

World Congress of Sterilization
Milan Italy
June 4-7, 2008

Patient Safety
Time for a change in design

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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

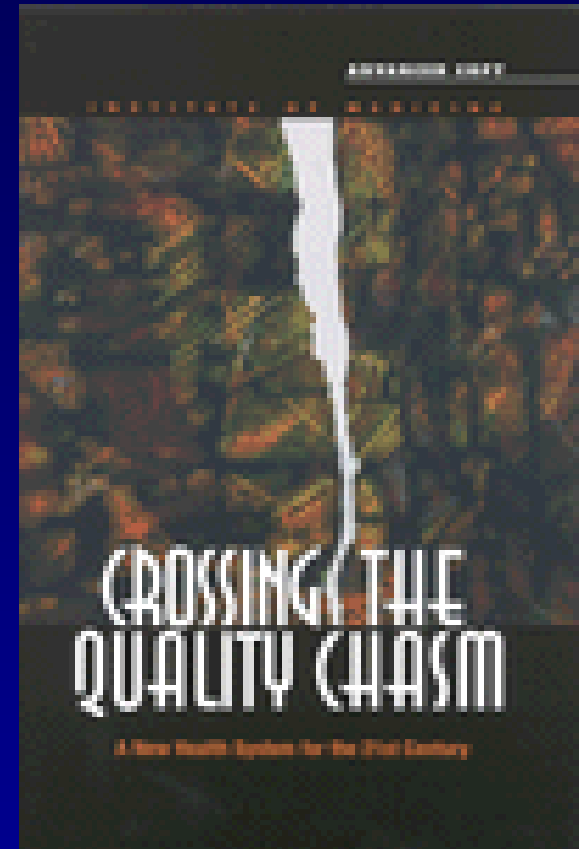
Healthcare in need of a redesign

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

McGlynn EA. *N Engl J Med* June 26, 2003; 348:2635-45

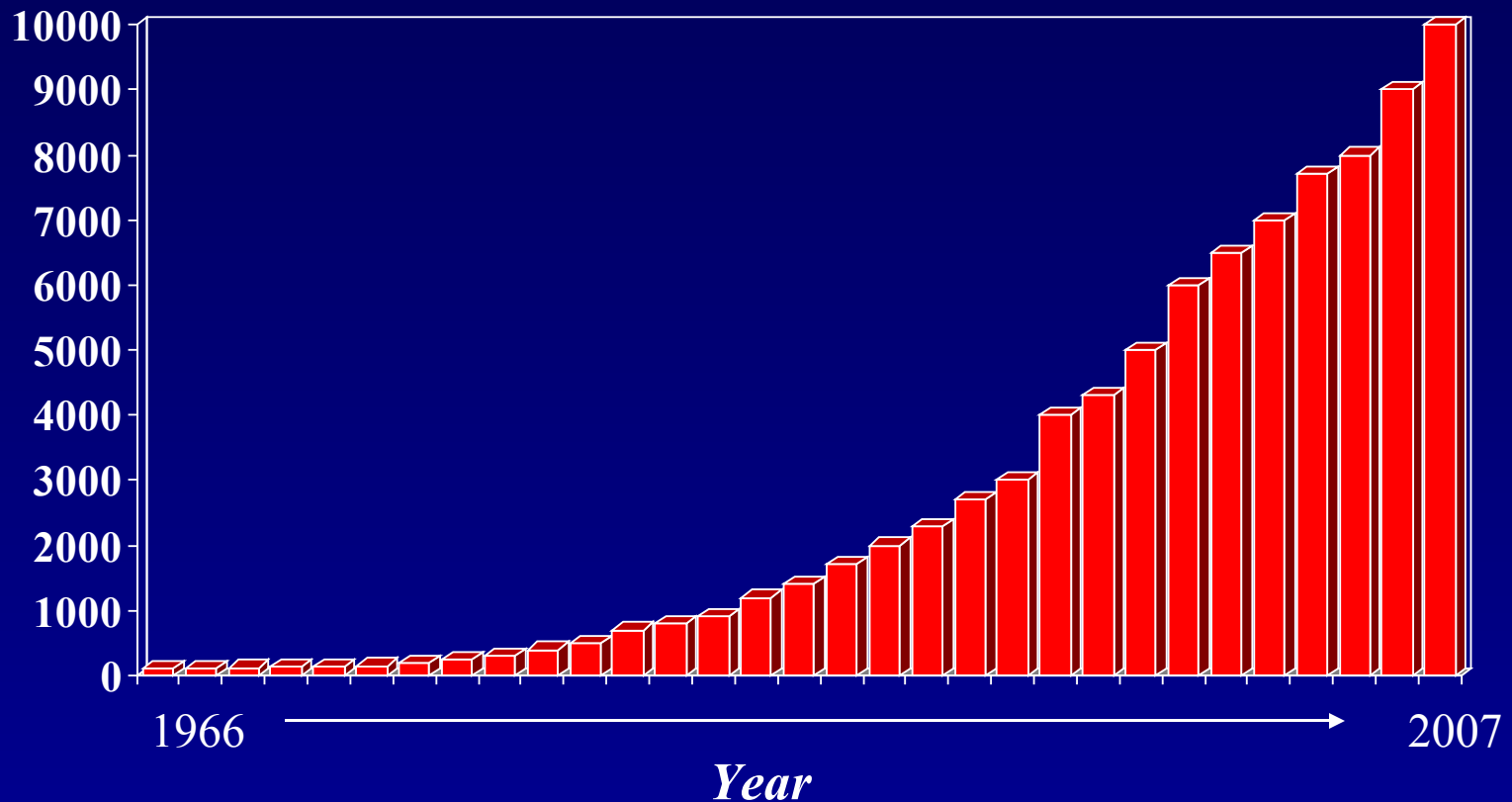
Institute of Medicine *Crossing the Quality Chasm, 2001*

