Patient Safety: Challenges and Ways to Overcome Them with a Systems-Based Approach

It’s Not Rocket Science

James P. Bagian, M.D., P.E.
Director
Center for Healthcare Engineering & Patient Safety
University of Michigan
jbagian@med.umich.edu
Objectives

• Define Goal
• Identify Challenges
• Discuss Tools and Approaches to Achieve Goals to Evolve into a High Reliability Organization
  – Examples
• Identify the Role that Leaders at All Levels Must Play to Make a Culture of Safety Integral to the Fabric of the Organization
• Goal – Prevent Inadvertent Harm To Patient While Under Our Care
Crossing the Global Health Care Quality Chasm
A Key Component of Universal Health Coverage

Despite years of investment and research, the quality of health care in every country is much worse than it should be. Problems range from disrespect of people when they are interacting with the health care system, to preventable mistakes and harm, to high rates of incorrect and ineffective treatment.

Among low- and middle-income countries (LMICs), the exact burden of poor quality is difficult to quantify because of a dearth of data, lack of standard metrics, and insufficient research on quality interventions. But new estimates suggest that globally between 5.7 and 8.4 million people die every year from poor-quality care in LMICs. These deaths, plus disabilities from poor-quality care, account for lost productivity totaling an estimated $1.4 trillion to $1.6 trillion dollars annually.

Wealthier countries have similar experiences in terms of death, disability, and needless cost due to fragmented care, waste, and care organized around facilities instead of patients. One estimate suggests that 15% of all hospital costs in Organisation for Economic Co-operation and Development (OECD) countries can be attributed to patient harms from adverse events.

In 2001, the Institute of Medicine published a landmark report on the quality of US health care: Crossing the Quality Chasm: A New Health System for the 21st Century. The report starkly documented major defects in 6 dimensions of quality: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. In the fundamental principles of design and human factors. The route to improvement places the "user"—patient, individual, community—at the center. This report recommends design principles that include full transparency, co-design with users, staff, and communities; care that is anticipatory, not merely reactive; care reflective of societal values; and care that bases decisions on clear evidence, continuous feedback, and learning (Box).

Redesign like this is evident, for example, in Kenya's Clinical Information Network, which was developed in 2013 as a mechanism to promote continuing improvement. Their leaders understand that health care is a complex adaptive system that requires multidisciplinary work, soft skills, and flexibility for ongoing change.

The NASEM report's idealized system empowers health care workers to solve problems at the front lines of care and integrates and coordinates care across the patient's "journey." Adherence to these principles supports a "learning health care system"—one that learns from both successes and failures and encourages innovation. This culture of continuous learning demands strong leadership, commitment, cooperation, and feedback to continually update policies, protocols, and systems.

Leveraging Universal Health Coverage
The path to achieving effective universal health coverage will be different for every country, but existing levers can be used in almost any setting to ensure and improve health care quality. This may include measures such as training and workforce development, the use of technology, and the incorporation of continuous feedback and learning systems. These strategies can work in tandem with the principles outlined in the NASEM report to improve health care quality and access across the globe.
Where Healthcare Was/Is

• Cottage Industry Mentality
• Virtually Total Reliance on:
  – Professional/Individual Responsibility
  – Individual Perfection
  – Train and Blame
• Little Understanding of Systems Relative to People and Processes
  – Ignorance vs Arrogance

Culturally Different!!!!
Typical Approach

• New Policies, Regulations, Reporting Systems, Training
• Good First Step But.....
  – Lack of Systems Insight
  – Superficial Solutions (?Answers)
  – Inadequate Follow-Up
  – Lost Opportunity
Program Elements

• Goal – Prevent Inadvertent Harm To Patient While Under Our Care
• Culture Not Compliance
• Identify Barriers
• Reporting Systems
Patient Safety System Design

- High Reliability Organizations
- Role of Reporting
  - Learning, NOT Accountability
- Systems-Based Solutions
  - Patient Centered – DUH!!!!
- Importance of Close Calls
Patient Safety System Design

THE "MISHAP DIAMOND"

Weak Program Model

Severity

Frequency

Type A

Type B

Type C

Incidents

Close Calls
Patient Safety System Design

THE "MISHAP PYRAMID"

