

# Clinical audit and quality improvement

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# Session Overview

# Learning objectives

Aim: To provide an introduction and overview of key themes in clinical audit and quality improvement

By the end of this session you should:

- Be able to list the defining characteristics of clinical audit
- Be familiar with the main stages of the audit cycle
- Be able to critically outline continuous quality improvement as an approach in healthcare, with examples
- Be aware of key design considerations for effective audit/QI, particularly relating to data collection, analytic and feedback considerations

# Session Plan

1. Defining clinical audit
2. Continuous quality improvement in healthcare
3. Key data considerations for audit and quality improvement

# 1. Defining clinical audit

# Origin of modern clinical audit

- Florence Nightingale: Mortality in Crimean War Military Hospitals (1856)
  - Conducted a systematic survey of causes of death
  - Presented data graphically to demonstrate comparative death rates
  - Found that a high proportion of injured soldiers died from preventable diseases linked to sanitation
  - Introduced improved drainage, ventilation, hospital hygiene and laundry services
  - Changes credited with reducing hospital mortality rate due to preventable disease from 40% to 2%

# Defining Clinical Audit

- Department of health (1993):
  - “Clinical audit involves systematically looking at the procedures used for diagnosis, care and treatment, examining how associated resources are used and investigating the effect care has on the outcome and quality of life for the patient”
- NICE endorsed definition:

*‘Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, process and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery.’<sup>18</sup>*

Principles for best practice in clinical audit. NICE, London March 2002


- Audit = a method for systematically reviewing practice

# Basic audit design

- There are several possible types of audits (though the terms are often used inconsistently):
  - Criteria based audits
  - Adverse event screening
  - Critical incident audits
  - Peer reviews
  - Case note analysis
- Current guidance recommends that all audit follows a unified “audit cycle”
- A useful framework for topic selection was proposed by Donabedian (1966):

- **Structure** The availability and organisation of resources and personnel.
- **Process** The activities undertaken, that is, what is done with the service’s resources.
- **Outcome** The effect of the activities on the ‘health/well-being’ of the service user, that is, changes for the individual which can be attributed to the clinical intervention they received.





What are the differences between research, clinical audit and service evaluation?

Research	Clinical Audit	Service Evaluation
Designed to derive generalisable new knowledge	<b>Designed and conducted to produce information to inform delivery of best care</b>	Designed and conducted solely to define or judge current care
Designed to test a hypothesis	<b>Designed to answer ‘does this service reach a predetermined standard’?</b>	Designed to answer ‘what standard does this service achieve’?
Addresses clearly defined questions, aims and objectives	<b>Measures against a standard</b>	Measures without reference to a standard
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care	<b>Usually involves analysis of existing data but may include administration of simple interview or questionnaire</b>	Usually involves analysis of existing data but may include administration of simple interview or questionnaire
Study design may involve allocating patients to intervention groups	<b>No allocation to intervention</b>	No allocation to intervention
May involve randomisation	<b>No randomisation</b>	No randomisation
Normally requires Research Ethics Committee review	<b>Does not typically require Research Ethics Committee review</b>	Does not require Research Ethics Committee review

**1**  
Select audit topic

**2**  
Identify best practice

**3**  
Agree criteria and standards

**4**  
Collect data

**5**  
Analyze data

**6**  
Implement necessary changes

**7**  
Conduct re-audit

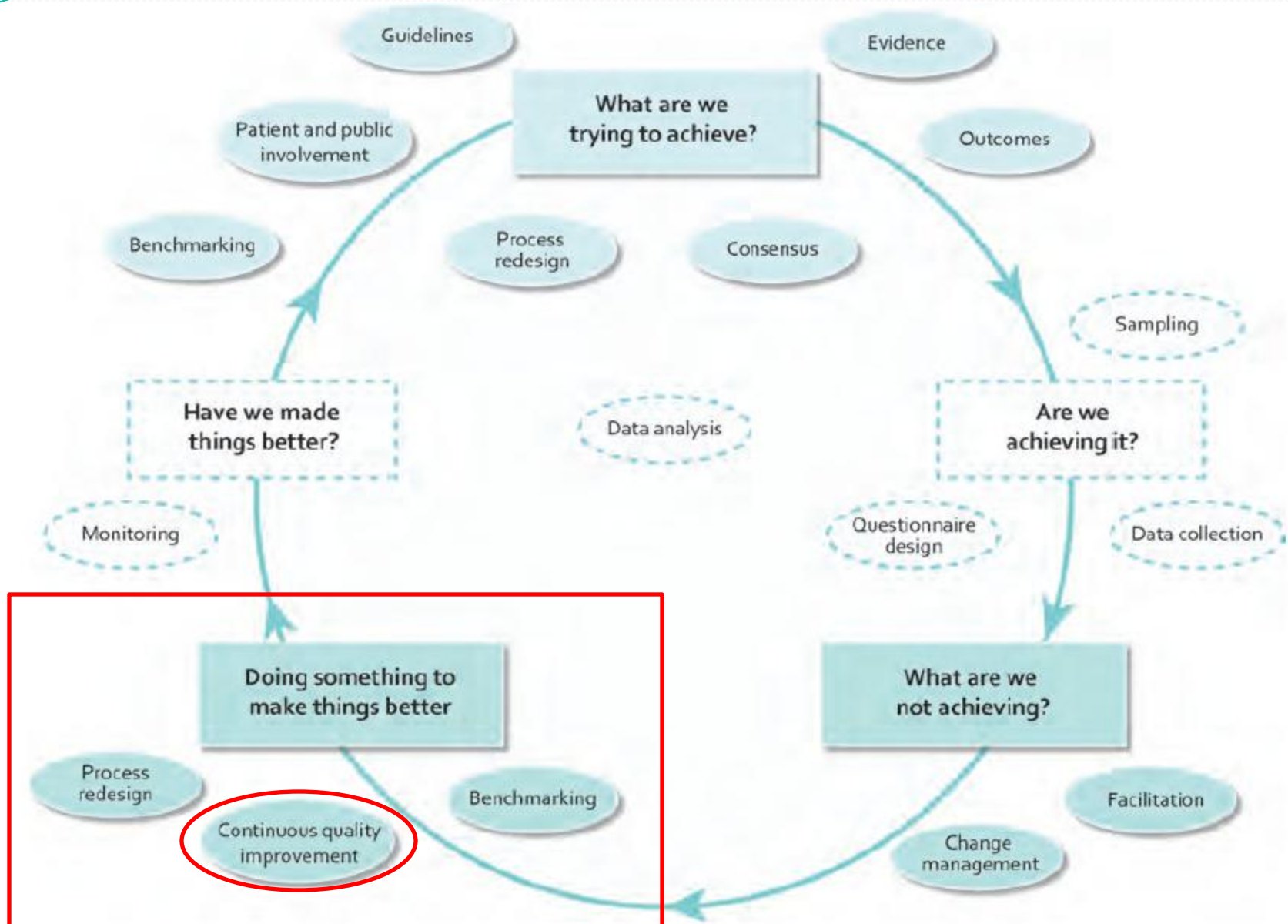
**8**  
Write audit report and share learning



# Where audit fails: Feedback & follow-up

- Effective clinical audit “closes the loop” through effective feedback and follow-up:
  - Feedback: Dissemination of findings and learning from audit.
  - Follow-up: Implementation of actions to address identified issues/opportunities for improvement.
  - Repeated monitoring and evaluation: To assess the efficacy of the implemented solution

# The audit process in context



## 2. Continuous quality improvement in healthcare

# From clinical audit to continuous quality improvement (CQI)

**Raising the Standard:**  
a compendium of audit recipes  
*for continuous quality improvement in anaesthesia*



3<sup>rd</sup> Edition

Royal College of  
Anaesthetists

2012



# Continuous Quality Improvement (CQI): Some definitions and distinctions

- Key components of a CQI approach (Locock, 2003):
  - Incremental improvement of existing processes rather than radical redesign
  - Repeated testing and evaluation of small scale changes
  - Responsibility for quality placed in hands of frontline staff (empowerment)
  - Collective team responsibility that crosses professional boundaries
  - Culture of open learning and analysing errors without fear of blame
  - Strong emphasis upon measurement
  - Systems approach to causes of high/low quality that takes in the whole care process
  - “Bottom-up” change rather than “top-down”
- Continuous Quality Improvement draws upon established industry quality improvement models: Total Quality Management, Six Sigma and Lean (Boaden, 2008)



# Review of current UK health care practice

- Report commissioned by the NHS Institute for Innovation and Improvement: Current practice in NHS clinical systems improvement (Walley et al., 2006)
  - NHS orgs largely do not have embedded clinical systems improvement cultures or processes
  - Financial targets were the main drivers of improvement, not quality of care
  - Improvement efforts were largely project based rather than part of routine operations
  - Orgs showed high variability in terms of infrastructure for improvement and use of QI tools (e.g. PDSA, SPC, Process mapping, etc.)

# DMAIC methodology for improvement projects (Six Sigma)

- *Define* the problem and the project goals.
- *Measure* the current process and create a baseline.
- *Analyze* the data to investigate cause-and-effect relationships. Identify the root causes of undesirable variation.
- *Improve* the process and evaluate pilot runs using data.
- *Control* the future state of the process through continuous monitoring and correcting variation as it's detected.

# The Model for Improvement

IHI.org

A resource from the  
Institute for Healthcare Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What changes can we make that will result in improvement?



## Setting Aims

Improvement requires setting aims. The aim should be time-specific and measurable; it should also define the specific population of patients that will be affected.

## Establishing Measures

Teams use quantitative measures to determine if a specific change actually leads to an improvement.

## Selecting Changes

All improvement requires making changes, but not all changes result in improvement. Organizations therefore must identify the changes that are most likely to result in improvement.

## Testing Changes

The Plan-Do-Study-Act (PDSA) cycle is shorthand for testing a change in the real work setting — by planning it, trying it, observing the results, and acting on what is learned. This is the scientific method used for action-oriented learning.