- Total system redesign



Articles published from randomized controlled trials 1966 to 2007

Many support sterilization and disinfection procedures

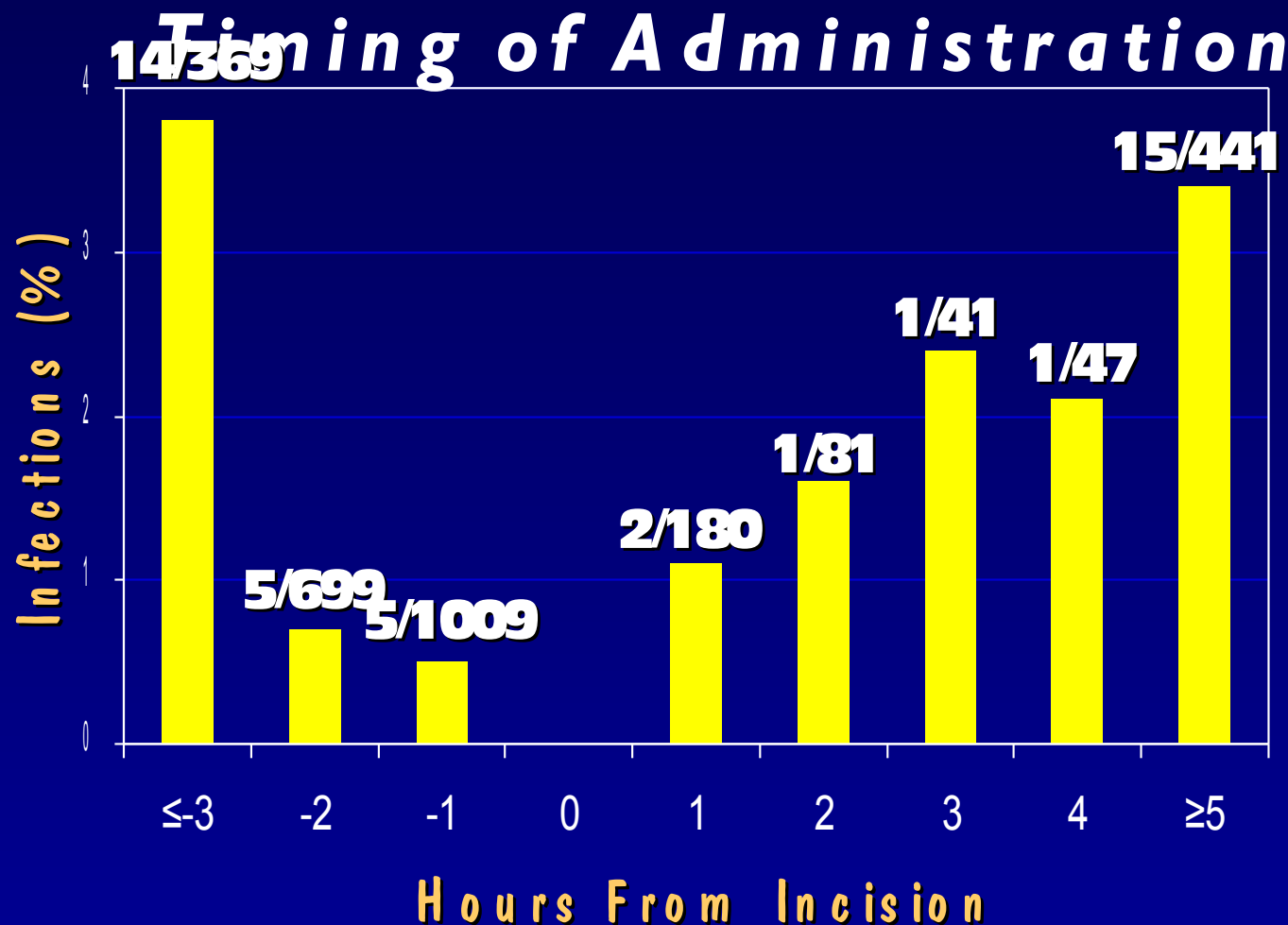


Diffusion of Knowledge

