Better Quality Through Better Measurement

Asia Pacific Forum on Quality Improvement in Health Care

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Discussion Topics

- Why are you measuring?
- The Quality Measurement Journey
- Understanding variation conceptually
- Understanding variation statistically
- Linking measurement to improvement

Exercise

Quality Measurement Journey Self-Assessment

This self-assessment is designed to help quality facilitators gain a better understanding of where they personally stand with respect to the milestones in the Quality Measurement Journey (QMJ). What would your reaction be if you had to explain why using a run or control chart is preferable to computing only the mean, the standard deviation or calculating a p-value? Can you construct a run chart or help a team decide which control is most appropriate for their data?

You may not be asked to do all of the things listed below today or even next week. But, if you are facilitating a QI team or advising a manager on how to evaluate a process improvement effort, sooner or later these questions will be posed. How will you deal with them?

The place to start is to be honest with yourself and see how much you know about the QMJ. Once you have had this period of self-reflection, you will be ready to develop a learning plan for self-improvement and advancement.

Use the following Response Scale. Select the one response which best captures your opinion.

1. I could teach this topic to others!
2. I could do this by myself right now but would not want to teach it!
3. I could do this but I would have to study first!
4. I could do this with a little help from my friends!
5. I'm not sure I could do this!
6. I'd have to call in an outside expert!

### Quality Measurement Journey Self-Assessment


<table>
<thead>
<tr>
<th>Measurement Topic or Skill</th>
<th>Response Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moving a team from concepts to set of specific quantifiable measures</td>
<td></td>
</tr>
<tr>
<td>Building clear and unambiguous operational definitions</td>
<td></td>
</tr>
<tr>
<td>Developing data collection plans (including frequency and duration of data collection)</td>
<td></td>
</tr>
<tr>
<td>Helping a team figure out stratification strategies</td>
<td></td>
</tr>
<tr>
<td>Explain and design probability and nonprobability sampling options</td>
<td></td>
</tr>
<tr>
<td>Explain why plotting data over time is preferable to using aggregated data and summary statistics</td>
<td></td>
</tr>
<tr>
<td>Describe the differences between common and special causes of variation</td>
<td></td>
</tr>
<tr>
<td>Construct and interpret run charts (including the run chart rules)</td>
<td></td>
</tr>
<tr>
<td>Decide which control chart is most appropriate for a particular measure</td>
<td></td>
</tr>
<tr>
<td>Construct and interpret control charts (including the control chart rules)</td>
<td></td>
</tr>
<tr>
<td>Link measurement efforts to PDSA cycles</td>
<td></td>
</tr>
<tr>
<td>Build measurement plans into implementation and spread activities</td>
<td></td>
</tr>
</tbody>
</table>

### The Model for Improvement

When you combine the 3 questions with the... PDSA cycle, you get...  
... the Model for Improvement.


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Measurement should help you connect the dots!

The Model for Improvement

The three questions provide the strategy

- What are we trying to Accomplish?
- How will we know that a change is an improvement?
- What change can we make that will result in improvement?

The PDSA cycle provides the tactical approach to work

Source:
How will we know that a change is an improvement?

1. By *understanding* the variation that lives within your data

2. By making good management *decisions* on this variation (i.e., don’t overreact to a special cause and don’t think that random movement of your data up and down is a signal of improvement).

Why are you measuring?

Research? Judgment? Improvement?

The answer to this question will guide your entire quality measurement journey!
The Three Faces of Performance Measurement

Aspect | Improvement | Accountability | Research
--- | --- | --- | ---
Aim | Improvement of care (efficiency & effectiveness) | Comparison, choice, reassurance, motivation for change | New knowledge (efficacy)
Methods: • Test Observability | Test observable | No test, evaluate current performance | Test blinded or controlled
| • 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 | Flexible hypotheses, changes as learning takes place | No hypothesis | Fixed hypothesis (null hypothesis)
| • Testing Strategy | Sequential tests | No tests | One large test
| • Determining if a change is an improvement | Run charts or Shewhart control charts (statistical process control) | No change focus (maybe compute a percent change or rank order the results) | 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
Three approaches to research:

Research for Efficacy
(experimental and quasi-experimental designs/clinical trials, p-values)

Research for Efficiency

Research for Effectiveness

Tin Openers and Dials

- Concept from Carter and Klein (1992)
- Tin openers open up cans of worms
- Dials measure things to make judgements
- Most of the time you need to ask the right questions before you try and get the right answers
Graphic Displays of Data

You need to determine not only why you are measuring but also determine how you are going to analyze the data and then present it.

**You do have choices!**

All too often, however, health care professionals present data in ways that only lead to judgment:

- Aggregated data and descriptive statistics
- Static displays of data (e.g., pie charts, bar charts)
- Performance against a target or goal

---

Example of Data for Judgment

**CMS/HQA Core Measures**

Does this tabular display of data help us understand the variation in these measures?

Are we getting better, getting worse or demonstrating no change?

