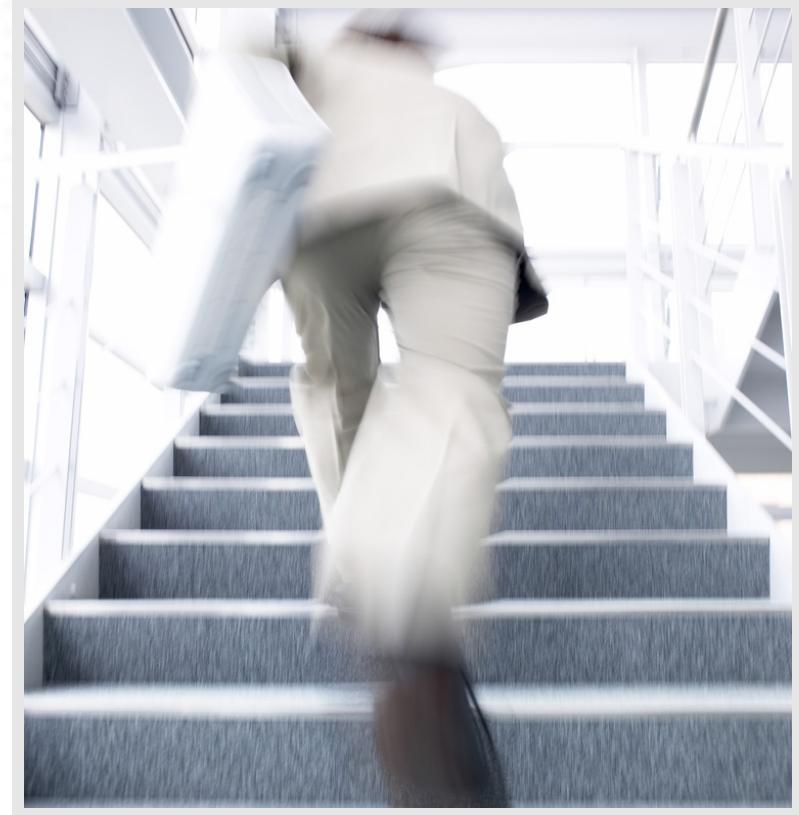


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# Eight Steps to Developing Successful Indicators

1. objective
2. methodology
3. limits
4. interpretation
5. limitations
6. presentation
7. action plan
8. exit plan