	Landmark Trial	Current Rate of use
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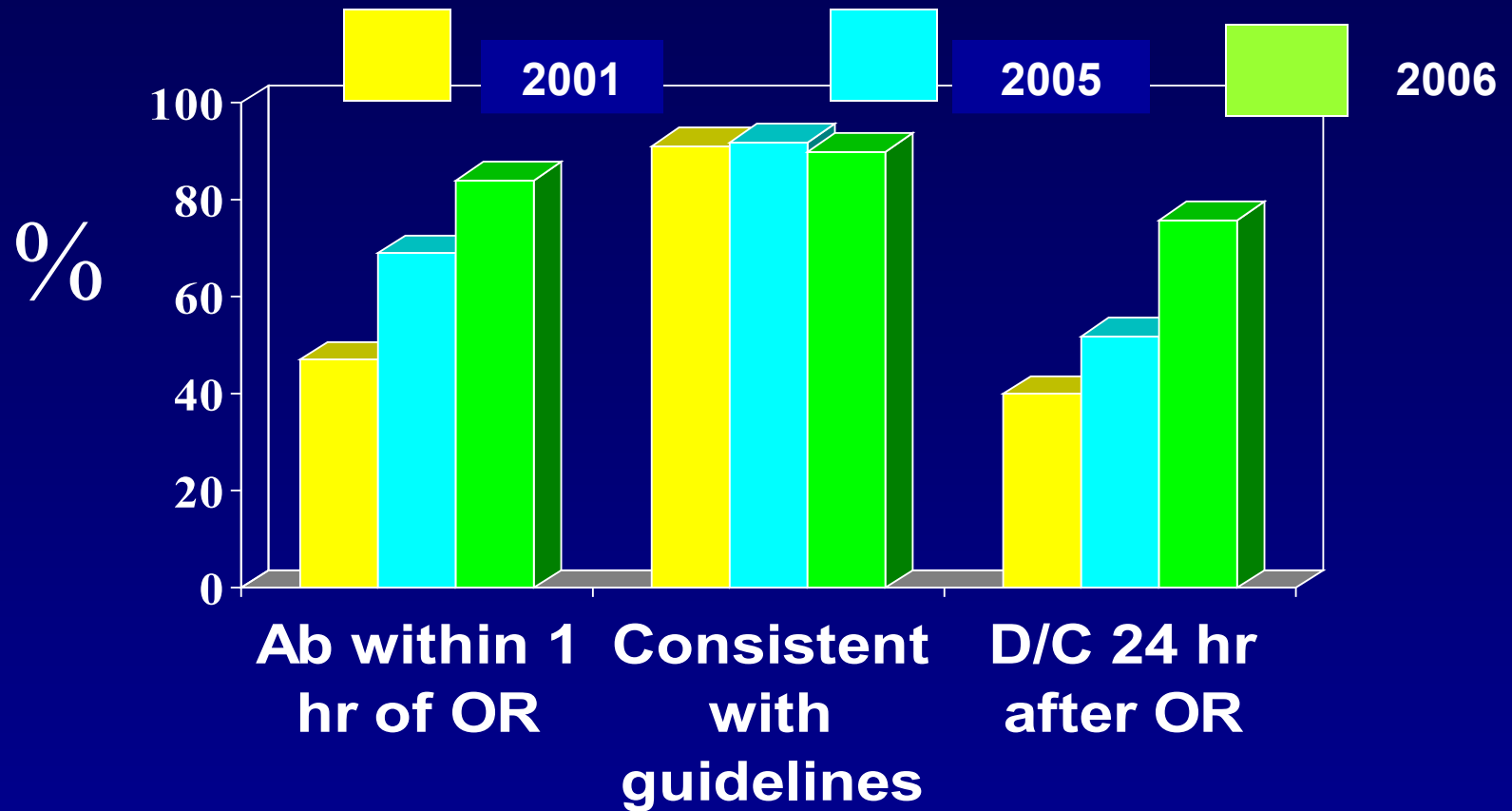
Influenza vaccine	1968	64%
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Perioperative Prophylactic Antibiotics