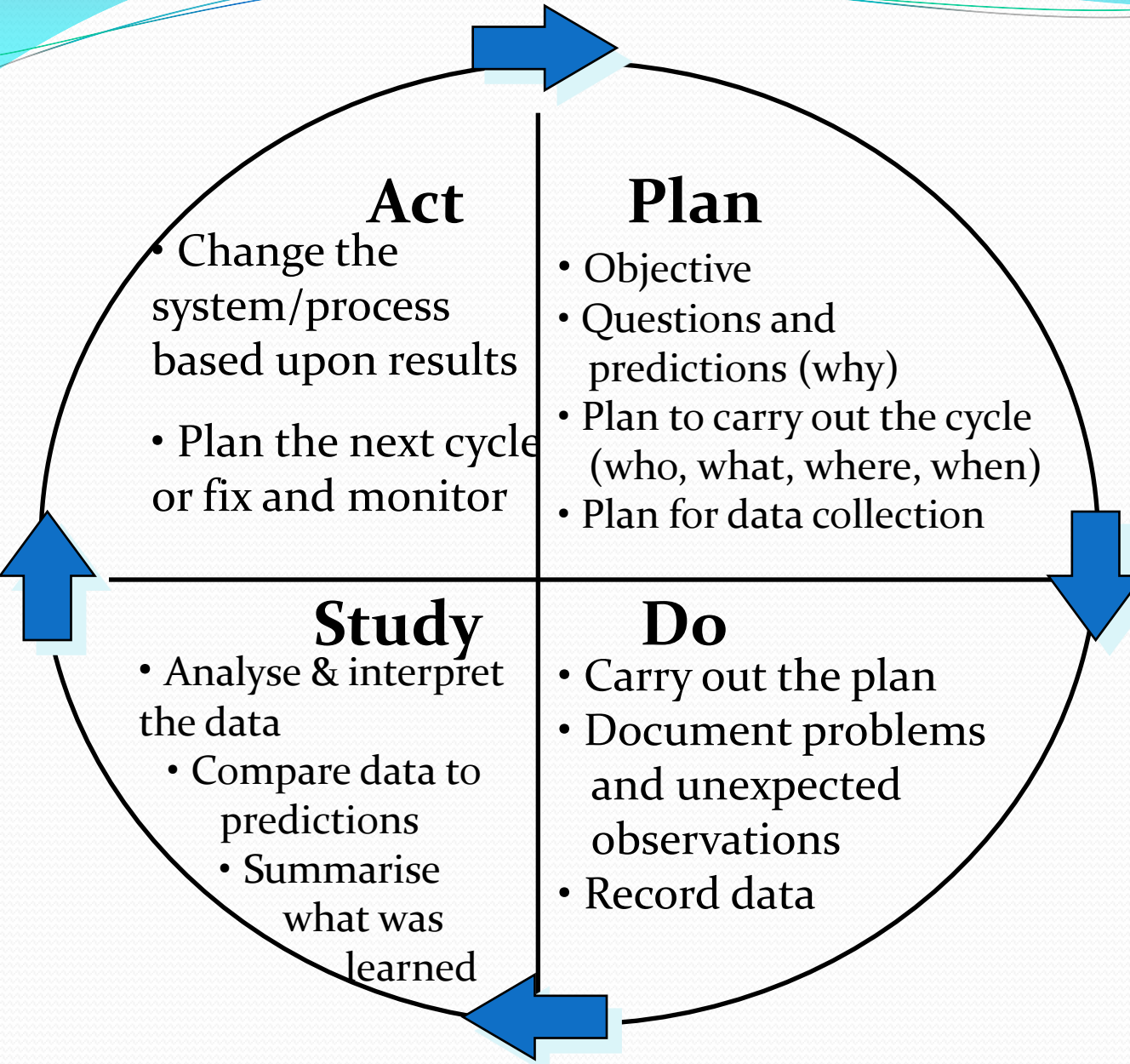
## Implementing Changes

After testing a change on a small scale, learning from each test, and refining the change through several PDSA cycles, the team can implement the change on a broader scale — for example, for an entire pilot population or on an entire unit.

## Spreading Changes

After successful implementation of a change or package of changes for a pilot population or an entire unit, the team can spread the changes to other parts of the organization or in other organizations.

# Plan-Do-Study-Act Cycles (Langley)

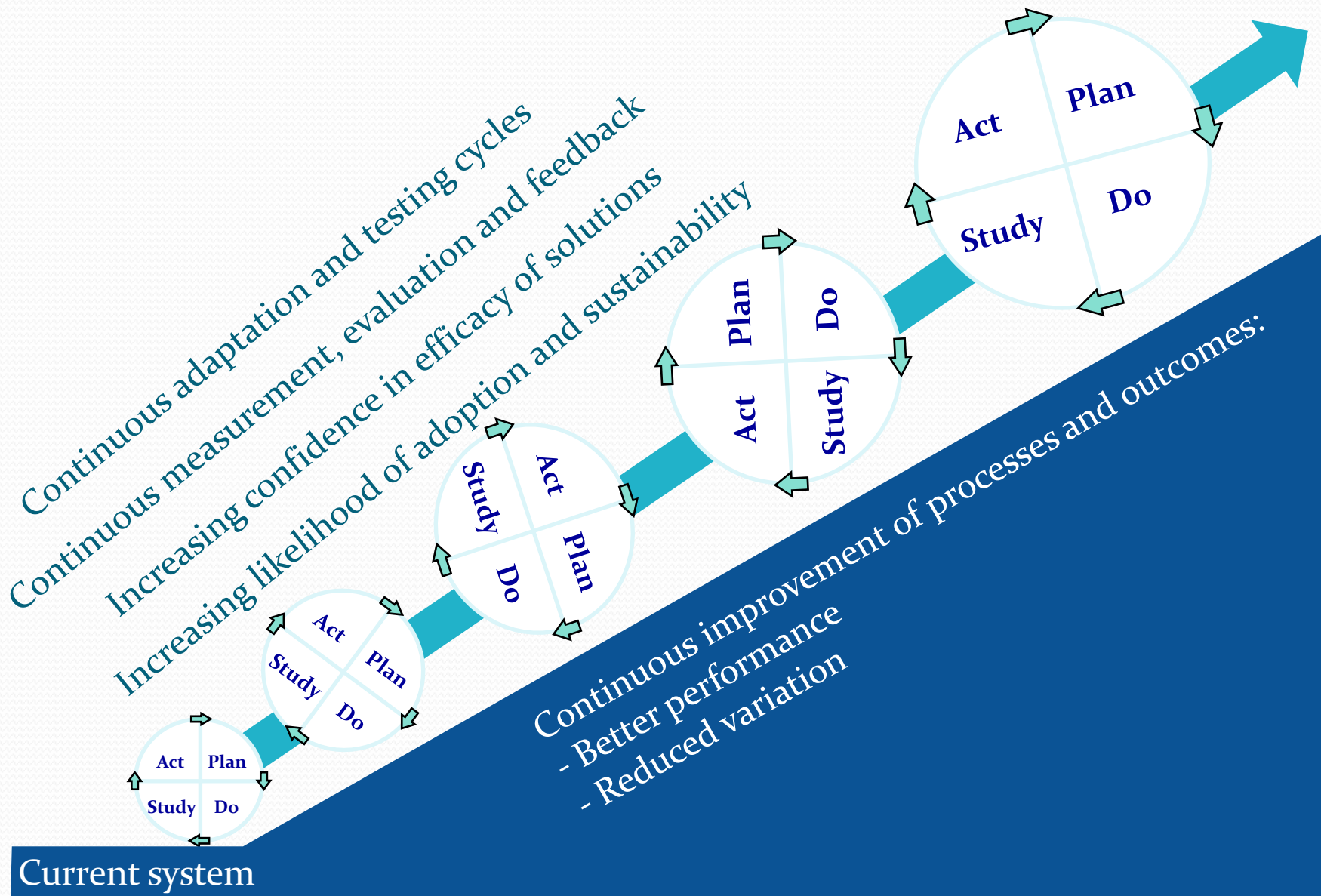


Rapid, iterative development cycles

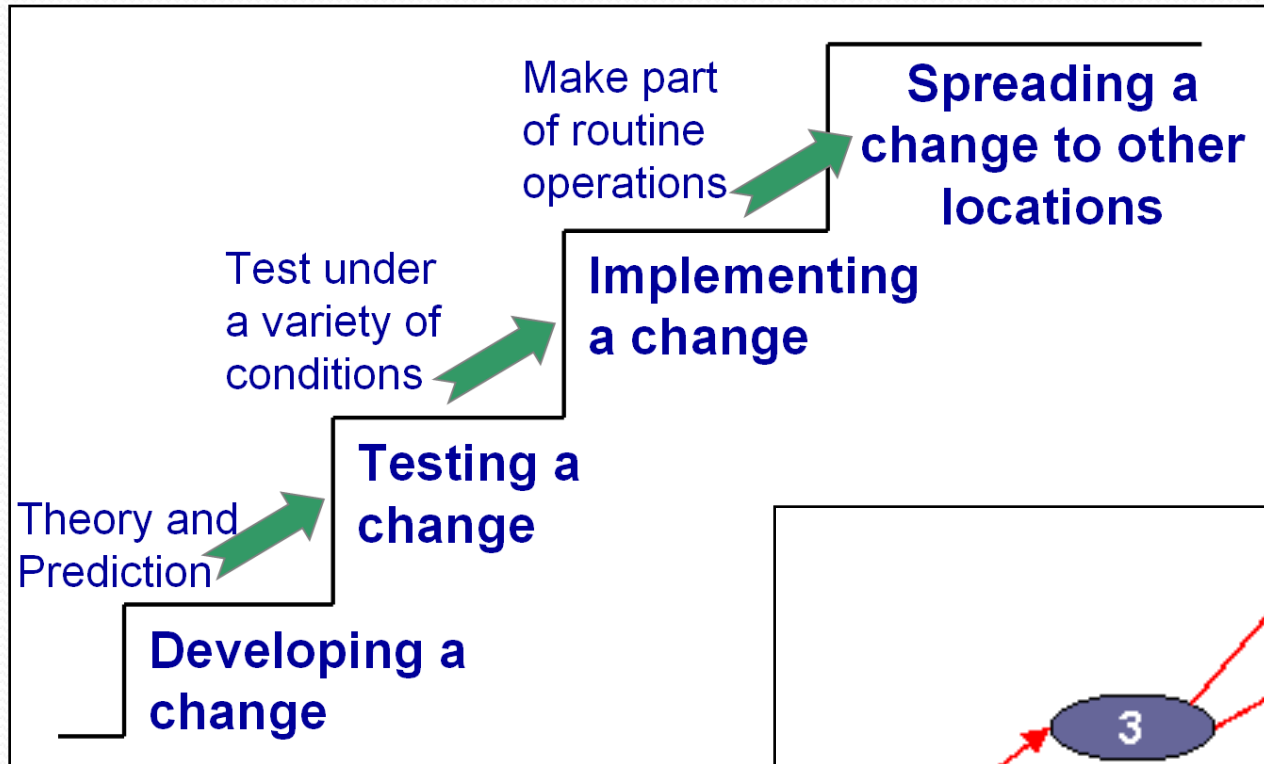
A scientific but action-oriented method for application in a real work setting

Important to document learning and rationale across successive cycles

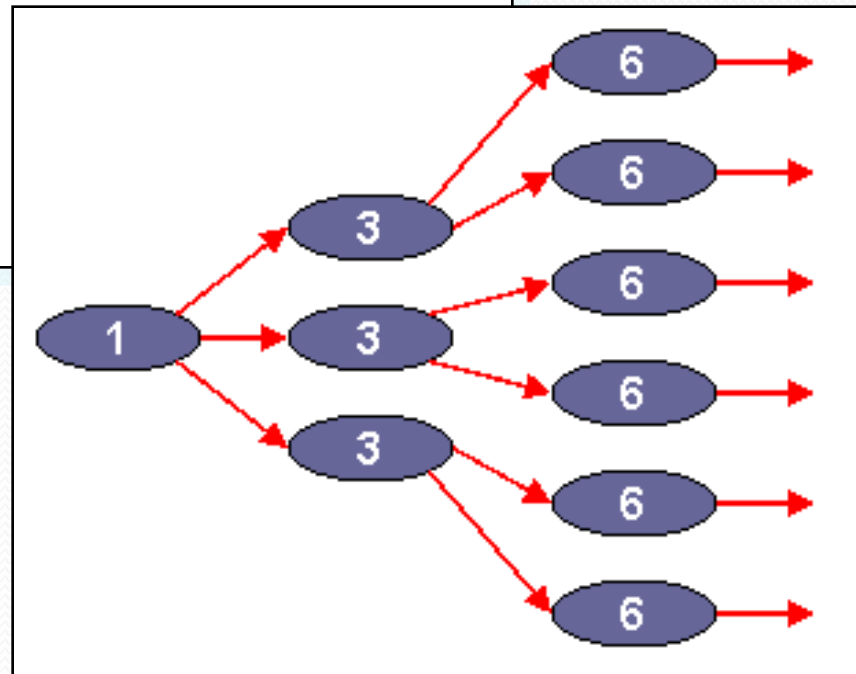
# The PDSA Ramp



# Continuous Quality Improvement approach to systems level change



- Rapid improvement cycles
- Iterative development
- Sensitivity to local context
- Incremental spread



