Using Data to Inform Quality Improvement

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Disclosures

• None of the presenters today have relevant personal or financial conflicts of interest.

• All of us have screwed up quality improvement projects through poor data management.
Outline

• Ethan: Measures and measurement

• Aparna: Data use in research and QI

• Justin: Challenges in data interpretation

PROTECTING PROVIDERS AND PATIENTS THROUGH BETTER MEASUREMENT

Reducing unnecessary physician alerts
Objectives

1. Define outcome, process, and balance measures for QI projects

2. Identify balance measures to assess potential unintended consequences

Venous Thromboembolism (VTE)

• VTE are common, bad, and preventable

• They are tracked through core measures:
  – Floor patients on appropriate prophylaxis (VTE-1)
  – ICU patients on appropriate prophylaxis (VTE-2)
  – Preventable hospital-acquired VTE (VTE-6)
Our local process

- We designed (several) Epic Best Practice Advisories (BPAs) to identify patients with at least one VTE risk factor and no prophylaxis

- Measures
  - % of patients receiving appropriate VTE prophylaxis (VTE-1, VTE-2)
  - # of patients with preventable VTE (VTE-6)

Did the process work?

- The designers said “yes”
  - Performance on prophylaxis > 90%
  - There were 0 preventable VTE detected

- BUT...
  - The alert fired 1200 times weekly
  - Only 11% of patients with alerts received pharmacoprophylaxis during their stay
  - Most ACTUAL hospital-acquired VTE were missed
The conundrum: broken measures

- Excessive alerts were a major provider complaint and a safety hazard
- Attempts to decrease alerts were vetoed as a potential risk to patient safety
- Core measure safety data was delayed by 3-6 months...and few patients were evaluated
- Measure performance ≠ Clinical performance

The importance of measurement

- Don’t take this for granted

- Reasons to make good measures
  - Tells you if you’re succeeding
  - Helps share your results with leadership
  - Helps align your stakeholders behind your mission
Writing measures

• Identify measures that cover all aspects of your project:
  – Outcomes measures: What do you want to change?
  – Process measures: Is your change happening?
  – Balance measures: Is your change causing harm?

• Create “operational” measures
  – WHAT are you measuring?
  – HOW will you measure?
  – Analogous to “outcomes” in scientific literature

Which is the most essential element of a good balance measure?

A. Accurately reflects potential negative consequences

B. Easy to measure

C. Is relevant to patient outcomes

D. Makes me look good to senior leadership
Which is the most essential element of a good balance measure?

A. Accurately reflects potential negative consequences.

B. Easy to measure.

C. Is relevant to patient outcomes.

D. Makes me look good to senior leadership.

E. All of the above.
Our challenge: Fix VTE alerts!

• Create new measures that could:
  – Track our VTE prophylaxis performance in near-time
  – Safeguard patients from harm
  – Determine how often alerts fired
  – Obtainable with minimal effort

Enter eCQM

• Electronic Clinical Quality Measures

• Automated evaluation of performance on ALL qualifying patients

• Can be translated into a daily or weekly report for near-time performance evaluation
The Project

• Aim: Maintain current VTE performance while reducing provider alerts by 50% in the next 6 months

• Our Measures:
  – Outcome: Weekly performance on VTE eCQM
  – Process: Weekly # of VTE BPAs
  – Balance: ????

Which of the following would be a good “balance measure” for this project?

A. VTE prophylaxis core measure failures

B. % of alerts resulting in new prophylaxis orders

C. % of patients eligible for VTE prophylaxis

D. # of hospital-acquired VTE
How to write a balance measure?

• Understand your process
  – Consider making a map

• Invoke Murphy’s law

• Find your critics
OUR RESULTS

Results: VTE-1 Compliance Rates

Rate per Week

Baseline
Mean: 79%

Cycle 1
Mean: 77%

Cycle 2
Mean: 78%

Jan-17 Feb-17 Mar-17 Apr-17 May-17 Jun-17
Results: Weekly provider alerts

- **Baseline**
  - Mean: 1,194

- **Cycle 1**
  - Mean: 722

- **Cycle 2**
  - Mean: 615

% inpatients eligible for prophylaxis

- **Baseline**
  - January 2017: 48%
  - February 2017: 47%
  - March 2017: 46%

- **Cycle 1**
  - April 2017: 47%

- **Cycle 2**
  - May 2017: 46%
Summary

• There was no change in VTE core measure compliance...but auto-detected rates were much lower than manually audited rates

• VTE alerts were decreased by 48% after 2 rounds of improvements

• There was no change in the number of patients who were disqualified for VTE prophylaxis

Conclusions

• Data can ensure that process improvement doesn’t compromise patient safety

• Understand your process before you start making changes

• Design your measures to demonstrate both the benefits and (potential) harms of your change
QUALITY IMPROVEMENT OR RESEARCH?

