The presenters have nothing to declare

The 27th Annual National Forum on Quality Improvement in Health Care

Better Quality Through Better Measurement

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7 December 2015
8:30 - 4:00

Our Objectives for today…
To answer Six Key Questions on Measurement

1. What is your current level of knowledge about quality measurement?
2. What is your motivation for measuring?
3. Do you know the milestones in the Quality Measurement Journey (QMJ)?
4. Do you understand variation conceptually?
5. Do you understand variation statistically?
6. How well do you link measurement to improvement

Note that the Morning Break will be from 10:00 AM – 10:30 AM,
Lunch will be from 12:00 PM – 1:00 PM and the Afternoon Break will be from 2:30 PM – 3:00 PM
1. What is your current level of knowledge about quality measurement?

2. What is your motivation for measuring?

3. Do you know the milestones in the Quality Measurement Journey (QMJ)?

4. Do you understand variation conceptually?

5. Do you understand variation statistically?

6. How well do you link measurement to improvement?

Question #1
What is your current level of knowledge about quality measurement?

This self-assessment is designed to help quality facilitators and improvement team members 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 it is preferable to plot data over time rather than using aggregated statistics and tests of significance? Can you construct a run chart or help a team decide which measure is more appropriate for their project?

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 expect to be able to demonstrate improvement, 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 concepts and methods related to the QMJ. Once you have had this period of self-reflection, you will be ready to develop a learning plan for yourself and those on your improvement team.

Exercise
Measurement Self-Assessment

Select the one response which best captures your opinion:

1. I'd definitely have to call in an outside expert to explain and apply this topic.
2. I've heard of this topic but I would not feel comfortable applying it to a team's work.
3. I am familiar with this topic but would have to study it further before I felt comfortable explaining it to a team.
4. I have knowledge about this topic and feel confident that I could help a team apply it to their improvement efforts but I would not want to stand up and teach this to a large group.
5. I consider myself an expert in this area and could apply easily to a team's work as well teach this topic to large groups.


Exercise: Measurement Self-Assessment

<table>
<thead>
<tr>
<th>Measurement Topic or Skill</th>
<th>Response Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Help people in my organization determine why they are measuring (improvement, judgment or research)</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>Move teams from concepts to specific quantifiable measures</td>
<td></td>
</tr>
<tr>
<td>Building clear and unambiguous operational definitions for our measures</td>
<td></td>
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<tr>
<td>Develop data collection plans (including stratification and sampling strategies)</td>
<td></td>
</tr>
<tr>
<td>Explain why plotting data over time (dynamic display) is preferable to using aggregated data and summary statistics (static display)</td>
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<tr>
<td>Explain the differences between random and non-random variation</td>
<td></td>
</tr>
<tr>
<td>Construct run charts (including locating the median)</td>
<td></td>
</tr>
<tr>
<td>Explain the reasoning behind the run chart rules</td>
<td></td>
</tr>
<tr>
<td>Interpret run charts by applying the run chart rules</td>
<td></td>
</tr>
<tr>
<td>Explain the statistical theory behind Shewhart control charts (e.g., sigma limits, zones, special cause rules)</td>
<td></td>
</tr>
<tr>
<td>Describe the basic 7 Shewhart charts and when to use each one</td>
<td></td>
</tr>
<tr>
<td>Help teams select the most appropriate Shewhart chart for their measures</td>
<td></td>
</tr>
<tr>
<td>Describe the rules for special cause variation on a Shewhart chart</td>
<td></td>
</tr>
<tr>
<td>Help teams link measurement to their improvement efforts</td>
<td></td>
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</tbody>
</table>
Question #2
What is your motivation for measuring?

Old Way
(Quality Assurance)

New Way
(Quality Improvement)


The Three Faces of Performance Measurement

Research?
(testing theory and building new knowledge; efficacy)

Accountability or Judgment?
(making comparisons; no change focus)

Improvement?
(improving the effectiveness or efficiency of a process)
# The Three Faces of Performance Measurement

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Improvement (efficiency &amp; effectiveness)</th>
<th>Accountability (Judgment)</th>
<th>Research (efficacy)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td>Improvement of care</td>
<td>Comparison, choice, reassurance, motivation for change</td>
<td>New knowledge (efficacy)</td>
</tr>
<tr>
<td><strong>Methods:</strong></td>
<td></td>
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<td></td>
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<tr>
<td>• Test Observability</td>
<td>Test observable</td>
<td>No test, evaluate current performance</td>
<td>Test blinded or controlled</td>
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<tr>
<td>• Bias</td>
<td>Accept consistent bias</td>
<td>Measure and adjust to reduce bias</td>
<td>Design to eliminate bias</td>
</tr>
<tr>
<td>• Sample Size</td>
<td>&quot;Just enough&quot; data, small sequential samples</td>
<td>Obtain 100% of available, relevant data</td>
<td>&quot;Just in case&quot; data</td>
</tr>
<tr>
<td>• Flexibility of Hypothesis</td>
<td>Flexible hypotheses, changes as learning takes place</td>
<td>No hypothesis</td>
<td>Fixed hypothesis (null hypothesis)</td>
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<tr>
<td>• Testing Strategy</td>
<td>Sequential tests</td>
<td>No tests</td>
<td>One large test</td>
</tr>
<tr>
<td>• Determining if a change is an improvement</td>
<td>Analytic Statistics (statistical process control) Run &amp; Control charts</td>
<td>No change focus (maybe compute a percent change or rank order the results)</td>
<td>Enumerative Statistics (t-test, F-test, chi square, p-values)</td>
</tr>
<tr>
<td>• Confidentiality of the data</td>
<td>Data used only by those involved with improvement</td>
<td>Data available for public consumption and review</td>
<td>Research subjects identities protected</td>
</tr>
</tbody>
</table>

**Example of Data for Judgement**

### FY 2009 Hospital System-Level Measures

![Table of Hospital System-Level Measures](image)

### Example of Data for Judgement

![Table of Data](image)
How Is Error Rate Doing?

Source: Provost, Murray & Britto (2010)

How is Perfect Care Doing?

Source: Provost, Murray & Britto (2010)
20-20 Hindsight

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

D. Wheeler
Understanding Variation, 1993.

So, how do you view the Three Faces of Performance Measurement?

As... Improvement, Judgment, Research

Or,

As a...
The Critical Role of Translators

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.

A few concluding considers...

- Limits to traditional statistical methods are frequently not well understood and often minimized.
- Improvement methods based on analytic statistics are powerful and rigorous, yet frequently misunderstood and under-applied in healthcare settings.
- The purpose, context and questions you are trying to answer should always dictate the measures and methods used.
Dialogue
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?
- Is your organization building silos or a Rubik’s cube when it comes to data collection and measurement?
- Do you think the three approaches can be integrated or are they in fact separate and distinct silos?
- How many “translators” exist within your organization? Are people being developed for this role?

Question #3
Do you know the milestones in the Quality Measurement Journey (QMJ)?

MILESTONES
“Dr. Edwards Deming made an important contribution to the science of improvement by recognizing the elements of knowledge that underpin improvements over a wide range of applications.

He called this body of knowledge a System of Profound Knowledge. Profound denotes the deep insight that this knowledge provided into how to make changes that will result in improvement in a variety of settings. System denotes the emphasis on the interaction of the components rather than on the components themselves.”

It starts with the Lens of Profound Knowledge

"The system of profound knowledge provides a lens. It provides a new map of theory by which to understand and optimize our organizations.”

W. E. Deming

It provides an opportunity for dialogue and learning!

The Lens of Profound Knowledge
The framework for Learning and Change

When you combine the 3 questions with the PDSA cycle, you get…

...the Model for Improvement.

But do you have a roadmap and a good driver to guide your quality measurement journey?