# Tools to support continuous improvement

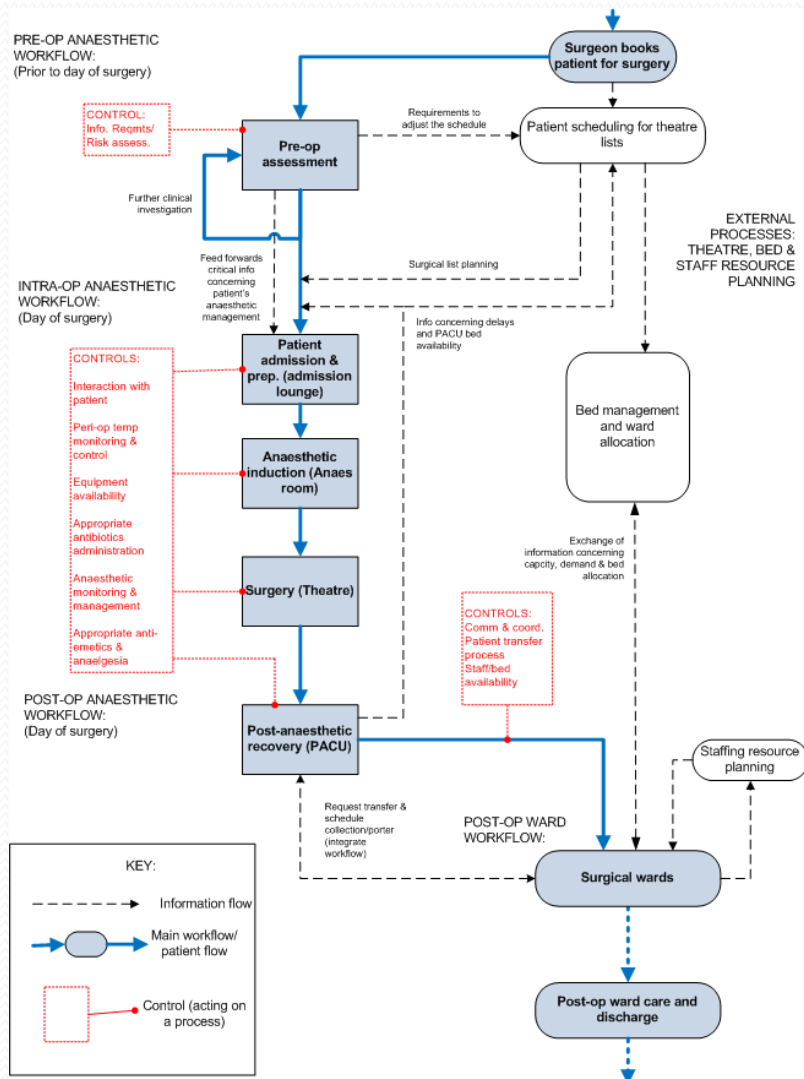
PROBLEM SOLVING	Flow diagrams	Brainstorming	Cause-Effect diagrams	Data collection	Graphs & charts	Stratification	Pareto analysis	Histograms	Scatter diagrams	Control charts
1. List and prioritise problems	Secondary	Secondary	Primary	Secondary	Secondary	Primary				
2. Define project & team	Secondary			Secondary	Secondary					
3. Analyse symptoms	Primary		Primary	Secondary	Secondary	Primary	Secondary		Secondary	
4. Formulate theories of causes	Secondary	Primary			Secondary					
5. Test theories	Primary		Primary	Primary	Primary	Primary	Primary	Primary	Primary	Primary
6. Identify root causes	Primary		Primary	Primary	Primary	Primary	Primary	Primary	Primary	Primary
7. Consider alternative solutions	Primary	Primary	Secondary		Secondary					
8. Design solutions and controls	Primary		Primary	Primary	Secondary		Secondary	Primary	Primary	Primary
9. Address resistance to change	Secondary	Primary	Secondary							
10. Implement solutions & controls	Primary			Secondary		Secondary	Secondary	Secondary		
11. Check performance	Secondary		Primary	Primary	Primary	Primary	Primary	Secondary		Primary
12. Monitor control system	Secondary		Primary	Primary	Primary	Primary	Secondary			Primary

KEY:

- Primary or frequent application of the tool
- Secondary, infrequent or circumstantial
- None or very rare



# Process mapping/process flow diagrams



- Origins: Task analysis/Business Process Modelling
- Requires multi-disciplinary team input
- Defines the current system prior to change
- Ensures we take a systems view (rather than narrow focus upon one stage)
- Generates insights into problem areas/opportunities
- Facilitates reasoning around effects of potential changes to the system



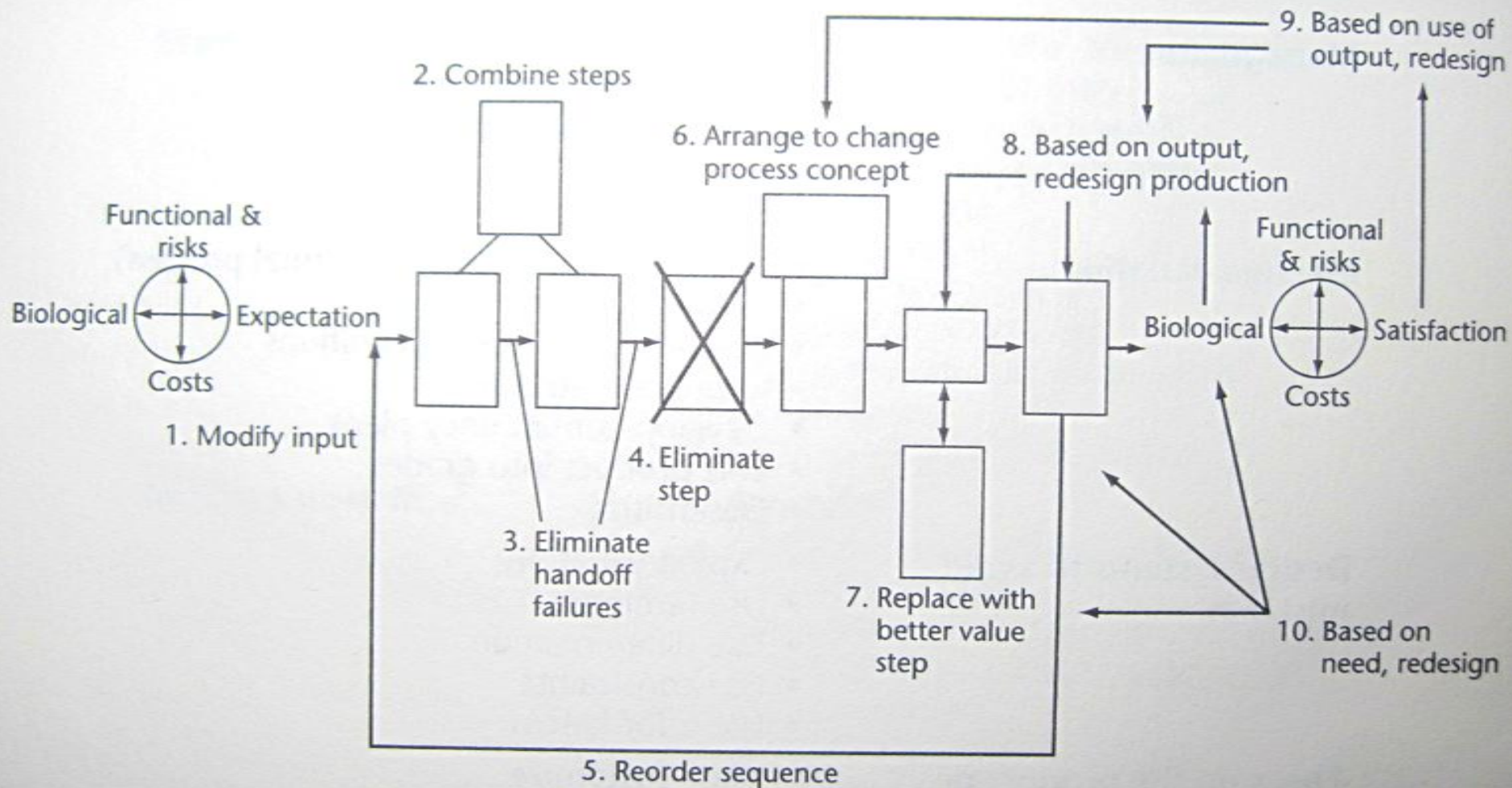
# Failure Modes and Effects Analysis (FMEA)

FMEA Process (executed by multidisciplinary team):

1. Define the steps (and sub-steps) in the process.
2. Identify the failure modes associated with each step (how things can go wrong)
3. Identify the route causes of failure modes (why the failure occurs)
4. Quantify the risk associated with the failure (RPN = Likelihood of Occurrence x Detectability x Severity of consequences)
5. Act on high priority risks

# Process improvement/redesign

- Following process mapping and identification of failure modes



# Reasoning about cause and effect: Driver diagrams

## Outcomes

Improved perioperative outcomes  
(Reduced perioperative adverse events: infections, cardiovascular events)