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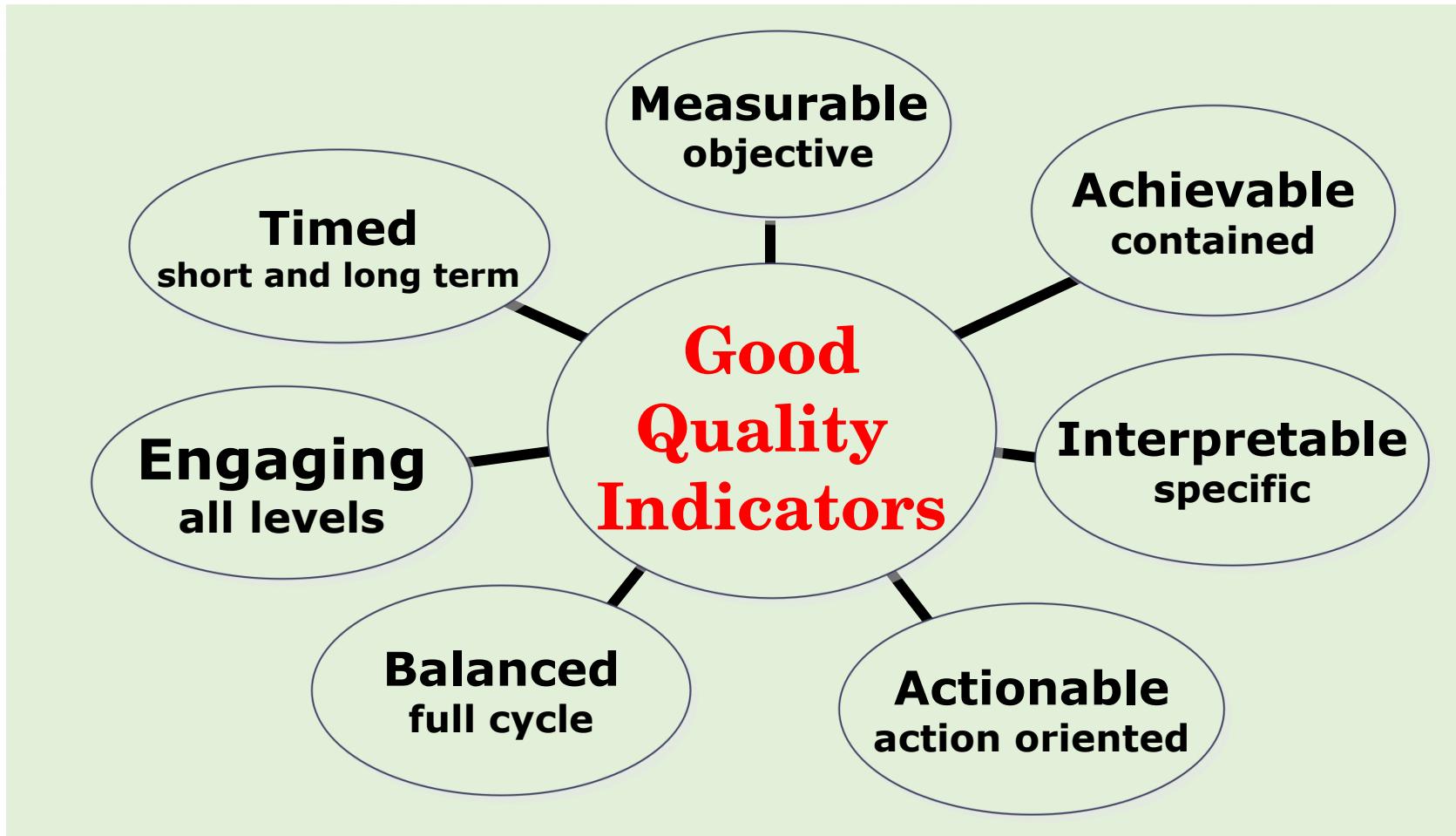
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# The BIG SECRET for Quality Indicator Team

Engage the folks who do the work, because they know what they do!



# Characteristics of Good Indicators



# Keeping Score

“Many organizations spend thousands of hours collecting and interpreting data. However many of these hours are nothing more than wasted time because they analyze the wrong measurements, leading to inaccurate decision making.”

**Mark Graham Brown**  
*Using the Right Metrics to Drive World Class Performance*  
1996



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# Computer Nonsense Indicators

[urine culture] \* [glucose] \* [INR]

X100

[NUPA hr] \* [Telephone minutes]



Just because a computer can calculate a value, doesn't mean that it should.

# Quality Indicators Examples

System	Pre-exam	Examination	Pos- texam
test order accuracy and appropriate ness	patient identification adequacy	accuracy of point-of-care testing	critical values reporting turnaround time
clinician satisfaction	accuracy of sample information	cervical cytology/biopsy correlation	clinician satisfaction
clinician follow-up	accuracy of sample information	cervical cytology/biopsy correlation	clinician follow-up
diabetes monitoring	accuracy of sample information	cervical cytology/biopsy correlation	accuracy of sample information

