Lab Efficiency and Patient Safety

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Learning Objectives

- Examine the science of Patient Safety
- Review approaches for Laboratory Efficiency, including Lean and Six Sigma
- Share some thoughts on implementation and rollout
Origins of the Science of Patient Safety

- Originated with the Institute of Medicine’s Report in the 1990’s
- Overview provided via Wikipedia:
- Variety of Initiatives
  - Review of sources/topics follows…..
U.S. Hospitals Underperform on Patient Safety Measures

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U.S. Hospitals Underperform on Patient Safety Measures

An update to the Hospital Safety Score released by The Leapfrog Group revealed that while some hospitals reliably deliver safe healthcare, many still lag in their ability to protect patients from preventable medical errors, injuries, accidents, and infections.

Launched in June 2012, the Hospital Safety score uses 26 measures of publicly available hospital safety data to assign an A, B, C, D, or F score to U.S. hospitals. This new update to the report summarizes data from the past 6 months that was collected from 2,618 hospitals and primarily covers their performance in 2011. On the Hospital Safety Score website, Leapfrog recommends consumers go to hospitals that received an A rating; however, of the hospitals studied, only 30% earned this top score, with 6% getting a D or F score. These two lowest grades are new additions to the Hospital Safety Score rankings and denote hospitals with the most hazardous environments for patients.
NIH uses genome sequencing to help quell bacterial outbreak in Clinical Center

Genomics and microbiology experts collaborate in hospital infection control

For six months last year, a deadly outbreak of antibiotic-resistant bacteria kept infection-control specialists at the National Institutes of Health’s Clinical Center in a state of high alert. A New York City patient carrying a multi-drug resistant strain of Klebsiella pneumoniae, a microbe frequently associated with hospital-borne infections, introduced the dangerous bacteria into the 243-bed research hospital while participating in a clinical study in the summer of 2011.

Despite enhanced infection-control practices, including patient isolation, the K. pneumoniae began to spread to other Clinical Center patients at the alarming rate of one a week, ultimately colonizing 17 patients, of whom 11 died — six from infection and five from their underlying disease while infected.

To get the outbreak under control, Clinical Center staff collaborated with investigators at the National Human Genome Research Institute (NHGRI), also part of NIH, to use genome sequencing in the middle of this active hospital epidemic to learn how the microbe spread. A report in the Aug. 22, 2012, early online edition of Science Translational Medicine describes how that collaboration helped quell the outbreak.

"Infectious outbreaks happen in every hospital in the world, afflicting millions of patients each year in the United States alone," said NHGRI Director Eric D. Green, M.D., Ph.D. "By marshaling the ability to sequence bacterial genomes in real time to accurately trace the bacteria as it spread among our Clinical Center patients, our researchers successfully elucidated what happened, which in turn has taught us some important lessons. This study gives us a glimpse of how genomic technologies will alter our approach to microbial epidemics in the future."
What Exactly Is Patient Safety?

Linda Emanuel, MD, PhD; Don Berwick, MD, MPP; James Conway, MS; John Combes, MD; Martin Hatlie, JD; Lucian Leape, MD; James Reason, PhD; Paul Schyve, MD; Charles Vincent, MPhil, PhD; Merrilyn Walton, PhD

Abstract

We articulate an intellectual history and a definition, description, and model of patient safety. We define patient safety as a discipline in the health care professions that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. We also define patient safety as an attribute of health care systems that minimizes the incidence and impact of adverse events and maximizes recovery from such events. Our description includes: why the field of patient safety exists (the high prevalence of avoidable adverse events); its nature; its essential focus of safety works (e.g., high-reliability design, use of safety sciences, methods for causing change, including cultural change);

Bottom Line: Drive by Process (and not Finger Pointing)
NPSG for Laboratory Services
JCAHO...Specifics on Laboratory Goals

2013 Laboratory National Patient Safety Goals

The purpose of the National Patient Safety Goals is to improve patient safety. The goals focus on problems in healthcare safety and how to solve them.

<table>
<thead>
<tr>
<th>Identify patients correctly</th>
<th>NPSG.01.01.01</th>
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<tbody>
<tr>
<td>Use at least two ways to identify patients. For example, use the patient's name and date of birth. This is done to make sure that each patient gets the correct medicine and treatment.</td>
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<th>Improve staff communication</th>
<th>NPSG.02.03.01</th>
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<td>Get important test results to the right staff person on time.</td>
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<th>Prevent Infection</th>
<th>NPSG.07.01.01</th>
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<td>Use the hand cleaning guidelines from the Centers for Disease Control and Prevention or the World Health Organization. Set goals for improving hand cleaning. Use the goals to improve hand washing.</td>
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AHRQ Patient Safety Net-
Search on laboratory-and filter by target
http://psnet.ahm.gov/search.aspx?searchStr=laboratory
Tool to Take Home:
Patient Safety Training Course.....

Time to move to a discussion of Efficiency.....

Efficiency ~ Improved Patient Safety
Integrating Efficient Laboratory Processes with Patient Outcomes

- Systems Approach
- Selection of Methodology
- Improved Patient Outcomes

- ISO 15189?
- Lean-Six Sigma?
- Lean?
- Six Sigma?
- GP26 A4?
- Other?
Systems Approach-Quality Systems

- Originated as Business Tool
  - Processes/Policies specific for an institution the promote Quality Outputs
- Can drive the entire process of ongoing improvement
- Now referenced in multiple regulated environments
  - Pharma
    - Guidance Document
  - Device
    - 21CFR820
  - CLIA
    - CLSI GP26A4
    - ISO 15189
    - Other
How do the Laboratory Systems differ?