Milestones in the Quality Measurement Journey

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

ACTION


AIM – reduce patient falls by 37% by the end of the year
Concept – reduce patient falls
Measures – Inpatient falls rate (falls per 1000 patient days)
Operational Definitions - # falls/inpatient days
Data Collection Plan – monthly; no sampling; all IP units
Data Collection – unit collects the data
Analysis – control chart (u-chart)
Identifying and Defining Improvement Measures

First let’s find out a few things…

- If you received the pre-work email, please stand up.
- If you read the CAUTI Case Study remain standing.
- If you read the CAUTI Case Study and watched at least one Whiteboard video remain standing.
- If you read the CAUTI Case Study, watched at least one Whiteboard video and read all three articles remain standing.
- If you brought documents for your Own Project such as driver diagrams, process maps, measurement plans, please remain standing.

THANK YOU!

Those standing are today’s TABLE LEADS

We will call on you to lead the discussions at your table!
Following the CAUTI Case Study...

1. Baselines, Gaps, Aims, Outcomes
   Where are we now, and what are we trying to accomplish? (pages 1-3)

2. Building a Theory of Improvement (Driver Diagram)
   What should we measure and why? (pages 3-4)

3. Mapping the measures (Measure Tree)
   How will we calculate the measures? (pages 4-7)

4. Defining the Measures
   Attributes of Useful Improvement Measures (pages 7-9)

5. Collecting Data and Testing Changes (pages 9-13)

Case Study Background: Reducing CAUTIs

A medium sized acute care hospital has noticed that there has been an increasing occurrence of catheter associated urinary tract infections (CAUTIs) over the past year. Not only has the occurrence of CAUTIs been gradually going up but also the severity of the infections has been increasing.

Indwelling urinary catheters are commonly used medical devices within acute and non-acute settings. But their use does increase the risk of CAUTIs by:

- Enabling organisms to gain entry to the bladder via external surface or opened connections
- Reducing the body’s defense of flushing out organisms during urination
- Facilitating biofilm formation

Reducing CAUTIs would contribute to:

- Improving the patient experience
- Reducing the cost of antibiotic prescribing
- Reducing inpatient length of stay
- Reducing readmissions
- Improving patient outcomes

Spend a few minutes discussing the CAUTI Case Study to make sure everyone at your table knows:

- Why this is an important topic.
- The conditions that are motivating the CAUTI team to improve this process.
- What the baseline data reveal.
Milestones in the Quality Measurement Journey

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

ACTION

Measurement begins with an Aim

When you combine the 3 questions with the…
PDSA cycle, you get…

Model for Improvement
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 Model for Improvement.


Constructing an Aim Statement

- **Boundaries**: the system to be improved (scope, patient population, processes to address, providers, beginning & end, etc.)
- Specific **numerical goals** for **outcomes**
  - Ambitious but achievable
- Includes **timeframe** *(How good by when?)*
- Provides **guidance** on sponsor, resources, strategies, barriers, interim & process goals

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**Constructing an Aim Statement**

**Involves senior leaders**
- Obtain sponsorship (geared to the project’s complexity)
- Provide frequent and brief updates (practice the 2 minute elevator speech)

**Focus on issues that are important to your organization**
- Connect the team Aim Statement to the Strategic Plan
- Build on the work of others (steal shamelessly!)
Baseline Data – Key Outcome

Given this data what is the CAUTI aim?

What is the CAUTI Aim?

AIM: Reduce CAUTI infections in all units below 1.6 (10\textsuperscript{th} percentile) within 12 months and to zero within 24 months.

How good? By when?
Does the aim seem reasonable?
Is it too ambitious? Not ambitious enough?

- **System**: CAUTI infections in all units
- **Goal**: Be below 1.6 and then to zero
- **Timeframe**: 12 month for 1.6 and 24 month for zero
- **Guidance**: ?
Exercise

1. **CAUTI Case Study**
   - **AIM:** Reduce CAUTI infections in all units below 1.6 (10th percentile) within 12 months and to zero within 24 months.

2. **Your Own Project: Reflect and discuss in pairs**
   - What are you trying to accomplish (your aim?)
   - What is the outcome measure that best captures the aim of your project?
   - What is the baseline level of performance on the outcome? How much does the outcome need to improve?

3. **Share with the group**

**TIP:** A Driver Diagram is a good way to show your aim and the system you want to improve.

The CAUTI Driver Diagram on page 5 of the Case Study provides a picture of the system to be improved and the theories as to how improvement can occur.

NOTE: See the article by Bennett and Provost sent as pre-work for details on Driver Diagrams.
Exercise

Use the **CAUTI Driver Diagram** (page 5) to guide the following:

- **CAUTI Case Study Discussion**
  - Do you have questions or issues about the CAUTI driver diagram?
  - Discuss and resolve. If you get ‘stuck’, raise the question to the group.

- **Your Own Project Discussion**
  - Review (or create) the driver diagram for your project
  - Discuss in pairs (or to table)
  - Be prepared to share with the group

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**Measurement begins with an Aim**

When you combine the 3 questions with the...

PDSA cycle, you get...

...the Model for Improvement.

Milestones in the Quality Measurement Journey

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


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&lt;br&gt;Ounces of gel used per staff&lt;br&gt;Percent of staff washing their hands (before &amp; after visiting a patient)&lt;br&gt;Percent of inpatients with <em>C.Diff</em></td>
</tr>
<tr>
<td>Patient Falls</td>
<td>Percent of patients who fell&lt;br&gt;Fall rate per 1000 patient days&lt;br&gt;Number of falls&lt;br&gt;Days between a fall</td>
</tr>
<tr>
<td>Employee Evaluations</td>
<td>Percent of evaluations completed on time&lt;br&gt;Number of evaluations completed&lt;br&gt;Variance from completion due date</td>
</tr>
</tbody>
</table>

A classic approach to developing measures

Dr. Avedis Donabedian (1919-2000)

**S + P = O**

Structure + Process = Outcomes

Attributes of Useful Improvement Measures

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsive</td>
<td>The measure is sensitive to changes in the system state. When the system improves, the measure says so.</td>
</tr>
<tr>
<td>Valid</td>
<td>The measure aligns with the theory of changes (driver diagram). Improvement in the measure means improvement in the system.</td>
</tr>
<tr>
<td>Comprehensible</td>
<td>The intended audience understands the meaning of the measure for system improvement.</td>
</tr>
<tr>
<td>Timely</td>
<td>The data are available soon enough to inform improvement decisions (project planning, PDSA testing).</td>
</tr>
<tr>
<td>Feasible</td>
<td>The data can be collected with minimum effort and cost, and in a timely fashion.</td>
</tr>
<tr>
<td>Relevant</td>
<td>The measure supports problem identification and testing at the appropriate level of management.</td>
</tr>
<tr>
<td>Consistent</td>
<td>The measure has a clear definition; it yields consistent results when applied in different places and at different times.</td>
</tr>
<tr>
<td>Ownership</td>
<td>Someone is explicitly assigned to monitor the measure on a regular basis, detect problems, and initiate change.</td>
</tr>
</tbody>
</table>

Three Types of Measures

- **Outcome Measures**
  - Point to qualities that stakeholders value (voice of the customer)
  - Is this system meeting the needs of those who care about its operation?
  - Is our improvement work making a meaningful impact?

- **Process Measures**
  - Voice of the process.
  - Are the parts/steps in the system performing as planned? Are processes reliable? Efficient? Patient-Centered?
  - Are we on track to influence the Outcome measure(s)?

- **Balancing Measures**
  - Are we producing unintended consequences in our efforts to improve?
  - What other factors may be affecting results?
  - Looking at a system from different directions/dimensions.
  - What happened to the system as we improved the outcome and process measures?
### Potential Set of Measures for Improvement in a Family Practice Clinic

<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 family practice clinic</td>
<td>Total Length of Stay (in minutes) for a scheduled appointment at the clinic</td>
<td>Time from check-in till seeing the doctor</td>
<td>Volume of patients</td>
</tr>
<tr>
<td></td>
<td>% of patients marking Strongly Agree to the question: “Would you recommend our clinic to family and friends?”</td>
<td>Patient /staff comments on flow</td>
<td>% of patients leaving without being seen by the doctor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>% of patient receiving discharge materials</td>
<td>Staff satisfaction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wait time for ancillary services (lab, x-ray, ultra-sound) during a visit</td>
<td>Financials</td>
</tr>
</tbody>
</table>

**Balancing Measures help you capture Unintended Consequences**
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

Balancing measures help keep you from sub-optimizing the system!