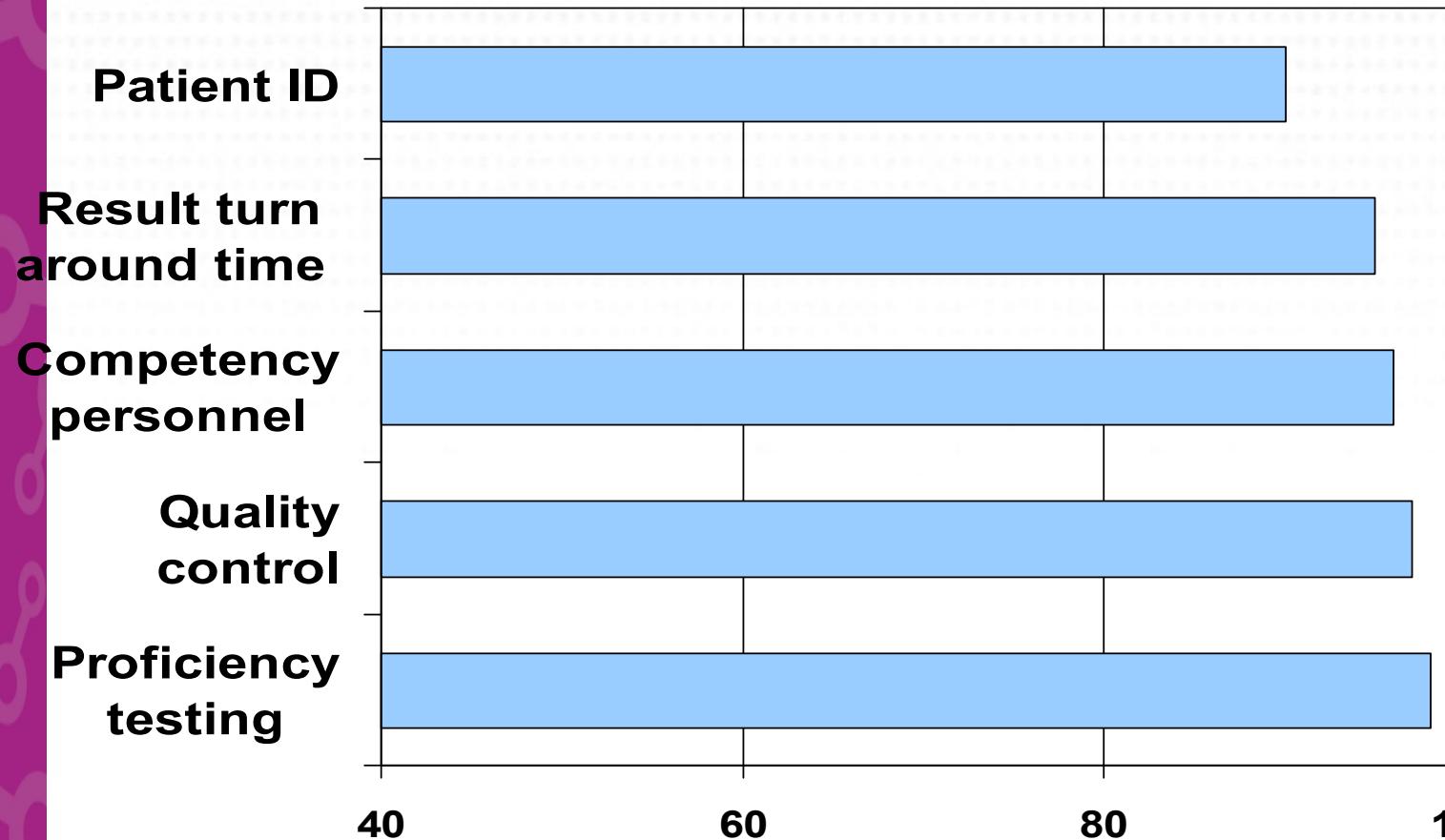


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diabetes monitoring

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# Most common indicators tracked (%) 2005



Reference: Hilborne L. Developing a core set of laboratory based quality indicators. IQLM Conference; 2005 Apr 29.



# Caution

Theoretically, patient outcome indicators best assess quality, but are the most difficult to measure.

- too many variables
- require large amounts of data
- need extended collection periods

David Hsia

**Medicare Quality Improvement Bad Apples  
or Bad Systems?**

JAMA. 2003;289:354-356.



