

AAMI Conference and Expo  
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**Patient Safety :  
Where do *we* fit in?**

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# Today's Agenda

- Evolving focus on improving patient safety
- Application of human factors engineering and reliability concepts to redesign systems to enhance patient safety
- Our role in patient safety

# Recent Associated Press Stories

## Deaths from Medical Errors

- 6 yr/o – oxygen tank crushes boy in MRI machine
- 5 day old infant gets tube feeding in IV line
- 55 y/o gets wrong blood in surgery

# Why do we have a safety-quality gap?

- More to do...
- More to manage.....
- More to watch.....
- More people involved.....
- Lack of rudimentary clinical information capabilities
- Poorly designed processes set up to fail

# Public Fears

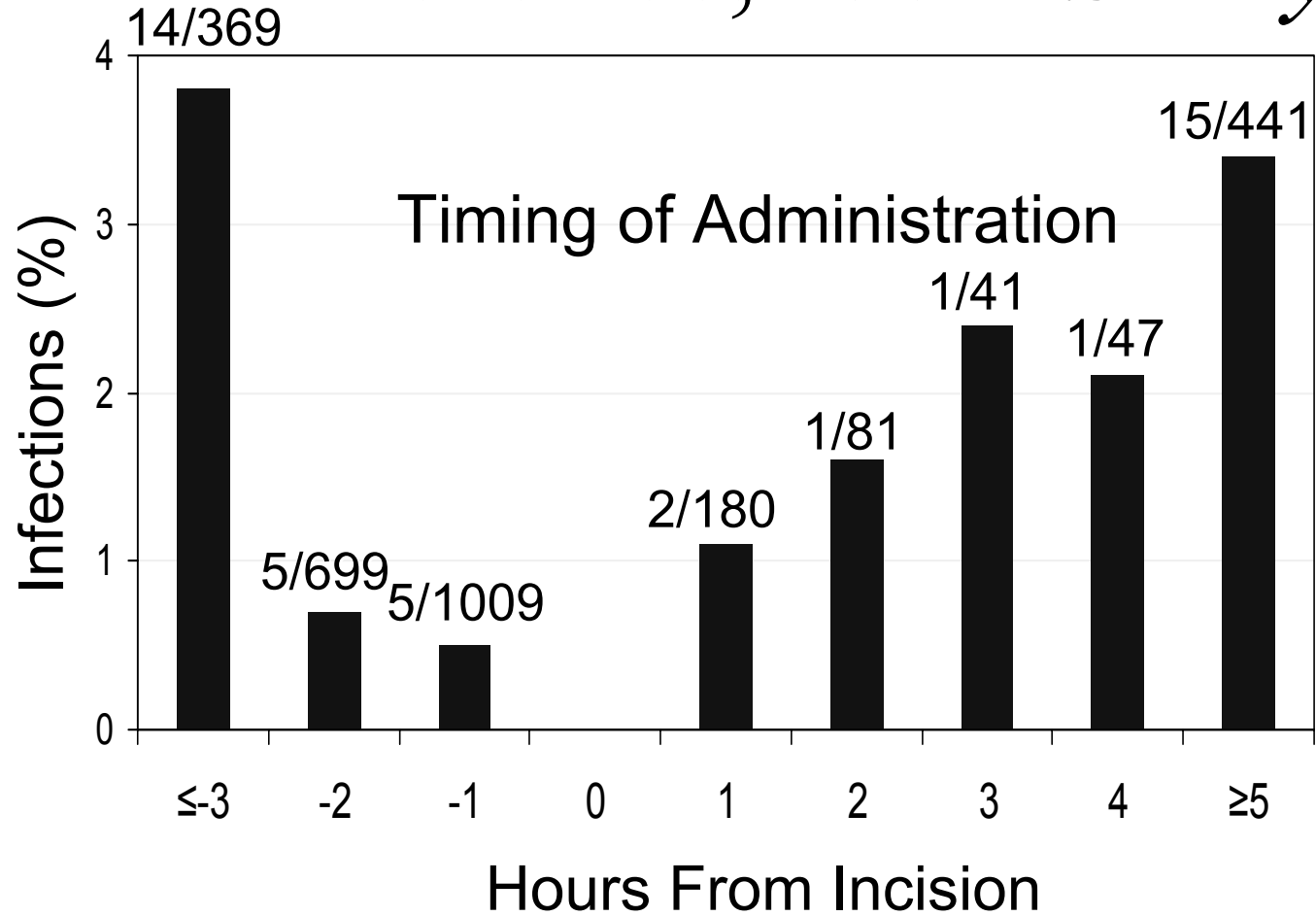
# Causes of Quality-Safety Problems

- Overuse
- Underuse
- Misuse

# Quality of Care in US

- 54% of patients receive recommended care
  - Under-use - 46%
  - Overuse/potentially harmful - 11.3%