## Primary Drivers (processes, rules of conduct, structure)

Prevent Surgical Site Infections

Create a team culture attuned to detecting and rectifying intraoperative errors

Prevent perioperative cardiovascular events

## Secondary Drivers (components, activities leading to Pr. Dr.)

Administer prophylactic antibiotics appropriately\*

Use recommended hair removal\*

Maintain glycemic control for: cardiothoracic/known diabetic patients\*

Maintain perioperative normothermia\*

Use briefings\*

Use standard intra-operative procedures to prevent AEs

Undergo team training\*

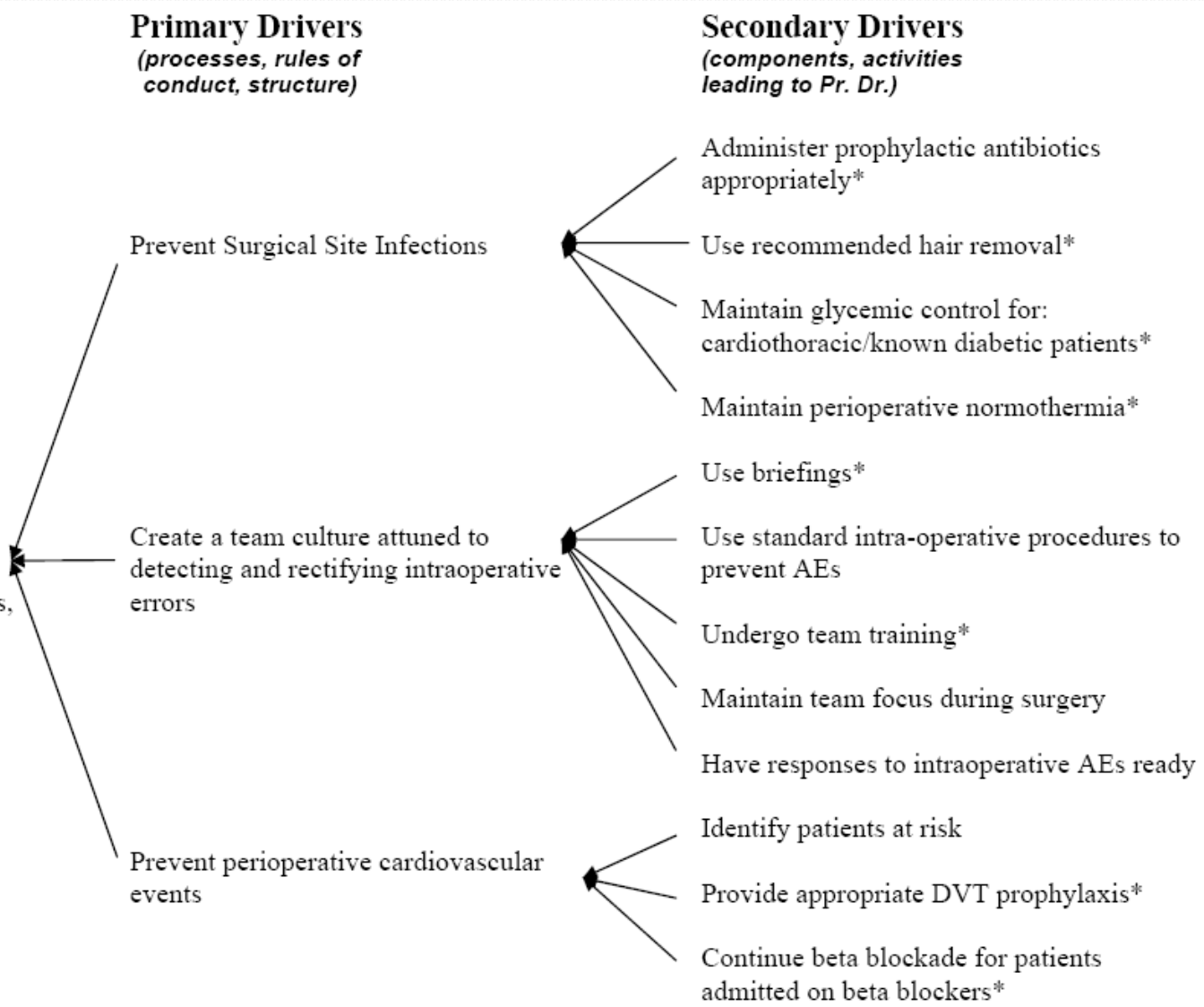
Maintain team focus during surgery

Have responses to intraoperative AEs ready


Identify patients at risk

Provide appropriate DVT prophylaxis\*

Continue beta blockade for patients admitted on beta blockers\*



# 3. Key data considerations for audit and quality improvement

- 
- How do we know that we have a problem?
  - How do we understand the extent of the problem?
  - How do we know that a change is an improvement that addresses the problem?

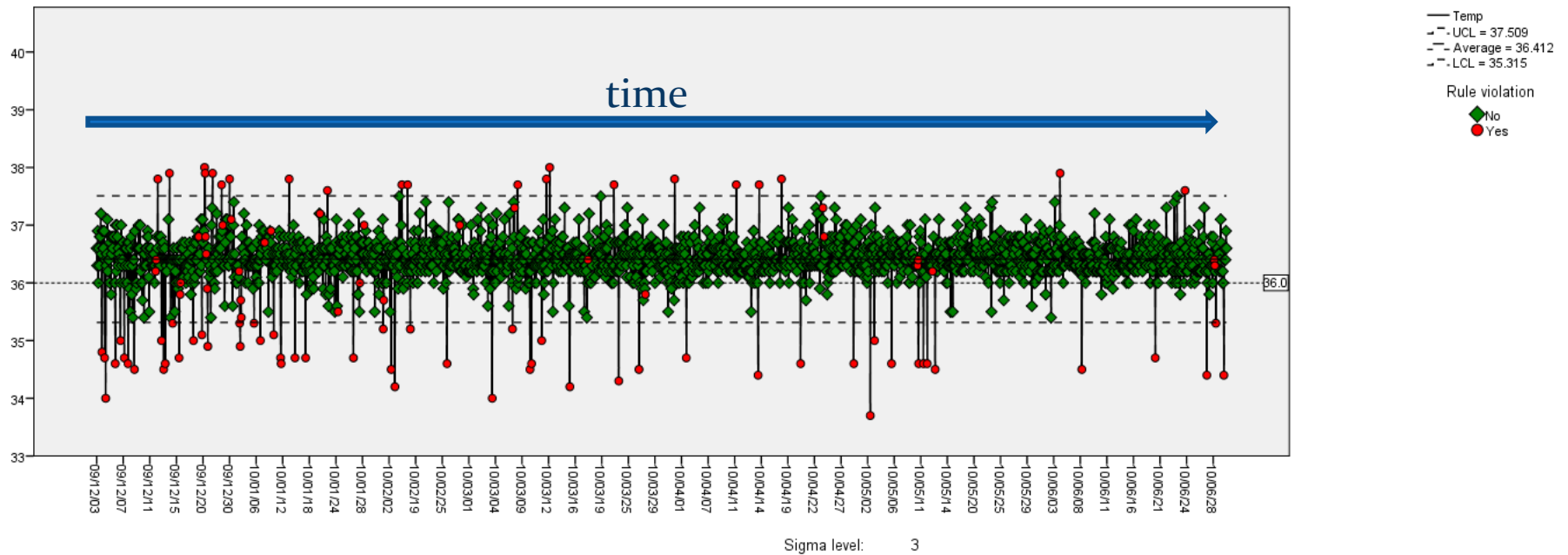
# 3 different approaches to measurement

Aspect	Improvement	Accountability	Research
<b><u>Aim</u></b>	Improvement of care	Comparison, choice, reassurance, spur for change	New knowledge
<b><u>Methods:</u></b>	Test observable	No test, evaluate current performance	Test blinded or controlled
• Test Observability			
• Bias	Accept consistent bias	Measure and adjust to reduce bias	Design to eliminate bias
• Sample Size	“Just enough” data, small sequential samples	Obtain 100% of available, relevant data	“Just in case” data
• Flexibility of Hypothesis	Hypothesis flexible, changes as learning takes place	No hypothesis	Fixed hypothesis
• Testing Strategy	Sequential tests	No tests	One large test
• Determining if a change is an improvement	Run charts or Shewhart control charts	No change focus	Hypothesis, statistical tests (t-test, F-test, chi square), p-values
• Confidentiality of the data	Data used only by those involved with improvement	Data available for public consumption and review	Research subjects' identities protected

Source: Institute for Healthcare Improvement

# All human processes vary over time

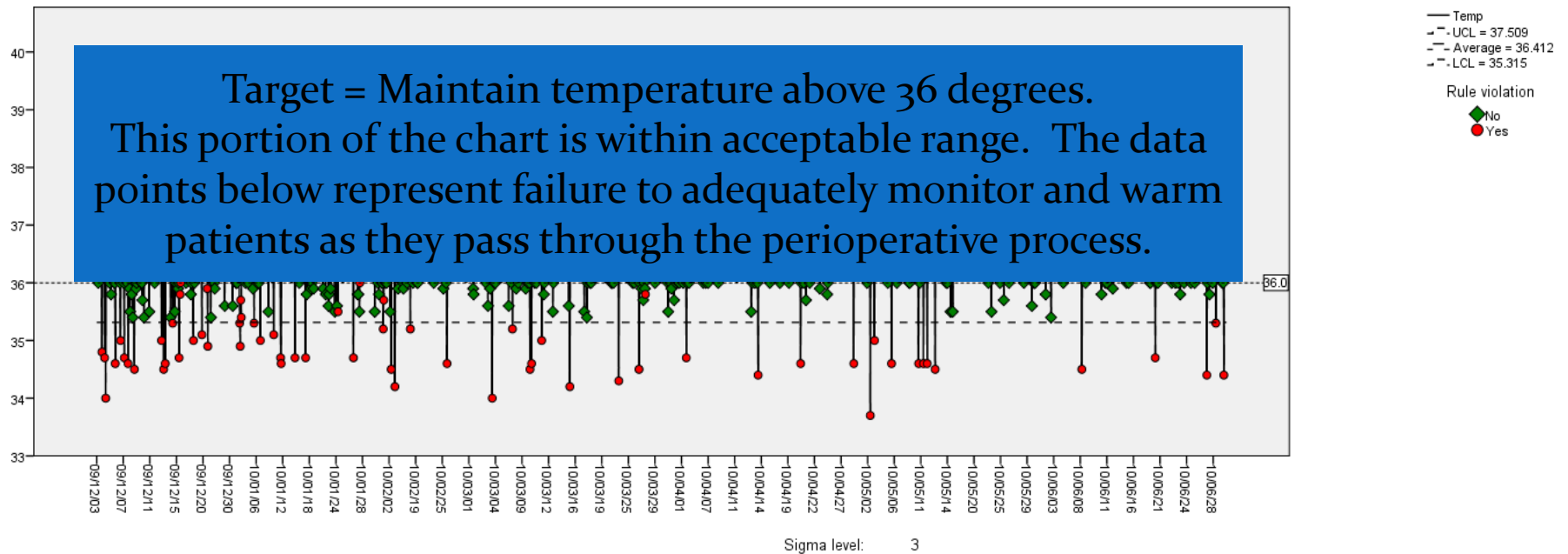
Variation in core temperature upon arrival in the recovery room of 3200 consecutive surgical patients





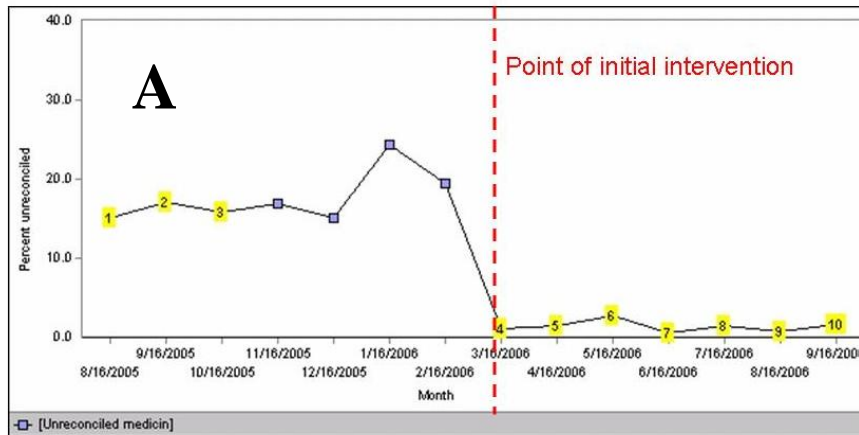
# Quality improvement is about detecting and reducing unacceptable variation

Variation in core temperature upon arrival in the recovery room of 3200 consecutive surgical patients



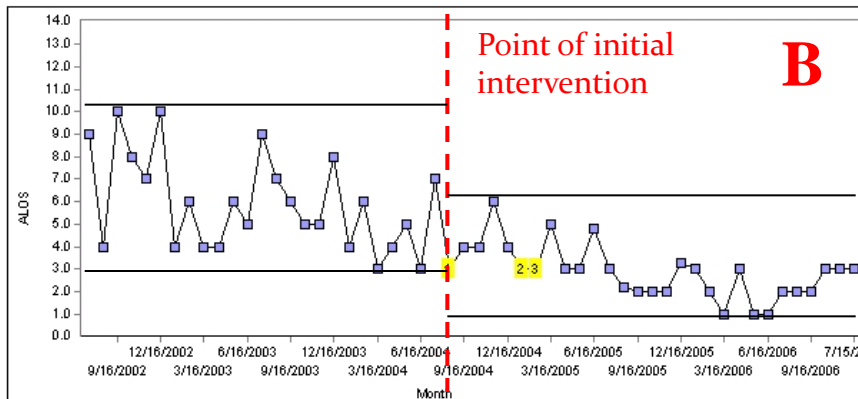
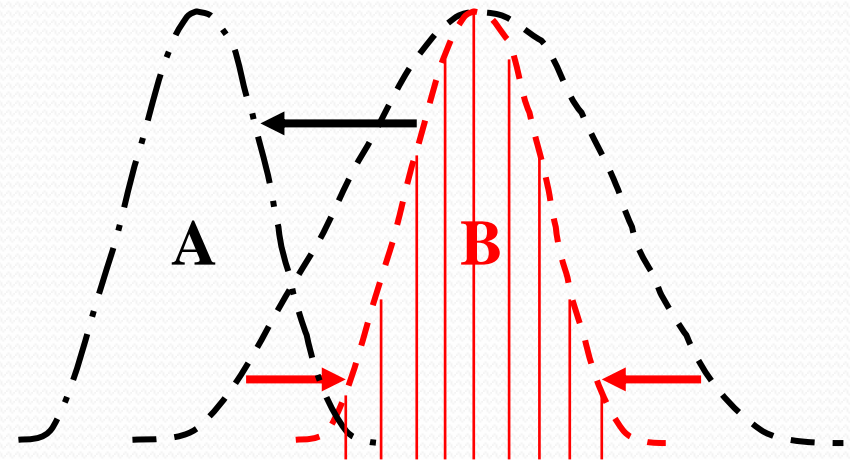