CAUTI Priority Measure Concepts

- Insert catheters only for appropriate indications.
  - **Theory:** The most effective way to eliminate the possibility of a CAUTI is to eliminate an unneeded catheter.
- Remove when no longer required.
  - **Theory:** Since the risk of infection is roughly proportional to the time the catheter is in place, removing catheters as soon as possible will reduce the risk.
- Standard insertion procedure.
  - **Theory:** If trained staff follow strict protocols for aseptic insertion of catheters, the risk of bacterial infection will be minimized.
- Standard cleaning and maintenance procedure.
  - **Theory:** Similarly, careful adherence to the components of the maintenance bundle will reduce risk.

NOTE: The Ss above (e.g., S4, S7, etc.) refer to a “Secondary Driver” in the Driver Diagram on page 5 of the CAUTI Case Study. There are 11 Secondary Drivers.
Conclusions: Moving from a Concept to a Measure

1. Moving from concept to measures requires focused work to create agreement about adjectives such as recovery, major, timely, complete, accurate or excellent.

2. A concept may need more than one measure and, therefore, the development of more than one operational definition.

3. The transition from concept to measure doesn’t just happen, it requires both technical and clinical decision-making to be blended with pragmatism and acceptance of the imperfections of the measures.

4. There is no such thing as a fact! (W. E. Deming)

Mapping the Measures

- Measure Tree Diagram
- Organizing Your Measures
CAUTI Priority Measure Concepts

- Insert catheters only for appropriate indications.
  - **Theory:** The most effective way to eliminate the possibility of a CAUTI is to eliminate an unneeded catheter.

- Remove when no longer required.
  - **Theory:** Since the risk of infection is roughly proportional to the time the catheter is in place, removing catheters as soon as possible will reduce the risk.

- Standard insertion procedure.
  - **Theory:** If trained staff follow strict protocols for aseptic insertion of catheters, the risk of bacterial infection will be minimized.

- Standard cleaning and maintenance procedure.
  - **Theory:** Similarly, careful adherence to the components of the maintenance bundle will reduce risk.

NOTE: The Ss above (e.g., S4, S7, etc.) refer to a “Secondary Driver” in the Driver Diagram on page 5 of the CAUTI Case Study. There are 11 Secondary Drivers.
CAUTI Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Type</th>
<th>Driver</th>
<th>Desired Direction of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>M1</td>
<td>Percent of patients with appropriate catheter placements</td>
<td>Process S4</td>
<td>Insert catheters only for appropriate indications</td>
</tr>
<tr>
<td>M2</td>
<td>Average catheter duration</td>
<td>Process S7</td>
<td>Remove when no longer required</td>
</tr>
<tr>
<td>M3</td>
<td>Count of CAUTIs</td>
<td>Outcome N/A</td>
<td></td>
</tr>
<tr>
<td>M4</td>
<td>CAUTIs per 1000 patient days</td>
<td>Outcome N/A</td>
<td></td>
</tr>
<tr>
<td>M5</td>
<td>Percent of catheter insertions with all insertion bundle elements in compliance</td>
<td>Process S9</td>
<td>Standard insertion procedure</td>
</tr>
<tr>
<td>M6</td>
<td>Percent of catheter placements with all maintenance bundle elements in compliance</td>
<td>Process S11</td>
<td>Standard cleaning and maintenance procedure</td>
</tr>
</tbody>
</table>

CAUTI Reduction Measures: Measure Tree

D1 Count of patients with catheters in situ in measurement month
D2 Count of catheters inserted in measurement month
D3, N2 Sum of days with catheters in situ
N1 Count of patients meeting criteria for catheter insertion
N3, M3 Count of CAUTIs in measurement month
N4 Count of catheter insertions with all insertion bundle elements in compliance
N5 Count of catheters with all maintenance bundle elements in compliance
N6 Percent of catheter placements with all maintenance bundle elements in compliance
M1 Percent of patients with appropriate catheter placements
M2 Average catheter duration
M3 Count of CAUTIs
M4 CAUTIs per 1000 patient days
M5 (alternate) Catheter days between CAUTI events
M6 Percent of catheter insertions with all insertion bundle elements in compliance
M7 Percent of catheter insertions with all maintenance bundle elements in compliance

See page 7 of the CAUTI Case Study
Exercise

- **CAUTI Case Study Discussion**
  - Do you have questions or issues about the CAUTI measure tree?
  - Discuss and resolve. If you get 'stuck', raise the question to the group.

- **Your Own Project Discussion**
  - Based on your own driver diagram, identify the outcome, key process measures and any balancing measures you will need (1 outcome, no more than 4 process and 1-2 balancing)
  - Use the *Measure Tree* format to think about the numerators and denominators for your measures.
  - Be sure your process measures are linked to drivers.
  - Use the *Organizing Your Measures Worksheet* to create or revisit your potential measures.

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**Organizing Your Measures Worksheet**

<table>
<thead>
<tr>
<th>Concept</th>
<th>Potential Measure(s)</th>
<th>Outcome</th>
<th>Process</th>
<th>Balancing</th>
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<tbody>
<tr>
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Example
Organizing Your Measures Worksheet

Topic for Improvement: Inpatient Falls

<table>
<thead>
<tr>
<th>Concept</th>
<th>Potential Measure(s)</th>
<th>Outcome</th>
<th>Process</th>
<th>Balancing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Harm</td>
<td>Inpatient falls rate</td>
<td></td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Patient Harm</td>
<td>Number of falls</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compliance</td>
<td>Percent of inpatients assessed for falls</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff Education</td>
<td>Percent of staff fully trained in falls assessment protocol</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment Time</td>
<td>The additional time it takes to conduct a proper falls assessment</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Milestones in the Quality Measurement Journey

AIM (How good? By when?)

Concept
Measure
Operational Definitions
Data Collection Plan
Data Collection
Analysis
ACTION

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 detailed criteria for inclusion and exclusion.
- Provides guidance on sampling


Failure to develop a clear Operational Definition often leads to confusion and misunderstanding

How do you define these concepts?

A “fair tax”       A “tax loophole”
A “good vacation”   A “great movie”
Rural, Urban or Suburban
The “rich”           The “poor”
The “middle class”
“Jump start” the economy
What is the difference between sleet and freezing rain?

The Condition

Freezing rain and sleet!

- If the depth of subfreezing air, however, is great enough and if its temperature is low enough, the raindrops will freeze before reaching the surface and the result is sleet.
- To make things even more confusing, this condition is also called ice pellets.

- But, if the rain drops do not freeze on the way down, the result is freezing rain (i.e., rain that freezes on impact to form a glaze on the ground and exposed objects).

Chicago Tribune 12 December 2014

What is an “organic fish”?

“The U.S. government has been wrestling with the definition of organic fish for the better part of the past decade.”

Chicago Tribune
November 15, 2008
What is a goal?
The whole ball or half the ball?

September 23, 1999
An expensive operational definition problem!

NASA lost a $125 million Mars orbiter because one engineering team used metric units (newton-seconds) to guide the spacecraft while the builder (Lockheed Martin) used pounds-second to calibrate the maneuvering operations of the craft.

Information failed to transfer between the Mars Climate Orbiter spacecraft team at Lockheed Martin in Colorado and the mission navigation team in California. The confusion caused the orbiter to encounter Mars on a trajectory that brought it too close to the planet, causing it to pass through the upper atmosphere and disintegrate.
How do you define the following healthcare concepts?