- Type A
- Type B
- Type C
- Incidents
- Close Calls

Severity

Frequency

Strong Program Model
Corrective Actions from Close Call Reports

- Modifications/Repairs: 51%
- Training, Counseling or Increased Awareness: 26%
- Procedure Changes or Inspections: 15%
- Further Study or No Action Needed: 8%
Root Cause Analysis Reports

RCA Reports 1998 through 1999
99.95%
0.05%

RCA Reports 2000 through 2006
50.00%
50.00%

Legend:
- Red: RCA Close Calls
- Green: RCA Actual Events
Program Elements

• Goal – Prevent Inadvertent Harm To Patient While Under Our Care
• Culture Not Compliance
• Identify Barriers
• Reporting Systems
  – Learning, Not Accountability
  – Identify Vulnerabilities, Not for Counting
    – Transparency, Meaningful Feedback, Resulting Actions
• Systems-Based Solutions
Safety & Human Error: Challenges

- Healthcare Views Errors as Failings Which Deserve Blame - Fault
- Train and Blame Mentality vs Systems-Based
- Blind Adherence To Rules
- Corrective Actions Focusing on Individual
- No Blood No Foul Philosophy
Safety & Human Error: Cornerstones

• People Don’t Come to Work to Hurt Someone or Make a Mistake
• Must Keep Asking “Why?”
Safety – Human Error

LATENT FAILURES

DEFENSES
- Policies/Procedures
- Institution
- Profession
- Team
- Individual
- Technical

Triggers
- Incomplete procedures
- Production pressures
- Responsibility shifting
- Inadequate training
- Attention Distractions
- Deferred Maintenance

Clumsy Technology

Accident
Causation/Actions: Who vs. What & Why

• Who
  – ‘Whose Fault Is This?’
  – Actions focused on correcting individual
  – ‘Corrects’ only after problem occurs
  – Limited scope of action and generalizability

• What & Why
  – Actions focus on systems level causation
  – Widespread applicability
  – Stronger preventive strategy
Systematic
(5 Rules of Causation)

• Cause and Effect
• **Human Error Must Have Preceding Cause**
• **Failure to Follow Procedure By Itself Is NOT a Root Cause**
• Negative Descriptors Aren’t Actionable
• Failure To Act Is **Not** A Cause Without Pre-existing Requirement To Act

Human Factors Engineering and “Actions”

- Warnings and labels (watch out!)
- Training (don’t do that)
- Procedure changes (work around that)
- Interlock, lock-in, lock-out, etc (design it so you cannot do that – forcing functions)
- Is there one right action???
### Action Hierarchy

<table>
<thead>
<tr>
<th>Less memory or reliance on individual performance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stronger Actions</strong></td>
</tr>
<tr>
<td>Architectural/physical plant changes</td>
</tr>
<tr>
<td>New devices with usability testing before purchasing</td>
</tr>
<tr>
<td>Engineering control or interlock (forcing functions)</td>
</tr>
<tr>
<td>Simplify the process and remove unnecessary steps</td>
</tr>
<tr>
<td>Standardize on equipment or process</td>
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<tr>
<td>Tangible involvement and action by leadership in support of patient safety</td>
</tr>
<tr>
<td><strong>Intermediate Actions</strong></td>
</tr>
<tr>
<td>Redundancy</td>
</tr>
<tr>
<td>Increase in staffing/decrease in workload</td>
</tr>
<tr>
<td>Software enhancements/modifications</td>
</tr>
<tr>
<td>Education using simulation-based learning with a competency assessment completed on a recurring basis</td>
</tr>
<tr>
<td>Eliminate/reduce distractions (sterile medical environment)</td>
</tr>
<tr>
<td>Checklist/cognitive aid</td>
</tr>
<tr>
<td>Eliminate look and sound-alikes</td>
</tr>
<tr>
<td>Repeat-back/Read-back</td>
</tr>
<tr>
<td>Enhanced documentation/communication</td>
</tr>
<tr>
<td><strong>Weaker Actions</strong></td>
</tr>
<tr>
<td>Double checks</td>
</tr>
<tr>
<td>Warnings and labels</td>
</tr>
<tr>
<td>New procedure/memorandum/policy</td>
</tr>
<tr>
<td>Traditional training</td>
</tr>
<tr>
<td>Additional study/analysis</td>
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Action Assessment