- Both have considerable Overlap in components
  - Primarily differ in terminologies w/similar outputs
- ISO 15189 offers accreditation
- CLSI GP26 is a choice

Key Point for Your Needs:
Figure out what is of most value
What about the Methodologies?

- Do I really need to select a particular methodology?
  - Short answer: It depends
    - On your
      - Needs
      - Approach to System Implementation
      - Executive Support
Clash of the Titans

- Six Sigma vs Lean
  - Endless Debate
    - Specialized versus Hybrid
Methodologies: Multiple Flavors of Each Method

- **Six Sigma**—“reduction of errors”
  - Classified by “Belt Color”
  - White-Green-Black

- **Lean**—“reduction of waste”
  - Multiple classifications
  - 3P-5S-Kaizen etc etc

- See Combo versions as well
  - 5S-3P-Lean-Six Sigma
History of Six Sigma


18th Century Europe: “normal curve metric”

Walter Shewhart & 3 sigma deviation

Motorola coins term “Six Sigma”
Six Sigma in Healthcare


- Article emphasizing fit for Six Sigma and Laboratory Operations & Processes
  - Definition (especially of the customer)
  - Prioritization
  - Itemization
  - Completion

- Notes: Not all issues will be a fit for Six Sigma, but

- Six Sigma can be a very good fit for a Healthcare setting due to “the repetition of processes”
A Brief History of Lean Manufacturing

Eli Whitney Invents the Cotton Gin (1794) and interchangeable parts

Frederick Taylor published the Principles of Scientific Management (1911)

Henry Ford invents the moving assembly line, and dozens of innovations between 1908 and 1913

Training Within Industry (TWI) developed to increase production in WWII.

W Edwards Deming transfers info to Japanese companies in the reconstruction

Taiichi Ohno, Kiichiro Toyoda and Shigeo Shingo invent mfg methods, JIT and SMED

Womack and Jones Publish Lean Thinking in 1995
How to figure out what you need...

http://www.epa.gov/lean/environment/methods/index.htm
BUT……..

Systems & methodologies alone do not guarantee Quality

http://www.huffingtonpost.com/2013/01/30/toyota-recall_n_2579685.html
Owing “It”

• Communicating use of methodologies…
  • Doesn’t always translate to practice

• When systems approach practices
  • Errors are found before they impact customer (patient)

• Challenges
  • Corporate promises
  • Timelines
  • Resources

SOOOO……..
Resources:
Key Factor in Improved Efficiency-

• Executive Support
  • The opposite of micro management
    • Illustrates understanding of Systems approach
  • Supportive

• Who’s Driving?? One needs the right people
  • Owner & Delegates
  • Need Leaders & Managers
  • Open to Flexibility and Change
Over-engineering can be an issue

- Plan up front (Hybrid approach??)
- Drive by measurable desired outcomes
- RACI Matrix
    - Who’s Responsible (aka who does the work)
    - Who’s Accountable (aka “who’s neck is on the line”)
    - Who get’s Consulted (but doesn’t necessarily get a vote)
    - Who is Informed?
Methodologies-Six Sigma

- Quality Systems should encompass all programs/tools for Efficiency & Patient Safety
  - Six Sigma—See chapter 1—Henry
    - Defect Reduction
    - DMAIC (Lots of similarities w/ CLSI Process Mgt QSE)
      - Define
      - Measure
      - Analyze
      - Improve
      - Control
Lean Processes: 5S and 3P

**5S**
- Workplace Organization
  - Sorting
  - Straightening
  - Sweeping
  - Standardizing
  - Sustaining

http://en.wikipedia.org/wiki/5S_(methodology)

**3P**
- Similar to Design Control
  - Production
  - Preparation
  - Process

http://www.epa.gov/lean/environment/methods/threep.htm
Questions to Ask Before Adopting Methodology (vs. defining your own custom methodologies)

- What is the desired output?
- Will consolidation increase the probability of success?
- What are my metrics (and how will they be measured?)
- What are the acceptance criteria?
- What will I do if I don’t make my timelines, or the data suggests something else should have been measured?
Once all is in place, Where to Start?

- Process Flow Charts
  - Need to have your processes mapped out to communicate to all
  - Aids in defining specifications and where (and what) you want to measure
- Ask: Where do I want to go?
  - Work with applying basics of methodologies to see what fits best
- Keep revisiting your existing processes and make your system work
Potential of Improved Efficiency

- Improved
  - Patient Safety
  - Worker Safety
  - Cost Savings
Questions for Consideration?

- When might 3P be used in favor of 5S?
- When might the reverse be true?
- How to incorporate Six Sigma into your recipe?
Self-Assessment Questions

1. The Six Sigma Methodology addresses
   A. Design processes
   B. Statistical assessment of error
   C. A & B
   D. All of the Above

2. The 3P Methodology does NOT address design
   A. True
   B. False

3. Which of the following is a true statement:
   A. Methodologies for improvement are part of a Quality System
   B. A Quality System is part of the Lean Methodology
   C. 5S is a type of Lean Methodology
   D. A & C

4. Individuals assigned to Lean-Six Sigma Teams should be open to change
   A. True
   B. False
Additional References


Any Questions??

THANK YOU!!