“What is the variation in one system over time?”

Walter A. Shewhart - early 1920’s, Bell Laboratories
“What is the variation in one system over time?”
Walter A. Shewhart - early 1920’s, Bell Laboratories
“What is the variation in one system over time?”
Walter A. Shewhart - early 1920’s, Bell Laboratories
“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
A Stable Process

A predictable (thus manageable) process exhibits a stable distribution, when viewed across time.

Successive samples from a stable or random process differ only by chance.

Courtesy of Richard Scoville, PhD, IHI Improvement Advisor
Common Cause Variation

- Points equally likely above or below center line
- There will be a high data point and a low, but this is expected
- No trends or shifts or other patterns

Courtesy of Richard Scoville, PhD, IHI Improvement Advisor
A Successful Change is a Special Cause

New samples from a successfully changed process display more than chance variation

Intervention

Courtesy of Richard Scoville, PhD, IHI Improvement Advisor
Decision Tree for Managing with Data

Are special causes present?

No

Are outcomes acceptable?

Yes

Do nothing

No

Change the process

Yes

Investigate & eliminate special causes

© Richard Scoville & IHI
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.
Exercise
Common and Special Causes of Variation

• Select several measures your organization is tracking for the HEN Collaborative.

• 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?
There are many examples of Common and Special Causes of Variation in healthcare. Find ones that work for you.

Common Cause Variation
There are many examples of Common and Special Causes of Variation in healthcare. Find ones that work for your you.
There are many examples of Common and Special Causes of Variation in healthcare. Find ones that work for your you.

Normal Sinus Rhythm (a.k.a. Common Cause Variation)
There are many examples of Common and Special Causes of Variation in healthcare. Find ones that work for your you.

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

...see why they call the P waves "Saw Tooth"??

ATRIAL FLUTTER
How do we analyze variation for quality improvement?

*Run* and *Control Charts* are the best tools to determine if our improvement strategies have had the desired effect.
How many data points do I need to make a chart?

*Typically* you should have between 15 – 20 data points before constructing a chart.

- 15 – 20 patients
- 15 – 20 days
- 15 – 20 weeks
- 15 – 20 months
- 15 - 20 quarters...?
Guiding Principles for Creating Charts

• If you have **less than 10 data points**, make a simple line graph to see where the data points are going.

• If you have **10 and 12 data points** you can convert the simple line graph to a run chart (place the median on the line graph and apply the run chart rules).

• When you have **12 -15 data points** you can calculate a control chart but you should note that the control limits are “trial control limits.”
Elements of a Run Chart

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

Measure
Pounds of Red Bag Waste

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

\[ \bar{X} \] (CL)

Time

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

©Copyright 2012 IHI/R. Lloyd
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

Now, let’s go...
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, and zones** 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 (Shewhart) Chart

- **Measure**: Number of Complaints
- **Time**: Month

**Graph Details**:
- **Upper Control Limit (UCL)**: 44.855
- **Center Line (CL)**: 29.250
- **Lower Control Limit (LCL)**: 13.645

**Note**: An indication of a special cause.
Rules for Detecting Special Causes

1. A single point outside the control limits
2. Six consecutive points increasing (trend up) or decreasing (trend down)
3. Two or three consecutive points near a control limit (outer one-third)
4. Eight or more consecutive points above or below the centerline
5. Fifteen consecutive points close to the centerline (inner one-third)
## Notes on Special Cause Rules

<table>
<thead>
<tr>
<th>Rule #1: 1 point outside the +/- 3 sigma limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule #2: 8 successive consecutive points above (or below) the centerline</th>
</tr>
</thead>
<tbody>
<tr>
<td>A point exactly on the centerline does not cancel or count towards a shift.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule #3: 6 or more consecutive points steadily increasing or decreasing</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule #4: 2 out of 3 successive points in Zone A or beyond</th>
</tr>
</thead>
<tbody>
<tr>
<td>When there is not a lower or upper control limit Rule 4 does not apply to the side missing a limit.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule #5: 15 consecutive points in Zone C on either side of the centerline</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is known as “hugging the centerline”</td>
</tr>
</tbody>
</table>
A Quick Test to Identify Special Causes
Is there a Special Cause on this chart?