Classen. NEJM. 1992;328:281.

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



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

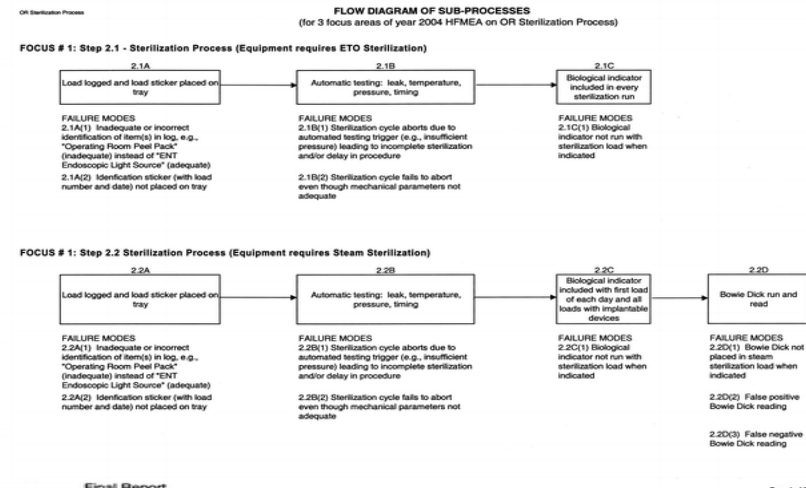
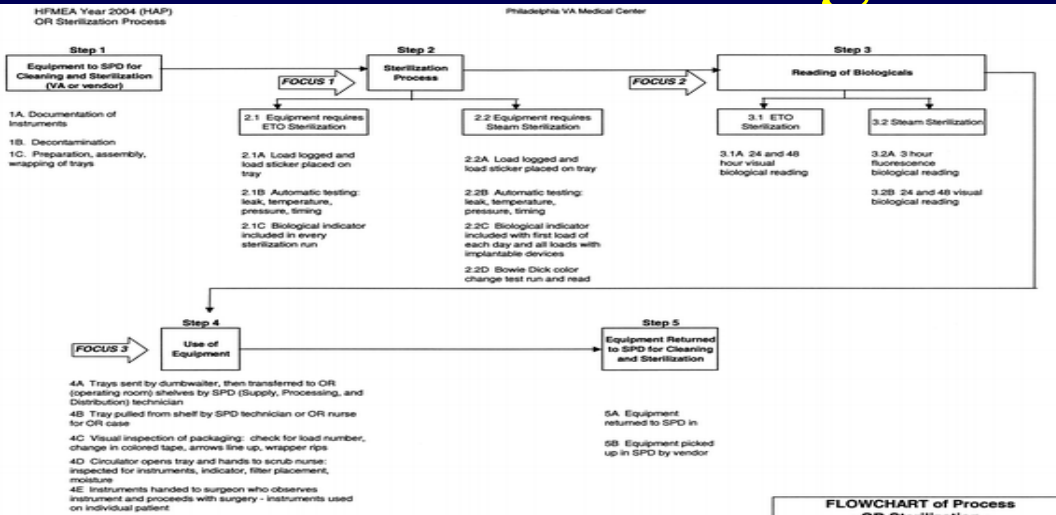
Change concepts using human factors engineering principles

- 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

No. of steps in the process	Error rate for each step	
	0.05 with 95% confidence	0.01 with 99% confidence
1	.05	.01
5	.33	.05
25	.72	.22
50	.92	.39
100	.99	.63

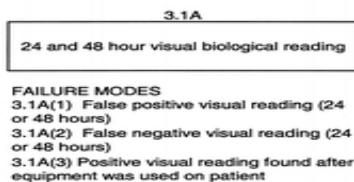
Steps in Process for Sterilization and Use of Surgical Instruments



