Using Practices and Tools LEAN to Improve Patient Safety

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Disclosure Summary
David W. Bates, MD, MSc

Consultant; EarlySense
Cash compensation; CDI (Negev), Ltd
Equity; Ethosmart
Equity; Clew
Equity; MDClone

Do not intend to discuss off-label/investigative use
Overview

• Background on safety
• An update on “To Err Is Human”
• Some frameworks used in improving safety
• Some specific examples of how safety has been improved
• Conclusions

The Extent of Medical Injury

<table>
<thead>
<tr>
<th>Location</th>
<th>Year</th>
<th>Adverse Event Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York MPS</td>
<td>1991</td>
<td>3.7%</td>
</tr>
<tr>
<td>Colorado/Utah</td>
<td>1999</td>
<td>3.3%</td>
</tr>
<tr>
<td>Australia</td>
<td>1995</td>
<td>13%</td>
</tr>
<tr>
<td>UK Pilot</td>
<td>2000</td>
<td>11%</td>
</tr>
<tr>
<td>New Zealand</td>
<td>2001</td>
<td>13%</td>
</tr>
<tr>
<td>Denmark</td>
<td>2001</td>
<td>9%</td>
</tr>
<tr>
<td>Canada</td>
<td>2004</td>
<td>7.5%</td>
</tr>
</tbody>
</table>
Preventable Injuries and Deaths – U.S.

- MPS: 1.2 million serious injuries; 98,000 deaths
- CDC: 1.7 million infections; 99,000 deaths
- IOM: 1.5 million adverse drug events
- Thomas: 3.5 million postoperative complications
- Ayello: 2.5 million pressure ulcers
- IHI: 15 million injuries
To Err Is Human: Building a Safer Health System

The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the systems.

What Have We Learned About Making Care Safer?

- Implementing safe practices is difficult
- Safety is not just about systems, it is about relationships, about culture
- Creating a culture of safety is very difficult
A Human Factors Expert Looks at Health Care

- No one in charge
- Safety is not a priority
- Fail to implement basic safety practices
- Tolerance of unsafe practices
- Rely on training & punishment
- No training in safety, teamwork
- No systematic data collection
- Lack analytic response to accidents

An Update on “To Err is Human”
Article Overview

- To Err is Human was a key milestone
- What has been learned since
- What organizations have done
- What remains to be learned/done
  - Diagnostic error
  - Safety issues outside hospital
  - Safety implications of aging population
  - HIT and safety
  - Policy implications
- Conclusions
HIT Adoption

- Levels have increased dramatically as a result of the federal meaningful use program
  - Appear to be over 90% in both hospitals and outpatient setting
  - Some sectors still left out like long-term care, psychiatric facilities
- Not clear yet though to what extent adoption has improved safety or quality
  - To get value from HIT adoption refining the associated clinical decision support will be essential

Progress Since to Err Is Human: Knowledge

- Specific areas of progress
  - HAIs
  - Medication safety
  - Handoffs
  - Surgical checklists
  - Pressure ulcers, falls, failure to rescue
  - Infusion of science from other disciplines (human factors, engineering); patient engagement initiatives; culture, reliability, teamwork initiatives
Progress Since To Err Is Human: What Organizations Have Done

- HAIs
- Medication safety
- Handoffs
- Surgical checklists
- Pressure ulcers, falls, failure to rescue
- Infrastructure
  - Reporting systems
  - Learning healthcare systems

Conclusions of this Paper

- Great deal of room to improve in safety still
  - Some progress has been made but more in inpatient than outpatient setting
  - Don’t yet have good approaches for measuring safety routinely
- Outpatient and leveraging HIT are high priorities
  - Also developing approaches for measuring harm routinely using HIT
- Reason to believe that disadvantaged populations are likely at higher risk than others although safety issues occur in all groups
Safety and Quality Frameworks

IOM Definition of Quality (STEEEP)

- Six Dimensions of Quality in Healthcare
  - Safe
  - Effective
  - Timely
  - Patient centered
  - Efficient
  - Equitable

IOM, Crossing the Quality Chasm
Frameworks for Improvement of Safety

• Continuous quality improvement
• Systems changes (often technical)
• Safety culture efforts
• Lean

QI Methodology

• Focus on systems—use systems theory
• Develop ideas for change and test them (scientific method)
• Understand the variation of data measured continuously over time (statistical process control)
• Understand reasons and motivation of people to act on data (common cause, special cause variation, diffusion of innovation)
• Use a balanced set of measures
Improvement Science Frameworks

Improvement Continuum
• Identifies four levels of improvement—topic/microsystem, care coordination, defined population and community health—and outlines the key skills, tools and teams necessary for success at each level.
• These levels build upon one another.