# Statistical definition of improvement in process data



**A = A stable shift in the level of the process in a desirable direction**

➡ Improved “Capability”

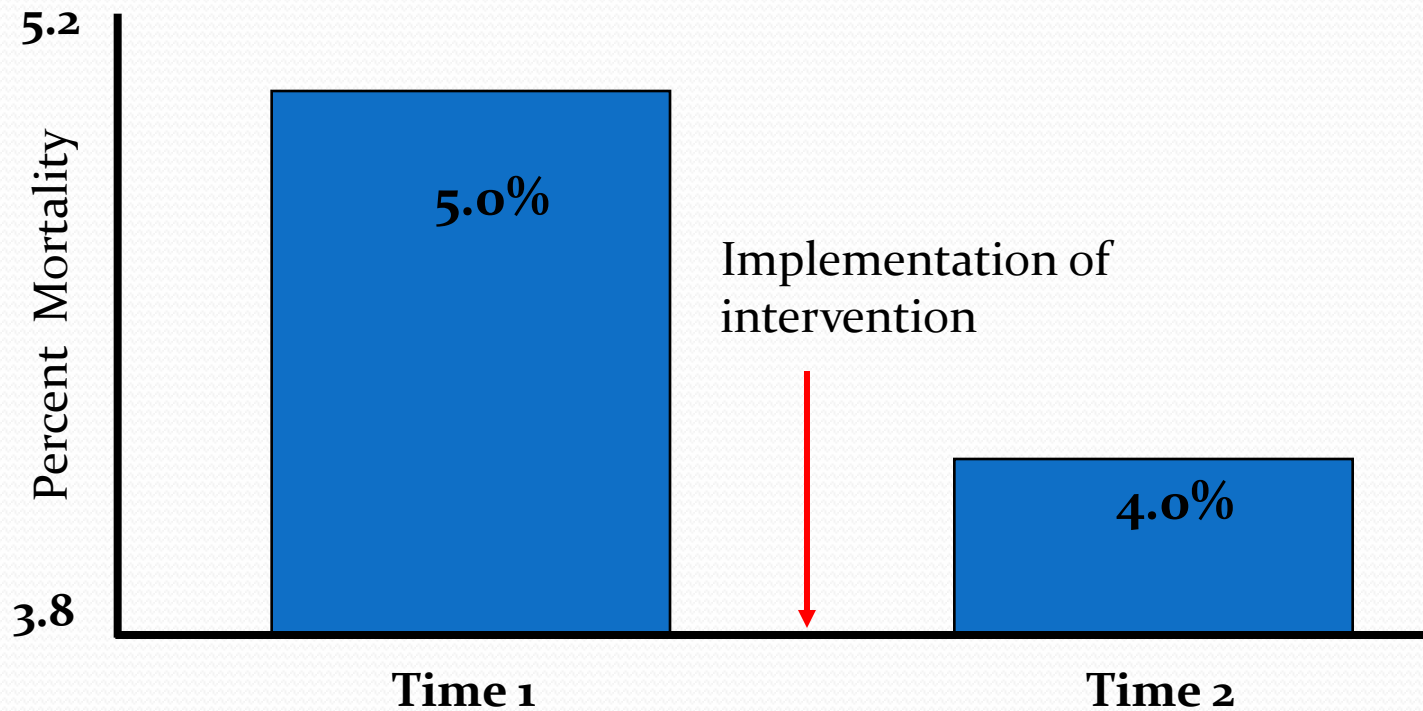


**B = Reduction in degree of variation in consecutive data points over time**

➡ Improved “Reliability”

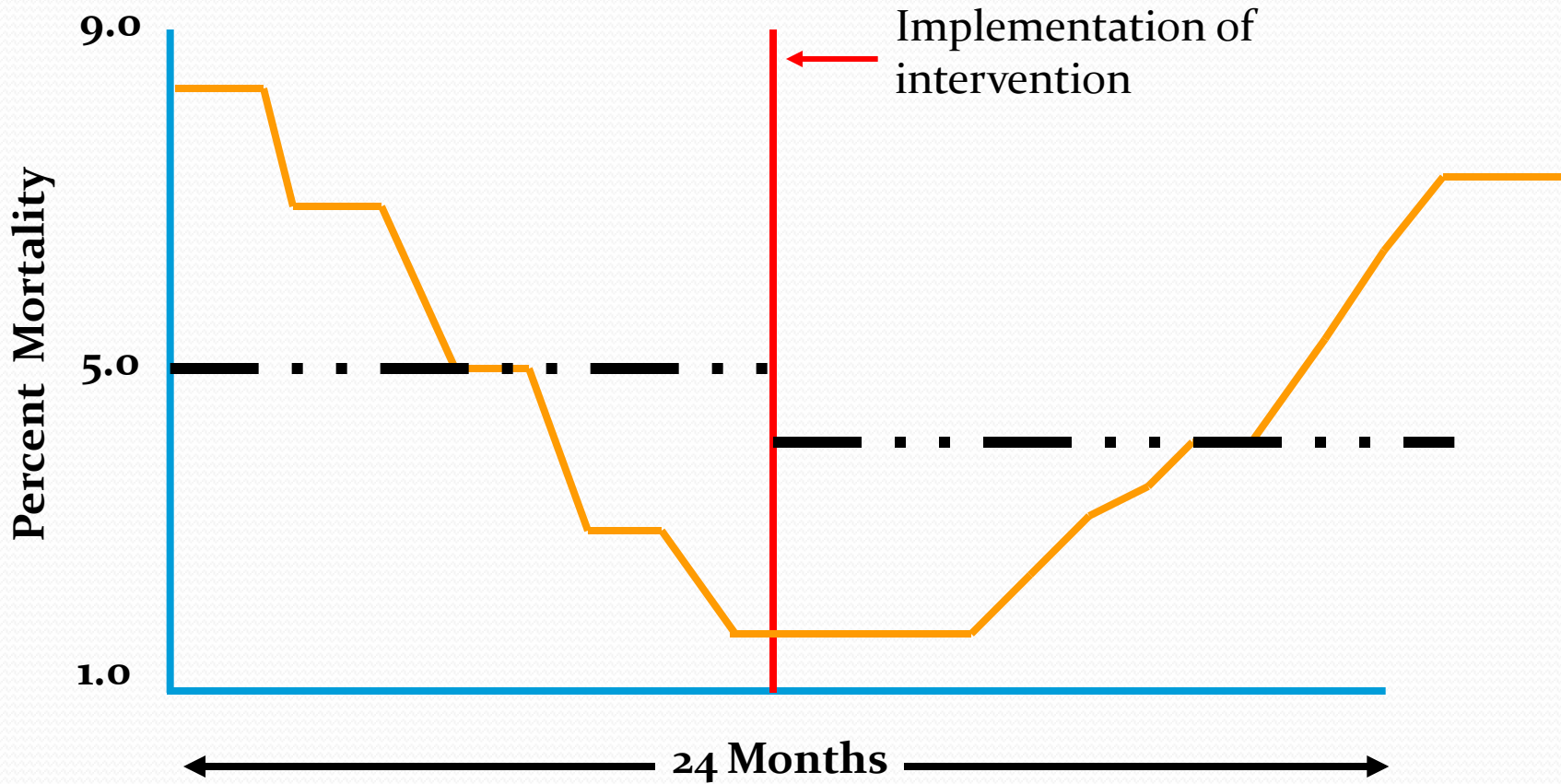
# Mortality following Coronary Artery Bypass Graft (CABG)