# Perioperative Prophylactic Antibiotics, *1992 Study*

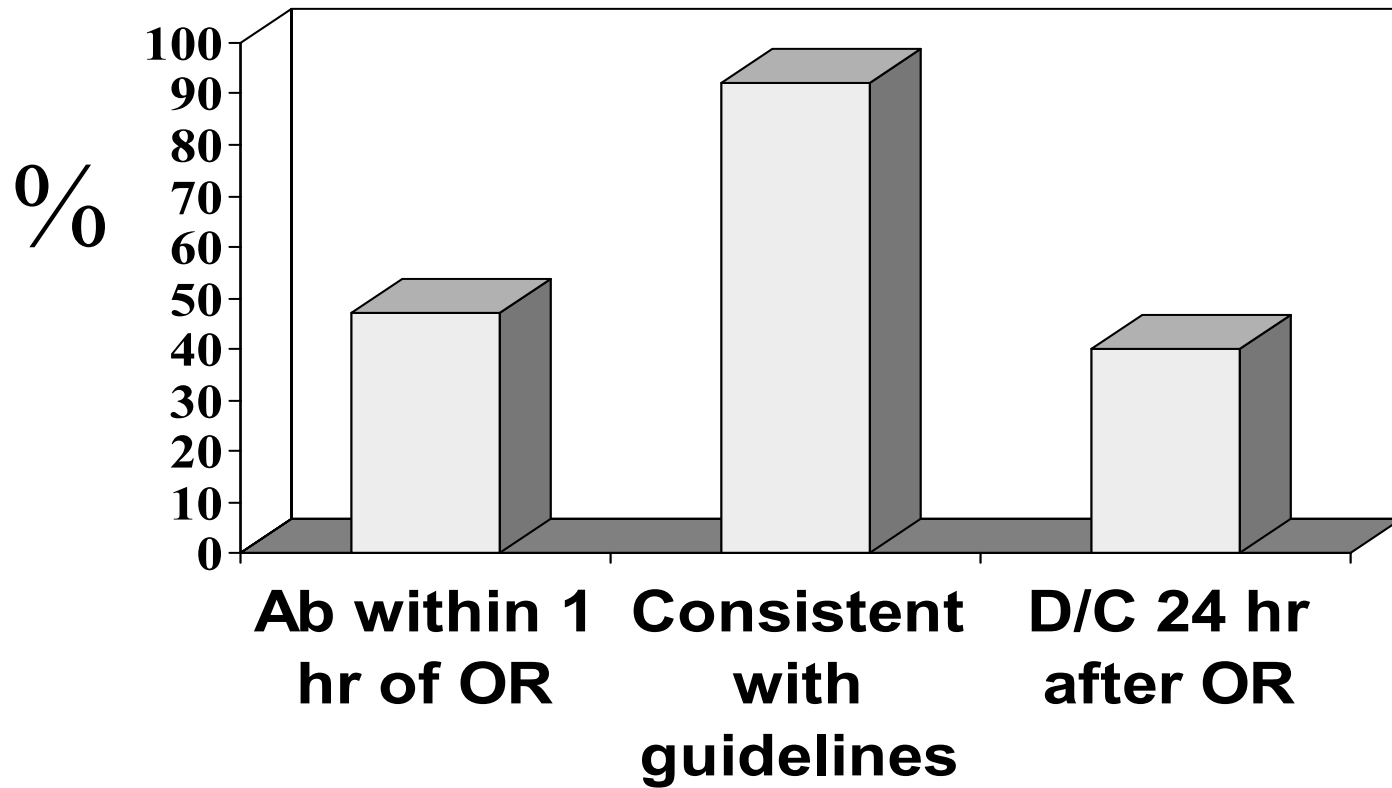


Classen. NEJM. 1992;328:281.