<table>
<thead>
<tr>
<th></th>
<th>State Average</th>
<th>Q3 04</th>
<th>4Q 04</th>
<th>Q1 05</th>
<th>Q2 05</th>
<th>YTD 05</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMI</td>
<td>79</td>
<td>77</td>
<td>79</td>
<td>81</td>
<td>80</td>
<td>79</td>
</tr>
<tr>
<td>CHF</td>
<td>61</td>
<td>56</td>
<td>56</td>
<td>63</td>
<td>62</td>
<td>60</td>
</tr>
<tr>
<td>PN</td>
<td>46</td>
<td>16</td>
<td>16</td>
<td>20</td>
<td>31</td>
<td>20</td>
</tr>
<tr>
<td>SIP</td>
<td>52</td>
<td>41</td>
<td>43</td>
<td>54</td>
<td>49</td>
<td>47</td>
</tr>
</tbody>
</table>

**Legend**

- Better than or Equal to State Average
- Worse than State Average

*(Perfect Care Bundles – all aspects of a bundle must be met in order to receive credit)*
So, how do you view the Three Faces of Performance Measurement?

As...  As a...

Or,
Relating the Three Faces of Performance Measurement to your work

The three faces of performance measurement should not be seen as mutually exclusive silos. This is not an either/or situation.

All three areas must be understood as a system. Individuals need to build skills in all three areas.

Organizations need translators who and be able to speak the language of each approach.

The problem is that individuals identify with one of the approaches and dismiss the value of the other two.

Dialogue #1

Why are you measuring?

– How much of your organization’s energy is aimed at improvement, accountability and/or research?

– Does one form of performance measurement dominate your journey?

– Does your organization approach measurement from an enumerative or an analytic perspective?
Do you have a plan to guide your quality measurement journey?

“The greatest thing in the world is not so much where we stand, as in what direction we are going.” Oliver Wendell Holmes

The Quality Measurement Journey

**AIM** (How good? By when?)
- Concept
- Measure
- Operational Definitions
- Data Collection Plan
- Data Collection Analysis

ACTION

The Quality Measurement Journey

AIM – freedom from harm
Concept – reduce patient falls
Measure – IP falls rate (falls per 1000 patient days)
Operational Definitions - # falls/inpatient days
Data Collection Plan – monthly; no sampling; all IP units
Data Collection – unit submits data to RM; RM assembles and send to QM for analysis
Analysis – control chart
Tests of Change

The Quality Measurement Journey

AIM (Why are you measuring?)
Concept
Measure
Operational Definitions
Data Collection Plan
Data Collection
Analysis
ACTION
Moving from a Concept to Measure

“Hmmmm…how do I move from a concept to an actual measure?

Every concept can have MANY measures. Which one is most appropriate?

Every concept can have many measures

<table>
<thead>
<tr>
<th>Concept</th>
<th>Potential Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand Hygiene</td>
<td>Ounces of hand gel used each day</td>
</tr>
<tr>
<td></td>
<td>Ounces of gel used per staff</td>
</tr>
<tr>
<td></td>
<td>Percent of staff washing their hands (before &amp; after visiting a patient)</td>
</tr>
<tr>
<td>Medication Errors</td>
<td>Percent of errors</td>
</tr>
<tr>
<td></td>
<td>Number of errors</td>
</tr>
<tr>
<td></td>
<td>Medication error rate</td>
</tr>
<tr>
<td>VAPs</td>
<td>Percent of patients with a VAP</td>
</tr>
<tr>
<td></td>
<td>Number of VAPs in a month</td>
</tr>
<tr>
<td></td>
<td>The number of days without a VAP</td>
</tr>
</tbody>
</table>
Three Types of Measures

- **Outcome Measures**: Voice of the customer or patient. How is the system performing? What is the result?

- **Process Measures**: Voice of the workings of the system. Are the parts/steps in the system performing as planned?

- **Balancing Measures**: Looking at a system from different directions/dimensions. What happened to the system as we improved the outcome and process measures? (e.g. unanticipated consequences, other factors influencing outcome)

Potential Set of Measures for Improvement in the ED

<table>
<thead>
<tr>
<th>Topic</th>
<th>Outcome Measures</th>
<th>Process Measures</th>
<th>Balancing Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve waiting time and patient satisfaction in the ED</td>
<td>Total Length of Stay in the ED Patient Satisfaction Scores</td>
<td>Time to registration Patient / staff comments on flow % patient receiving discharge materials Availability of antibiotics</td>
<td>Volumes % Leaving without being seen Staff satisfaction Financials</td>
</tr>
</tbody>
</table>
Balancing Measures: Looking at the System from Different Dimensions

- Outcome (quality, time)
- Transaction (volume, no. of patients)
- Productivity (cycle time, efficiency, utilisation, flow, capacity, demand)
- Financial (charges, staff hours, materials)
- Appropriateness (validity, usefulness)
- Patient satisfaction (surveys, customer complaints)
- Staff satisfaction

The Quality Measurement Journey

AIM (Why are you measuring?)

Concept

Measure

Operational Definitions

Data Collection Plan

Data Collection

Analysis

ACTION
Operational Definitions

“Would you tell me, please, which way I ought to go from here,” asked Alice?

“That depends a good deal on where you want to get to,” said the Cat.

“I don’t much care where” - said Alice.

“Then it doesn’t matter which way you go,” said the Cat.


An Operational Definition...

... is a description, in quantifiable terms, of what to measure and the steps to follow to measure it consistently.

- It gives communicable meaning to a concept
- Is clear and unambiguous
- Specifies measurement methods and equipment
- Identifies criteria
### How do you define the following Concepts?