Before and After the Implementation of a New Protocol



**Conclusion: the protocol was successful in reducing mortality?**

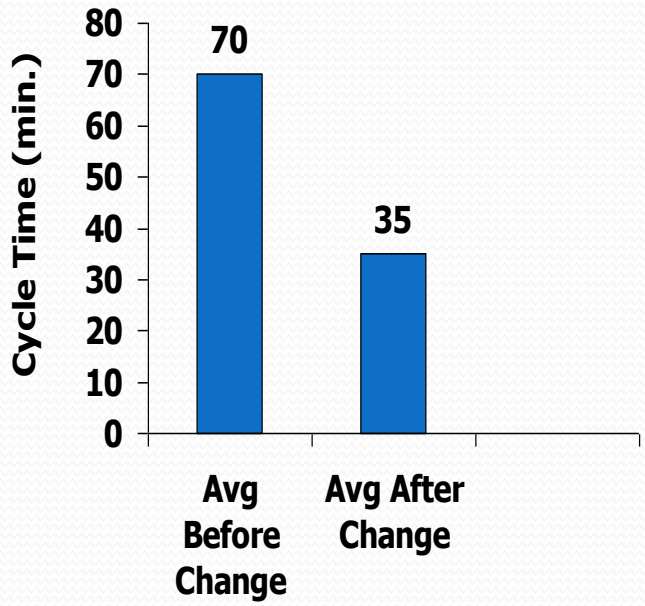
# CABG Mortality in time series



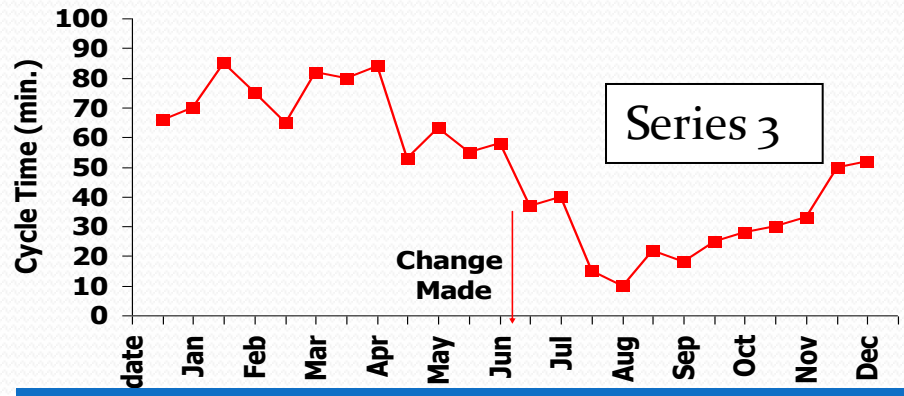
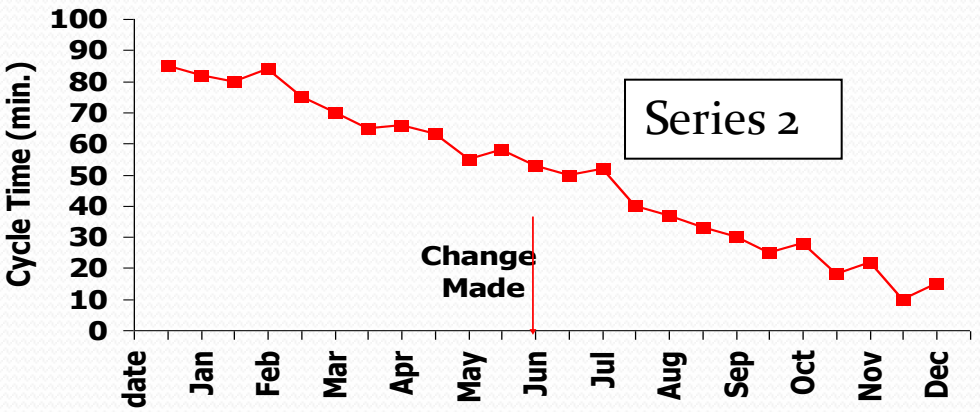
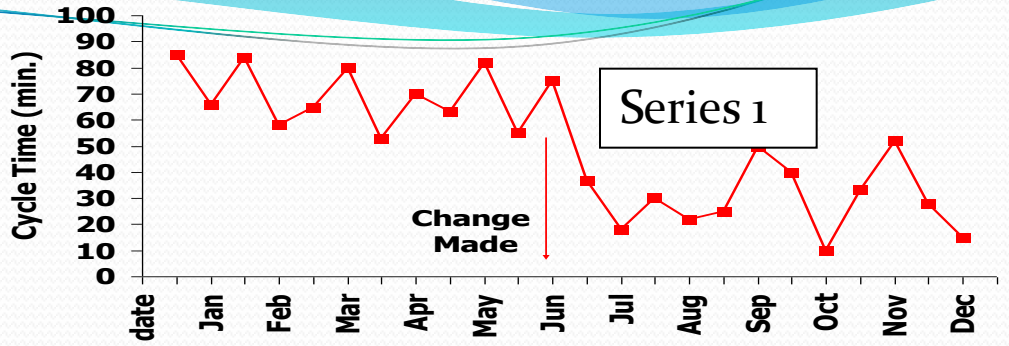
...has the new protocol really been effective?

# Aggregated vs. time series data

Aggregated pre- and post-comparison: process cycle time (improvement = reduction)



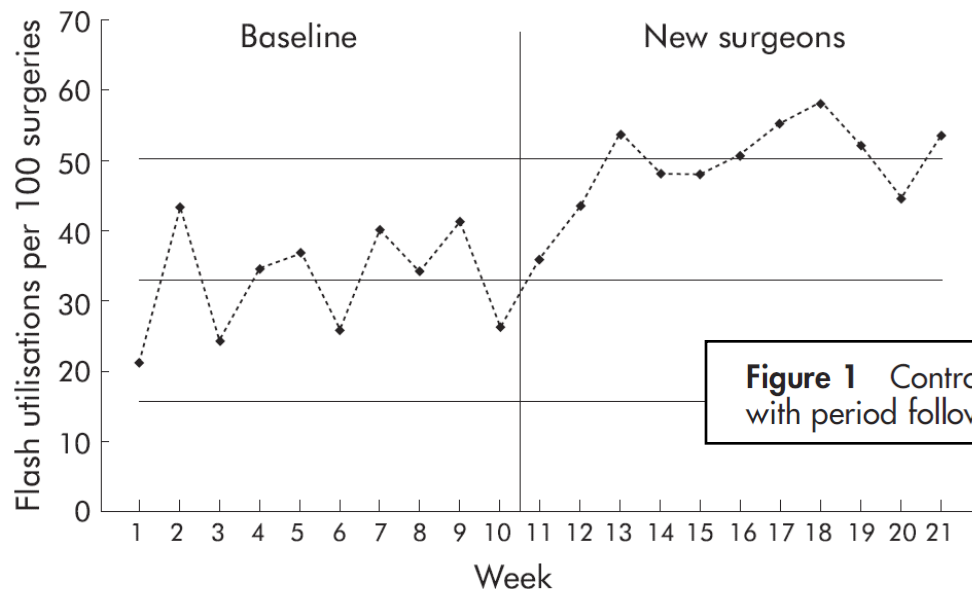
Data in time series (run charts):



- Which of the units above show improvement?
- Which of the units above show improvement attributable to the intervention?

# Detecting significant change: Sources of process variation

- **Common Cause Variation** — those causes inherent in the process over time, affect everyone working in the process, and affect all outcomes of the process
  - Caused by random or normal variation in the process
  - Occurs in stable processes
  - Process in statistical control
- **Special Cause Variation** — those causes *not* part of the process all the time or that do not affect everyone, but arise because of specific circumstances
  - Cause attributable to specific influence (e.g. intervention)
  - A sign of unstable process
  - Process not in statistical control

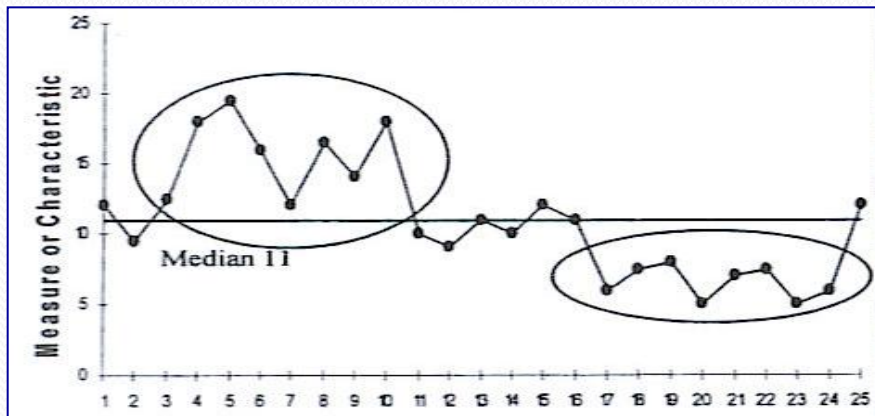


**Figure 1** Control chart for flash sterilization rate: baseline compared with period following arrival of new surgical group.

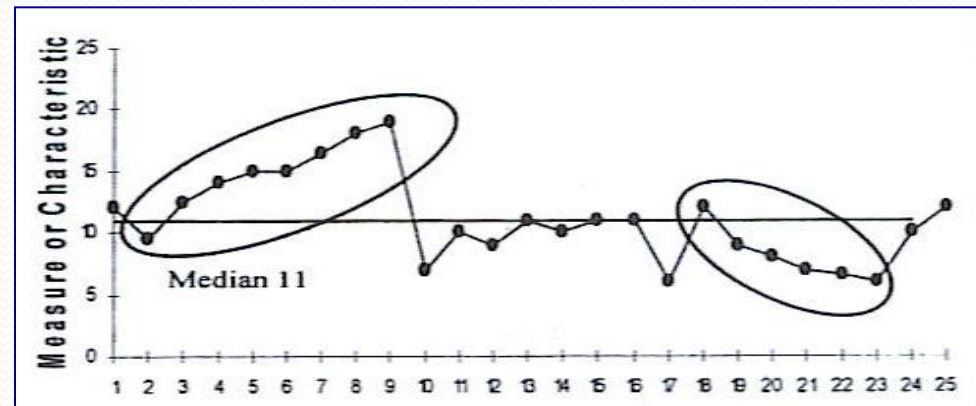
# Rules to identify special causes in Run Charts

**Definition of a Run:** A run is one or more consecutive data points appearing on the same side of the centre line, ignoring those points that fall on the median

- **Rule 1: A shift in the process**, or too many data points in a run (7 or more consecutive points above or below the median)
- **Rule 2: A trend** (6 or more consecutive points all increasing or decreasing)
- **Rule 3: Variation** - Too many or too few runs (for a given number of observations - comparison tables exist to help: e.g. for 24 data points, if there are less than 8 Runs or more than 17 Runs we conclude special causes are responsible)