Unplanned Returns to Ed w/in 72 Hours

<table>
<thead>
<tr>
<th>Month</th>
<th>ED/100 Returns</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>41.78</td>
</tr>
<tr>
<td>A</td>
<td>43.89</td>
</tr>
<tr>
<td>M</td>
<td>39.86</td>
</tr>
<tr>
<td>J</td>
<td>40.03</td>
</tr>
<tr>
<td>J</td>
<td>38.01</td>
</tr>
<tr>
<td>A</td>
<td>43.43</td>
</tr>
<tr>
<td>S</td>
<td>41.90</td>
</tr>
<tr>
<td>O</td>
<td>41.78</td>
</tr>
<tr>
<td>N</td>
<td>43.00</td>
</tr>
<tr>
<td>D</td>
<td>39.66</td>
</tr>
<tr>
<td>J</td>
<td>40.03</td>
</tr>
<tr>
<td>F</td>
<td>48.21</td>
</tr>
<tr>
<td>M</td>
<td>43.89</td>
</tr>
<tr>
<td>A</td>
<td>39.86</td>
</tr>
<tr>
<td>M</td>
<td>36.21</td>
</tr>
<tr>
<td>J</td>
<td>41.78</td>
</tr>
<tr>
<td>J</td>
<td>39.66</td>
</tr>
<tr>
<td>A</td>
<td>43.89</td>
</tr>
<tr>
<td>S</td>
<td>31.45</td>
</tr>
</tbody>
</table>

Rate per 100 ED Patients

UCL = 0.88
Mean = 0.54
LCL = 0.19

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

### Unplanned Returns to ED within 72 Hours

<table>
<thead>
<tr>
<th>Month</th>
<th>ED/100 Returns</th>
<th>Rate per 100 ED Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>41.78</td>
<td>17</td>
</tr>
<tr>
<td>A</td>
<td>43.89</td>
<td>13</td>
</tr>
<tr>
<td>M</td>
<td>39.86</td>
<td>24</td>
</tr>
<tr>
<td>J</td>
<td>43.89</td>
<td>27</td>
</tr>
<tr>
<td>J</td>
<td>41.90</td>
<td>19</td>
</tr>
<tr>
<td>A</td>
<td>39.66</td>
<td>33</td>
</tr>
<tr>
<td>S</td>
<td>48.21</td>
<td>20</td>
</tr>
<tr>
<td>D</td>
<td>43.89</td>
<td>17</td>
</tr>
<tr>
<td>J</td>
<td>40.03</td>
<td>22</td>
</tr>
<tr>
<td>F</td>
<td>43.90</td>
<td>16</td>
</tr>
<tr>
<td>M</td>
<td>41.78</td>
<td>24</td>
</tr>
<tr>
<td>A</td>
<td>43.89</td>
<td>27</td>
</tr>
<tr>
<td>S</td>
<td>48.21</td>
<td>19</td>
</tr>
<tr>
<td>O</td>
<td>39.66</td>
<td>22</td>
</tr>
<tr>
<td>N</td>
<td>41.90</td>
<td>17</td>
</tr>
<tr>
<td>D</td>
<td>43.00</td>
<td>20</td>
</tr>
<tr>
<td>J</td>
<td>41.78</td>
<td>22</td>
</tr>
<tr>
<td>A</td>
<td>43.89</td>
<td>17</td>
</tr>
<tr>
<td>S</td>
<td>48.21</td>
<td>20</td>
</tr>
</tbody>
</table>

### u chart

- **UCL = 0.88**
- **Mean = 0.54**
- **LCL = 0.19**
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 (desirable) upward trend.
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>July01</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>July02</td>
<td>50.0</td>
</tr>
<tr>
<td>Sept02</td>
<td></td>
</tr>
<tr>
<td>Nov02</td>
<td></td>
</tr>
</tbody>
</table>

UCL = 44.855
CL  = 29.250
LCL = 13.645

©Copyright 2012 IHI/R. Lloyd
Number of Patient Complaints by Month
(XmR chart)
Are there any special causes present? If so, what are they?
What do you conclude about this chart?