*Underuse and Misuse*

# Surgical Infection Prevention Project (SIPP)

Medicare Quality Improvement Project  
*Preliminary Baseline Data for US*



# IOM Institute of Medicine Report Crossing the Quality Chasm

- Total system redesign

# How good are you at....?

- Doing multiple tasks at same time?
- Recalling detailed information quickly?
- Math computation in your head?
- Operate all the buttons on your rental car?
- Can you concentrate..
  - when there is noise or interruption?
  - when you are angry, in a hurry, tired, or bored?
  - Before your first cup of coffee?

Redesign  
Using principles from  
**Human Factors Engineering**

or  
Reliability Science  
Ergonomics  
Six Sigma  
Lean

Unstable or unreliable process  
if failure is greater than  
20% of opportunities

$10^{-6}$  or 6 sigma 1 failure out of 1million

Where we are now? no common processes  
 $10^{-1}$  Performance (1-2 failures out of 10)  
only 80-90% Success

- Good intent
- Trying harder
- Some common equipment
- Standard orders
- Feedback on compliance
- Awareness and training

# Human Factors Engineering HFE:

*Design it so it easy to do it **right** and  
difficult to do it **wrong***

- Simplify
- Standardize
- Reduce reliance on vigilance and memory
- Use constraints or forcing functions

Every system is  
perfectly designed  
to achieve exactly  
the results it gets.

*Don Berwick*

*Institute for Healthcare  
Improvement*

# Ballot- Palm Beach County FL

(Republican)

George W. Bush- President  
Dick Cheney- Vice President

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3 → ○

(Democrat)

Al Gore -President  
Joe Lieberman - Vice President

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5 → ○

(Libertarian)

Harry Brown- President  
Art Oliver- Vice President

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7 → ○

(Reform)

Pat Buchanan-President  
Ezola Foster- Vice President

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○ ← 4

(Socialist)

David McReynolds- President  
Mary Cal Holeb- Vice President

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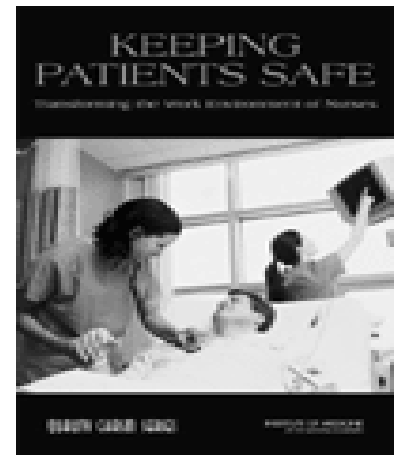
○ ← 6

# IOM: Keeping Patients Safe

Transforming the Work Environment ... 2004

*Health care is a high risk environment*

- Highly technical & hazardous procedures and equipment
- Incomplete and rapidly changing medical knowledge
- Workforce shortages
- Autonomy; lack of teamwork



# Challenge #1



Getting clinicians and technology  
staff to recognize that

*system redesign is  
everyone's job*

# Redesign the Process

- Design jobs for safety
  - Staffing; overtime, shift rotation, turnover, float personnel, skills

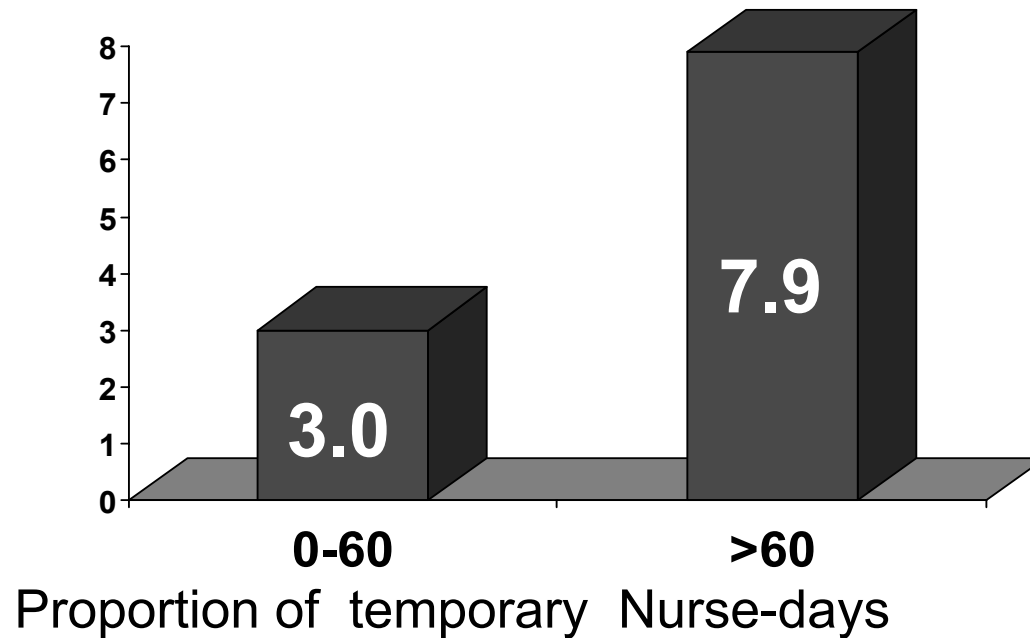
“..lower nurse staffing  
linked with  
higher 30-day risk-adjusted  
mortality”