<table>
<thead>
<tr>
<th>Concept</th>
<th>Concept</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Class Performance</td>
<td>Delayed discharges</td>
</tr>
<tr>
<td>Alcohol related admissions</td>
<td>End of life care</td>
</tr>
<tr>
<td>Teenage pregnancy</td>
<td>Falls (with/without injuries)</td>
</tr>
<tr>
<td>Cancer waiting times</td>
<td>Childhood immunisations</td>
</tr>
<tr>
<td>Health inequalities</td>
<td>Maternity services</td>
</tr>
<tr>
<td>Asthma admissions</td>
<td>Engagement with measurement for improvement</td>
</tr>
<tr>
<td>Childhood obesity</td>
<td>Moving services closer to home</td>
</tr>
<tr>
<td>Patient education</td>
<td>Breastfeeding</td>
</tr>
<tr>
<td>Health and wellbeing</td>
<td>Ambulatory care</td>
</tr>
<tr>
<td>Adding life to years and years to life</td>
<td>Access to health in deprived areas</td>
</tr>
<tr>
<td>Children's palliative care</td>
<td>Diagnostics in the community</td>
</tr>
<tr>
<td>Safe services</td>
<td>Productive community services</td>
</tr>
<tr>
<td>Smoking cessation</td>
<td>Vascular inequalities</td>
</tr>
<tr>
<td>Urgent care</td>
<td></td>
</tr>
</tbody>
</table>

Exercise: Developing a Set of Measures and Operational Definitions

- Identify a project you are currently working on or plan to address in the near future.

- Select **1-2 Process**, **1-2 Outcome** and **1 Balancing** measure and develop a clear operational definition for each measure.

- Use the **Measurement Plan** and **Operational Definitions Worksheet**s to record your work.
Measurement Plan Worksheet

<table>
<thead>
<tr>
<th>Measure Name</th>
<th>Type (Process, Outcome or Balancing)</th>
<th>Operational Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>B</td>
<td></td>
</tr>
</tbody>
</table>

Source: Lloyd & Scoville 2010

Operational Definition Worksheet

Team name: ____________________________________________________________
Date: _______________ Contact person: ________________________________

WHAT PROCESS DID YOU SELECT?

WHAT SPECIFIC MEASURE DID YOU SELECT FOR THIS PROCESS?

OPERATIONAL DEFINITION
Define the specific components of this measure. If it is a percent or a rate, specify the numerator and denominator. If it is an average, identify the calculation for deriving the average. Include any special equipment needed to capture the data. If the measure is a score (such as a patient satisfaction score) describe how the score is derived. When a measure reflects concepts such as accuracy, complete, timely, or an error, describe the criteria to be used to determine accuracy.

Operational Definition Worksheet® (cont’d)


DATA COLLECTION PLAN
Who is responsible for actually collecting the data?
How often will the data be collected? (e.g., hourly, daily, weekly or monthly?)
What are the data sources (be specific)?
What is to be included or excluded (e.g., only inpatients are to be included or only stat lab requests should be tracked).
How will these data be collected?
   Manually _______ From a log _______ From an automated system

BASELINE MEASUREMENT
What is the actual baseline number? __________________________________________
What time period was used to collect the baseline? _______________________________

TARGET(S) OR GOAL(S) FOR THIS MEASURE
Do you have target(s) or goal(s) for this measure?
Yes ___ No ___
Specify the External target(s) or Goal(s) (specify the number, rate or volume, etc., as well as the source of the target/goal.)
Specify the Internal target(s) or Goal(s) (specify the number, rate or volume, etc., as well as the source of the target/goal.)

Dashboard Worksheet®

Name of team: __________________________ Date: _____________

<table>
<thead>
<tr>
<th>Measure Name</th>
<th>Operational Definition</th>
<th>Data Source(s)</th>
<th>Data Collection</th>
<th>Baseline</th>
<th>Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Provide a specific name such as medication error rate)</td>
<td>(Define the measure in very specific terms. Provide the numerator and the denominator of a percentage or rate. Indicate what is to be included and excluded. Be as clear and unambiguous as possible)</td>
<td>(Indicate the sources of the data. These could include medical records, logs, surveys, etc.)</td>
<td>(Schedule: daily, weekly, monthly or quarterly)</td>
<td>(Indicate if period is short, long term)</td>
<td>(Specify the number, rate or volume, etc., in the source of the target/goal.)</td>
</tr>
</tbody>
</table>

