Agenda

1. Process Control Charts (Chapter 14) - Sarah
2. Risk-Adjusted Comparisons (Chapter 15) - Maggie
3. Quality Concepts (Chapter 16) - Susan

- We will briefly review some content.
- We will test your knowledge.
- Turn the time over to UDHHS to review a case study to apply these principles.
Process Control Charts
Statistical Process Control 101

- Originally designed as a way to monitor manufacturing processes, but not utilized in healthcare settings.
- Main purpose is to recognize and understand common versus special cause variations that affect a process.
- We use Statistical Process Control to determine and eliminate variation to bring a process back into control.
Anatomy of a Run Chart

- Simple, easy tool
- Best to use if you have <25 data points
Rates of Ventilator-associated Events, January 2011 to July 2012

- **X-Axis**: Time (Jan 2011 to Jul 2012)
- **Y-Axis**: Rate of Ventilator-associated Events
- **Data Point**: Specific data point indicating an event rate change
- **Median**: Horizontal line indicating the median rate of events
Detecting Variation on a Run Chart

- Seven or more consecutive points on either side of the center line (median).
- Five or more consecutive points increasing or decreasing.
- Fourteen or more consecutive points alternating up and down.
Seven or more consecutive points on either side of the median.
Five or more consecutive points increasing or decreasing.
Rates of Ventilator-associated Events, January 2011 to July 2012

Fourteen or more consecutive points alternating up and down.
Anatomy of a Control Chart

- A little more complex
- Use when you have >25, but <50 data points
Rates of CLABSI, January 2011 to January 2013

- Mean
- +1 SD
- -1 SD
- +2 SD
- -2 SD
- +3 SD
- -3 SD

Data Point

Upper Control Limit (UCL)

Lower Control Limit (LCL)

Center Line (CL)

Rate Per 1,000 Line Days
Detecting Variation on a Control Chart

- Any point above the Upper Control Limit (UCL) or below the Lower Control Limit (LCL).
- One of two points above +2 SD or below -2 SD.
- Four of five points above +1 SD or below -1 SD.
- Eight consecutive points above or below the Center Line (CL).
- Six consecutive points increasing or decreasing.
- Fifteen consecutive points between +1 SD and -1 SD.
- Fourteen consecutive points alternating up and down.
- Eight consecutive points above +1 SD and/or below -1 SD.
Tests for Control

Source: Lloyd S. Nelson, Director of Statistical Methods, Nashua Corporation, New Hampshire
Common Questions for Investigating an Out-of-Control Process

- Are there differences in the measurement accuracy of instruments/methods used?
- Are there differences in the methods used by different personnel?
- Is the process affected by the environment (e.g., temperature, humidity)?
- Has there been a significant change in the environment?
- Is the process affected by predictable conditions (e.g., tool wear)?
Common Questions for Investigating an Out-of-Control Process

- Were any untrained personnel involved in the process at the time?
- Has there been a change in the source for input to the process?
- Is the process affected by employee fatigue?
- Has there been a change in policies or procedures?
- Is the process frequently adjusted?
- Did samples come from different parts of the process? Shifts? Individuals?
- Are employees afraid to report “bad news”?
Risk-Adjusted Comparisons
Standardized Infection Ratio

- Used as a way to statistically compare healthcare-associated infection experiences in a hospital to national hospital data.
- Used to compare a facility to itself over time.
- Can look at risk for specific locations and infection type in a facility.
Standardized Infection Ratio

- Standardized infection ratio (SIR) - a risk-adjusted summary measure to track HAIs at a national, local, and state level over time.
- There are SIR for three types of HAIs
  - Device associated infections, such as Catheter-associated urinary tract infections (CAUTIs)
  - Procedure-associated infections, such as surgical site infections (SSI) or Central Line-associated Bloodstream Infection (CLABSI)
  - Laboratory-identified events (LabID), such as *C. diff* infection (CDI)
Standardized Infection Ratio

Standardized infection ratio (SIR) = \( \frac{\text{Observed (O)}}{\text{Expected (E)}} \)

SIR >1 indicates there are more HAIs than are expected
SIR <1 indicates there are less HAIs than are expected
# predicted CAUTI= urinary catheter days \( \times \) NHSN Pooled mean \( \frac{1,000}{1,000} \)

# predicted CAUTI= 789 urinary catheter days \( \times \) \( \frac{2.0}{1,000} \) = 1.578
Hypothesis

- A null hypothesis ($H_0$) is a statement, in which there is no relationship between two variables.
- An alternative hypothesis ($H_a$) is statement in which there is some statistical significance between two measured phenomenon.
Type I vs. Type II Error

- A type I error (false-positive) occurs if an investigator rejects a null hypothesis that is actually true in the population;
- A type II error (false-negative) occurs if the investigator fails to reject a null hypothesis that is actually false in the population.
Alpha and Beta

- Alpha ($\alpha$) level is the probability of rejecting the null hypothesis when the null hypothesis is true. (Type I error)
- Beta ($\beta$) level is the probability that we would accept the null hypothesis even if the alternative hypothesis is actually true. (Type II error)
Null hypothesis