• Characteristics of Actions
  – Temporary vs. Permanent
  – Procedural vs. Physical

• Action Evaluation
  – Process
  – Outcome
<table>
<thead>
<tr>
<th>Cause/Contributing Factor (CCF) Statement #1:</th>
<th>The lack of a ferromagnetic detection system at the entrance into the MR magnet room increased the likelihood that the patient’s oxygen cylinder would be permitted in the room resulting in the cylinder being drawn into the bore of the magnet, the magnet being quenched, and the MR room being out of service for 5 days.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action 1</td>
<td>Install a ferromagnetic detection system at the entrance to all four MRI magnet rooms.</td>
</tr>
<tr>
<td>Action Due Date</td>
<td>April 30, 2015</td>
</tr>
<tr>
<td>Date Action Completed</td>
<td>Pending</td>
</tr>
<tr>
<td>Responsible Person:</td>
<td>Ms. B, Facility Engineer</td>
</tr>
<tr>
<td>Process/Outcome Measure 1 (Each Process/Outcome Measure needs to include: what will be measured; how long it will be measured; and the expected level of compliance.)</td>
<td>Five ferrous objects including an oxygen cylinder will be passed by the ferromagnetic sensors of each detector and 100% will result in alarms sounding in the adjacent MR Control Room.</td>
</tr>
<tr>
<td>Date To BeMeasured:</td>
<td>May 10, 2015</td>
</tr>
<tr>
<td>Responsible Person:</td>
<td>Dr. A, MRI Safety Officer</td>
</tr>
<tr>
<td>Was the Compliance Level Met?</td>
<td>To be determined</td>
</tr>
<tr>
<td>Management concurs with this Action and Process/Outcome Measure</td>
<td>Yes</td>
</tr>
<tr>
<td>If No, why not? (Answered by Management)</td>
<td>Is the identification of another action required?</td>
</tr>
</tbody>
</table>
Trust Everyone
But Always Cut the Cards
Pre-induction Checklist Adherence, (n=64)

- Provider Introductions
- Procedure
- Pt. DOB
- Pt. Name
- Consent Present
- ABX
- Site Marking Verified*
- Positioning
- Equip. Needed
- Pt. Allergies
- Diag. Images Reviewed

Legend:
- 2011
- 2012
- 2014
- 2015

Note: n/a
Endorsing Organizations
Is There A Business Case?

• **YOU BET!!!**
• **Examples:**
  – “Easy CAP” CO$_2$ Detector
    • $125$/detected esophageal intubation
  – Ventilator Humidification System
    • $114$k/facility/yr and reduced risk
• RCA/45person-hrs X 12RCA/yr =

  \[0.25\text{FTEE}\]
Leadership -
What Can Be Done Right Now?

• **Lead by Example**
• Relentless Drumbeat
• Eliminate ‘Whose fault is it?’
• Encourage Skepticism
  – Devil’s Advocate is Valued
• Distinguish **Real** Priorities From Official Priorities
• Part of Every Agenda
• **What Happened?, What Should Have Happened?, What Usually Happens?**
Leadership - Key Points

• Transparent Risk-Based Prioritization Methodology
• Non-Punitive Approach – Blameworthy Definition
• Emphasize Systems-Based Solutions
  – Determination of Real Underlying Causes
  – Seek Out Stronger Solutions
• Emphasize Formal Scrutiny of Close-Calls
• Verify that work as imagined is the same as the work as actually performed – Robust QA Processes

• **Interventions Must Go Farther Than Simply Training and Policy**
• It’s Everyone’s Job
• Not About Errors!!!
• Counting reports **is not** the objective, identifying Vulnerabilities **is**
  – Hope they increase
  – **Analysis, Action, & Feedback are the key**
• Prevention NOT Punishment
• Cultural change is the key

• **Safety is the Foundation Upon which Quality is Built**
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