Special cause: A shift in the process

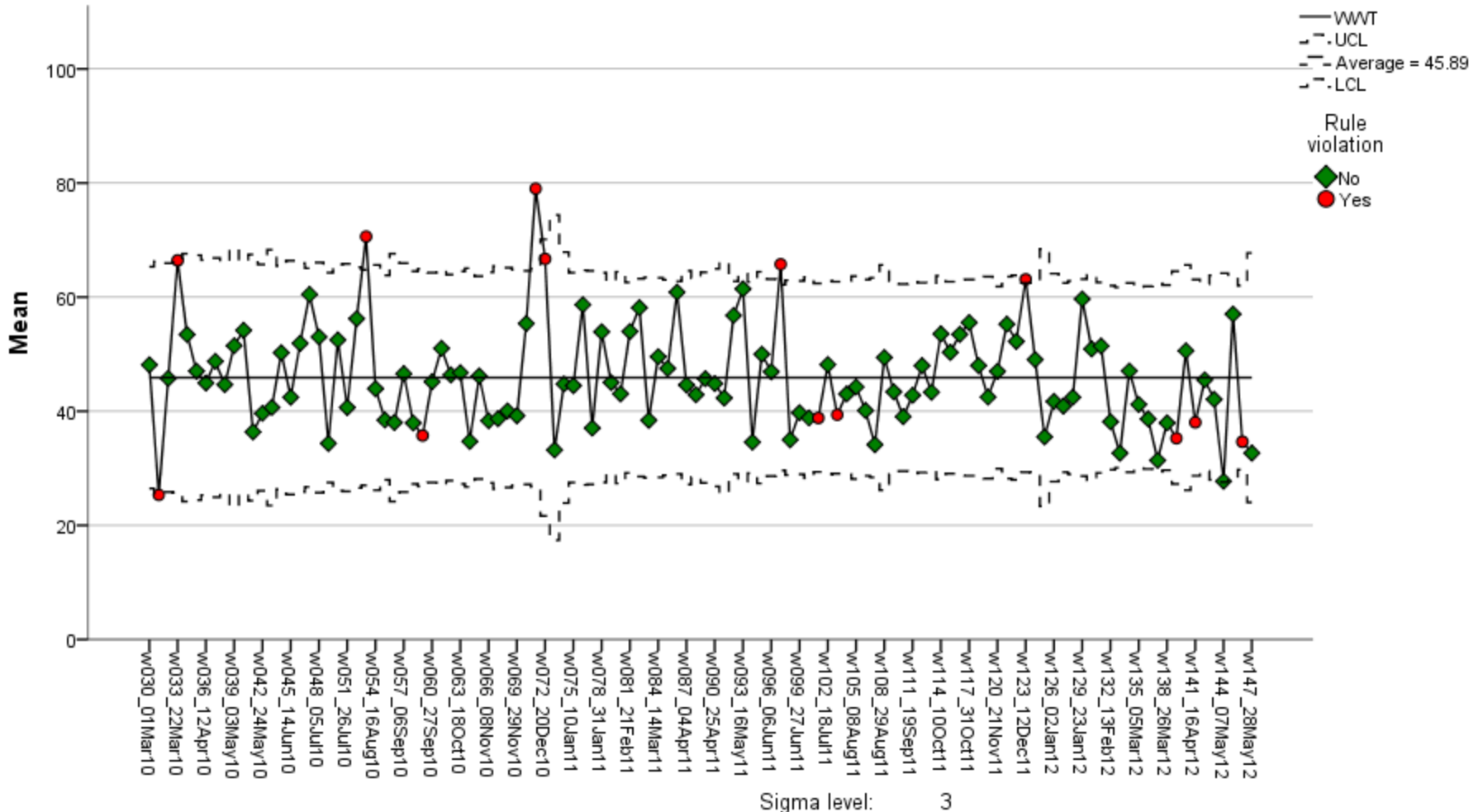


Special cause: A trend

# Segmenting systems (and data): Mean delay in patient transfer from PACU

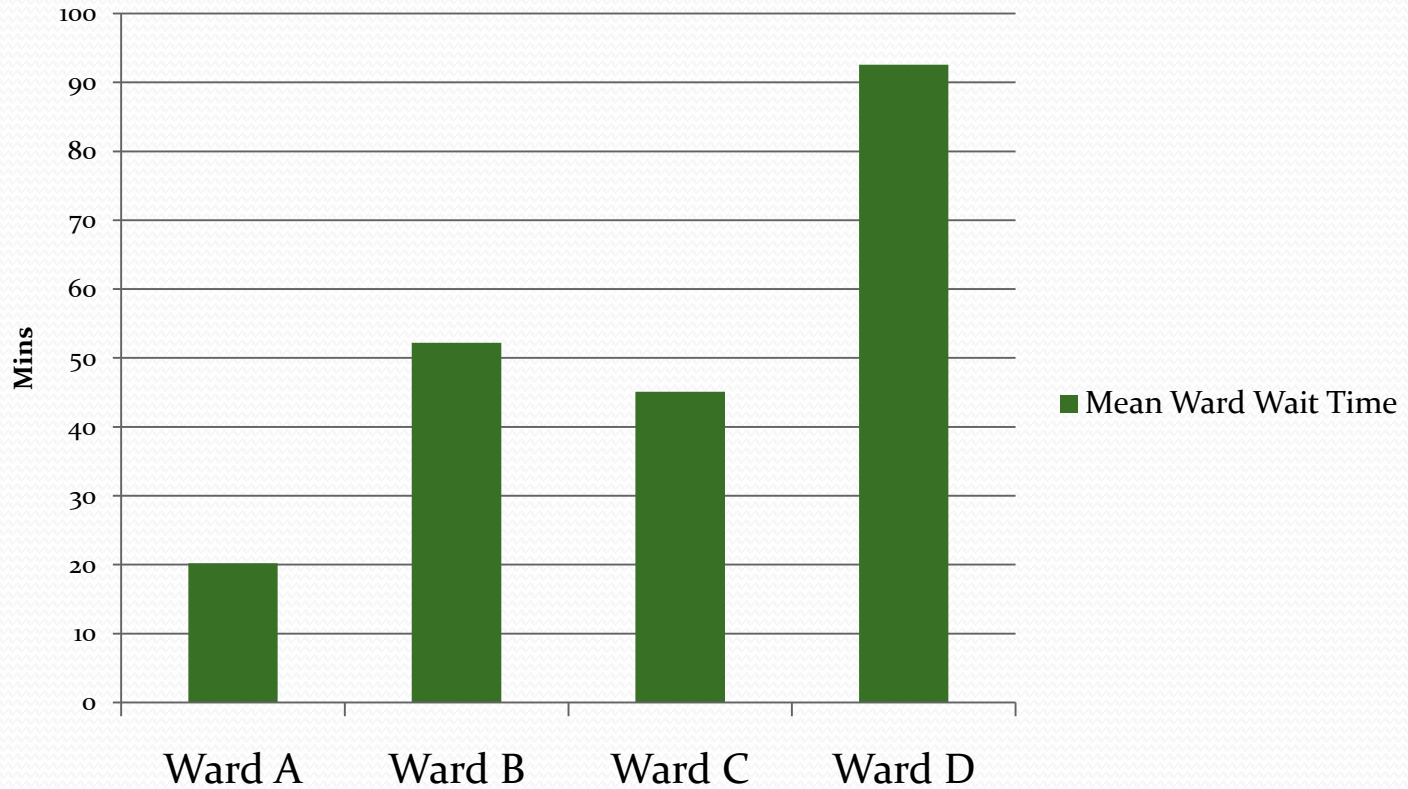
Time series chart (control chart)