### NON-SPECIFIC CHEST PAIN PATHWAY MEASUREMENT PLAN

<table>
<thead>
<tr>
<th>Measure Name</th>
<th>Operational Definition</th>
<th>Data Source(s)</th>
<th>Data Collection:</th>
<th>Baseline</th>
<th>Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of patients who have MI or Unstable Angina as diagnosis</td>
<td>Numerator = Patients entered into the NSCP path who have Acute MI or Unstable Angina as the discharge diagnosis&lt;br&gt;Denominator = All patients entered into the NSCP path</td>
<td>1. Medical Records&lt;br&gt;2. Midas&lt;br&gt;3. Variance Tracking Form</td>
<td>• Schedule (daily, weekly, monthly or quarterly)&lt;br&gt;• Method (automated systems, manual, telephone, etc.)</td>
<td>1. Discharge diagnosis will be identified for all patients entered into the NSCP pathway&lt;br&gt;2. QA-UR will retrospectively review charts of all patients entered into the NSCP pathway. Data will be entered into MIDAS system</td>
<td>1. Currently collecting baseline data.&lt;br&gt;2. Baseline will be completed by end of 1st Q 2010</td>
</tr>
<tr>
<td>Number of patients who are admitted to the hospital or seen in an ED due to chest pain within one week of when we discharged them</td>
<td>Operational Definition: A patient that we saw in our ED reports during the call-back interview that they have been admitted or seen in an ED (ours or some other ED) for chest pain during the past week</td>
<td>All patients who have been managed within the NSCP protocol throughout their hospital stay&lt;br&gt;1. Patients will be contacted by phone one week after discharge&lt;br&gt;2. Call-back interview will be the method</td>
<td>1. Currently collecting baseline data.&lt;br&gt;2. Baseline will be completed by end of 1st Q 2010</td>
<td>Ultimately the goal is to have no patients admitted or seen in the ED within a week after discharge. The baseline will be used to help establish initial goals.</td>
<td></td>
</tr>
<tr>
<td>Total hospital costs per one cardiac diagnosis</td>
<td>Numerator = Total costs per quarter for hospital care of NSCP pathway patients&lt;br&gt;Denominator = Number of patients per quarter entered into the NSCP pathway with a discharge diagnosis of MI or Unstable Angina</td>
<td>1. Finance&lt;br&gt;2. Chart Review</td>
<td>Can be calculated every three months from financial and clinical data already being collected</td>
<td>1. Calendar year 2010&lt;br&gt;2. Will be computed in June 2010</td>
<td>The initial goal will be to reduce the baseline by 5% within the first six months of initiating the project.</td>
</tr>
</tbody>
</table>

Now that you have selected and defined your measures, it is time to head out, cast your net and actually gather some data!
Key Data Collection Strategies

**Stratification**
- Separation & classification of data according to predetermined categories
- Designed to discover patterns in the data
- For example, are there differences by shift, time of day, day of week, severity of patients, age, gender or type of procedure?
- Consider stratification BEFORE you collect the data

What does a stratification problem look like?

- Measure: running calorie total
- There are two distinct processes at work here!
The data should be divided into two stratification levels

Common Stratification Levels

- Day of week
- Shift
- Severity of patients
- Gender
- Type of procedure
- Payer class
- Type of visit
- Unit
- Age

What factors might influence your process?
Track them in your data to provide insights about variation and how to change the process!

What stratification levels are appropriate for your data?
Sampling

When you can’t gather data on the entire population due to time, logistics or resources, it is time to consider sampling.

The Relationships Between a Sample and the Population

Population

What would a “good” sample look like?

Negative Outcome  Positive Outcome

Source: R. Lloyd

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The Relationships Between a Sample and the Population

A representative sample has the same shape and location as the total population but have fewer observations (curve A).

Randomization is key – every element of the population has the same chance of being selected.

Sampling Bias

A sample improperly pulled could result in a positive sampling bias (curve B) or a negative sampling bias (curve C).

Estimates of the population based on a biased sample will be incorrect.
Sampling Methods

**Probability Sampling Methods**
- Simple random sampling
- Stratified random sampling
- Stratified proportional random sampling
- Systematic sampling
- Cluster sampling

**Non-probability Sampling Methods**
- Convenience sampling
- Quota sampling
- Judgment sampling


Sampling Options

**Simple Random Sampling**

**Stratified proportional Random Sampling**

**Judgment Sampling**

**Analytic Approach**
Judgment Sampling

Especially useful for PDSA testing. Someone with process knowledge selects items to be sampled.

Characteristics of a Judgment Sample:

• Include a wide range of conditions
• Selection criteria may change as understanding increases
• Successive small samples instead of one large sample

Judgment Sampling in Action!

Well the night shift is totally different from the day shift!

It always seems pretty calm to me here in the afternoon.

It is absolutely nuts here between 8 and 10 AM!
How often and for how long do you need to collect data?

- **Frequency** – the period of time in which you collect data (i.e., how often will you dip into the process to see the variation that exists?)
  - Moment by moment (continuous monitoring)?
  - Every hour?
  - Every day? Once a week? Once a month?

- **Duration** – how long you need to continue collecting data
  - Do you collect data on an on-going basis and not end until the measure is always at the specified target or goal?
  - Do you conduct periodic audits?
  - Do you just collect data at a single point in time to “check the pulse of the process”

- Do you need to pull a sample or do you take every occurrence of the data (i.e., collect data for the total population)
The Question:
Does the airline need data at a fixed point in time or data over time?

It depends on the question you are trying to answer!

The idea for this example was proposed by Alastair Philip, Quality Improvement Scotland, 2010
Exercise: Data Collection Strategies (frequency, duration and sampling)

- This exercise has been designed to test your knowledge of and skill with developing a data collection plan.
- In the table on the next page is a list of eight measures.
- For each measure identify:
  - The frequency and duration of data collection.
  - Whether you would pull a sample or collect all the data on each measure.
  - If you would pull a sample of data, indicate what specific type of sample you would pull.
- Spend a few minutes working on your own then compare your ideas with others at your table.

The need to know, the criticality of the measure and the amount of data required to make a conclusion should drive the frequency, duration and whether you need to sample decisions.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Frequency and Duration</th>
<th>Pull a sampling or take every occurrence?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vital signs for a patient connected to full telemetry in the ICU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood pressure (systolic and diastolic) to determine if the newly prescribed medication and dosage are having the desired impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent compliance with a hand hygiene protocol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol levels (LDL, HDL, triglycerides) in a patient recently placed on new statin medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient satisfaction scores on the inpatient units</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central line blood stream infection rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent of inpatients readmitted within 30 days for the same diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent of surgical patients given prophylactic antibiotics within 1 hour prior to surgical incision</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Quality Measurement Journey

AIM (Why are you measuring?)