- Medication error
- Co-morbid conditions
- A healthy lifestyle
- Cancer waiting times
- Health inequalities
- Asthma admissions
- Childhood obesity
- Patient education
- Health and wellbeing
- Adding life to years and years to life
- Children’s palliative care
- Safe services
- Smoking cessation
- Urgent care
- Complete history & physical
- Surgical Screening
- Delayed discharges
- End of life care
- Falls (with/without injuries)
- Childhood immunizations
- Complete maternity service
- Patient engagement
- Moving services closer to home
- A well-baby visit
- Ambulatory care
- Access to health in deprived areas
- Diagnostics in the community
- Productive community services
- Vascular inequalities
- Breakthrough priorities

Example Medication Error Operational Definition

**Measure Name:** Percent of medication errors

**Numerator:** Number of outpatient medication orders with one or more errors. *An error is defined as: wrong med, wrong dose, wrong route or wrong patient.*

**Denominator:** Number of outpatient medication orders received by the family practice clinic pharmacy.

**Data Collection:**
- This measure applies to all patients seen at the clinic
- The data will be stratified by type of order (new versus refill) and patient age
- The data will be tracked daily and grouped by week
- The data will be pulled from the pharmacy computer and the CPOE systems
- Initially all medication orders will be reviewed. A stratified proportional random sample will be considered once the variation in the process is fully understood and the volume of orders is analyzed.
Example Surgical Screening
Operational Definition

Measure: Percentage of patients undergoing hip and knee replacement surgery during the measurement period who have had preoperative nasal swabs to screen for Staphylococcus aureus carriage

Goal: 95%

Measurement Period Length: Monthly

Numerator Definition: Number of patients undergoing hip or knee replacement surgery who have had a nasal swab specimen processed to screen for Staphylococcus aureus carriage prior to surgery

Denominator Definition: Number of patients undergoing elective hip or knee replacement surgery

Numerator and Denominator Exclusions:
- Patients who are less than 18 years of age
- Patients who had a principal or admission diagnosis suggestive of preoperative infectious diseases
- Patients with physician-documented infection prior to surgical procedures
- Patients undergoing non-elective hip or knee replacement surgery

Definition of Terms:
Hip or knee replacement surgery includes operations involving placement of a nonhuman-derived device into the hip or knee joint space. ICD-9 Codes include 00.70-00.73, 00.85-00.87, 81.51-81.53, 00.80-00.84, 81.54, and 81.55.

Calculate as: \((\text{numerator/denominator} \times 100)\)

Exercise
Building Your Operational Definitions

- Select one measure for your project (outcome or process) and write a clear and specific Operational Definition.
- Is the measure clearly defined? If you gave the definition of your measure to another person would they know precisely what you are attempting to measure?
- Are you clear about the name of the measure, what is to be included and the measurement steps required to obtain data?

Use the Operational Definition Worksheet to record your responses.
Operational Definition Worksheet

Measure Name: ________________________________________
(Remember this should be specific and quantifiable, e.g., the time it takes to..., the number of..., the percent of... or the rate of...)

Operational Definition
Define the specific components of this measure. Specify the numerator and denominator if it is a percent or a rate. If it is an average, identify the calculation for deriving the average. Include any special equipment needed to capture the data. If it 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©
(continued)

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 in this measure 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.)

Operational Definition Worksheet©
(continued)

Conclusions: Developing Operational Definitions

➢ Operational definitions are not universal truths!

➢ Operational definitions require agreement on terms, measurement methods and decision criteria.

➢ Operational definitions need to be reviewed periodically to make sure everyone is still using the same definitions and that the conditions surrounding each measure have not changed.
Milestones in the Quality Measurement Journey

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


Key Aspects of Data Collection

- Stratification
- Sampling Methods
- Frequency of Data Collection
- Duration of Data Collection

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

**Common Stratification Levels**
- Day of week
- Time of day or Shift
- Stat vs routine orders
- Severity of patients
- Co-morbid conditions
- Gender and Age
- Facility or service area
- Units within a facility
- Socio-economic status

---

**What does a stratification problem look like?**

There are two **distinct** processes here!
The data should be divided into two stratification levels

2 minute discussion!

1. Have you applied stratification to your team’s project?
2. What stratification factors might influence your team’s processes?

Sampling

When you can’t gather data on the entire population due to time, logistics, resources or size of the population, 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

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

A representative sample has the same chance of being selected.

Source: R. Lloyd
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
Population → Sample

Stratified proportional Random Sampling
Population → Sample

Judgment Sampling

Non-Probability Sampling

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
We are absolutely crazy around here between 9 and 11 AM!

But, things are pretty quiet after 3 PM.

What do I know? I usually work afternoon shift and that is a different process altogether!

Judgment Sampling takes advantage of the knowledge of those who own the process.

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 obtain data?)

- Moment by moment (continuous monitoring)?
- Every hour? Every day?
- Once a week? Once a month?
- Point prevalence or periodic audit? (not recommended for improvement work)
- Do you need to pull a sample or do you take every occurrence of the data? (i.e., collect data for the total population)

Duration – how long will you continue to collect data?

- Will you collect data on an on-going basis and not end until the measure has achieved the aim, target or goal?
- Will you just collect data at the beginning of a project and then at the end (a pre-post comparison)
- Or, will you periodically collect data during the life of the project?
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.
Exercise: Data Collection Strategies
(frequency, duration and sampling)

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>1. Vital signs for a patient connected to full telemetry in the ICU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. 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>3. Percent compliance with a hand hygiene protocol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Cholesterol levels (LDL, HDL, triglycerides) in a patient recently placed on new statin medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Patient satisfaction scores on the inpatient units</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Central line blood stream infection rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Percent of inpatients readmitted within 30 days for the same diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Percent of surgical patients given prophylactic antibiotics before surgical incision</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Exercise
Data Collection Plan for your Team

- This exercise has been designed to help you clarify the data collection plan for the team you are coaching.

- For each measure that you identified earlier in this section, outline the decisions related to stratification of the data, sampling (if appropriate), frequency and duration of data collection.

- Use the Data Collection Plan Worksheet on the next page to record your ideas.

- Spend a few minutes working on your own then compare your ideas with others at your table and critique each person’s plan.
### Data Collection Plan Worksheet

**Project name & location:**

<table>
<thead>
<tr>
<th>Measure Name</th>
<th>Is Stratification appropriate? If Yes, list the levels of stratification</th>
<th>Will you use sampling? If Yes, describe the sampling method you will use</th>
<th>Frequency of data collection (e.g., hourly, daily weekly?)</th>
<th>Duration of data collection (i.e., how long do you plan to collect the data?)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**See Worksheet Packet**

### Conclusions: Data Collection

1. Sampling should produce representative and workable numbers for the unit of interest.
2. Customers providing feedback about their service or care they receive can be very susceptible to sampling bias (sampling and recall biases).
3. Sampling bias can be introduced if you always use the same place or time and this is not representative of the whole. This is a major problem for when single point in time audits are relied on as the sampling method.
4. When conducting surveys recall bias occurs if the questions are reliant on the individual’s memory.
5. The worst case scenario occurs when you have no idea where the sample came from or how representative it is of the population or organisation overall.
6. Clear guidance on data collection methods, in particular sampling and stratification, are required whether you are collecting data for improvement, judgement or research.
7. Data on ‘why did this happen’ are critical to improvement efforts!
Now that you understand how to select, define and collect data for your measures, consider developing a dashboard of key measures!

Measurement Dashboard Worksheet©

Name of team: Ward 20 Medication Reconciliation Team  Date: 1 August 2014

<table>
<thead>
<tr>
<th>Measure Name</th>
<th>Operational Definition</th>
<th>Data Collection Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of inpatient medication orders with an error</td>
<td>Numerator: Number of inpatient medication orders with one or more errors</td>
<td>• This measure applies to all inpatient units</td>
</tr>
<tr>
<td></td>
<td>Denominator: Number of inpatient medication orders received by the pharmacy</td>
<td>• The data will be stratified by shift and by type of order (stat versus routine)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The data will be tracked daily and grouped by week</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The data will be pulled from the pharmacy computer and the CPOE systems</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Initially all medication orders will be reviewed. A stratified proportional random</td>
</tr>
<tr>
<td></td>
<td></td>
<td>sample will be considered once the variation in the process is fully understood and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the volume of orders is analyzed.</td>
</tr>
</tbody>
</table>

Quality Measurement Journey Part 2
Questions 4 - 6

1. What is your current level of knowledge about quality measurement?
2. What is your motivation for measuring?
3. Do you know the milestones in the Quality Measurement Journey (QMJ)?
4. Do you understand variation conceptually?
5. Do you understand variation statistically?
6. How well do you link measurement to improvement
Question #4
Quality Measurement Journey: Understanding Variation Conceptually

The Quality Measurement Journey

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

You have data! Now, what do you do with it?