OR Sterilization Process

FLOW DIAGRAM OF SUB-PROCESSES
(for 3 focus areas of year 2004 HFMEA on OR Sterilization Process)

FOCUS # 2: Step 3.1 - ETO Sterilization - (reading of biologicals)



FOCUS # 2: Step 3.2 Steam Sterilization (reading of biologicals)



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%

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

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

An Outbreak of *Pseudomonas aeruginosa* Infections Associated with Flexible Bronchoscopes

Arjun Srinivasan, M.D., Linda L. Wolfenden, M.D., Xiaoyan Song, M.D., Karen Mackie, R.N., Theresa L. Hartzell, M.D., Ph.D., Heather D. Jones, M.D., Gregory B. Diette, M.D., M.H.S., Jonathan B. Orens, M.D., Rex C. Yung, M.D., Tracy L. Ross, B.S., William Merz, Ph.D., Paul J. Scheel, M.D., Edward F. Haponik, M.D., and Trish M. Perl, M.D.

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

Location or institution, year	Instrument involved	No. of persons exposed
Sacramento, CA, 2002	Endoscope	750
Toronto, ON, 2003	Endoscope	146
Seattle, WA, 2004	Endoscope	600
Sacramento, CA, 2004	Endoscope	1,331
San Francisco, CA, 2004	Endoscope	2,000
Long Island, NY, 2004	Endoscope	177
Charleston, NC, 2004	Endoscope	1,383
Toronto, ON, 2003	Prostate biopsy probe	900
Pittsburgh, PA, 2005	Endoscope	200
Leesburg, VA 2005	Endoscope	144
San Diego, CA, 2006	Endoscope	300
Augusta, ME, 2006	Prostate biopsy needle	481
Dept Veterans Affairs, 2006	Prostate biopsy equipment	2,075
San Diego, CA, 2006	Surgical instrument	82

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

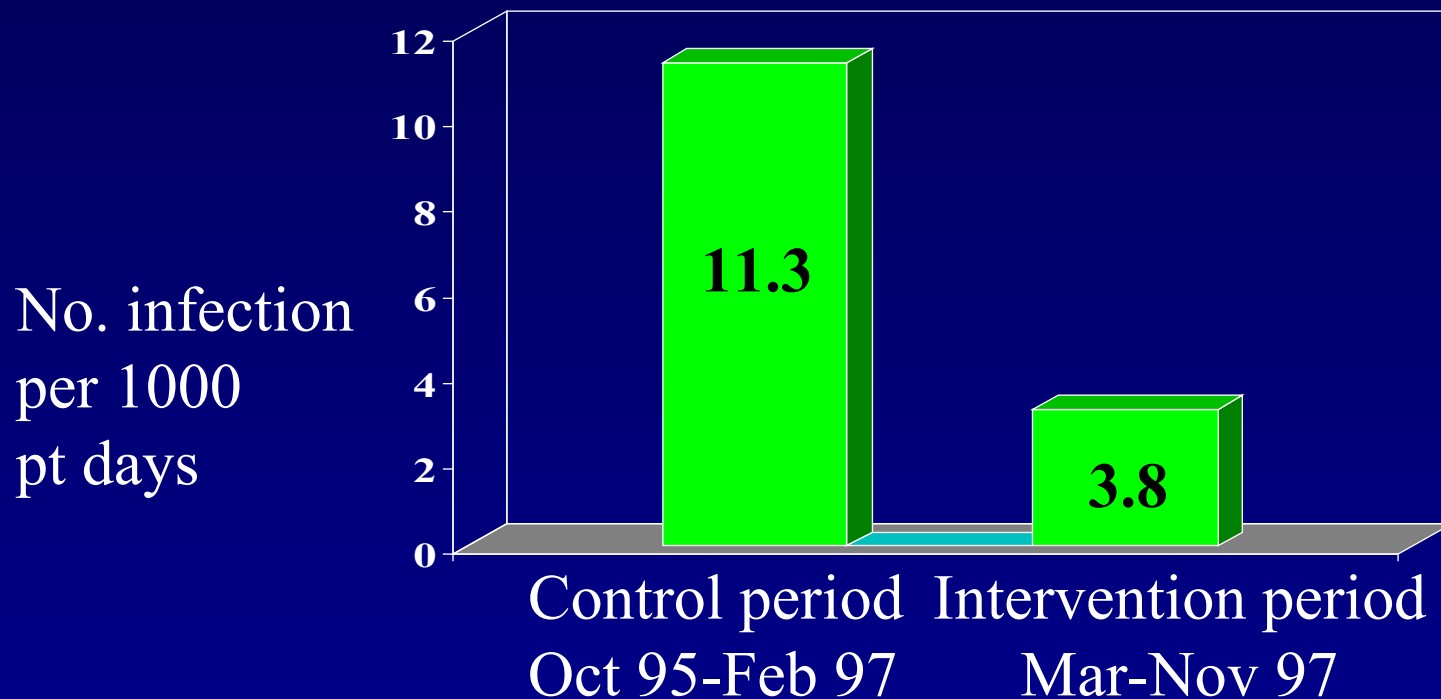
Reuse of Single-Use Devices (SUDs)