7% increase risk of dying within 30 days for each  
additional patient added to nurse load

Aikens LH. JAMA Oct 23 2002 288:1987-93

# Effect of temporary staff in the intensive care unit on the risk of IV Catheter – Bloodstream Infections

CVC-associated  
BSI  
Per 1000 Central  
Line days



CVC-Central Venous Catheter; BSI- Blood Stream Infections

FROM: Alonso-Echanove J. Infect Control Hosp Epidemiol Dec 2003

# ICU Mortality Rates and Physician Staffing

- 30% reduction in mortality in ICUs managed by Board-certified “intensivists”:

# Staffing levels predictor of needlesticks

- Nurses working on hospital units with lower staffing were *twice* as likely to sustain needlestick injuries

Clark SP Am J Pub Health July 2002; 92: 1115-9

# Challenge # 2

Vigilance will not prevent mistakes –  
It is too easy to get distracted

# Can't rely on vigilance

- Factors affecting vigilance:
  - Fatigue
  - Competing demands
  - Psychological conditions (anger)
  - Distractions

# 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

# Omissions are single most common human error

- Too many steps
- Interruptions
- Noise
- No cues

# Everyday strategies to assist memory

- Notes and Post-its 65%
- Diaries 57%
- Lists 55%
- Writing on hand 43%
- Object positioning 41%
- Ask others to remind 34%
- Mental checking 8%
- Forming associations 6%
- visualization 4%
- Clocks,watches& alarms 3%