My pizza says to bake for 18-21 minutes, how do I bake something for -3 minutes?

Opinions vs. Data!

I LIKE TO HAVE OPINIONS
BUT NOT INFORMED OPINIONS
THE POINT IS THAT IT FEELS GOOD
THAT'S TOTAL NUTS
OH, IS IT?
UNLESS YOU HAVE HARD DATA TO BACK UP THAT COMMENT, IT WAS NOTHING BUT AN UNINFORMED OPINION THAT FELT GOOD
WHAT EXACTLY DO YOU THINK IS THE POINT OF HAVING AN OPINION?
GAAA!! YOU'RE STARTING TO MAKE SENSE!
YOUR WHOLE LIFE IS A LIE
Question #4
Do you understand variation conceptually?

“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.
So, what is the variation in this system over time? How can you tell from these numbers?


Figure 36


Source: Swedish Cancer Registry, Swedish National Board of Health and Welfare.
Average Percent of Patients who Fall
Before and After the Implementation of a New Protocol

<table>
<thead>
<tr>
<th>Time</th>
<th>Percent of Patients who Fall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time 1</td>
<td>5.0%</td>
</tr>
<tr>
<td>Time 2</td>
<td>4.0%</td>
</tr>
</tbody>
</table>

WOW! A “significant drop” from 5% to 4%

Conclusion - The protocol was a success!
A 20% drop in the average mortality!
Average Percent of Patients who Fall
Before and After the Implementation of a New Protocol

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
And Sometimes you discover that what you see does not match reality!

Count the Black Dots!
How many do you see?

What is reality here?
The goal is to make sense out of the data!

How many legs does this elephant have?

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!
Distorting the Data!

"You’ll be happy to see that I’ve finally managed to turn things around!"

Deming’s Cycle of Fear

Campbell's Insight on Distortion

“The more any quantitative social indicator is used for social decision-making, the more subject it will be to corruption pressures and the more apt it will be to distort and corrupt the social processes it is intended to monitor.”

“Campbell's Law” from Assessing the Impact of Planned Social Change, 1976

Donald T. Campbell, Ph.D., social psychologist (1916-1996)


“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”

Dr. Walter A Shewhart

W. 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

Exercise
Common & Special Causes of Variation

- The team you are coaching has collected some data for their improvement project.
- You have been telling them, “When we get the data on our measures we will be able to understand if the variation is common cause or special cause.”
- Since they had no data while you were telling them this they really did not pay much attention to your words.

- Now that they have data one of the team members raises their hand during the meeting and says, “OK, we have data so what’s all this about common and special causes of variation you have been referencing? We don’t understand what you’re talking about. What is it and why should we care?”
- What would you tell the team?
Exercise
Common & Special Causes of Variation

If you can’t explain it simply, you don’t understand it well enough.

Spend a few minutes talking with your neighbor and prepare a simple explanation of common and special causes of variation and an example of each.

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
A demonstration of Random and Non-Random Variation

A classic example of random and non-random variation!
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.

### 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>Increased variation!</td>
<td>Wasted resources! (time, effort, morale, money)</td>
</tr>
</tbody>
</table>

Overreacting to a Special Cause
(The Wrong Choice!)

2 Questions ...

1. Is the process stable?
   If so, it is predictable.

2. Is the process capable?

   The chart will tell you if the process is stable and predictable.
   You have to decide if the output of the process is capable of meeting the target or goal you have set!
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
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?
Conclusions
Understanding Variation

1. The same data can show different patterns of variation dependent on how much of it you present and how you statistically analyse and display the data.

2. Data presented over time (i.e., plotting the data by day, week or month) is the only way you will ever be able to improve any aspect of quality or safety!

3. Avoid using aggregated data and enumerative statistics if you are serious about improving quality and safety!

4. A leaders job is to understand patterns of variation and ask why!

Question #5
Quality Measurement Journey: Understanding Variation Statistically
The joy of “sadistics”

3. Find x.

Here it is x

The joy of “sadistics”

After explaining to a student through various lessons and examples that:

$$\lim_{x \to 8} \frac{1}{x-8} = \infty$$

I tried to check if she really understood that, so I gave her a different example. This was the result:

$$\lim_{x \to 5} \frac{1}{x-5} = \infty$$

$$\frac{1}{\pi} \sin x = ?$$

$$\frac{1}{\pi} \sin x =$$

six = 6
Do you understanding variation statistically? You have two routes to follow…

**STATIC VIEW**
- 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)

Static view at a single point in time leads to Judgement not Improvement!

Source: Alastair Philip, Quality improvement Scotland, 2010
Moving from data for Judgment (static) to data for Improvement (dynamic)

The idea for this example was proposed by Alastair Philip, Quality improvement Scotland, 2010

You do have a choice!

Data for Improvement

Data for Judgment

How can I depict variation?

See Appendix?

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)
The SPC Pioneers

W. Edwards Deming
(1900 - 1993)

Walter Shewhart
(1891 – 1967)

Joseph Juran
(1904 - 2008)

How do we analyze variation for quality improvement?

Run and Control Charts are the best tools to determine:

1. *The variation that lives in the process*
2. *if our improvement strategies have had the desired effect.*
Key Run Chart questions

Can you answer the following questions:
1. What are the three primary reasons why we use SPC charts?
2. How many data points do we need before starting a run chart? Why this number?
3. Name the elements of a run chart and lay one out on the flipchart.
4. What is the centerline on a run chart and how do you locate it? Show the formula you use to locate and determine the centerline.
5. What is a run and how do you count the number of runs on a run chart?
6. Explain the run chart rules to identify non-random variation. Why is it not appropriate to use the term “special cause” on a run chart?
7. Explain why a shift and a trend are defined by a specific number of data points. How many data points define a shift and a trend?
8. If you have one really high and one really low data point are these considered astronomical?
9. When would you change the centerline on a run chart? When would you not change the centerline?
The following slides provide answers to the 9 question about Run Charts. Do we need to review the details?

NOTE: Answers to the run chart questions were discussed in the pre-work article “Navigating in the Turbulent Sea of Data: The Quality Measurement Journey.”

How many data points do I need?

_Ideally_ you should have between 10 – 15 data points before constructing a run chart

10 – 15 patients
10 – 15 days
10 – 15 weeks
10 – 15 months
10 – 15 quarters...

• _If you are just starting to measure, plot the dots and make a line graph._

• _Once you have 8-10 data points make a run chart._
Elements of a Run Chart

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

Run Chart
How do you find the median?

\[
\frac{n + 1}{2} = \frac{29 + 1}{2} = 30/2 = 15
\]

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

The Median Lives here at the 15th data point.

But, the Median Value = 4.6
First, you need to determine the number of Runs

**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 many Runs?**

Run = series consecutive points above or below the median, ignore points equal to median

Points on the Median (don’t count these when counting the number of runs)
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

A Shift:
6 or more

An astronomical data point
Too many or too few runs

A Trend
5 or more

Probability of a “trend”

Why do we need 5 data points for a trend?
What is the probability of a coin landing heads or tails?

One head or tail     = .5
.5 x .5 = .25
.5 x .5 x .5 = .125
.5 x .5 x .5 x .5 = .0625
.5 x .5 x .5 x .5 x .5 = .03125
.5 x .5 x .5 x .5 x .5 x .5 = .015625
Non-Random Rules for Run Charts

Rule #3: Too few or too many runs

To determine if the data is random, calculate the number of "useful observations" in your data set. This is done by subtracting the number of data points on the median from the total number of data points. Then, find this number in the first column. The lower number of runs is found in the second column. The upper number of runs can be found in the third column. If the number of runs in your data falls below the lower limit or above the upper limit then this is a signal of a special cause.