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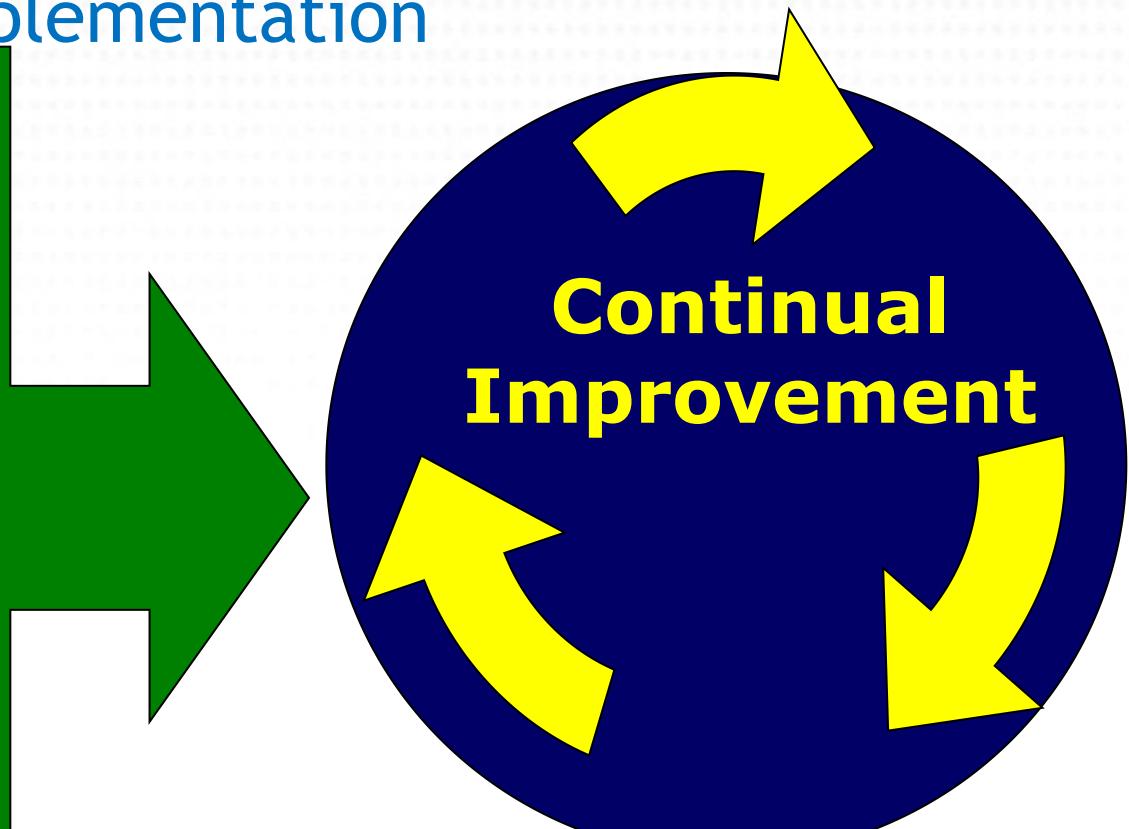
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# 4. Implementing Process Improvement

## Essentials for Implementation

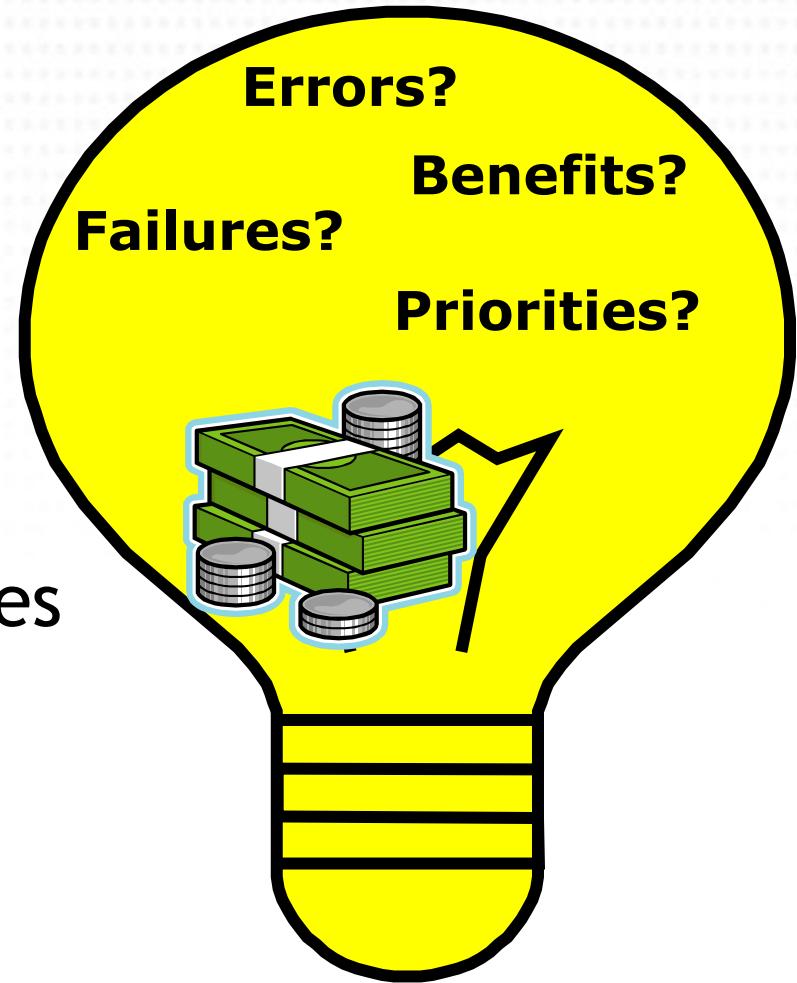
Commitment  
Planning  
Structure  
Leadership  
Participation  
and Engagement



