"The real problem isn't how to stop bad doctors from harming, even killing, their patients. It's how to prevent good doctors from doing so."
Atul Gawande, the New Yorker, Feb 1, 1999, p.40

Institute of Medicine: Safety

• “Safety” means the absence of preventable harm
• “Medical Error” means failure to carry out an intended plan or implementation of a faulty plan
• “Adverse Event” means temporary or permanent harm to a patient caused by medical intervention

Safety: Absence of Preventable Harm

Although medical care is not without risk, there are certain things that patients expect will not occur when they are admitted to a hospital
• Fall with injury
• Medication error with harm
• Procedure error with harm
• Pressure ulcer
• Hospital acquired infection
• Preventable known complications, e.g. blood clots
• Preventable birth injury
• Delay in diagnosis or treatment with harm
• “Never events”
Quality: Maximizing Outcomes

• “Quality” means maximizing the chance of getting the outcome the patient wants
• The best way to get that outcome is by following the best evidence
• Evidence-based medicine is implemented through reliable processes
• Too often evidence is lacking, so we rely on professional opinion, experience and judgment

Quality and Personalized Medicine
The “New” Ideal of Quality

- Patient care should be based on the best available evidence
- Care should be delivered in the context of a highly reliable system
- No two patients should ever receive exactly the same care because every patient differs in genetic, cultural and environmental factors
- Every patient should receive exactly the same personalized care regardless of the individual clinician
- The patient (customer) must define important elements of care

Outcomes

- All outcomes (except one) are intermediate
- Mortality as an outcome may be meaningful in very low risk or in very high risk situations; it is less helpful in intermediate-risk situations
- Other outcomes are currently more difficult to define precisely and meaningfully:
  - functional status,
  - physical or work capability,
  - sense of well-being.

Maximizing the Chance of a Desirable Outcome

- Good outcomes involve much more than “safety”
- What outcomes are important in
  - TURP surgery?
    - Continence, sexual function, nocturia
  - Cancer chemotherapy?
    - 5 yr survival, well-being, mucositis, personal image
  - Knee replacement?
    - Return to work, functional assessment, patient reported outcomes
  - Heart attack?
    - 5 yr survival, angina, exercise capacity, work capacity, left ventricular function
  - Caesarian section?
    - Apgar, infection rate, hospital LOS, subsequent pregnancy course

High Reliability

Aircraft Hydraulic Architectures
Example Block Diagrams – Boeing 777

- Systems with Redundancy, or with a Safety Layer
  - 2 Independent systems
  - 2 Functional Levels of the system; each level is equipped with sensors, relays, and modules
  - Not only high-level risk can be reduced with independent safety layers
  - Systems with Redundancy, or with a Safety Layer
  - All critical systems are equipped with redundant systems to ensure safety
High Reliability

A High Reliability Organization (HRO) is a social system that has developed a culture sensitive to safety that makes it possible for employees to cope with uncertain and time-dependent threats.

These organizations are characterized by low probability of adverse events and the ability to prevent or mitigate almost all the accidents and errors.

High Reliability

They are organizations that can perform relatively accident-free operations because they are able to carry out proactive analysis and repair and correct mishaps continuously and constantly.

They include aircraft carriers and nuclear power plants

They do not include hospitals

High Reliability: 3 Key Requirements

1. Leadership
   • Create the vision
   • Prioritize the resources
   • Model the behavior

2. Robust Process Improvement
   • Lean/Six Sigma/PDCA
   • Human factors engineering, forcing functions

3. Culture of Safety
   • Flattening of Authority Gradients
   • “Just” culture (freedom from wanton blame)
   • “Stop the line”
   • Equivalent actors

Leadership

“By leadership commitment, we mean the aligned agreement of the governing body, typically a board of trustees or directors, senior management, and physician and nurse leaders. All the constituencies of leadership, both formal and informal, must share the same singular vision of eventually eliminating harms to patients...The goal of zero also is important because one of the most salient characteristics of high-reliability organizations is that they are not satisfied with whatever their current level of safety might be.”

Process Improvement

• Process Improvement: A formal system of identifying gaps in performance from unintended variation, suboptimal quality or non valuable work, and implementing change in structure or function in order to close those gaps.

Process Improvement: PDCA

1. PLAN
2. DO
3. CHECK
4. ADJUST (ACT)
Six Sigma: Minimize defects

How Safe is Commercial Aviation?
Fatalities per 100,000 departures

How Safe are Motorcycles?
Fatalities per 100,000 registered vehicles


How Safe is Hip Replacement?
In-hospital deaths per 100 surgeries
How Safe is Hip Replacement?
In-hospital deaths per 100 surgeries


3 per 1,000 = 4 σ

Lean A3 Approach

|----------------------|-----------------|----------------|----------------|--------------------|---------------------|----------------------|--------------------|------------|

Lean: Eliminate Waste

<table>
<thead>
<tr>
<th>Type of Waste</th>
<th>Brief Description</th>
<th>Hospital examples</th>
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What Waste? Cost of Health Care

For 31 of the past 40 years, health care costs have increased at a greater rate than the economy as a whole

- Health care costs constitute 18% of U.S. GDP
- 30% increase in personal income over the past decade effectively eliminated by a 76% increase in health care costs
- $750B in waste

What Waste? Complexity of Health Care

Increasing amounts of information

200,000
400,000
600,000
800,000
1,000,000
2016
2020
2024
Year

General Electric 1994

Lean A3 Approach

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**What Waste? Complexity of Health Care**