Objectives

1. Compare traditional research and quality improvement methodology

2. Contrast the measurement of data in research and quality improvement
Improving medication reconciliation at a local hospital

The need: patient safety
  • Local cases
The evidence

- Overwhelming published evidence:
  - MARQUIS Study
- A systematic review reported that the use of clinical pharmacists in the inpatient setting improved the quality, safety, and efficiency of care
- Pharmacist-supported medication reconciliation programs, especially when performed in close collaboration with the physician team have been shown to reduce medication discrepancies and improve post-hospital healthcare utilization

Environmental scan: informal survey of physicians and pharmacists

- Discharge medication reconciliation process at our hospital:
  - Not standardized
- Collaborative medication reconciliation efforts between physicians and pharmacists were lacking although pharmacy students (supervised by clinical pharmacists) were part of the resident teams
- Anecdotal evidence and no actual data to assess trends
- Barriers with trying to obtain baseline data by retrospective chart review process
Next steps: QI vs. Research?

Determining QI versus research

• Direct benefits to patients involved
• Imposition of additional risks or burdens
• Will the activities occur within the standard of care
• Is the project primarily intended for generalizable knowledge
• Does the project involve vulnerable population

1. Casarett et al. Determining when quality improvement initiatives should be considered research. JAMA. 2000;283:2275-2280
### Research vs. QI

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Quality Improvement</th>
<th>Clinical Research with Human Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Background</td>
<td>Describes the nature and significance of the local problem.</td>
<td>Identifies a specific deficit in scientific knowledge from the literature.</td>
</tr>
<tr>
<td></td>
<td>Focus is to improve a specific aspect of health or healthcare delivery that is currently NOT consistently and appropriately being implemented at this site.</td>
<td>Proposes to address or identify specific hypotheses in order to develop new knowledge or advance existing knowledge</td>
</tr>
<tr>
<td>Methods</td>
<td>Mechanisms of the intervention are expected to change over time (i.e., an iterative activity) in response to ongoing feedback</td>
<td>Specific protocol defines the intervention, interaction, and use of collected data and tissues, plus project may rely on the randomization of individuals to enhance confidence in differences</td>
</tr>
<tr>
<td></td>
<td>Plan for intervention and analysis includes an assessment of the system(s), process flow diagram, flowchart, etc. and the context.</td>
<td>May use qualitative or quantitative methods to make observations, make comparisons between groups, or generate hypotheses</td>
</tr>
<tr>
<td></td>
<td>Statistical methods evaluate system level processes and outcomes over time with statistical process control or other methods.</td>
<td>Statistical methods primarily compare differences between groups or correlate observed differences with a known health condition</td>
</tr>
<tr>
<td>Intended Benefit</td>
<td>Intervention would be considered within the usual clinician-patient therapeutic relationship</td>
<td>Intervention, interaction, or use of identifiable private information occurs outside of the usual clinician-patient therapeutic relationship</td>
</tr>
<tr>
<td></td>
<td>Direct benefit to participants is indicated (e.g., decrease in risk by receiving a vaccination or by creating a safer institutional system)</td>
<td>Direct benefit to each individual participant or for the institution is not typically the intent or is not certain</td>
</tr>
<tr>
<td></td>
<td>Potential local institutional benefit is specified (e.g., increased efficiency or decreased cost)</td>
<td>Potential societal benefit in developing new or advancing existing knowledge</td>
</tr>
</tbody>
</table>

Measuring patient data for a project is always considered research

A. True
B. False
Intent to publish is considered research

A. True

B. False
Overlap: Research and QI

- Systematic data guided activities

- Generalizable knowledge (the intent to publish or actual publication does not make a QI activity into a research study)

