Patient Safety
Time for a change in design

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World Congress of Sterilization
Milan Italy
June 4-7, 2008
Today’s Agenda

• Why we make mistakes
• What we can learn from human factors engineering and reliability science
• How we can redesign our systems- to prevent errors and improve patient safety
• How to create a culture of safety that focuses on system redesign and not blame
Why do we have safety risks in healthcare?

• More to do...
• More to manage....
• More complex medical devices..
• More advanced sterilization technology..
• Poorly designed processes
• Human error
Cause of most outbreaks from contaminated medical-surgical devices

Not following standard processes for sterilization and disinfection

US Centers for Disease Control and Prevention (CDC)
Challenges for Sterilization

*Complexity*

- Complexity of medical devices and sterilization technology has exploded
- Complexity is a hazard
- Complexity can overwhelm human capabilities
Healthcare in need of a redesign

- Quality of care in US
  - Only 54% of patients receive recommended care

Institute of Medicine
Crossing the Quality Chasm, 2001

- Total system redesign
Articles published from randomized controlled trials 1966 to 2007
Many support sterilization and disinfection procedures
Diffusion of Knowledge

Landmark Trial  Current Rate of use

Influenza vaccine  1968  64%
Perioperative Prophylactic Antibiotics

Timing of Administration

Hours From Incision

Infections (%)

U.S. Surgical Infection Prevention Project 2001 (Baseline) to 2006

Ab within 1 hr of OR
Consistent with guidelines
D/C 24 hr after OR

FROM: Bratzler Clin Inf Dis; Aug 2006
Redesign Goal

- Goal
  - Change the process to make it easy to do the right thing and hard to do the wrong thing
Tools to redesign the process to improve quality and safety:

• Human factors engineering concepts
• Six sigma
• Bundling
• Failure mode and effects analysis (FMEA)
• Root cause analysis (RCA)
Human Factors Engineering

Why do we make mistakes?
Every system is perfectly designed to achieve exactly the results it gets.

Don Berwick
Institute for Healthcare Improvement
Bancomat
Light or fan switch?
Hold the elevator door please…
How do I turn off the wipers?
How reliable are our current processes?
Where are we now?
80-90% Reliable

• Some common equipment
• Some standard procedures
• Trying harder
• Feedback on compliance
• Vigilance
• Training
Can’t rely on vigilance

- Factors affecting vigilance:
  - Fatigue
  - Competing demands
  - Distractions
99% Reliable

- 1 major plane crash every 3 days
- 16,000 items of lost mail per hour
- 37,000 ATM errors per hour
Change concepts using human factors engineering principles

• Reduce reliance on memory and vigilance
• Simplify
• Standardize
• Make the correct action the default
• Use forcing function
  — making it difficult to do it wrong
• Use checklists
## Error Rates for Processes with Multiple Steps

<table>
<thead>
<tr>
<th>No. of steps in the process</th>
<th>Error rate for each step</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.05 with 95% confidence</td>
</tr>
<tr>
<td>1</td>
<td>0.05</td>
</tr>
<tr>
<td>5</td>
<td>0.33</td>
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<tr>
<td>25</td>
<td>0.72</td>
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<tr>
<td>50</td>
<td>0.92</td>
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<tr>
<td>100</td>
<td>0.99</td>
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</tbody>
</table>
Steps in Process for Sterilization and Use of Surgical Instruments

FROM:
Linkin DR. FMEA in Sterilization. Clinical Infectious Disease
Oct 2005
Omissions are single most common human error

• Too many steps
• Interruptions
• Noise
• No cues
Everyday strategies to assist memory

• Handwritten notes 65%
• Diaries 57%
• Lists 55%
• Writing on hand 43%
• Ask others to remind 34%
• Mental checking 8%
• Visualization 4%
• Clocks, watches & alarms 3%

FROM: J Reason Qual Safety HC Mar 2002
Need to standardize the process
Deaths associated with use of a recalled device

- No standard process for recalls
- 414 patients had a bronchoscopy with recalled device
- 39 (9.4%) patients developed infections; 3 died

Jan 2003
Recalls – Challenges

• Lack of efficient recall system in many hospitals
• Recall notices not sent to appropriate person
• Degree of urgency unclear
• Need a standardized process
• Company role: Ask for verification of receipt of recall notice
Lack of Standard Process
Factors contributing to outbreaks from contaminated bronchoscopes 1975 to present