Concept
Measure
Operational Definitions
Data Collection Plan
Data Collection
Analysis

ACTION

You have performance data. Now what the heck do you do with it?
Old Way versus the New Way

Old Way (Quality Assurance)

New Way (Quality Improvement)

Threshold

No action taken here

Action taken on all occurrences

Better Quality Worse

Better Quality Worse

Understanding Variation Statistically

“If I had to reduce my message for management to just a few words, I’d say it all had to do with reducing variation.”

W. Edwards Deming
The Problem

Aggregated data presented in tabular formats or with summary statistics, will not help you measure the impact of process improvement efforts. Aggregated data can only lead to judgment, not to improvement.

Thin-Slicing

“Thin-slicing refers to the ability of our unconscious to find patterns in situations and behavior based on very narrow slices of experience.”  
Malcolm Gladwell, blink, page 23

When most people look at data they thin-slice it. That is, they basically use their unconscious to find patterns and trends in the data. They look for extremely high or low data points and then make conclusions about performance based on limited data.  
R. Lloyd
### 20-20 Hindsight!

“Managing a process on the basis of monthly averages is like trying to drive a car by looking in the rear view mirror.”


### Average CABG Mortality

**Before and After the Implementation of a New Protocol**

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th>Time 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent Mortality</td>
<td>5.2%</td>
<td>4.0%</td>
</tr>
<tr>
<td>WOW! A “significant drop” from 5% to 4%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Conclusion** - The protocol was a success! A 20% drop in the average mortality!
Average CABG Mortality
Before and After the Implementation of a New Protocol A Second Look at the Data

Now what do you conclude about the impact of the protocol?

The average of a set of numbers can be created by many different distributions
If you don’t understand the variation that lives in your data, you will be tempted to ...

• Deny the data (It doesn’t fit my view of reality!)
• See trends where there are no trends
• Try to explain natural variation as special events
• Blame and give credit to people for things over which they have no control
• Distort the process that produced the data
• Kill the messenger!

The key to understanding quality performance, therefore, lies in understanding variation over time not in preparing aggregated data and calculating summary statistics!
"A phenomenon will be said to be controlled when, through the use of past experience, we can predict, at least within limits, how the phenomenon may be expected to vary in the future"

Shewhart - Economic Control of Quality of Manufactured Product, 1931

"What is the variation in one system over time?" Walter A. Shewhart - early 1920's, Bell Laboratories

Every process displays variation:
- **Controlled variation**
  - stable, consistent pattern of variation
  - "chance", constant causes

- **Special cause variation**
  - "assignable"
  - pattern changes over time
Types of Variation

**Common Cause Variation**
- Is inherent in the design of the process
- Is due to regular, natural or ordinary causes
- Affects all the outcomes of a process
- Results in a “stable” process that is predictable
- Also known as random or unassignable variation

**Special Cause Variation**
- Is due to irregular or unnatural causes that are not inherent in the design of the process
- Affect some, but not necessarily all aspects of the process
- Results in an “unstable” process that is not predictable
- Also known as non-random or assignable variation

Point …

Common Cause does not mean “Good Variation.” It only means that the process is stable and predictable. For example, if a patient’s systolic blood pressure averaged around 165 and was usually between 160 and 170 mmHg, this might be stable and predictable but completely unacceptable.

Similarly Special Cause variation should not be viewed as “Bad Variation.” You could have a special cause that represents a very good result (e.g., a low turnaround time), which you would want to emulate. Special Cause merely means that the process is unstable and unpredictable.

You have to decide if the output of the process is acceptable!
Decision Tree for Managing Variation

Are special causes present?
- No
  - Are outcomes acceptable?
    - Yes: Do nothing
    - No: Change the process
- Yes: Investigate & eliminate special causes

Statistically relevant variation in “real” time

- Plot goes up when there is a death
- Plot can never fall below zero
- Alert signalled when a patient survives
Responding to alerts in real time

Continuous background monitoring → Alert!! → Initial analysis

Local, detailed clinical review → Central clinical review

Artefact → Improvement plan → No issue

Responding to alerts in real time

Common Cause Variation
Deaths from accidental causes

Special Cause Variation
Referral rate

Normal Sinus Rhythm (a.k.a. Common Cause Variation)

Atrial Flutter Rhythm (a.k.a. Special Cause Variation)

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Attributes of a Leader Who Understands Variation

Leaders understand the different ways that variation is viewed.

They explain changes in terms of common causes and special causes.

They use graphical methods to learn from data and expect others to consider variation in their decisions and actions.

They understand the concept of stable and unstable processes and the potential losses due to tampering.

Capability of a process or system is understood before changes are attempted.

Dialogue #2
Common and Special Causes of Variation

• Select several measures your organization tracks on a regular basis.

• Do you and the leaders of your organization evaluate these measures according the criteria for common and special causes of variation?

• If not, what criteria do you use to determine if data are improving or getting worse?
Understanding Variation Statistically

Descriptive Statistics
- Mean, Median & Mode
- Minimum/Maximum/Range
- Standard Deviation
- Bar graphs/Pie charts

DYNAMIC VIEW
- Run Chart
- Control Chart
- (plot data over time)
- Statistical Process Control (SPC)

Elements of a Run Chart

The centerline (CL) on a Run Chart is the Median

Four simple run rules are used to determine if special cause variation is present

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What is a Run?