Leadership Action Model
• Includes four steps to help leaders apply the Improvement Continuum:
  1. Identify a strategy.
  2. Identify the skills, tools and teams necessary.
  3. Plan to sustain the improvement.
  4. Plan to spread the improvement.

www.hpoa.org

Need an 8-dimensional Lens for Improvement

Need an 8-dimensional Lens for Improvement

Organizational Policies, Procedures, & Culture
Workflow & Communication
User Interface
Content
Hardware & Software
Personnel
Measurement & Monitoring
External Rules & Regulations

Sitp Singh QSMHC 2010
Recommended Practices in SAFER Guides

https://www.healthit.gov/topic/safety/safer-guides

What Is Lean?

"**Lean** means creating more value for customers with fewer resources. A **lean** organization understands customer value and focuses its key **processes** to continuously increase it. The ultimate goal is to provide perfect value to the customer through a perfect value creation **process** that has zero waste."

Lean Institute
Lean vs. Six Sigma

“Lean focuses on analyzing workflow to reduce cycle time and eliminate waste. Lean strives to maximize value to the customer while using a few resources as possible. ... To summarize the main difference between Lean vs Six Sigma, lean looks at ways to increase flow while Six Sigma focuses on achieving consistent results.”

Lean Institute

5 Principles of Lean

• Value. The Lean approach begins with a detailed understanding of what value the customer assigns to product and services
• The Value Stream. Identify and map the value stream
• Flow. After removing wastes, ensure the flow of the remaining steps run smoothly
• Pull. Limit inventory and work in process items
• Perfection. Every employee should strive toward perfection. Every organization should be a learning organization
Safety and LEAN

- So far has only been used in selected instances
- Safety events represent waste in the LEAN paradigm
- Six sigma has been used in safety but has often seemed unreachable—often we are at one or two sigma in healthcare
  - “68-95-99.7 rule”
- Have often been tolerated or viewed as “a cost of doing business”
  - Now increasing number of examples suggesting that is bad practice
- Have not been good at all at tracking, improving flow in most processes
- Increasingly have supports through IT to make it possible to use at scale

Flow and RTLS—Real-Time Locating Systems

- Enable tracking of personnel, objects through use of RFID or other technologies
- Widely used in industry
- Helpful both for finding things and for improving efficiency of personnel
  - Can be used e.g. to determine whether or not an individual washed their hands
- Very useful tool for assessing flow objectively
Examples of Safety Improvement

Study Overview

- Catheter-related bloodstream infections are associated with significant morbidity
- In Michigan, a state-wide initiative to reduce catheter-related bloodstream infections in intensive care units (ICUs) was implemented
- This simple intervention included washing hands, using full-barrier precautions with central-line placement, cleaning the skin with chlorhexidine, avoiding the femoral site if possible, and removing unnecessary catheters
- The median rate of infection per 1000 catheter-days decreased from 2.7 at baseline to 0 throughout all periods after implementation of the study intervention

Pronovost et al
A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

- In eight hospitals throughout the world, implementation of a 19-item surgical safety checklist was associated with improved outcomes
- Use of the checklist may improve the safety of surgical procedures in hospitals in various economic circumstances

Conclusion

- Implementation of the checklist was associated with concomitant reductions in the rates of death and complications among patients at least 16 years of age who were undergoing noncardiac surgery in a diverse group of hospitals

Gawande et al, NEJM

Common Elements in These Efforts

- Careful design of checklists
  - Iterative refinement
- Use of implementation science principles
  - Tracking of use of instrument and conformance with it
- Development of “change packages”
  - Level of improvement still variable when spread to many settings
Examples of IT Applications With Safety Benefits

- Medications (CPOE, bar-coding, smart pumps)
- Patient monitoring
- Coverage application
- Computerized notification about critical test results
- Tracking abnormal test results
EarlySense: Continuous Patient Supervision on General Care Floors