<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>14</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>15</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>16</td>
<td>5</td>
<td>16</td>
</tr>
<tr>
<td>17</td>
<td>5</td>
<td>17</td>
</tr>
<tr>
<td>18</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>19</td>
<td>6</td>
<td>19</td>
</tr>
<tr>
<td>20</td>
<td>6</td>
<td>20</td>
</tr>
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<td>21</td>
<td>7</td>
<td>21</td>
</tr>
<tr>
<td>22</td>
<td>7</td>
<td>22</td>
</tr>
<tr>
<td>23</td>
<td>7</td>
<td>23</td>
</tr>
<tr>
<td>24</td>
<td>8</td>
<td>24</td>
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<tr>
<td>25</td>
<td>8</td>
<td>25</td>
</tr>
<tr>
<td>26</td>
<td>9</td>
<td>26</td>
</tr>
<tr>
<td>27</td>
<td>10</td>
<td>27</td>
</tr>
<tr>
<td>28</td>
<td>10</td>
<td>28</td>
</tr>
<tr>
<td>29</td>
<td>10</td>
<td>29</td>
</tr>
<tr>
<td>30</td>
<td>11</td>
<td>30</td>
</tr>
</tbody>
</table>


So, for 27 useful observations we should have between 10 and 19 runs.
Non-Random Rules for Run Charts


Rule #4: An Astronomical Data Point

25 Men and a Test

What do you think about this data point?
Is it astronomical?
So, let’s practice...

Exercise
Hand Hygiene Compliance Run Chart

• The team you are coaching is trying to improve hand hygiene compliance.

• You advised them on a measurement plan and selected Percent Compliance with Hand Hygiene as the outcome measure.

• You helped them develop a weekly data collection plan and the data are presented on the next slide.

• The team has asked you, “So now what?”

• You responded, “We need to make a run chart to understand the variation in the process.”

• They respond, “OK, show us how to make a run chart.”

• So, show them!
12/6/2015

Measure is the percent compliance with proper hand hygiene by week. Numerator = number of properly completed hand washings Denominator = total number of hand washing observations

<table>
<thead>
<tr>
<th>Week</th>
<th>Percent Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>79</td>
</tr>
<tr>
<td>2</td>
<td>82</td>
</tr>
<tr>
<td>3</td>
<td>86</td>
</tr>
<tr>
<td>4</td>
<td>84</td>
</tr>
<tr>
<td>5</td>
<td>85</td>
</tr>
<tr>
<td>6</td>
<td>79</td>
</tr>
<tr>
<td>7</td>
<td>77</td>
</tr>
<tr>
<td>8</td>
<td>86</td>
</tr>
<tr>
<td>9</td>
<td>82</td>
</tr>
<tr>
<td>10</td>
<td>74</td>
</tr>
<tr>
<td>11</td>
<td>85</td>
</tr>
<tr>
<td>12</td>
<td>74</td>
</tr>
<tr>
<td>13</td>
<td>78</td>
</tr>
<tr>
<td>14</td>
<td>83</td>
</tr>
<tr>
<td>15</td>
<td>81</td>
</tr>
<tr>
<td>16</td>
<td>81</td>
</tr>
<tr>
<td>17</td>
<td>74</td>
</tr>
<tr>
<td>18</td>
<td>84</td>
</tr>
<tr>
<td>19</td>
<td>78</td>
</tr>
<tr>
<td>20</td>
<td>75</td>
</tr>
<tr>
<td>21</td>
<td>74</td>
</tr>
<tr>
<td>22</td>
<td>68</td>
</tr>
<tr>
<td>23</td>
<td>81</td>
</tr>
<tr>
<td>24</td>
<td>84</td>
</tr>
<tr>
<td>25</td>
<td>70</td>
</tr>
<tr>
<td>26</td>
<td>85</td>
</tr>
<tr>
<td>27</td>
<td>77</td>
</tr>
</tbody>
</table>

- Make a run chart with the data shown in the table to the left.
- Decide how you want to lay out the X (horizontal) axis and Y (vertical) axis.
- Plot the data points.
- Calculate the median. Hint: use the \((n + 1)/2\) formula to find the median position first.
- Then determine the median value.
- Determine the number of runs on the chart.
- Apply the run chart rules and interpret the results
  - **DO NOT use your calculator or Excel!!!**
Exercise
Percent Compliance with Proper Hand Hygiene

Median = 81
\[ (27+1) = 28/2 = 14 \]

How many runs on this chart

Week

15 runs

Apply the rules and interpret the chart.
NOTE: 27 data points with 3 on the median gives you 24 “useful observations.” For 24 useful observations you expect between 8 and 18 runs.
What are 4 reasons why Shewhart Charts are 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 Shewhart Control Chart

Three key questions related to using Shewhart Control Charts

1. How many data points do I need?

2. What is a sigma limit? And, why do I need 3 of them?

3. How do I use the zones on a Shewhart control chart?
Question #1: How many data points?

Typically you should have a minimum of 20 data points before constructing a control chart

- 15 – 20 patients
- 15 – 20 days
- 15 – 20 weeks
- 15 – 20 months
- 15 - 20 quarters...

Principles for Creating Limits

If you have less than 12 data points use run chart rather than control chart

Is Our Volume of Net New Patients Stable?

![Graph showing the number of patients over sequential months]
Principles for Creating Limits

When you have 12 - 15 data points you should calculate and use “trial control limits”

Is Our Volume of Net New Patients Stable?

Sequential Months

<table>
<thead>
<tr>
<th># of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

Mean = 45.9, UCL = 94.0, LCL = -2.2 (mR=2) (temp)

The UCL and LCL are known as Sigma Limits.

The challenge is to develop appropriate estimates of the mean and standard deviation for the process measure.

Each type of control chart has its own formula with the most appropriate statistic used for each formula.


Question #2: What is a Sigma Limit?

The UCL and LCL are known as **Sigma Limits**.

The challenge is to develop appropriate estimates of the mean and standard deviation for the process measure.

Each type of control chart has its own formula with the most appropriate statistic used for each formula.

The UCL and LCL are known as Sigma Limits (SLs).
They ARE NOT standard deviations!

The standard deviation (sd) is a statistic of a fixed distribution.
Sigma Limits (SLs) are parameters of a process that is changing over time.

A Practical Note: If you calculate a standard deviation (the one you were taught in basic statistics), multiple it by 3 and then add and subtract this value to the average, you will get the wrong control limits!

You need SPC software to make proper sigma limits!

Question #3: How do I use the Zones on a control chart?

NOTE: Each zone is equal to 1 sigma
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.

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
Using the Zones and the Special Cause Rules

### Notes on Special Cause Rules

**Rule #1: 1 point outside the +/- 3 sigma limits**
Note: 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**
Note: 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**
Note: 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**
Note: 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 in Zone C on either side of the centerline**
This is known as “hugging the centerline”
SPC Knowledge Tests

Is there a Special Cause on this chart?
Special Cause: Point Outside the UCL

Is there a Special Cause on this chart?
Special Cause: 2 Out of 3 Consecutive Points in Outer Third of Limits or Beyond

Number of Patient Complaints by Month
(XmR chart)

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

Are there any special causes present? If so, what are they?

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

Are there special causes on this chart?
But how do we know which one is the right one?

I know the right chart has to be hiding in here somewhere!

SPC
Sphere of Knowledge

Types of Quantitative Data

Variables Data

Attributes Data

Defectives (occurrences plus non-occurrences)
Nonconforming Units

Defects (occurrences only)
Nonconformities

Types of Quantitative Data

Variables Data

Attributes Data

Defectives (occurrences plus non-occurrences)
Nonconforming Units

Defects (occurrences only)
Nonconformities
Defectives & Defects

- **Defectives (classification)** — there are only two outcomes here. An item or event is either “ok” or “not ok” (a binomial condition).

- **Defects (count)** — you look at something that is “not ok” (i.e., defective) and count how many specific things make the item or event not ok.

OK?
If Yes, then the car is fit to be shipped out!