Observed Value

Confidence Interval

Healthy Choices. Healthy People. Healthy Communities.
Quality Concepts

- Healthcare quality improvement uses interdisciplinary teams
- Quality improvement is broad and continuous
- Toolbox includes a variety of tools
- Performance improvement focuses on patient clinical outcomes, customer satisfaction and service
- Continuous surveillance
Performance Improvement Teams

- Interdisciplinary
- Team leader (management), subject matter experts including front line employees
- Continuous
- Use systematic programs and tools to determine outcomes
- Determine the best methods to achieve desired outcomes
- Performs observational audits, root cause analysis, benchmark comparisons, create guidance teams, surveillance oversight
Quality Toolbox

- Strategic Plan
- Gap Analysis
- Root Cause Analysis
  - Fishbone Diagram
- Strengths, Weaknesses, Opportunities, Threats
- Failure Mode Effect Analysis
- Process Control, Charts, Graphs, Clinical Practice Guidelines
- Plan, Do, Study, Act
Gap Analysis

Current State → GAP → Desired State

Key steps to bridge gap

Action Plan
Root Cause Analysis

A process used to find the origin of a problem to identify the best solutions. Look beyond surface-level issues or symptoms to the underlying cause of the problem.

- Focus on how and why the incident occurred, instead of who is responsible
- Focus on the most recurring incidents, especially when there are lots of symptoms of the underlying issue
- Gather information to clearly identify the root cause
- Create a plan to prevent the root cause from recurring in the future
- Use a simple, proven, repeatable process
Ishikawa Diagram (Fishbone)

Use to identify various compartments and specific actions that contribute to the problem.

A good way to illustrate elements that can be improved.

CC-BY 2021 with attribution link to https://www.getguru.com/templates/root-cause-analysis-template
Failure Mode Effect Analysis

Proactive, preventative approach to identify potential failures and opportunities for error.

1. Determine the process or topic to study
2. Convene a multidisciplinary team
3. Develop a flow diagram that clearly identifies each step
4. Brainstorm possibilities for failure and rate using Likert scale
5. Team determines actions to take
6. Identify outcomes measures to test the redesigned process
Strengths, Weaknesses, Opportunities, Threats (SWOT)

How to Do a SWOT Analysis

**Internal**
- **Strengths**
  - What do we do well?
  - What have our customers or partners told us they like about us?
  - In what areas do we outpace our competitors?
  - What’s unique about our business, products, or services?
  - What assets do we own? (Intellectual property, proprietary technology, capital)
- **Weaknesses**
  - What can we improve?
  - What are our customers or partners dissatisfied with?
  - Where do we fall behind our competitors?
  - Where are we lacking in knowledge or resources?

**External**
- **Opportunities**
  - What emerging trends can we take advantage of?
  - Which of our strengths might be valuable to potential partners?
  - What adjacent markets might we tap into?
  - Are there geographic locations with less competition?
- **Threats**
  - What is our competition doing?
  - How could our weaknesses leave us vulnerable?
  - What market trends are we unprepared for?
  - What economic or political issues could impact our business?

IPs use SWOT to investigate public health issues and improve healthcare outcomes.
Plan, Do, Study, Act (PDSA)

The cycle encourages continuous planning, developing, analysis, and re-evaluation of processes.
Clinical Practice Guidelines (Operating Procedures)

Interdisciplinary teams develop or direct the development of Clinical Practice Guidelines.

- Standardize practice
- Reduce variance
- Improve clinical outcomes
- Determine how to disseminate and implement guidance
- Incorporate evidence-based clinical practice guidelines
- Goal to insure optimal outcomes
Questions for Review
An IP is evaluating her control chart and notices that several points in a row are above the mean line. This probably indicates:

a. The mean is incorrectly calculated.
b. S/he should investigate potential sources of special cause variation.
c. There is common cause variation in her process and it requires no correction.
d. She is using the incorrect type of control chart.
B. She should investigate potential sources of special cause variation.

Eight consecutive points above or below the mean is a sign that the process is out of control. The IP should use this information to determine what the issue may be and adjust quality.
Last year, a hospital identified 21 CLABSIIs. Which type of chart would be most useful to provide feedback regarding the effectiveness of CLABSI reduction strategies?

a. Control chart  
b. Pie chart  
c. Run chart  
d. Display of normal distribution and standard deviation
C. Run chart

A run chart can help identify upward and downward trends and it can show a general picture of a process.

Control charts are more sensitive at detecting abnormalities, but require at least 25 data points for reliability and validity. Run charts require at least 20 points. With such a small number of observations in our data set, the run chart would be the most appropriate choice.
Which letter labels the areas under the curve that represent special cause variance in healthcare-associated CLABSI?

a. K
b. L
c. M
d. N
D.  N

Special cause variation is variation that lies more than 3 standard deviations outside the mean of the sample distribution. Common cause variation represents variation within 3 standard deviations of the mean.
True or False. A common cause variation is one that is caused by significant changes in or related to the process.
FALSE.