• One or more consecutive data points on the same side of the Median
• Do not include data points that fall on the Median

How do we count the number of runs?

• Draw a circle around each run and count the number of circles you have drawn
• Count the number of times the sequence of data points crosses the Median and add “1”

Run Chart: Medical Waste

How many runs are on this chart?
Run Chart: Medical Waste

How many runs are on this chart?

Rules to Identify non-random patterns in the data displayed on a Run Chart

• Rule #1: A shift in the process, or too many data points in a run (6 or more consecutive points above or below the median)

• Rule #2: A trend (5 or more consecutive points all increasing or decreasing)

• Rule #3: Too many or too few runs (use a table to determine this one)

• Rule #4: An “astronomical” data point
Non-Random Rules for Run Charts

**Rule 1**
A Shift: 6 or more

**Rule 2**
A Trend: 5 or more

**Rule 3**
Too many or too few runs

**Rule 4**
An astronomical data point


This is NOT a trend!
Rule #3: Too many or too few runs

• If our change is successful, we will have disrupted the previous process

• How many runs should we expect if the values all come from a stable process?

• If there are fewer runs (or more), we have evidence that our change has made a difference

<table>
<thead>
<tr>
<th># of Useful Observations</th>
<th>Lower Number of Runs</th>
<th>Upper Number of Runs</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>16</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>17</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>18</td>
<td>6</td>
<td>14</td>
</tr>
<tr>
<td>19</td>
<td>6</td>
<td>15</td>
</tr>
<tr>
<td>20</td>
<td>6</td>
<td>16</td>
</tr>
<tr>
<td>21</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>22</td>
<td>7</td>
<td>17</td>
</tr>
<tr>
<td>23</td>
<td>7</td>
<td>17</td>
</tr>
<tr>
<td>24</td>
<td>8</td>
<td>18</td>
</tr>
<tr>
<td>25</td>
<td>8</td>
<td>18</td>
</tr>
<tr>
<td>26</td>
<td>9</td>
<td>19</td>
</tr>
<tr>
<td>27</td>
<td>10</td>
<td>19</td>
</tr>
<tr>
<td>28</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>29</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>30</td>
<td>11</td>
<td>21</td>
</tr>
</tbody>
</table>

Total useful observations
Rule #4: An Astronomical Data Point

25 Men and a Test

What do you think about this data point?
Is it astronomical?

Run Chart Exercise

Now it is your turn!

- Interpret the following run charts
- Is the median in the correct location?
- What do you learn by applying the run chart rules?

1. % of patients with Length of Stay shorter than six days

2. Average Length of Stay DRG373

3. Number of Acute Surgical Procedures

Source: Peter Kammerlind, (Peter.Kammerlind@lj.se), Project Leader Jönköping County Council, Jonköping, Sweden.
% of patients with Length of Stay shorter than six days

Sekvensdiagram DRG 373

Source: Peter Kammerlind, (Peter.Kammerlind@lj.se), Project Leader Jönköping County Council, Jonkoping, Sweden.

Grundläggande statistik och analys

Source: Peter Kammerlind, (Peter.Kammerlind@lj.se), Project Leader Jönköping County Council, Jonkoping, Sweden.
Number of Acute Surgical Procedures

Source: Peter Kammerlind, (Peter.Kammerlind@lj.se), Project Leader
Jönköping County Council, Jonkoping, Sweden.

Why are Control Charts preferred over Run Charts?

Because Control Charts...

1. Are more sensitive than run charts
   - A run chart cannot detect special causes that are due to point-to-point variation (median versus the mean)
   - Tests for detecting special causes can be used with control charts

2. Have the added feature of control limits, which allow us to determine if the process is stable (common cause variation) or not stable (special cause variation).

3. Can be used to define process capability.

4. Allow us to more accurately predict process behavior and future performance.
Elements of a Control Chart

How do we classify Variation on control charts?

**Common Cause Variation**
- Is inherent in the design of the process
- Is due to regular, natural or ordinary causes
- Affects all the outcomes of a process
- Results in a “stable” process that is predictable
- Also known as random or unassignable variation

**Special Cause Variation**
- Is due to irregular or unnatural causes that are not inherent in the design of the process
- Affect some, but not necessarily all aspects of the process
- Results in an “unstable” process that is not predictable
- Also known as non-random or assignable variation
How do I use the Zones on a control chart?

Measure

Time

UCL

Zone A

Zone B

Zone C

Zone C

Zone B

Zone A

+3 SL

+2 SL

+1 SL

-1 SL

-2 SL

-3 SL

\bar{x} \ (CL)

LCL

Rule #1: 1 point outside the +/- 3 sigma limits

Rule #2: 8 successive consecutive points above (or below) the centerline

Rule #3: 6 or more consecutive points steadily increasing or decreasing

Rule #4: 2 out of 3 successive points in Zone A or beyond

Rule #5: 15 consecutive points in Zone C on either side of the centerline

Rules for Special Causes on Control Charts

There are many rules to detect special cause. The following five rules are recommended for general use and will meet most applications of control charts in healthcare.
Rules for Detecting Special Causes

Rule #1: 1 point outside the +/- 3 sigma limits
A point exactly on a control limit is not considered outside the limit. When there is not a lower or upper control limit Rule 1 does not apply to the side missing the limit.