# Planning for Quality Improvement

## Consider:

- root causes of error
- risk management
- failures and potential failures and near-misses
- costs, benefits, and priorities
- costs of inaction



# Role of Leadership

Fosters the culture for improvement:

- openness that others have good ideas

- commitment that improvement will occur

- opportunity that staff can participate



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# Participation in the process

- Management does not always know what workers know and do
- Continual improvement requires leadership and team participation



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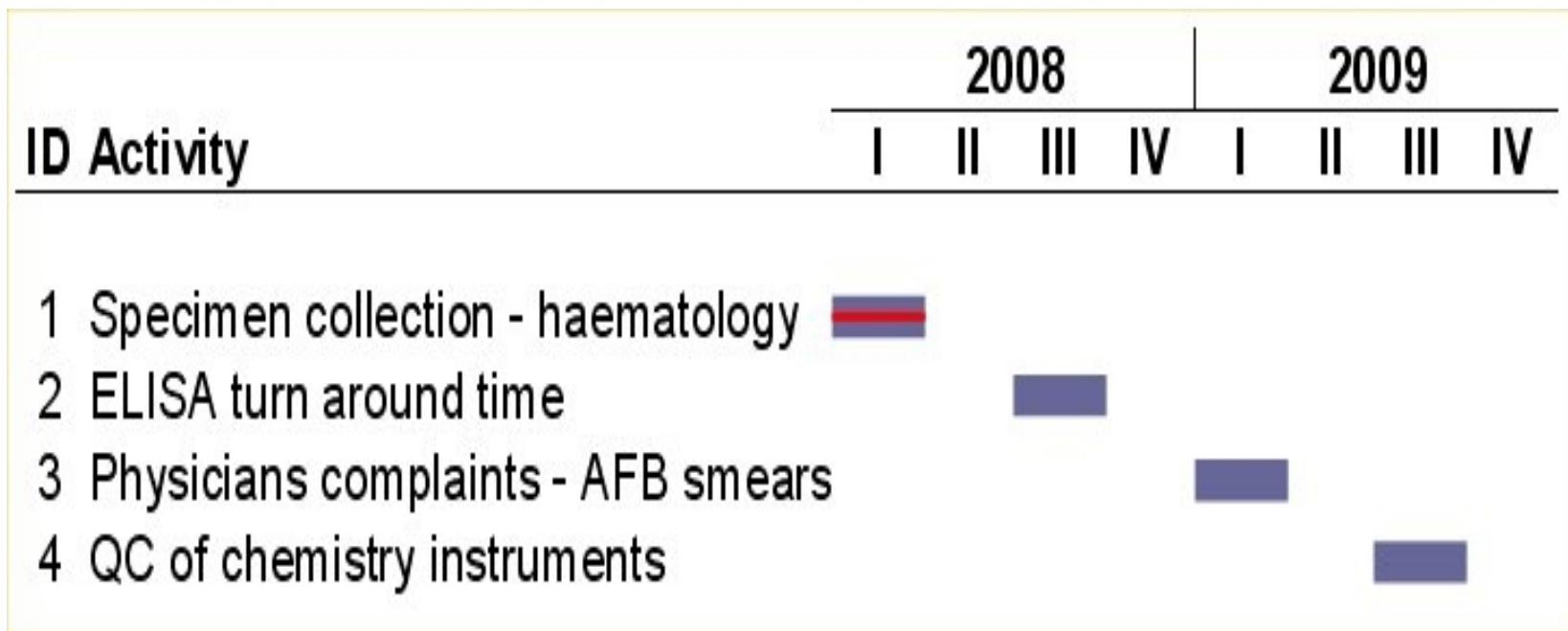
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# Quality Improvement Activities

One project every 6 months.