Hastings report 2006. Ethics of using QI methods to improve healthcare quality and safety

PROJECT AIM

Evaluate the effectiveness of supervised pharmacy students in improving the safety of discharge process by detecting discharge medication reconciliation errors
Intervention

- QI project
- Setting: Pilot project to involve 4 inter-professional teams involving resident physicians, pharmacy students and their supervisors.
- Design:

  Initial 2X2 cross over design (to include 2 control and 2 intervention teams) changed after 2 PDSA cycles and all 4 teams included in the intervention for the subsequent period
Metrics

- Process measures:
  - Time taken to complete the medication reconciliation process
- Outcome measures:
  - Number of patients with errors as identified by pharmacists
  - Number of errors as identified by pharmacists
  - Probability of a change being made to the medication list by the physician given there was a pharmacy-identified error
- Balance measures:
  - Time taken from completion of medication reconciliation to patient discharge

Patient consent is needed for measuring patient data for projects

A. Yes
B. No
C. Maybe
D. I don’t know
Common rule - Updated

• Informed consent is required by default except when:
  – Research involves no more than minimal risk to the subjects
  – Waiver or alteration will not adversely affect the rights and welfare of the subjects
  – Research could not be practicably carried out without the waiver or alteration
  – Subjects whenever appropriate will be provided with additional pertinent information about participation

• When in doubt check with institutional IRB or equivalent entity for evaluating QI projects.
Measurement for research vs. QI

<table>
<thead>
<tr>
<th></th>
<th>Measurement for research</th>
<th>Measurement for QI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tests</strong></td>
<td>One large blind test</td>
<td>Many sequential, observable tests</td>
</tr>
<tr>
<td><strong>Biases</strong></td>
<td>Control for as many as possible</td>
<td>Stabilize the bias from test to test</td>
</tr>
<tr>
<td><strong>Data</strong></td>
<td>Gather as much as possible, “just in case”</td>
<td>Data to learn and complete another cycle</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>Can take long periods of time to obtain results</td>
<td>Small tests of significant changes accelerate the rate of improvement</td>
</tr>
</tbody>
</table>

Data to prove effectiveness in QI (pre and post measurements research design) does not lead to sustainable improvement of health system.

Continuous QI involves cycles of testing with continuous measurement of the metric of interest.

http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementEstablishingMeasures.aspx

Results

- Intervention period: 11/2016 to 6/2017
- Total number of patients discharged with the new process: 322
- Total number excluded from the final n = 12 (3 duplicates, 1 missing information, 8 with errors)
## Results

### Error identified

<table>
<thead>
<tr>
<th>Error identified</th>
<th>Total N = 322</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>256 (79.50%)</td>
</tr>
<tr>
<td>Yes</td>
<td>66 (20.50%)</td>
</tr>
</tbody>
</table>

- Types of errors:
  - **Duplication**: 12 (12.63%)
  - **Improper dose**: 15 (15.78%)
  - **Improper frequency**: 14 (14.74%)
  - **Improper form**: 5 (5.26%)
  - **Improper quantity**: 4 (4.21%)
  - **Not covered by insurance**: 6 (6.32%)
  - **Drug-drug interaction**: 3 (3.16%)
  - **Unintentional omission**: 5 (5.26%)
  - **Improper medication selection**: 6 (6.32%)
  - **Other error**: 25 (26.32%)

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## Results

### Pharmacy recommended change to DC med list after physician medication reconciliation

<table>
<thead>
<tr>
<th>Pharmacy recommended change to DC med list after physician medication reconciliation</th>
<th>Total N = 322</th>
</tr>
</thead>
<tbody>
<tr>
<td>No recommendation</td>
<td>256 (79.50%)</td>
</tr>
<tr>
<td>Physician did not agree w/ recommendation</td>
<td>18 (5.59%)</td>
</tr>
<tr>
<td>Recommendation led to change</td>
<td>48 (14.91%)</td>
</tr>
</tbody>
</table>
Results

• Probability of an error is $\frac{66}{322} = 0.2050$
  • Standard Error = 0.0225
  • 95% exact confidence interval of (0.1622, 0.2532)

• Probability of a change being made to the med list given there is an error is $\frac{48}{66} = 0.7273$
  • Standard Error = 0.0548
  • 95% exact confidence interval of (0.6036, 0.8297)