A common cause variation is one that is inherent to a process. A special cause variation is caused by significant changes in or related to a process, such as external factors.
The IP is reviewing her control chart for *C. diff* toxin-positive specimens and notices that the last 6 data points have been decreasing, meaning infections are happening less frequently than expected. This indicates:

a. The process is out of control. The IP should investigate to determine the cause of variation.

b. The process is in control. This is likely due to new disinfection procedures that staff has been training on over the last few months which has resulted in fewer infections.

c. The process is in control. The IP should continue to monitor.
A. The process is out of control. The IP should investigate to determine the cause of variation.

The process is considered out of control, but is providing a “good” result. If the same rule were violated with 6 data points consecutively increasing, the IP should investigate for issues. The provided training is likely the cause of a special cause variance. Since these points are due to some external influence, we don’t want those points influencing the mean and SD of the points that are due to common causes. We should remove these points, recalculate the mean and SD, then monitor again.
The hospital IP believes there may be more SSI associated with OR 1 compared to OR 2. The IP concludes that the SSI rate in OR 1 and OR 2 are equal, but in reality they are not equal. What type of statistical error has been committed:

a. No error has been committed.
b. Type I error.
c. Type II error.
d. An error equal to $\alpha$. 
C. Type II error.

A type II error (false-negative) occurs if the investigator fails to reject a null hypothesis that is actually false in the population. The IP concluded that OR 1 and OR 2 rates were equal, so she did not reject the null hypothesis, but in reality they are not equal so the null hypothesis should have been rejected.
The hospital IP has been tracking SSI over the past year and determined the hospital had 46 SSI in the ICU. The previous 5 years the ICU has seen an average of 30 SSI and 40 SSI not in the ICU. What should the IP not do?

a. Continue to monitor SSI in the ICU for the next year.
b. Educate staff on proper wound care.
c. Swab and test ICU rooms to determine the cause of SSI.
d. Ensure surgical instruments are being sterilized appropriately.
C. Swab and test ICU rooms to determine cause of SSI.

The SIR is greater than 1 (46/30=1.5), indicating that the hospital is experiencing more HAIs than is to be expected. The IP should continue to monitor SSI in the ICU for the next year to determine if SSI in the ICU have decreased after implementing infection reduction strategies, educate staff on proper wound care to reduce SSI, and ensure surgical instruments and being sterilized appropriately.
After reviewing a 6-month run chart of the incidence of CLABSI infections in the Adult ICU, the manager asks the Infection Preventionist for assistance in reducing the number of central line infections. Which of the following should the IP recommend:

a. Monitor the run chart for a 3 more months.

b. Provide an inservice to all nurses on CLABSI prevention.

c. Create an Intravascular team.

d. Develop a multidisciplinary team to review and implement best practices.
D. Develop a multidisciplinary team to review and implement best practices.

Multidisciplinary teams are a valuable tool in deploying a quality focused culture or process. Successful teams increase problem solving and efficiency, raise morale and productivity, use integrative rather than imposed solutions, and increase acceptance of solutions.
An Infection Preventionist has been assigned to co-facilitate in a root cause analysis of an adverse event in collaboration with the Performance Improvement team. What process improvement tool would be the best method to outline the possible causes of the adverse event?

a. Brainstorming  
b. Plan, Do, Study, Act  
c. Run Chart  
d. Ishikawa Diagram
D. Ishikawa diagram

Also, called a Fishbone diagram, an Ishikawa diagram allows a team to identify, explore and graphically display all of the possible causes related to the problem to discover the root cause or causes.
What is an example of actions taken during the Do phase of the “Plan, Do, Study, Act” Performance Improvement Model?

a. Conducting an observational audit of physician hand hygiene practices.
b. Trending and benchmarking the data collected.
c. Making a Fishbone Diagram.
d. Making tweaks to a pilot program.
A. Conducting an observational audit of physician hand hygiene practices—Do

B. Trending and benchmarking the data collected—Study
C. Making a Fishbone diagram—Plan
D. Making tweaks to a pilot program—Act
Managing infection prevention outcomes, analyzing trends, implementing and evaluating strategies, and developing best practices to achieve accreditation standards are all components of:

a. Gap Analysis
b. Peer review
c. Performance Improvement
d. Medical Review Process
C. Performance Improvement

Performance Improvement is measuring the output of a particular process or procedure, then modifying the process or procedure to increase the output, increase efficiency, increase the effectiveness, improve customer satisfaction, and improve safety. It is continuous and uses tools for measurement.
After an accident in which human milk from one mother was mistakenly fed to the infant of another mother, the infection preventionist is tasked with leading a team to determine how and why the event occurred and develop a plan to prevent this from occurring in the future. This process is called:

a. Strength, Weaknesses, Opportunity, Threat Analysis (SWOT)
b. Gap analysis
c. Six sigma analysis
d. Root cause analysis
D. Root cause analysis

Root cause analysis takes a retrospective look at an adverse outcome and determines what happened, why it happened, and what the organization can do to prevent the event in the future.