FROM: J Reason Qual  
Safety HC Mar 2002

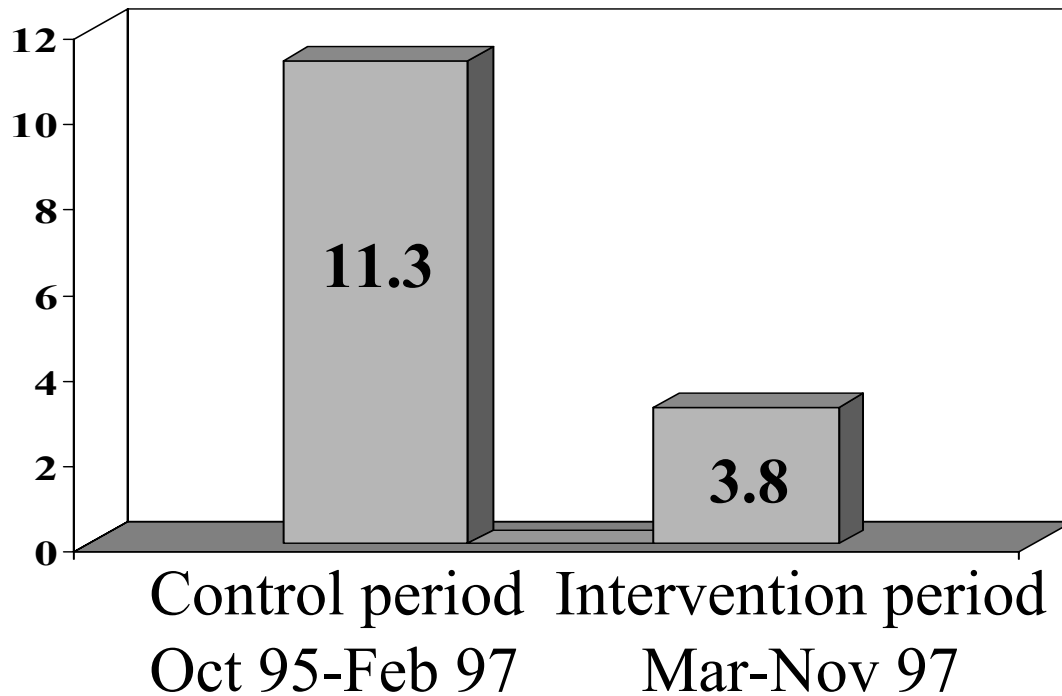
Standardize the process

# Systems Approach to Reducing Catheter-Associated Bloodstream Infections

Standardization and use of checklists  
and protocols

# Standardized Vascular Access Care Reduces Bloodstream Infection Rates

No. infection  
per 1000  
pt days



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, )

# Challenge # 3

## Eliminate confusing information

## Challenge # 4

Being innovative..  
when you redesign the system

A Novel redesign

*Bundling*

# Attributes of a bundle

- evidence based tasks
- grouped by time and space
- Implemented - all or nothing

# Ventilator-associated pneumonia (VAP)

- Occurs in 15 % of patients on ventilators
- Mortality rate 46%
- Increases length of stay and costs
- 1982 - evidence based guidelines from CDC

# Bundling measures to reduce ventilator-associated pneumonia

# FACT Sheet

## ICU Process Measures for Ventilated Patients

- Elevate HOB  $\geq 30$  degrees
  - Reduces risk of aspiration, LOS and ventilator days
- DVP prophylaxis
  - Heparin and mechanical prophylaxis (TED or SCDs)
- Peptic Ulcer Disease (PUD Prophylaxis)
  - Reduces risk of UGI bleeding
- “Sedation vacation” and assessment of readiness to wean
  - Reduces duration of vent days and LOS

# Baseline data

- Only 30 % of patients in ICU received all four measures
- 80% of nurses did not know evidence to support at least 1 of 4 measures
- Barriers to adoption: MD forget to write orders
- Intervention
  - Education to increase awareness of evidence
  - Daily checklist on rounds to ask providers if therapies received

# Compliance with processes and estimated impact

	% Compliance*		Prevented deaths	Avoided days in ICU	Cost savings Per year
	pre	post			
Implement all 4 processes	30%	96%	27	754	\$825,000