- LCD monitor
- Nurse’s phone
- Central Nurse’s Station
- Bed side monitor

- Full floor overview at a glance
- Real time alerts to nurses & supervisors + reports on team performance
- Nurse / physician communication support
- Facilitation of critical thinking by nurse

Continuous Monitoring in an Inpatient Medical-Surgical Unit: A Controlled Clinical Trial

Study Outcomes Comparing Study Units Before and After Implementation of Monitor

|                          | Control Unit | Intervention (Study) Unit | 3 Arms p value*
|--------------------------|--------------|----------------------------|----------------
|                          | Baseline (Pre) | Control (Post) | P Value | Baseline (Pre) | Intervention (Post) | P Value | % Reduction |
| LOS in Med. Surg./Units (mean) | 3.80 (1.26-4.25) | 3.61 (1.19-4.12) | 0.07 | 4.00 | 3.63 | 0.02 | 9% < 0.01 |
| LOS in ICU for patients coming from Med/Surg. units (mean) | 1.73 (1.06-2.28) | 4.48 (0.94-4.09) | 0.01 | 4.53 (2.33) | 2.45 (1.85) | 0.1 | 45% 0.04 |
| Code Blue Events/1000 Pt. | 3.9 | 2.1 | 0.16 | 0 (6.3) | 2 (0.9) | 0.05 | 86% 0.01 |

* P – value comparing 3 arms: intervention unit post, intervention unit pre and control unit post
Alert Frequency and Positive Predictive Value

- EarlySense had 2.2 alerts per 100 recording hours
  - 50% result in nurse action
- Pulse oximetry, telemetry, cardiovascular monitors have 161-730 alerts per 100 hours
  - Much lower proportions result in action

Economic Analysis of Smart Monitor

- Modeled only ICU length of stay and pressure ulcers

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<tr>
<th></th>
<th>5-year ROI</th>
<th>Annual Benefit</th>
<th>Breakeven</th>
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<tbody>
<tr>
<td>Base Case</td>
<td>$9.1 million</td>
<td>$2.1 million</td>
<td>0.5 years</td>
</tr>
<tr>
<td>Conservative</td>
<td>$3.3 million</td>
<td>$0.66 million</td>
<td>0.75 years</td>
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Slight, Critical Care Medicine 2014
Health IT Safe Practices for Closing the Loop

Mitigating Delayed, Missed, and Incorrect Diagnoses Related to Diagnostic Testing and Medication Changes Using Health IT

https://assets.ecri.org/PDF/HIT-Partnership/Closing-the-Loop-Toolkit.pdf

New Guidance Available

Closing the Loop
A Guide to Safer Ambulatory Referrals in the EHR Era

Measurement of Adverse Events in Routine Care

Numerous State and National Organizations have emerged that measure and track adverse events in healthcare settings

• Guidelines vary substantially
• No standard approach used across multiple organizations to track harm in the aggregate
Private companies have also developed tools to track adverse events in clinical settings

The SafeCare Study

• Funded by CRICO
  • Three years: July 1, 2017 – June 30, 2020
  • Underway now in a representative sample of Massachusetts hospitals

• Study Aims
  • Aim 1: Determining incidence of inpatient and outpatient adverse events
  • Aim 2: Developing an approach for ongoing operational evaluation of harm
Steps for Aim 2

- Catalog current efforts to monitor patient safety; identify state/national reporting requirements
- Based on goal 1 results, finalize list of adverse event triggers including those that can be collected from EHRs and those that cannot
- Create automated safety monitoring tools that can be integrated with inpatient/outpatient EHR systems
- Validate against manual chart review results
- Recommend an overall approach

Policy Implications

- On-going need to support research in safety improvement
- Organizations should be required to measure harm frequency across a number of domains
  - Initially in inpatient setting, but eventually in outpatient
- IT tools to enable transformation to becoming learning healthcare systems
- Measurement related policy implications, including tension b/w measures for public reporting/accountability vs. improvement
Conclusions

- Great deal of room to improve safety
  - Hard in part because events are fortunately rare
- Major limitation has been that organizations have not had tools to measure the frequency of harm routinely for many safety issues
  - That is changing rapidly
- Incentives have also been mixed
  - Will be different under accountable care
- Probably need to leverage a variety of tools/frameworks to get to high levels of performance
  - Culture, technical advances, but also CQI and LEAN to become learning healthcare systems
- So far even the best systems are just now approaching this