Rule #2: 8 successive consecutive points above (or below) the centerline
A point exactly on the centerline does not cancel or count towards a shift.

Rule #3: 6 or more consecutive points steadily increasing or decreasing
Ties between two consecutive points do not cancel or add to a trend. When control charts have varying limits due to varying numbers of measurements within subgroups, then rule #3 should not be applied.

Rule #4: 2 out of 3 successive points in Zone A or beyond
When there is not a lower or upper control limit Rule 4 does not apply to the side missing a limit.

Rule #5: 15 consecutive points close to the centerline (inner one-third)
This is known as “hugging the centerline”
Using the Zones on a control chart

Applying Control Chart Rules: You Make the Call!
Is there a Special Cause on this chart?

Unplanned Returns to ED within 72 Hours

<table>
<thead>
<tr>
<th>Month</th>
<th>ED/100 Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>April</td>
<td>39.58</td>
</tr>
<tr>
<td>May</td>
<td>39.35</td>
</tr>
<tr>
<td>June</td>
<td>39.55</td>
</tr>
<tr>
<td>July</td>
<td>39.45</td>
</tr>
<tr>
<td>August</td>
<td>39.35</td>
</tr>
<tr>
<td>September</td>
<td>39.20</td>
</tr>
<tr>
<td>October</td>
<td>39.10</td>
</tr>
<tr>
<td>November</td>
<td>39.00</td>
</tr>
<tr>
<td>December</td>
<td>39.10</td>
</tr>
</tbody>
</table>

**u chart**

- **LC L = 0.19**
- **Mean = 0.54**
- **U C L = 0.88**

Is there a Special Cause on this chart?

---

**PERCENT PATIENTS C/O CHEST PAIN SEEN BY CARDIOLOGIST WITHIN 10 MINUTES OF ARRIVAL TO ED**

**EXAMPLE CHART**

**What special cause is on this chart?**

**Target Goal / Desired Direction:**

*INCREASE in the PERCENT of patients c/o chest pain seen by cardiologist within 10 minutes of arrival to Emergency Department.*

**Interpretation:**

Current performance shows (desired) upward trend.

---

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Number of Patient Complaints by Month
(XmR chart)
Are there any special causes present? If so, what are they?

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of Complaints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan01</td>
<td>5.0</td>
</tr>
<tr>
<td>Mar01</td>
<td>10.0</td>
</tr>
<tr>
<td>May01</td>
<td>15.0</td>
</tr>
<tr>
<td>Jul01</td>
<td>20.0</td>
</tr>
<tr>
<td>Sept01</td>
<td>25.0</td>
</tr>
<tr>
<td>Nov01</td>
<td>30.0</td>
</tr>
<tr>
<td>Jan02</td>
<td>35.0</td>
</tr>
<tr>
<td>Mar02</td>
<td>40.0</td>
</tr>
<tr>
<td>May02</td>
<td>45.0</td>
</tr>
<tr>
<td>Jul02</td>
<td>50.0</td>
</tr>
</tbody>
</table>

UCL = 44.855
CL = 29.250
LCL = 13.645

Appropriate Management Response to Common & Special Causes of Variation

<table>
<thead>
<tr>
<th>Is the process stable?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of variation</td>
<td>Only Common</td>
<td>Special + Common</td>
</tr>
<tr>
<td>Right Choice</td>
<td>Change the process</td>
<td>Investigate the origin of the special cause</td>
</tr>
<tr>
<td>Wrong Choice</td>
<td>Treat normal variation as a special cause (tampering)</td>
<td>Change the process</td>
</tr>
<tr>
<td>Consequences of making the wrong choice</td>
<td><strong>Increased variation!</strong></td>
<td><strong>Wasted resources!</strong></td>
</tr>
</tbody>
</table>
I know the right chart has to be hiding in here somewhere!

The choice of a Control Chart depends on the Type of Data you have collected

### Variables Data

- Defectives
  - (occurrences plus non-occurrences)
  - Nonconforming Units

### Attributes Data

- Defects
  - (occurrences only)
  - Nonconformities
There Are 7 Basic Control Charts

Variables Charts

- \( \bar{X} \) & R chart
  (average & range chart)

- \( \bar{X} \) & S chart
  (average & SD chart)

- XmR chart
  (individuals & moving range chart)

Attributes Charts

- p-chart
  (proportion or percent of defectives)

- np-chart
  (number of defectives)

- c-chart
  (number of defects)

- u-chart
  (defect rate)

The Control Chart Decision Tree

### Key Terms for Control Chart Selection

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Observation</th>
<th>Area of Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>How you organize your data (e.g., by day, week or month)</td>
<td>The actual value (data) you collect</td>
<td>Applies to all attributes or counts charts</td>
</tr>
<tr>
<td>The label of your horizontal axis</td>
<td>The label of your vertical axis</td>
<td>Defines the area or frame in which a defective or defect can occur</td>
</tr>
<tr>
<td>Can be patients in chronological order</td>
<td>May be single or multiple data points</td>
<td>Can be of equal or unequal sizes</td>
</tr>
<tr>
<td>Can be of equal or unequal sizes</td>
<td>Applies to all the charts</td>
<td></td>
</tr>
<tr>
<td>Applies to all the charts</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### The choice of a control chart depends on the question you are trying to answer!