Set a timeline.



# Quality Improvement Activities

Use a team approach.

Involve bench-level staff.



# Quality Improvement Activities

## Use Quality Tools

● audits

● reviews

● EQA

● OFI

● indicators

● Six Sigma



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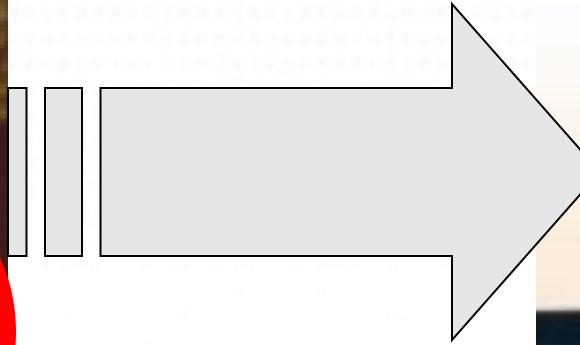


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# Quality Improvement Activities

Correct or prevent poor practices



Report progress to  
management and  
laboratory staff



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# Quality Improvement Activities

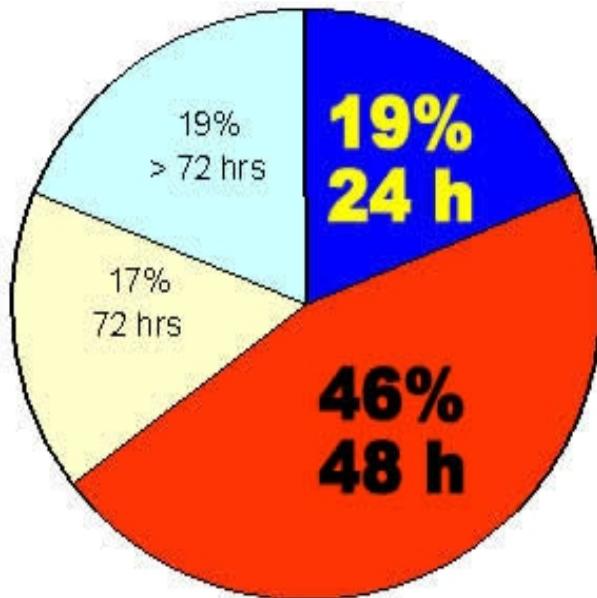
Use available information to study:

- customer's suggestions or complaints
- identified errors from occurrence management program
- problems identified in internal audits



# Quality Improvement Activities

If possible, design a study so that results can be statistically measured.

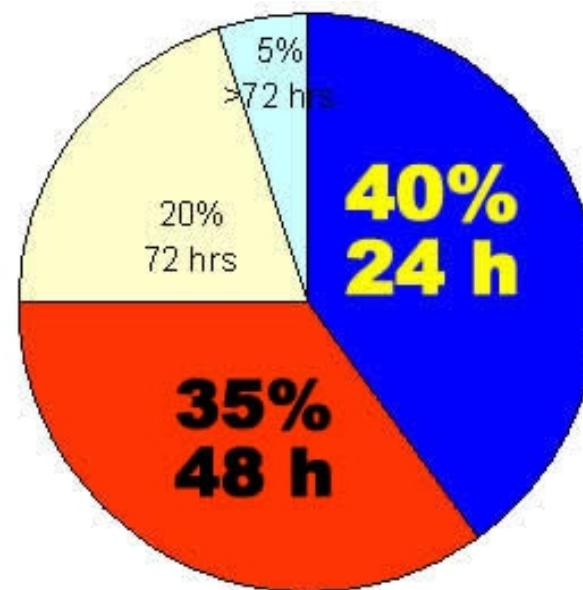


Pre lean state for final  
positive blood culture reports



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Post lean state for final  
positive blood culture reports