**Complexity**

Clinical Complexity

- Physician in private practice interact with as many as 229 other physicians in 117 different practices just for their Medicare patient population
- ICU clinicians have 180 activities per patient per day
- Chronic disease: 78 year old patient with osteoporosis, osteoarthritis, type 2 diabetes, hypertension, and chronic obstructive pulmonary disease: 19 medications per day

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**The Result?**

Representative timelines of a patient’s experiences in the U.S. health care system

1 out of every patient admitted within 30 days

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**Process Improvement:**

Lean/Six Sigma/PDCA

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**Levels of Reliability on the Journey Towards an HRO**

**Level 1: Intent, vigilance and hard work**

- Standardized protocols,
- Feedback,
- Training,
- Personal checklists

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**Activity (Assume no undue time pressure or stresses)**

<table>
<thead>
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<th>Activity</th>
<th>Rate</th>
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<td>Error of commission, e.g. misreading a label</td>
<td>.003</td>
</tr>
<tr>
<td>Error of omission without reminders</td>
<td>.01</td>
</tr>
<tr>
<td>Error of omission when item is embedded in a procedure</td>
<td>.003</td>
</tr>
<tr>
<td>Simple arithmetic errors with self checking</td>
<td>.03</td>
</tr>
<tr>
<td>Monitor or inspector fails to recognize an error</td>
<td>.1</td>
</tr>
<tr>
<td>Personnel on different shifts fail to check the condition of hardware unless directed by a checklist</td>
<td>.1</td>
</tr>
<tr>
<td>Error rate under very high stress when dangerous activities are occurring rapidly</td>
<td>.25</td>
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Adapted from Berwick, D. 2000

Levels of Reliability on the Journey
Towards an HRO

**Level 2: Design informed by reliability science and research in human factors**
- Decision aids and reminders built into the system
- Evidence as the default
- Redundancy
- Scheduling
- Connection to habits

Adapted from Berwick, D: 2000

**Level 3: Fundamental system redesign**
- Design the system to prevent failure (A breakdown in operation or function)
- Design procedures to make failures visible when they do occur so that they may be intercepted before causing harm
- Design procedures for mitigating the harm caused by failures when they are not detected and intercepted

Keeping Our Patients Safe: the Journey to High Reliability

- High reliability organizations start with vigilance and progress to system redesign to prevent, identify and mitigate failure
- Key components of high reliability organizations include leadership, robust process improvement and a culture of safety
- A culture of safety includes concepts of equivalent actors, “stop the line” encouragement, a “just” approach to accountability, and flattening of authority gradients

High Reliability is About People: 5 Key Features

1. **Mindfulness; Sensitivity to Surroundings**
   Safety is everyone’s job; if you’re unsure, speak up!
2. **Preoccupation with failure**
   Employ reliable design prevention into the workplace; worry about what could happen
3. **Commitment to Resilience**
   When adverse events occur, detect, understand, control and prevent them
4. **Reluctance to simplify**
   Understand root causes and address them robustly
5. **Deference to expertise**
   The staff who may know the most may be low in the hierarchy

High Reliability: the Physician’s Role

- knows her/his role as part of interdisciplinary health care team
- meets group-determined standards of care
- with other providers receives feedback and assesses success or failure
- as part of a team, helps design, implement and sustain the system redesign for high reliability
- acquires, through study and training, competence as a team leader and member to improve communication, assessment, and other skills

Examples
- Participate in Teamstepps
- Implement team-based practice
  - Operating room fire
  - Cardiac arrest
  - Office huddle
- Become a proponent of and participant in standard work
  - Order sets
  - Communication standards
  - Transitions of Care

Adapted from Berwick, D: 2000

Weick, Managing the Unexpected, Jossey-Bass, 2001
How Safe are We?

The statistical risk for groups and individuals is becoming clearer. Most would agree the odds are too high:

• a 1:2 chance of getting the right care; a
• 1:10 likelihood of being harmed in association with a hospital admission;
• a 1:50 possibility of system-induced death or major disability;
• and a 3:10 incidence of ultimately dying normally but with untreated pathology.
• If these factors overlap, then the chances are 50% of sustaining an error or near miss.

Braithwaite, J. R Soc Med 2010

Safety and regulatory agencies

2015 Hospital National Patient Safety Goals

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

Safety and financial incentives

A meta-analysis summarizing 128 studies indicates that such findings are representative of a consistent body of research. The conclusions that emerge from the extensive literature on motivational crowding include:

• Tangible rewards — particularly monetary ones — undermine motivation for tasks that are intrinsically interesting or rewarding, an effect that is quite large.
• Symbolic rewards (e.g., praise or reviews) do not crowd-out intrinsic motivation, and may augment it.
• The negative effects of monetary rewards are strongest for complex cognitive tasks.
• Crowding-out effects tend to reduce reciprocity and augment selfish behaviors.
• Crowding-out may spread (both to other tasks and to co-workers), decreasing intrinsic motivation for work not directly incentivized by the monetary rewards.
• Crowding-out is strongest when external rewards are large, perceived as controlling, contingent on very specific task performance, or associated with surveillance, deadlines or threats.

Woolhandler, Health Affairs, 2012

Take Aways

• U.S. Health Care is safer now than 10 years ago
• U.S. Health Care delivers lower value than competing industries or other western countries
• 30% of U.S. Health Care spending is wasteful
• Pay-for-performance programs have mixed results, and threaten the intrinsic motivation of healthcare workers
• In order to retain our singularly professional privilege, physicians must increase our participation and leadership in teamwork, process improvement and safety culture
Since you can’t make it safer just by being a better doctor, what changes would you make in order to prevent someone in the future from inadvertently killing another person by:

- mistaking innominate artery narrowing for septic shock?
- causing a plane to crash while investigating a faulty indicator light?
- inserting a feeding tube into the brain and spinal cord?