X-Bar Chart of Mean WWT by Week



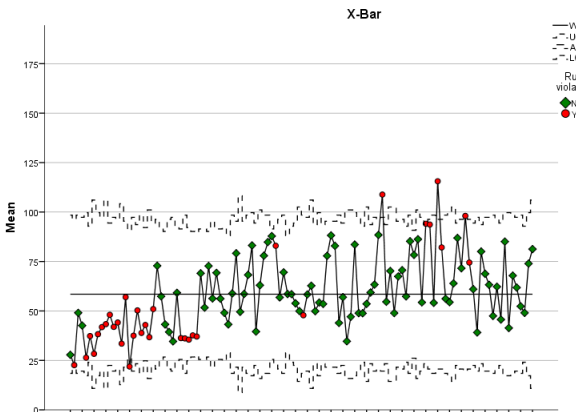
# Segmented by ward

## Mean Ward Wait Time

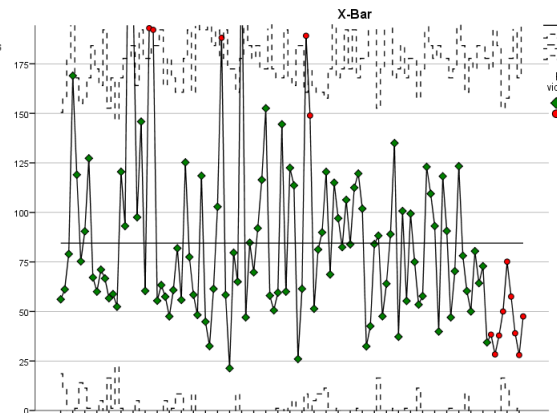




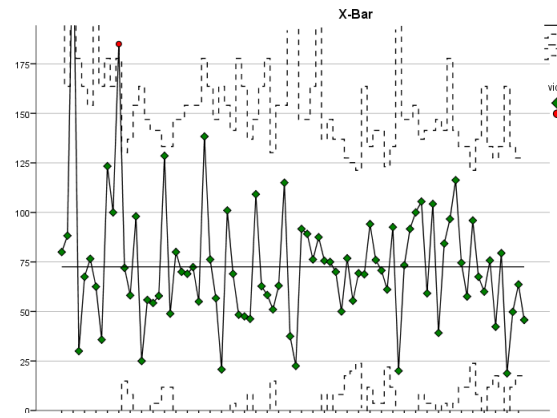
Mean weekly WWT - VEL



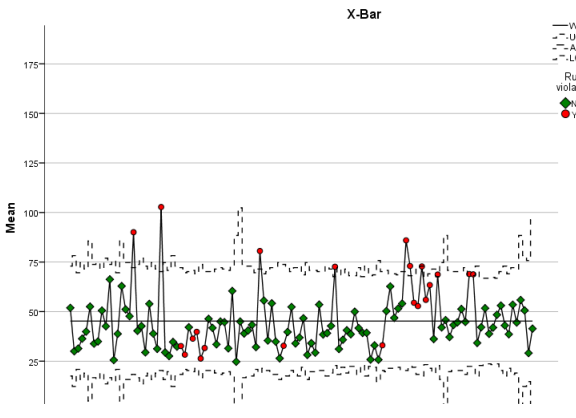
Mean weekly WWT - CPA



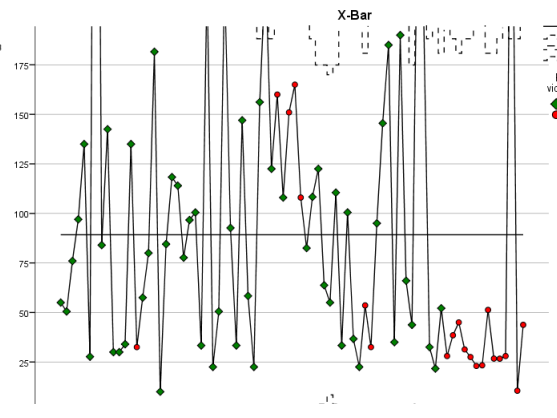
Mean weekly WWT - ZCH



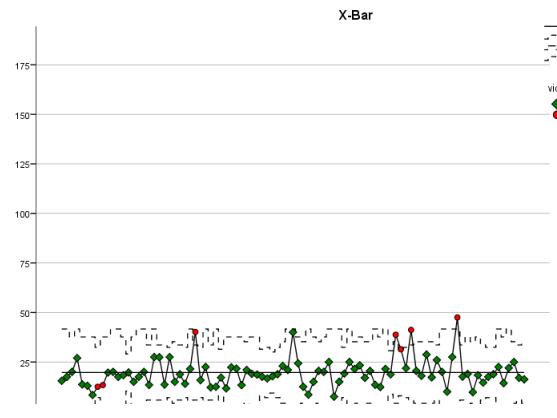
Mean weekly WWT - SAM



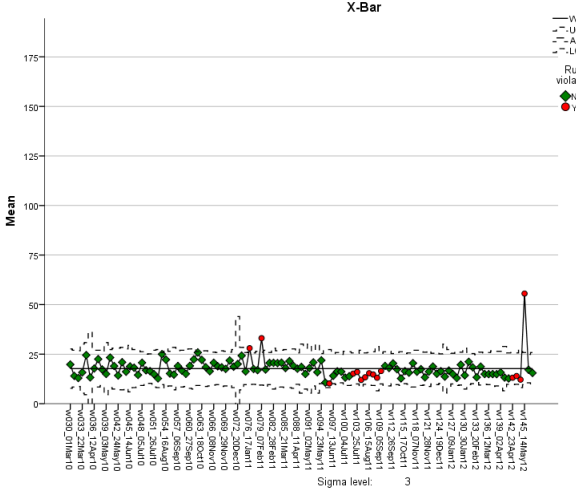
Mean weekly WWT - CPH



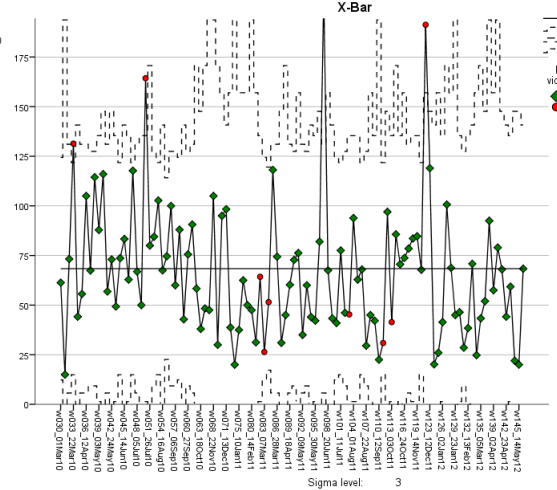
Mean weekly WWT - GW



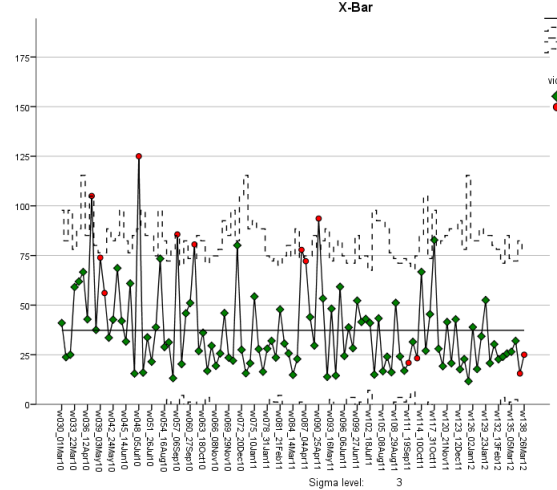
Mean weekly WWT - WW



Mean weekly WWT - ZCO



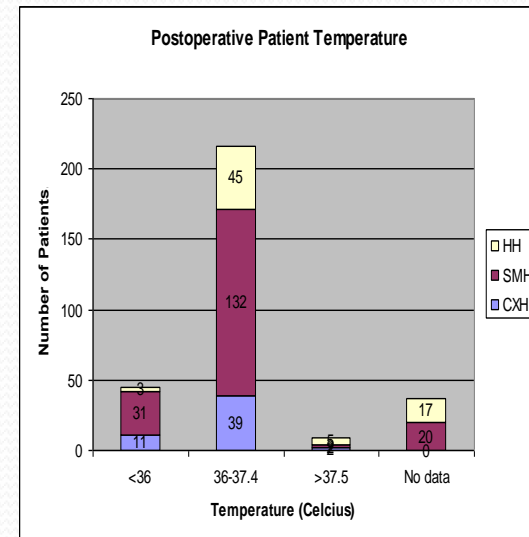
Mean weekly WWT - WIT



# Rationale for continuous audit

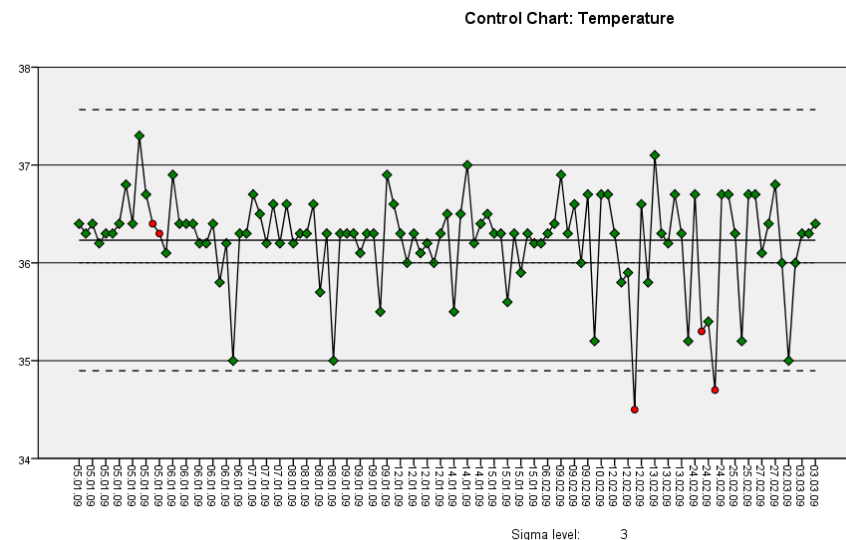
## Periodic measurement & summary reporting:

- Provides “Snapshot” summaries at specific time-points
- Masks natural process variation over time
- Supports periodic summative feedback that is retrospective in focus
- Supports summative pretest-posttest design but not iterative improvement work
- Is usually a “special project”



## Continuous process monitoring:

- Provides continuous signal of variation over time
- Can identify significant underlying process change against background noise
- Supports real-time continuous feedback that can detect harmful trends early
- Effects of interventions are observable over time and can be used to guide improvement work
- Must be integrated within routine operations



## Effective feedback from audit

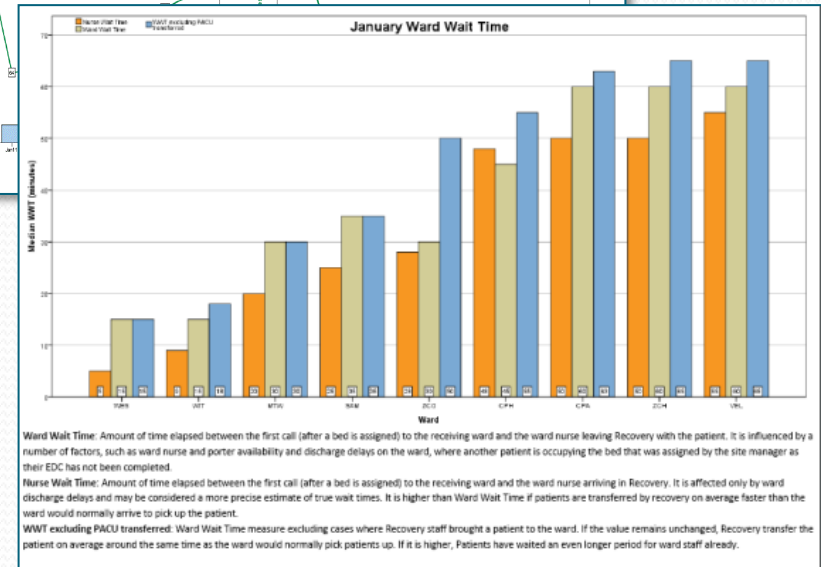
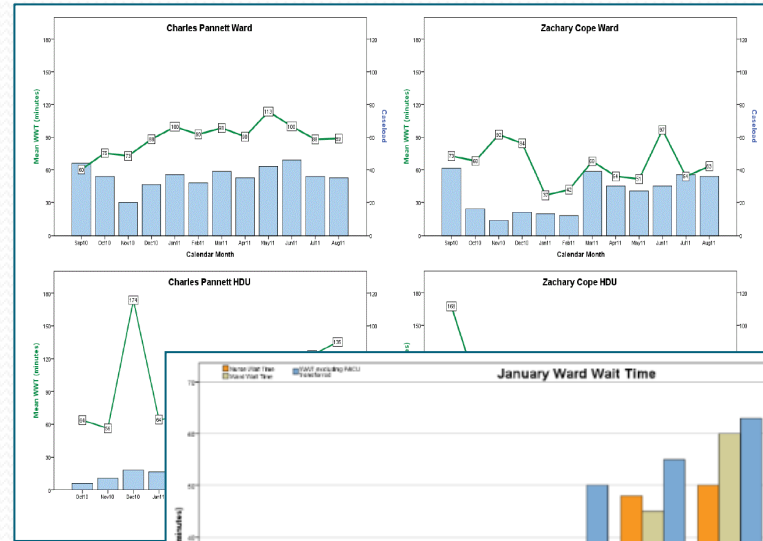
- Specifying valid and reliable measures is only the first step:
  - How can we use the data to drive improvement?
- Systematic reviews of the effects of audit and feedback on professional practice typically show small to moderate positive effects (Jamdvedt, 2005)
- Qualitative research suggests that effective data feedback for quality improvement has a number of characteristics (Bradley, 2004)
  - timeliness;
  - specific to the local context;
  - from credible sources;
  - non-punitive;
  - sustained over time

# Monthly PACU & Ward Feedback

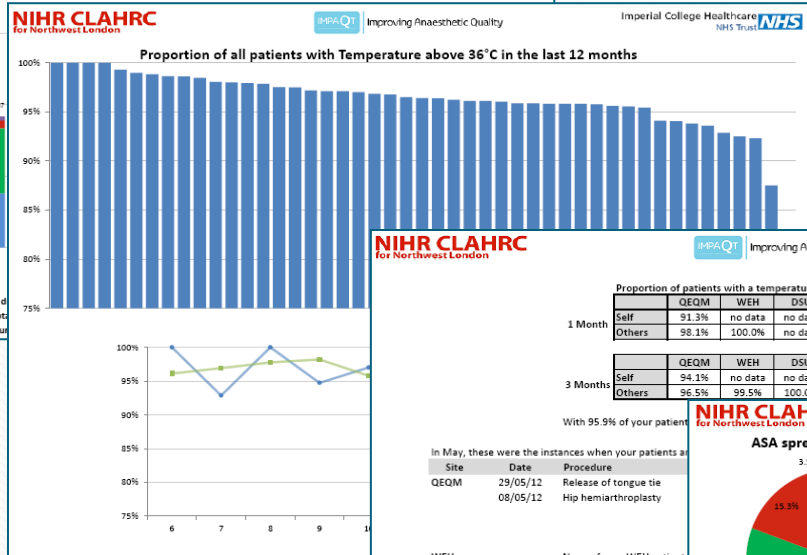
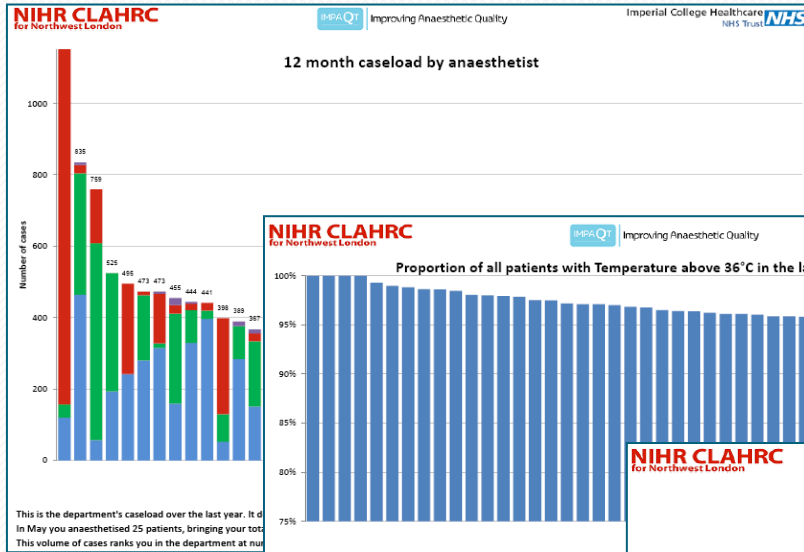
Data posted in recovery



Surgical ward reports



# Personalised anaesthetist feedback



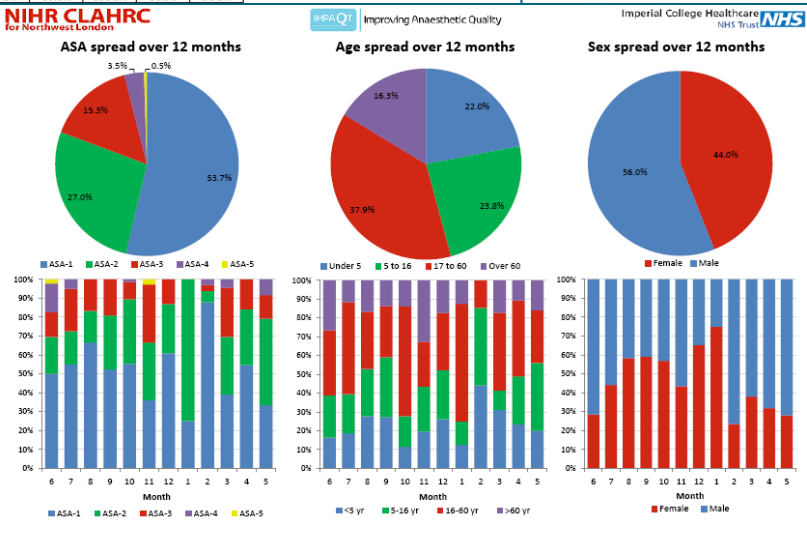
**Proportion of patients with a temperature over 36°C by site**

	QE/M	WEH	DSU	SIC	All	
1 Month	Self	91.3%	no data	no data	no data	91.3%
1 Month	Others	98.1%	100.0%	no data	95.2%	97.8%
3 Months	Self	94.1%	no data	no data	no data	94.1%
3 Months	Others	96.5%	99.5%	100.0%	96.0%	96.8%

With 95.9% of your patients...

In May, these were the instances when your patients a...

Site	Date	Procedure
QE/M	29/05/12	Release of tongue tie
QE/M	08/05/12	Hip hemiarthroplasty
WEH		None of your WEH patients
DSU		None of your DSU patients
SIC		None of your SIC patients a...





# References, further reading and resources

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