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# Quality Indicators and Timing

Use an indicator only as long as it  
provides  
**useful information.**

**Don't get tied to  
your indicators.**

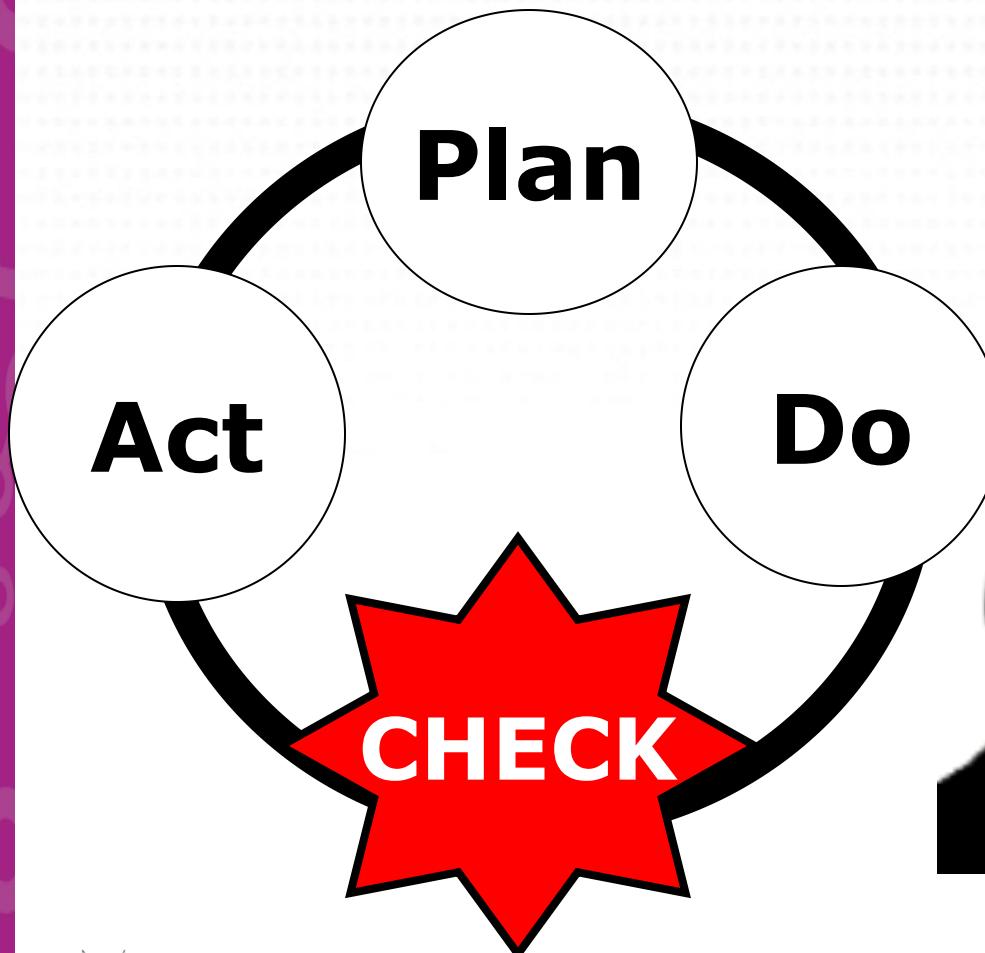


# Assessment

- What is the importance of process improvement in maintaining quality.
- List the need for tools to monitor laboratory processes.



# Summary



Each step is  
essential to keep  
the quality cycle  
cycling.



# Key Messages

- quality counts
- continual improvement is the core of quality management



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# Reference

ISO 15189:2012 Medical Laboratories - Requirements for Quality and Competence

« Clause 4.12, 4.14.7»

CLSI

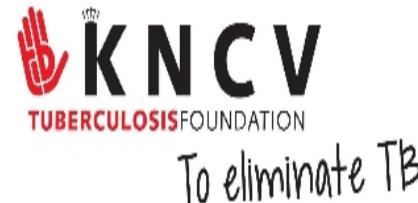
ASLM



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# Acknowledgement



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