• Patients who have a higher number of discharge meds are more likely to have an error ($p=0.0010$)

Conclusions

• QI and clinical research are distinct activities with some overlap

• When in doubt, consider institutional IRB or equivalent entity review of QI proposal to maintain highest ethical standards when measuring, recording, storing, and analyzing patient data
**PIE vs BAR:**
How do you like your data

**DATA MANAGEMENT**
Analyzing and presenting your data to prevent false interpretations
Objectives

1. Identify the importance of clear outcome definitions
2. Understand how the same data can tell a different story
3. Overview control charts as a data analytic tool

Project Background

• Christiana Early Warning System (CEWS)
• System concern regarding out of ICU cardiac arrest as well as RRT activations
• Risk score combines physiologic parameters with bedside assessments
• Tiered risk levels with corresponding interventions
Data Management

1. Know your baseline
   - How is the outcome defined, measured and collected
   - Are there relevant inclusion / exclusion criteria

2. Understand how audiences interpret graphs

The RRTs on unit C now exceed the RRTs on unit P
What measure would you use to compare RRTs between two units?

A. Rate of RRTs during the last month
B. Count of RRTs during the last month
C. Rate of RRTs averaged over the last 6 months
D. Count of RRTs averaged over the last 6 months

<table>
<thead>
<tr>
<th>Measure</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of RRTs during the last month</td>
<td>0%</td>
</tr>
<tr>
<td>Count of RRTs during the last month</td>
<td>0%</td>
</tr>
<tr>
<td>Rate of RRTs averaged over the last 6 months</td>
<td>0%</td>
</tr>
<tr>
<td>Count of RRTs averaged over the last 6 months</td>
<td>0%</td>
</tr>
</tbody>
</table>

Source: https://example.com/polling/123/polling-title
Number of RRT in January

- Cardiac: 24
- Pulmonary: 19
- Community: 8

# of Step-down RRT in January

- Cardiac: 25
- Pulmonary: 20
- Community: 10

Rate of Step-down RRT in January

- Cardiac: 20
- Pulmonary: 15
- Community: 10
Rate of Step-down RRT in January

6 month average RRT rate

Monthly RRT Rate
Data Management

1. Know your baseline
   - How is the outcome defined, measured and collected
   - Are there relevant inclusion / exclusion criteria
2. Understand how audiences interpret graphs
3. Is the process stable
Control Chart Basics

- Based on statistical process control work of Deming
- Define process mean and variability (control limits)
- Ideally have 20-25 points
- Sample size
  - Rate: \( 4/rate = N \)
  - Rare: Each point \( \sim 4 \) events

Control Chart Tests

1. Single point outside a control limit
2. 2 out of 3 consecutive points are on the same side of the mean and \( > 2 \) SD from mean
3. 8 consecutive points fall on the same side of center
4. 6 or more points in a row steadily increasing or decreasing
Data Management

1. Know your baseline
   - How is the outcome defined, measured and collected
   - Are there relevant inclusion / exclusion criteria
2. Understand how audiences interpret graphs
3. Is the process stable
4. Post-implementation monitoring
What measure would you use to compare RRTs between two units?

A. Rate of RRTs during the last month

B. Count of RRTs during the last month

C. Rate of RRTs averaged over the last 6 months

D. Count of RRTs averaged over the last 6 months
Conclusions

• Define all project measures clearly

• Don’t only use your data to tell a good story, but tell the right story

“I see you’re still fishing for that key piece of data.”

Additional Material
Control Chart Selection

1. Discrete / Attribute Data
   - Defects?
     - Multiple Defects / Unit
       - Defect Type?
         - Constant: C-Chart
         - Variable: U-Chart
     - Single Defect / Unit
       - Subgroup Type?
         - Constant: I Chart
         - Variable: X(Bar)-R Chart
       - Subgroup Size?
         - N=1
         - N=2 to 9
         - N >= 10
   - Continuous / Discrete Data?

2. Continuous Data
   - Subgroup Size?
     - N=1
     - N=2 to 9
     - N >= 10

3. Continuous / Continuous Data
   - Defects?
     - Multiple Defects / Unit
       - Defect Type?
         - Constant: C-Chart
         - Variable: U-Chart
     - Single Defect / Unit
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