Not OK?
If No, then the car is classified as being “defective” but we do not know why it is defective (not fit to be shipped) until we inspect it and count the number of specific “defects” that make the car “not OK” or defective.
Selecting the Type of Control Chart

Classification data & Count data (Attribute data)

**Defectives (Classification)** into 1 of 2 categories (a binomial situation) where you know both the occurrences and the non-occurrences

- conforming/not conforming
- harm/no harm
- go/no-go
- pass/fail
- good/bad

**Defects (Count)** data focuses on attributes that occur that are unusual, relatively rare or undesirable where you only know the occurrence of an event (i.e., you do not know the non-occurrences) and the object of inspection can have multiple occurrences (i.e., defects)

- number of defects
- number of mistakes
- number of accidents

---

**Defectives vs Defects**

**Percent of pages with 1 or more errors?**
**Count of the total number of errors?**

<table>
<thead>
<tr>
<th>Page 1</th>
<th>Page 2</th>
<th>Page 3</th>
<th>Page 4</th>
<th>Page 5</th>
<th>Page 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>bad</td>
<td>good</td>
<td>bad</td>
<td>bad</td>
<td>good</td>
<td>good</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Summary: Defectives  Defects

- 3/6 Bad = **50% bad pages**
- 8 mistakes in six pages = **1.33 mistakes per page**

---

Question: Do you know the differences between Proportions, Percentages and Rates?
You Make the Call!

This is a 2 minute quiz! Find a buddy and decide if each measure is a defective (classification) or a defect (count)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Defective (classification)</th>
<th>Defect (count)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Number of accidents per 1000 employee days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Number errors per 25 food trays</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Percent of AMI patients who received aspirin within 24 hours of arrival in ER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Percent of deaths per month</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Number of surgical complications per 1000 surgeries performed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Proportion of pneumonia patients who get antibiotics appropriately at time of admission</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Number of falls per 1000 patient days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Number of medication errors per 10,000 doses dispensed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There Are 5 Basic Control Charts

- **Variables Charts**
  - X & S chart (average & SD chart)
  - XmR chart (individuals & moving range chart)

- **Attributes Charts**
  - p-chart (proportion or percent of defectives)
  - c-chart (number of defects)
  - u-chart (defect rate)

The Control Chart Decision Tree

Variables Data
- More than one observation per subgroup?
  - Yes: X bar & S (Average and Standard Deviation)
  - No: XmR (Individual Measurements)

Attributes Data
- Occurrences & Non-occurrences?
  - Yes: p-chart
  - No: u-chart

Decide on the type of data
- Is there an equal area of opportunity?
  - Yes: c-chart
  - No: u-chart

Type of Chart | Medication Production Analysis
---|---
X bar & S Chart | TAT for a daily sample of 25 medication orders
Individuals Chart (XmR) | The number of medication orders processed each week
C-Chart | Using a sample of 100 medication orders each week, we count the errors (defects) on each order
U-Chart | Out of all medication orders each week, we calculate the number of errors (defects) per 10k orders
P-Chart | For all medication orders each week, we calculate the percentage that have 1 or more errors (i.e., are defective)

The choice of a control chart depends on the measure you have defined!
Milestones in the Quality Measurement Journey

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

ACTION


Question #6
How do you linking measurement to Improvement
## Exercise: Measurement Self-Assessment


<table>
<thead>
<tr>
<th>Measurement Topic or Skill</th>
<th>Response Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Help people in my organization determine why they are measuring (improvement, judgment or research)</td>
<td>1   2   3   4   5</td>
</tr>
<tr>
<td>Move teams from concepts to specific quantifiable measures</td>
<td></td>
</tr>
<tr>
<td>Building clear and unambiguous operational definitions for our measures</td>
<td></td>
</tr>
<tr>
<td>Develop data collection plans (including stratification and sampling strategies)</td>
<td></td>
</tr>
<tr>
<td>Explain why plotting data over time (dynamic display) is preferable to using aggregated data and summary statistics (static display)</td>
<td></td>
</tr>
<tr>
<td>Explain the differences between random and non-random variation</td>
<td></td>
</tr>
<tr>
<td>Construct run charts (including locating the median)</td>
<td></td>
</tr>
<tr>
<td>Explain the reasoning behind the run chart rules</td>
<td></td>
</tr>
<tr>
<td>Interpret run charts by applying the run chart rules</td>
<td></td>
</tr>
<tr>
<td>Explain the statistical theory behind Shewhart control charts (e.g., sigma limits, zones, special cause rules)</td>
<td></td>
</tr>
<tr>
<td>Describe the basic 7 Shewhart charts and when to use each one</td>
<td></td>
</tr>
<tr>
<td>Help teams select the most appropriate Shewhart chart for their measures</td>
<td></td>
</tr>
<tr>
<td>Describe the rules for special cause variation on a Shewhart chart</td>
<td></td>
</tr>
<tr>
<td>Help teams link measurement to their improvement efforts</td>
<td></td>
</tr>
</tbody>
</table>

---

### But the Charts Don’t Tell You…

- **The reasons(s) for a Special Cause.**
- **Whether or not a Common Cause process should be improved (is the performance of the process acceptable?)**
- **How the process should actually be improved or redesigned.**
You need a Framework for Performance Improvement

- Establish appropriate measures.
- Set an aim and goal for each measure.
- Develop theories and predictions on how you plan on achieving the aim and an appropriate time frame for testing.
- Test your theory, implement the change concepts, follow the measures over time and analyze the results.
- Revise the strategy as needed.

Finally, remember that data is a necessary part of the Sequence of Improvement
A closing thought...

It must be remembered that there is nothing more difficult to plan, more doubtful of success, nor more dangerous to manage than the creation of a new system.

For the initiator has the enmity of all who would profit by the preservation of the old institution and merely lukewarm defenders in those who would gain by the new one.

Machiavelli, The Prince, 1513

Appendices

• Appendix A: Faculty Bios
• Appendix B: General References on Quality
• Appendix C: References on Measurement
• Appendix D: Operational Definition Worksheet
• Appendix E: Basic “sadistical” principles
• Appendix F: When do we revise control limits?
• Appendix G: So how will you know when...
Thank you for joining us today!
Good luck with your Quality Measurement Journey!

Contact Information:
Bob Lloyd: rllloyd@ihi.org
Dave Williams: dwilliams@ihi.org

“Soon you will face a choice of what is right and what is easy.
But, remember that you will not be alone!”

Albus Dumbledore
Head Master, Hogwarts School for Witchcraft and Wizardry
Guidance to Harry Potter at the end of The Goblet of Fire
Practical Improvement Science in Healthcare: A Roadmap for Getting Results

- IHI and HarvardX have created a free, 6-week MOOC that starts on January 20, 2016
- Expert faculty: Don Goldmann, Dave Williams, Don Berwick, Karen Baldoza, and Amy Reid
- Learners have the option to earn 6 CEUs for $99 upon course completion

Enroll today on HarvardX or at www.ihi.org/ph556x

Appendices

- Appendix A: Faculty Bios
- Appendix B: General References on Quality
- Appendix C: References on Measurement
- Appendix D: Operational Definition Worksheet
- Appendix E: Basic “sadistical” principles
- Appendix F: When do we revise control limits?
- Appendix G: So how will you know when...
Appendix A: Robert Lloyd (rlloyd@ihi.org)

Robert Lloyd, PhD., Vice President, Institute for Healthcare Improvement provides leadership in the areas of performance improvement strategies, statistical process control methods, development of strategic dashboards and capacity and capability building for quality improvement. He also serves as faculty for the IHI Improvement Advisor (IA) Professional Development programme and various IHI initiatives and demonstration projects in the US, Canada, the UK, Sweden, Denmark, Africa, the Middle East and New Zealand. Dr. Lloyd an internationally recognized speaker on quality improvement concepts, methods and tools. He also advises senior leadership teams on how to create the structures and processes that will make quality thinking part of daily work. He is the author of two leading books on measuring quality improvement in healthcare settings and numerous articles and chapters on quality measurement and improvement. He lives in Chicago, Illinois with his wife Gwenn, daughter Devon and their ever entertaining dog Cricket.