Berenholtz SM Jt Comm J Qual Saf Apr 2004; 195-204

Compliance 12 months later- 100%

# Central venous catheter (CVC) associated bloodstream infections

- 80,000 cases in ICU annually, US
- Up to 35% increased mortality

# Bundling measures to reduce central venous catheter (CVC) -associated bloodstream infections

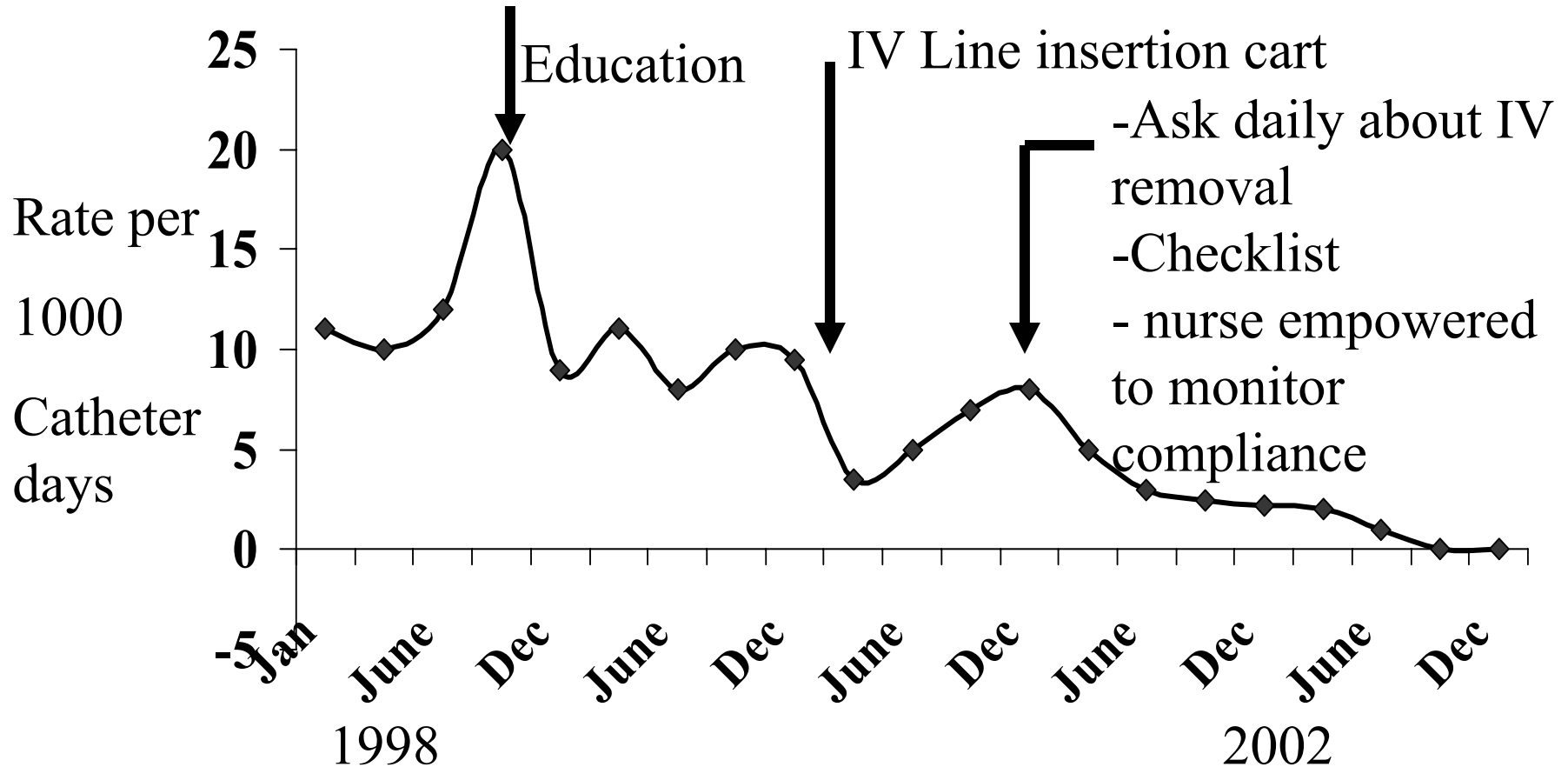
# Combined simple and inexpensive interventions to eliminate catheter-related bloodstream infections

- Staff education
- Catheter insertion cart
- Daily question to MD re: catheter removal
- Checklist for adherence to guidelines
- Empower nurses to stop insertion if violation of guideline

# Reduction in ICU



## CVC-related bloodstream infections with system redesign



# IHI's 100,000 Lives Campaign

## Prevent

- *\*Ventilator-associated pneumonia*
- *\*Surgical infections*
- *\*IV line-associated bloodstream infections*  
*\*with bundling of interventions*
- Adverse drug events with reconciliation
- Deaths from cardiac arrest with rapid response teams
- Mortality from acute myocardial infarction with evidenced based measures

*[www.qualityhealthcare.org](http://www.qualityhealthcare.org)*

# Effect of Medical Emergency Teams

	<b>Before MET</b>	<b>After MET</b>
<b>No of cardiac arrests</b>	<b>63</b>	<b>22</b>
<b>Deaths from cardiac arrest</b>	<b>37</b>	<b>16</b>
<b>No of days in ICU post arrest</b>	<b>163</b>	<b>33</b>
<b>No of days in hospital after arrest</b>	<b>1363</b>	<b>159</b>
<b>Inpatient deaths</b>	<b>302</b>	<b>222</b>

# Evolution of attention to HFE, design and safety of medical devices

- 1980      50% of recalls from design flaws
- 1990      FDA *Safe Medical Device Act*
- 1993      AAMI - *HFE Guidelines ..for Design of Medical Devices*
- 1997      FDA - *Do it By Design: An introduction to human factors in medical devices*
- 2001      AAMI – *Human Factors Design Process for Medical Devices*
- 2005      Premier, AHA.. Letter to FDA request bar coding of medical devices