• Improper pre-cleaning of device
• Wrong disinfectant, concentration, or exposure time
• Errors - automated endoscope reprocessing (AER)
  • Failure to use channel connectors
  • Inadequate rinsing (e.g., only tap water)
  • Failure to dry
  • Storage in contaminated container
Reprocessing failures resulting in patient notifications

<table>
<thead>
<tr>
<th>Location or institution, year</th>
<th>Instrument involved</th>
<th>No. of persons exposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sacramento, CA, 2002</td>
<td>Endoscope</td>
<td>750</td>
</tr>
<tr>
<td>Toronto, ON, 2003</td>
<td>Endoscope</td>
<td>146</td>
</tr>
<tr>
<td>Seattle, WA, 2004</td>
<td>Endoscope</td>
<td>600</td>
</tr>
<tr>
<td>Sacramento, CA, 2004</td>
<td>Endoscope</td>
<td>1,331</td>
</tr>
<tr>
<td>San Francisco, CA, 2004</td>
<td>Endoscope</td>
<td>2,000</td>
</tr>
<tr>
<td>Long Island, NY, 2004</td>
<td>Endoscope</td>
<td>177</td>
</tr>
<tr>
<td>Charleston, NC, 2004</td>
<td>Endoscope</td>
<td>1,383</td>
</tr>
<tr>
<td>Toronto, ON, 2003</td>
<td>Prostate biopsy probe</td>
<td>900</td>
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<tr>
<td>Pittsburgh, PA, 2005</td>
<td>Endoscope</td>
<td>200</td>
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<tr>
<td>Leesburg, VA 2005</td>
<td>Endoscope</td>
<td>144</td>
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<td>San Diego, CA, 2006</td>
<td>Endoscope</td>
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<td>Augusta, ME, 2006</td>
<td>Prostate biopsy needle</td>
<td>481</td>
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<td>Dept Veterans Affairs, 2006</td>
<td>Prostate biopsy equipment</td>
<td>2,075</td>
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<tr>
<td>San Diego, CA, 2006</td>
<td>Surgical instrument</td>
<td>82</td>
</tr>
</tbody>
</table>

Rutala WA Infect Control Hosp Epidemiol 2007; 28:146-55
Reprocessing of “single-use” devices in U.S. has been standardized

Original manufacturer and third party reprocessing have same requirements
US Government Accountability Office Report

Reuse of Single-Use Devices (SUDs)

Jan 2008

• >100 SUDs reprocessed
• 50% of US hospitals (>250 beds) use reprocessed SUDs
• No data to support an elevated health risk
• No “causative link” between reprocessed SUD and patient injury or death
200% reduction in bloodstream infections with standard process for IV catheter insertion


(3154 patients; 30 BSI -- prevented; savings $90,000 to $1,200,000
Pt Positioning, skin prep, barriers, training, insertion technique, )
1000% reduction in IV related bloodstream infections with a system redesign

- Education
- IV cart with standard supplies
- Daily reminder to remove IV
- Checklist to document compliance with all measures

Rate per 1000 Catheter days

Ventilator pneumonia drop to zero after *system redesign*:
Implementing a group or bundle of measures and monitoring for compliance with ALL of them.

![Graph showing the decrease in ventilator pneumonia rate after system redesign](image)

**Figure 1.** Medical intensive care unit ventilator-associated pneumonia (VAP) rate. NNIS = National Nosocomial Infections Surveillance System.
Simplify, Automate, Reduce Reliance on Vigilance
Examples of equipment redesign

**SMART IV Pumps**

- Name of drug on screen
- Software program has usual doses – so pump won’t allow wrong dose
- Battery life indicator
Redesign with “forcing functions” making it impossible to do it wrong
Tubing misconnections
A serious problem

Good news and bad news:

- Most tubing connects easily to other medical devices with totally different functions
Death of child from oxygen tubing misconnection

Oxygen disconnected from nebulizer on asthmatic child

Oxygen reconnected accidentally to IV line -

Oxygen line
Fatal tubing misconnection with infant tube feeding

Syringe with formula accidentally injected into sterile IV line with an identical connection
Redesign of infant oral feeding syringe and feeding tube

Standard syringe will no longer fit the new larger feeding tube port

Both the feeding tube port and oral syringe port made larger to fit perfectly
Mistake-Proofing the Design of Health Care Processes