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

United States Government Accountability Office	
GAO	Report to the Committee on Oversight and Government Reform, House of Representatives
January 2008	REPROCESSED SINGLE-USE MEDICAL DEVICES
	FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk

200% reduction in bloodstream infections with standard process for IV catheter insertion

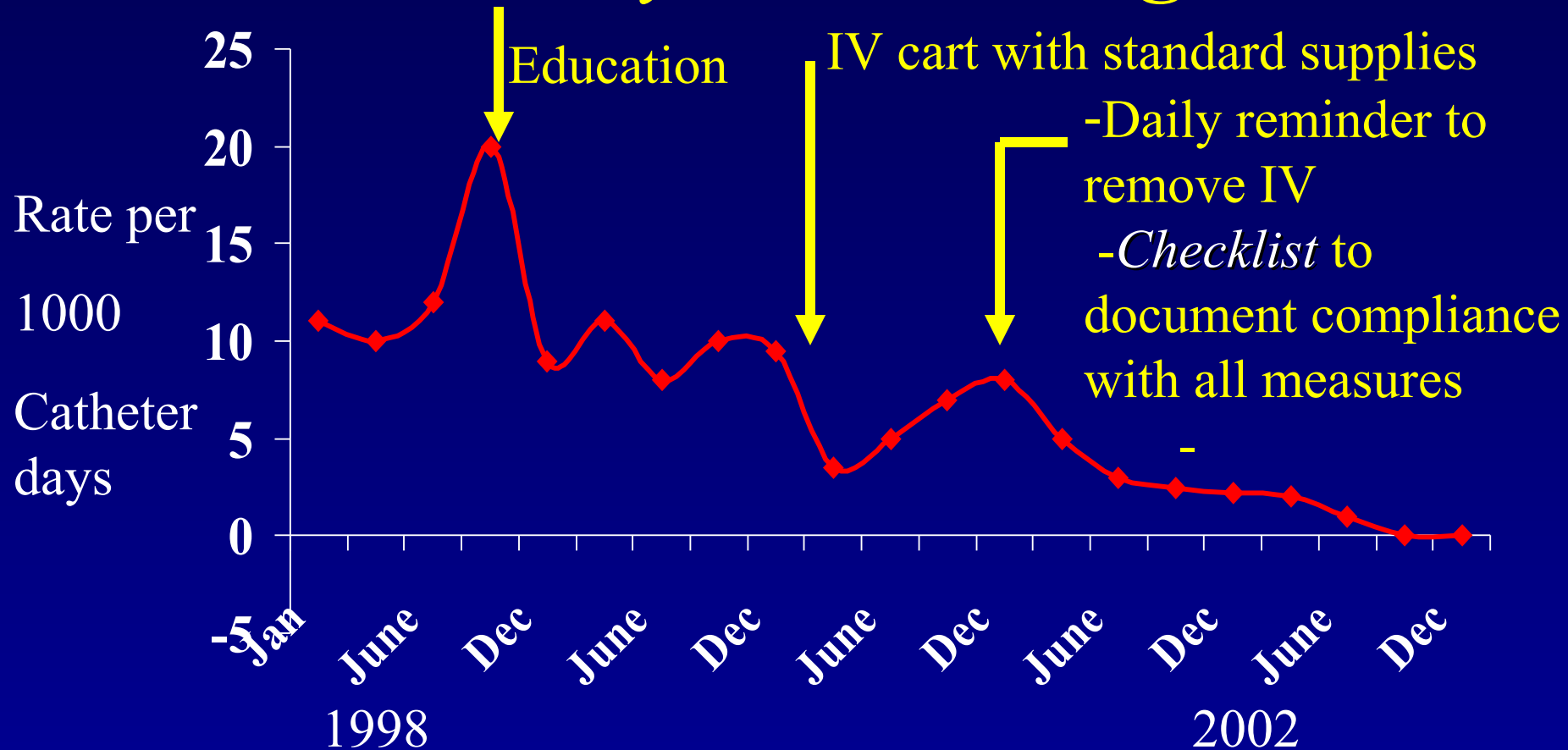


FROM: Eggimann P et al *Lancet* 2000; 1864-68

(3154 patients; 30 BSI -- prevented; savings \$90,000 to \$1,200,000

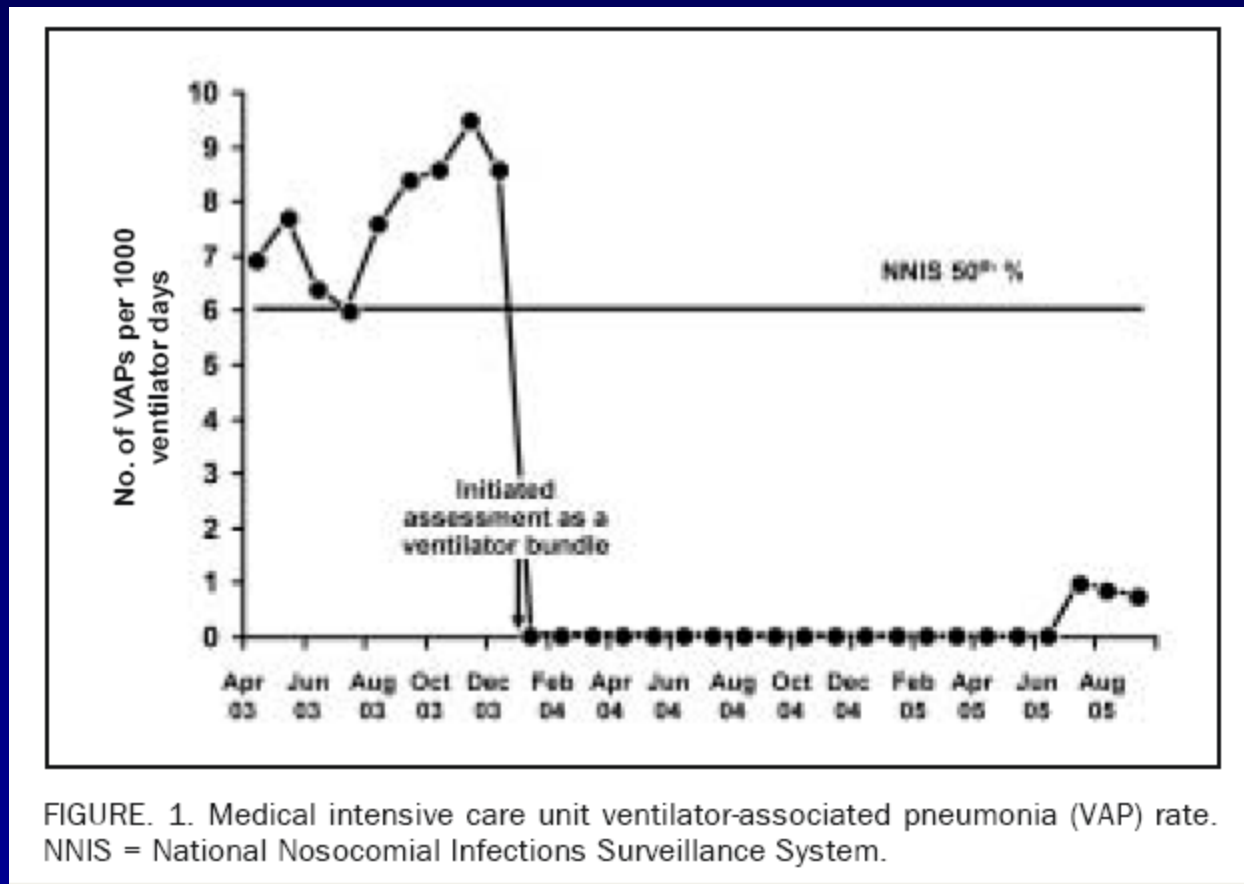
Pt Positioning, skin prep, barriers, training, insertion technique,)

1000% reduction in IV related bloodstream infections with a *system redesign*



Ventilator pneumonia drop to zero after *system redesign*:

