Measuring Patient Safety: How Do We Know We Are Safer?

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Section A

Measuring Safety: Theory and Practice
Have we made progress in improving safety now, six years after “To Err Is Human”?

How would we know?
Outline

- Where does safety fit into quality?
- Understand challenges to measuring safety
- Understand an approach to measuring safety
Domains of Quality

- Safety
- Effectiveness
- Patient centeredness
- Efficiency
- Timeliness
- Equity

“Measures are lenses to evaluate these domains”
— IOM. Crossing the Quality Chasm.
Have we created a culture of safety?

**Structure**
- Have we reduced the likelihood of harm?

**Process**
- How often do we do what we are supposed to?

**Outcome**
- How often do we harm?

**Context**
- Have we created a culture of safety?
Example

- Structure
  - Presence of a smoking cessation program or materials

- Process
  - Percentage of smoking patients given smoking cessation materials, total time spent in smoking cessation counseling

- Outcome
  - Percentage of patients who quit smoking, cardiovascular event rates
Attributes of System-Level Measure for an Organization

- Scientifically sound, feasible, important, usable
- Apply to all patients
- Aligned with value; encourage desired behaviors
- Meaningful to front-line staff who do the work
Balancing Theory and Practice

Scientifically sound — Feasible

Central mandate

Local wisdom
What Can Be Measured As a Valid Rate?

- Rate requires
  - Numerator—event
  - Denominator—those at risk for event
  - Time
- Minimal error
  - Random error
  - Systematic error
    - Bias
    - Confounding
Bias: Systematic Departure from Truth

- Selection bias
  - Do not capture all events or those at risk for event
- Information bias
  - Errors in measuring event or those at risk for event
  - Missing data/loss to follow-up
- Analytic bias
Bias: Systematic Departure from Truth

- Selection bias
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Safety Measures

- Measures valid as rates
  - How often do we harm patients?
  - How often do we do what we should?

- Non-rate measures
  - How do we know we learned from defects?
  - Have we created a culture of safety?
    ▶ Safety Attitudes Questionnaire (SAQ)
Section B

Examples of Process Measurement and Outcomes
<table>
<thead>
<tr>
<th></th>
<th>2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often we did harm (BSI)</td>
<td>2.8/1000</td>
</tr>
<tr>
<td>How often we do what we should</td>
<td>86%</td>
</tr>
<tr>
<td>How we know we learned</td>
<td>?</td>
</tr>
<tr>
<td>Safety climate</td>
<td>2.6%</td>
</tr>
<tr>
<td>Teamwork climate</td>
<td>2.6%</td>
</tr>
</tbody>
</table>
Outcome Measures: How Often Do We Harm?

- $V_{\text{outcome}} = V_{\text{data quality/definition/methods of collection}} + V_{\text{quality}} + V_{\text{case mix}} + V_{\text{chance}}$
- Health care acquired infections as model
  - National definitions
  - Infrastructure within hospitals to monitor
- Any self-reported measure should be interpreted with caution


$V = \text{variance}$
# How to Measure Medication Safety

<table>
<thead>
<tr>
<th>Study</th>
<th>Number studied</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Assessed by</th>
<th>Rate of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leape et al. (1991). <em>NEJM.</em></td>
<td>30,195 records</td>
<td>Disabling adverse events</td>
<td>Per record reviewed/admission</td>
<td>Physician Reviewer</td>
<td>3.7 per 100 admissions</td>
</tr>
<tr>
<td>Lesar and Briceland. (1990). <em>JAMA.</em></td>
<td>289,411 medication orders/one year</td>
<td>Prescribing errors</td>
<td>Number of orders written</td>
<td>Physicians</td>
<td>3.13 errors for each 1,000 orders</td>
</tr>
<tr>
<td>Lesar, Briceland, and Stein. (1997). <em>JAMA.</em></td>
<td>One year of prescribing errors detected and averted by pharmacist</td>
<td>Prescribing errors</td>
<td>Per medication orders written</td>
<td>Pharmacists, retrospectively evaluated by a physician and two pharmacists</td>
<td>3.99 errors per 1,000 orders</td>
</tr>
<tr>
<td>Cullet et al. (1997). <em>Crit Care Med.</em></td>
<td>4,031 adult admissions over six months</td>
<td>Adverse drug events</td>
<td>Number of patient days</td>
<td>Self report by nurse and pharmacists, daily review of all charts by nurse investigators</td>
<td>19 events per 1,000 ICU patient days</td>
</tr>
</tbody>
</table>
Process Measures: Frequency of Doing What We Should

- Implicit peer review
- **Explicit review**—adherence to criteria
- Direct observation
- Clinical vignettes
- Standardized patients
Explicit Review

- Criteria are developed by peers through review of evidence
- Expert judgment applied in measure development phase rather than in review phase
- Quality judgment is incorporated into criteria
Process Measures: Example

- Ventilated patients (ventilator bundle)
  - Prevention of VAP
  - Appropriate PUD prophylaxis
  - Appropriate DVT prophylaxis

- Acute myocardial infarction
  - Beta blockers
  - Aspirin
  - Cholesterol-lowering drug
Validity of Measure: Important to Consumers of Data?

- Increase validity
  - Standard definitions (selection bias)
  - Standard data collection tools (information bias)
  - Standard analysis (analytic bias)
  - Defined study sample
  - Minimize missing data
- Attempt to minimize burden
  - Sampling (risk selection bias)

Reduce noise so we can detect signal
Design Specifications

- Who will collect the measure?
- What will they measure?
- Where will they measure it?
- When will they measure it?
- How will they measure it?
Presenting Data

- Annotated run chart
- Graph tells story
- Unit of analysis should be as frequent as you provide test and provide feedback
CR-BSI Rate

How We Know We Learned from Mistakes

- Measure presence of policy or program
- Staff’s knowledge of policy or program
- Appropriate use of policy or program

- If policy or program involves communication, likely need to observe behavior to determine if used appropriately
- Measures early in development
Examples

- Measure policy or program
  - Pacing kit present
- Measure knowledge of policy or program
  - Central line certification test
- Measure use of policy or program
  - Observe OR briefings
Have We Created Safe Culture?

- Annual assessment of culture of safety
- Evaluates staff’s attitudes regarding safety and teamwork
- Safety Attitudes Questionnaire
How has this been applied?
**Keystone ICU Safety Dashboard**

<table>
<thead>
<tr>
<th>Category</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often we did harm (BSI)</td>
<td>2.8/1000</td>
<td>0</td>
</tr>
<tr>
<td>How often we do what we should</td>
<td>86%</td>
<td>92%</td>
</tr>
<tr>
<td>How we know we learned</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>Safety climate</td>
<td>2.6%</td>
<td>5.3%</td>
</tr>
<tr>
<td>Teamwork climate</td>
<td>2.6%</td>
<td>8%</td>
</tr>
</tbody>
</table>
System-Level Measures of Safety

- Cascading measures
  unit → department → hospital → system
- Methods evolving
“Ultimately, the secret of quality is love. You have to love your patients, you have to love your profession, you have to love your God. If you have love, you can work backward to monitor and improve the system.”

— Donabedian, Health Affairs