May 2007

www.ahrq.gov
search for “mistakeproof”
Eliminate confusing information
Confusing
Enalaprilat: For Blood pressure
Pancuronium, Causes paralysis
Fatigue increases risk of errors

- 24 hours without sleep is equal to the effects on performance has having a blood alcohol level of 0.1%

Nature 1997
Doctors in training who work >16 hours in intensive care make more serious medical errors

• Interns working more than 16 hrs continuously
  – 35% more serious medical errors
  – 20% more serious medication errors
  – 5.6 more diagnostic errors

FROM: Landrigan CP N Engl J Med 2004; 351:1838-48 and

*Continuous electrooculography – slow rolling eye movements during wakefulness
Establish an Organizational Culture of Safety

• *Redesign system* and processes to improve reliability & avoid failure

• Avoid blame and focus on a failure of the system not the individual

• View errors as opportunity to learn & improve

• Visible commitment from management
What is the biggest cause of error in your instrument processing system?

IAHCSMM On Line Survey

• 65% Human error – people problem
  – Examples given: Careless, not paying attention, rushing, distractions, not concentrating, no process, relying on memory
• 15% Missing instruments, incorrect count sheets
• 5% Lack of training
• 5% Poor communication
• 10% Other
Establish an Organizational Culture of Safety

• Redesign system and processes to improve reliability & avoid failure

• Avoid blame and focus on failure of the system, not the individual

• View errors as opportunity to learn & improve

• Visible commitment from management
People still want to blame!
Survey of health care workers about a culture that does not punish for mistakes

- Can’t weed out “bad apples:” 35%
- Tolerates failure: 15%
- Excuses poor performance: 15%
- Increases carelessness: 25%

ISMP Institute for Safety Medication Practices
When to Blame or Punish

Blameless
• Blame and punish IF:
  – The Unsafe Act Intended
  – The Bad Outcome Intended

• Other Examples of when to consider blame
  • Criminal behavior (alcohol-drug abuse)
  • Purposely violates safety mechanisms
  • Injury not reported in timely manner to intervene

Blame
Punish
Establish an Organizational Culture of Safety

- Redesign system and processes to improve reliability & avoid failure
- Avoid blame and focus on a failure of the system not the individual
- View errors as opportunity to learn & improve
- Visible commitment from management
Conduct a Root Cause Analysis

To learn from error and “near miss” and use to improve the process

- Cross functional team members
- Focus on system not the worker
- Fair and blame free environment
- Ask series of “why” questions to identify contributing factors
- Determine how a system redesign could reduce risk and make the changes

Wu, Lipshutz, Pronovost JAMA Feb 2008
Establish an Organizational Culture of Safety

- Redesign system and processes to improve reliability & avoid failure
- Avoid blame and focus on a failure of the system not the individual
- View errors as opportunity to learn & improve
- Visible commitment to safety from management
Concern for improving patient safety in U.S. is changing the way hospitals are being reimbursed for care
Concerns for patient safety and quality are changing the way U.S. hospitals are being reimbursed for healthcare expenses*

**Value-based purchasing**

- Pay for reporting of quality measures
  - Currently 27 measures; 30 by 2009; possibly 72 by 2010 to get full reimbursement

- Pay less for conditions acquired in the hospital
  - High cost, high volume conditions; reasonably preventable with evidence based practices

- Pay for performance – current pilot project
  - Reward high performing hospitals with additional $$

*Medicare: US government health care reimbursement program for people over 65

www.cms.hhs.gov
No additional payment for healthcare-associated conditions *not* present on admission

**Approved – Begin Oct 08**
- Object left in surgery
- Air embolism
- Blood incompatibility
- Press ulcers
- Falls
- Urinary Tract Infection (catheter associated)
- Vascular catheter associated infection
- Surgical Site Infection (mediastinitis with CABG)

**Proposed to add to Oct 08**
- More surgical infections
- Legionnaires disease
- Glycemic control
- Pneumothorax
- Delirium
- Ventilator pneumonia
- Venous thromboembolism
- *Staph aureus* septicemia
- *Clostridium difficile*
Summary

• To *err* is human – we all make mistakes
• Create an environment to make it easy to do it right and difficult to make mistake
• Create a blame free, non-punitive culture that rewards reporting of errors
• Analyze errors and learn from them to redesign our systems.
• Publicize what was learned
• Visible commitment from management
Thank you

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