<table>
<thead>
<tr>
<th>Type of Chart</th>
<th>Medication Production Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>X bar &amp; S Chart</td>
<td>What is the TAT for a daily sample of 25 medication orders?</td>
</tr>
<tr>
<td>Individuals Chart (XmR)</td>
<td>How many medication orders do we process each week?</td>
</tr>
<tr>
<td>C-Chart</td>
<td>Using a sample of 100 medication orders each week, how many errors (defects) are observed?</td>
</tr>
<tr>
<td>U-Chart</td>
<td>Out of all medication orders each week, how many errors (defects) are observed?</td>
</tr>
<tr>
<td>P-Chart</td>
<td>For all medication orders each week, what percentage have 1 or more errors (i.e., are defective)?</td>
</tr>
</tbody>
</table>
The Quality Measurement Journey

AIM (Why are you measuring?)
- Concept
- Measure
- Operational Definitions
- Data Collection Plan
- Data Collection
- Analysis

ACTION
A Simple Improvement Plan

1. Which process do you want to improve or redesign?
2. Does the process contain non-random patterns or special causes?
3. How do you plan on actually making improvements? What strategies do you plan to follow to make things better?
4. What effect (if any) did your plan have on the process performance?

Run & Control Charts will help you answer Questions 2 & 4. YOU need to figure out the answers to Questions 1 & 3.
Wait Time to See the Doctor

**XmR Chart**

**Baseline Period**

**Intervention**

Freeze the Control Limits and Centerline, extend them and compare the new process performance to these reference lines to determine if a special cause has been introduced as a result of the intervention.

**Where will the process go?**

**Freeze the Control Limits and Centerline, extend them and compare the new process performance to these reference lines to determine if a special cause has been introduced as a result of the intervention.**

**A Special Cause is detected**

A run of 8 or more data points on one side of the centerline reflecting a shift in the process.

16 Patients in February and 16 Patients in April

Minutes

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
Wait Time to See the Doctor

XmR Chart

Intervention

Baseline Period

Make new control limits for the process to show the improvement

“Change is possible if we have the desire and commitment to make it happen.”

Mohandas Gandhi
The Primary Drivers of Improvement

Having the **Will** (desire) to change the current state to one that is better

Developing **Ideas** that will contribute to making processes and outcomes better

Having the capacity to apply CQI theories, tools and techniques that enable the **Execution** of the ideas

---

**How prepared is your Organization?**

<table>
<thead>
<tr>
<th>Key Components*</th>
<th>Self-Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will (to change)</td>
<td>Low</td>
</tr>
<tr>
<td>Ideas</td>
<td>Low</td>
</tr>
<tr>
<td>Execution</td>
<td>Low</td>
</tr>
</tbody>
</table>

*All three components MUST be viewed together. Focusing on one or even two of the components will guarantee suboptimized performance. Systems thinking lies at the heart of CQI!
The Sequence of Improvement

- Testing a change
- Implementing a change
- Make part of routine operations
- Sustaining and improvements and Spreading a changes to other locations
- Developing a change
- Theory and Prediction
- Test under a variety of conditions

Summary of Key Points

- **Understand why you are measuring**
  - Improvement, Accountability, Research

- **Build skills in the area of data collection**
  - Operational definitions
  - Stratification & Sampling (probability versus non-probability)

- **Build knowledge on the nature of variation**
  - Understanding variation conceptually
  - Understanding variation statistically

- **Know when and how to use Run & Control Charts**
  - Numerous types of charts (based on the type of data)
  - The mean is the centerline (not the median which is on a run chart)
  - Upper and Lower Control Limits are sigma limits
  - Rules to identify special and common causes of variation
  - Linking the charts to improvement strategies
“Quality begins with intent, which is fixed by management.”

W. E. Deming, *Out of the Crisis*, p.5

Thanks for joining us!

Please contact us if you have any questions:

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Richard Hamblin
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Appendices

- Appendix A: General References on Quality
- Appendix B: References on Measurement
- Appendix C: References on Spread
- Appendix D: References on Rare Events
- Appendix E: Basic “Sadistical” Principles

Appendix A
General References on Quality


Appendix B
References on Measurement


Appendix C
References on Spread


Appendix D
References for Rare Events Control Charts


Appendix E
A few basic “Statistical” Principles

**Statistics related to depicting variation**

<table>
<thead>
<tr>
<th>The sum of the deviations $(x_i - \bar{x})$ of a set of observations about their mean is equal to zero.</th>
<th>$\sum (x_i - \bar{x}) = 0$</th>
</tr>
</thead>
<tbody>
<tr>
<td>The average deviation (AD) is obtained by adding the absolute values of the deviations of the individual values from their mean and dividing by $n$.</td>
<td>$AD = \frac{\sum</td>
</tr>
<tr>
<td>The sample variance $(s^2)$ is the average of the squares of the deviations of the individual values from their mean.</td>
<td>$s^2 = \frac{\sum (x_i - \bar{x})^2}{n - 1}$</td>
</tr>
</tbody>
</table>

Which finally leads us to our good old friend, the **standard deviation**, which is the positive square root of the variance. (See the next page for this fun formula!)
Appendix E (continued)

What is the Standard Deviation?

The Standard Deviation (sd) is created by taking the deviation of each individual data point (Xi) from the mean (X), squaring each difference, summing the results, dividing by the number of cases and then taking the square root.

\[
\sqrt{\frac{\sum (X_i - \bar{X})^2}{n-1}}
\]