Appendix A: Dave Williams (dwilliams@ihi.org)

David M. Williams, PhD, Executive Director, Institute for Healthcare improvement (IHI), is co-lead of the Improvement Capability Focus Area. He has served as the Improvement Advisor for large Collaboratives in the United States and Europe, including Impacting Cost + Quality in the US, the NHS South West Patient Quality and Safety Programme in England, and the Scottish Government Early Years Collaborative. Dr. Williams is faculty for the IHI Open School and the Massive Open Online Course (MOOC) being developed with HarvardX and the Harvard T.H. Chan School of Public Health. He created the Mr. Potato Head exercise used worldwide to teach PDSA testing and measurement. A paramedic by background, Dr. Williams practiced in urban EMS systems for many years and is internationally known as an expert on paramedic care and emergency medical services systems. Prior to joining IHI, he led a consulting practice focused on improvement science and expert consulting in education, public safety, and health care.
Appendix B
General References on Quality


Appendix C
References on Measurement

Appendix C

References on Measurement (cont.)


Appendix D

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. Specify the numerator and denominator if it is a percent or a rate. If it is an average, identify the calculation for deriving the average. Include any special equipment needed to capture the data. If it 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

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 in this measure 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.)


Appendix E
A few basic “sadistical” principles

Descriptive 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>(\text{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>
<tr>
<td>Which finally leads us to our good old friend, the standard deviation, which is the positive square root of the variance.</td>
<td>See the next page for this fun formula!</td>
</tr>
</tbody>
</table>
Appendix F
When do we revise control limits?

1. When “trial” limits have been calculated with fewer than 20 subgroups.

2. When the initial control chart has special causes and there is a desire to use the calculated limits for analysis of data to be collected in the future.

3. When improvements have been made to the process and the improvements result in special causes on the control chart.

4. When the control chart remains unstable for 20 or more subgroups and approaches to identify and remove the special causes have been exhausted.

5. When you change the operational definition.

Trial Limits versus Initial Limits

When “trial” limits have been calculated with fewer than 20 subgroups.
When do we revise control limits?

1. When “trial” limits have been calculated with fewer than 20 subgroups

2. When the initial control chart has special causes and there is a desire to use the calculated limits for analysis of data to be collected in the future

Including Special Causes in the Estimate

![Graph showing limits with and without special causes](image-url)
When do we revise control limits?

1. When “trial” limits have been calculated with fewer than 20 subgroups
2. When the initial control chart has special causes and there is a desire to use the calculated limits for analysis of data to be collected in the future
3. When improvements have been made to the process and the improvements result in special causes on the control chart

Wait Time to See the Doctor

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.
Wait Time to See the Doctor

Freeze the Control Limits and compare the new process performance to the baseline using the UCL, LCL, and CL from the baseline period as reference lines.

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

Intervention

Make new control limits for the process to show the improvement.

Baseline Period

UCL = 15.3
CL = 10.7
LCL = 6.1

Xm R Chart

Intervention

Wait Time to See the Doctor
Segmenting the Data to Show Improvement
Revising Limits After Evidence of Improvement

When do we revise control limits?

1. When “trial” limits have been calculated with fewer than 20 subgroups
2. When the initial control chart has special causes and there is a desire to use the calculated limits for analysis of data to be collected in the future
3. When improvements have be made to the process and the improvements result in special causes on the control chart
4. When the control chart remains unstable for 20 or more subgroups and approaches to identify and remove the special causes have been exhausted.
When do we revise control limits?

1. When "trial" limits have been calculated with fewer than 20 subgroups
2. When the initial control chart has special causes and there is a desire to use the calculated limits for analysis of data to be collected in the future
3. When improvements have been made to the process and the improvements result in special causes on the control chart
4. When the control chart remains unstable for 20 or more subgroups and approaches to identify and remove the special causes have exhausted.
5. When you change the operational definition
Changing an Operational Definition

When do we **NOT** revise control limits?

Soooo, let’s change the control limits!
Appendix G
So, how will you know...

1. If the change(s) you have made signal a true improvement?
2. If you have sustained improvement?
3. If it is the right time to implement the change(s)
4. If it is time to spread the change(s) to other areas?
5. If it is time to stop measuring?

So, how will you know...

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5. If it is time to stop measuring? SPSP
Run & Control Chart Rules are used to determine if a change has occurred.

**Use the run chart rules to determine if a change has occurred:**

- A shift = 6 or more data points above or below the baseline median (centerline)
- A trend = 5 data points constant going up or down

**Use control chart rules to determine if a change has occurred:**

- A shift = 8 or more data points above or below the baseline median (centerline)
- A trend = 6 data points constant going up or down

Any of the run chart rules found here?

Has anything changed here!
So, how will you know…

1. If the change(s) you have made signal a true improvement?

2. If you have sustained improvement?

3. If it is the right time to implement the change(s)

4. If it is time to spread the change(s) to other areas?

5. If it is time to stop measuring? SPSP

**Sustained Improvement**

- First identify a shift or a trend in the data
- Then look to see if 3 or more data point have stayed at the new level.
So, how will you know…

1. If the change(s) you have made signal a true improvement?
2. If you have sustained improvement?
3. If it is the right time to implement the change(s)
4. If it is time to spread the change(s) to other areas?
5. If it is time to stop measuring? SPSP

Degree of Belief When Making Changes to Improve

Implementing a Change

Unreconciled Meds

Begin implementation on pilot unit
Evidence of improvement during implementation

Current Situation | Resistant | Indifferent | Ready
--- | --- | --- | ---
Low Confidence that current change idea will lead to improvement
Risk of not succeeding large | Very Small Scale Test | Very Small Scale Test | Very Small Scale Test
Risk of not succeeding small | Very Small Scale Test | Very Small Scale Test | Small Scale Test
High Confidence that current change idea will lead to improvement
Risk of not succeeding large | Very Small Scale Test | Small Scale Test | Large Scale Test
Risk of not succeeding small | Small Scale Test | Large Scale Test | Implement

Note the conditions for implementing a change.
So, how will you know…

1. If the change(s) you have made signal a true improvement?
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3. If it is the right time to implement the change(s)
4. If it is time to spread the change(s) to other areas?
5. If it is time to stop measuring? SPSP

**Spreading a Change**

- First identify a shift or a trend in the data.
- Then look to see if 6 or more data points have stayed at the new level.
- This indicates that you are 'holding the gains.'

Source: John Whittington OSF Healthcare
So, how will you know…

1. If the change(s) you have made signal a true improvement?
2. If you have sustained improvement?
3. If it is the right time to implement the change(s)
4. If it is time to spread the change(s) to other areas?
5. If it is time to stop measuring?

Two Simple Rules for Measuring

Outcome Measures – always!

Process Measures – it depends!
How often do you need to measure?

It is not uncommon for a team to want to stop collecting data, especially after they have been at it for a year or two!

The reliability of the process and your need to know how the process is functioning should drive the frequency of data collection and analysis.

A Simple Rule for Outcomes

Outcome Measures – Always!
As long as you are concerned about the quality and safety of the care that you deliver, you should continue to track the outcomes!

For example, how long should these outcomes be measured?
• When do you stop measuring your financial results?
• When should a diabetic patient stop tracking his or her blood glucose?
• How long should we monitor the vital signs of an ICU patient?
• When should airport security stop assessing passengers for weapons?
• How long does a local water authority need to measure the quality of the water going through its pipes?
• When should schools stop measuring the progress of students?
A Simple Rule for Processes

Process Measures – it depends!
• Process measures usually demonstrate improvement before outcome measures.

• Process measures may be revised during an improvement project; new data will then need to be collected and tracked.

• A process measure should demonstrate improvement (against the run chart rules) and then **STAY at the new level of performance for at least 3 reporting periods to be considered “sustained.”**

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Frequency of Process Measures

**Regularly (daily, weekly or monthly)**
Done to improve a specific measure (reduce variation or shift the centerline of process performance)

**Periodically (once every 2 - 3 months)**
Done when statistical improvement has been noted, sustained AND the process is highly reliable (audit approach can be used here)

**Once or twice a year (why bother?)**

**Stop measuring!**
- Done when performance is so reliable, stable and capable that it is time to move on to measure something new.
- Or when the measure is no longer relevant.