Implementing a group or bundle of measures and monitoring
for compliance with ALL of them



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

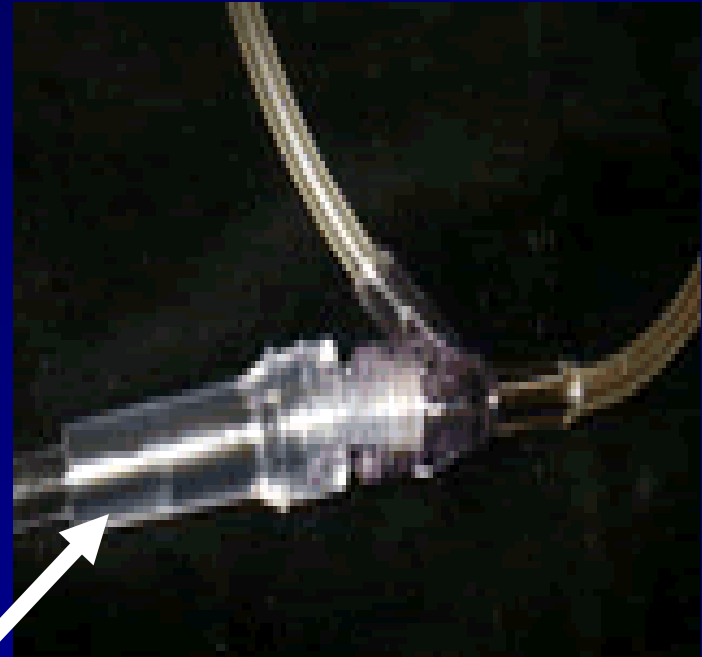
Good news and bad news:

- 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

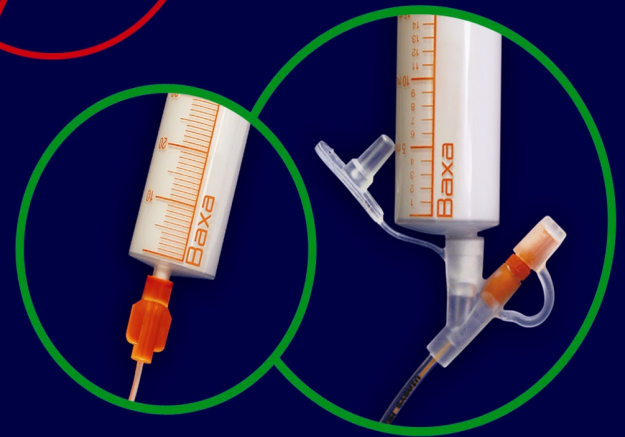


Redesign of infant oral feeding syringe and feeding tube

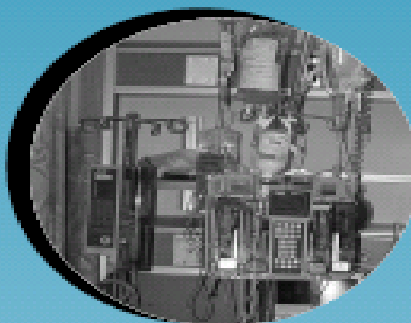
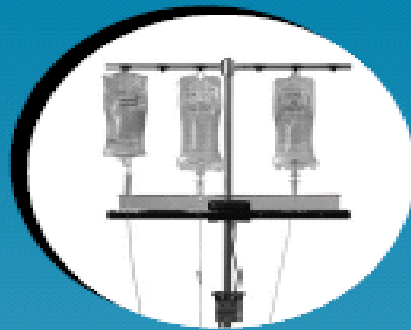
Standard syringe
will no longer fit
the new larger
feeding tube port



Both the feeding
tube port and oral
syringe port
made larger to fit
perfectly



www.ahrq.gov
search for “mistakeproof”



Mistake-Proofing the Design of Health Care Processes

May 2007



AHRQ

Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

**PATIENT
SAFETY**

Eliminate confusing information

Confusing

Enalaprilat: For Blood pressure
Pancuronium, Causes paralysis



FROM: ISMP Newsletter Sept 12, 2000 Special Alert www.ismp.org

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

Lockley SW N Engl J Med 2004; 351: 1829-37

*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

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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%

When to Blame or Punish



- 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

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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

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

No additional payment for healthcare-associated conditions *not* present on admission

Approved – Begin Oct 08

- Object left in surgery
- Air embolism
- Blood incompatibility
- Pressure 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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