Do you see any special causes?

What questions would you ask?

Tests performed with unequal sample sizes
This is actually four different charts. The data should have been stratified by severity.

P Chart of No COPD by stage

Tests performed with unequal sample sizes

UCL=0.0965

\bar{P}=0.0385

LCL=0
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**

**Attributes Data**

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

- **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)
# 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>
### Exercise
**You Make the Call on these HEN Measures**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Subgroup?</th>
<th>Type of Data?</th>
<th>Type of Chart?</th>
</tr>
</thead>
<tbody>
<tr>
<td>The daily total number of ED patients who have at least one medication order entered using computerized provider order entry (CPOE).</td>
<td></td>
<td>V or A</td>
<td></td>
</tr>
<tr>
<td>The number of central line insertions each week during which all elements of the bundle were followed divided by the total number of central line insertions that week</td>
<td></td>
<td>V or A</td>
<td></td>
</tr>
<tr>
<td>The weekly number of catheter-associated urinary tract infections per 1000 urinary catheter days</td>
<td></td>
<td>V or A</td>
<td></td>
</tr>
<tr>
<td>The total number of patient falls each month (with or without injury to the patient and whether or not assisted by a staff member) divided by the total patient days for the month</td>
<td></td>
<td>V or A</td>
<td></td>
</tr>
<tr>
<td>The number of hand hygiene performed consistent with guidelines divided by the total number of hand hygiene observation opportunities</td>
<td></td>
<td>V or A</td>
<td></td>
</tr>
</tbody>
</table>
## Exercise
You Make the Call on these HEN Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Subgroup?</th>
<th>Type of Data?</th>
<th>Type of Chart?</th>
</tr>
</thead>
<tbody>
<tr>
<td>The daily total number of ED patients who have at least one medication order entered using computerized provider order entry (CPOE).</td>
<td>Day</td>
<td>V or A</td>
<td>XmR</td>
</tr>
<tr>
<td>The number of central line insertions each week during which all elements of the bundle were followed divided by the total number of central line insertions that week</td>
<td>Week</td>
<td>V or A</td>
<td>p-chart</td>
</tr>
<tr>
<td>The weekly number of catheter-associated urinary tract infections per 1000 urinary catheter days</td>
<td>Week</td>
<td>V or A</td>
<td>u-chart</td>
</tr>
<tr>
<td>The total number of patient falls each month (with or without injury to the patient and whether or not assisted by a staff member) divided by the total patient days for the month</td>
<td>Month</td>
<td>V or A</td>
<td>u-chart</td>
</tr>
<tr>
<td>The number of hand hygiene performed consistent with guidelines divided by the total number of hand hygiene observation opportunities</td>
<td>?</td>
<td>V or A</td>
<td>?</td>
</tr>
</tbody>
</table>
The Quality Measurement Journey

When will we know that a change produces an improvement?

**Processes**

**Primary Drivers**
- Calories In
  - Daily calorie count
  - Exercise calorie count
- Calories Out
  - Exercise calorie count
- Limit daily intake
  - Avg cal/day
- Substitute low calorie foods
  - % of opportunities used
- Avoid alcohol
  - Avg drinks/week

**Secondary Drivers**
- Track Calories
  - Running calorie total
- Plan
  - Meals off-plan/week
- Drink H2O
  - Not Soda
  - Sodas/week
- Work out 5 days
  - Days between workouts
- Bike to work
  - Percent of days on bike
- Hacky Sack in office
  - Etc...

**Ideas for Process Changes**

**Outcomes**
- AIM: A New ME!
  - Weight
  - BMI
  - Body Fat
  - Waist size

**Outcome measures** change more slowly

**Process measures** change more quickly

© Richard Scoville & I.H.I.
The Sequence of Improvement

Prerequisites for change

Confidence that change is effective

Develop a change

Prototype a change

Test under a variety of conditions

Implement a change

Embed in daily operations

Spread throughout the system
The Formula for Improvement

Structure + Process + Culture* = Outcome

*Added to Donabedian’s original formulation by R. Lloyd and R. Scoville.

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.
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