# Technology increases complexity

- A poorly designed system is a latent error
  - (error waiting to happen)
- Error not seen till a trigger event
  - (IV pump misprogrammed –overdose)
- Trigger event thought to be cause – worker blamed

# Selected published studies on use of HFE to improve device design & safety

- PCA pump *Lin '98*
- Ultrasound machine *Aucela '94*
- Smart IV Pumps *Malashock '04;*  
*Fields 2005;*  
*Rothchild '05*

Vanderbilt University Medical Center

# SMART IV Pumps

## “safety wish list<sup>1</sup>”

- Automatic mechanism to prevent overdose
- Indicator that drug dose is out of limit
- Battery life indicator
- Back lit screen
- ATM key pad
- Light indicators
  - Green-ok Yellow-pause Red-Obstructed

Vanderbilt University Medical Center

## Smart IV Pumps

“safety wish list<sup>-2</sup>”

- Light weight battery
- Modularity
- Single power cord
- Space saving
- Adjustable alarm volume
- Quiet

# Smart Infusion Pump Reduces Risk of

## IV Infusion Errors

### Nebraska Medical Center

- Three ICU units- 8 mos
- Of > 4,000 infusions
- 157 Alerts (17 life-threatening)
  - Alerts resulted in discontinuing initial entry and reprogramming

# Use human factors engineering concepts to evaluate technology

- Before you buy
- Before you build
  - designing own software, implementing CPOE, bar coding
- After you buy
  - Ongoing surveillance
  - Analysis of adverse events

# Before you buy –

## Use HFE as part of decision

- Usability testing (measure errors, recovery etc)
- Scenarios, simulations, cognitive walk through
  - gather users, walk through the complete use of system
- HFE guideline checklist
- If limited resources: ask vendor a series of questions
  - 1) Does time pressure effect operation
  - 2) Are error rates affected by environment (noise, lighting)
  - 3) *How long does it take to learn to operate*
  - 4) How long to complete typical set-up tasks;
  - 5) What are the types and frequency of errors that could happen and the systems to thwart them?

# Ongoing surveillance

- Educate all users about HFE
- Reward collaboration of users and biomedical engineering for problem solving
- Use equipment repair logs for “no problems found”
- Get detailed info from FRONT-LINE users on device issues
- Coordinated recall procedures

# Med Sun

*www.medsun.net*



- Pilot, launched in 2002 by FDA
  - Nearly 300 sites
  - Assists FDA with post market device surveillance
  - Work with manufacturers to create safer device
  - Share info on problems with use of medical devices
- Internet reporting
  - Details about device issues beyond what is required under SMDA mandatory reporting
    - serious illness, injury and death; close calls

# System-wide training and co-ownership of HFE issues with devices

- New device training
- New employee orientation
- Annual reviews
- Skills assessment
- Unit briefings
- Executive walkarounds
- Purchasing committee meetings

# Analysis of adverse events

# Root Cause Analysis (RCA) of adverse events related to device use

- If mindset is on people and not system- then worker blamed because of lack of training and skill
- Need to review the device purpose; user population, skill and activities; characteristics of the environment

# Root Cause Analysis

## Questions to ask

- Prompts and feedback for each action?
- Displayed messages easy to understand?
- Load on user memory?
- Clearly marked “exit” and “cancel?”
- Existing knowledge make it difficult to learn how to use?
- Multiple users that will use differently?
- Easy switch from auto to manual operation?
- Symbols, alarms, controls similar to other devices?
- Create workarounds to bypass problems?
- Environmental conditions effect operation (noise, lights, )

# Safety and Quality- in Healthcare Facility Design

St. Joseph Community Hospital West Bend, WI

- Standardization & simplification
- Automate (EMR, Bar coding, CPOE)
- Adaptability
- Noise Reduction
- Minimize worker fatigue (desk height, lighting)
- Design for vulnerable patients
- Involved patients and family in care

## Challenge # 5

Don't wait till there is a problem  
to redesign

Stuff happens

# Impact of Organizational and Professional Culture and Teamwork

# Culture

- Obstacles and difficulties part of the job
- Work arounds and patching to fix
- Lack of teamwork
- Blame and punish the worker
- Deny fatigue on performance
  
- Common to hear
  - “hmmmmm wonder why its doing this???”

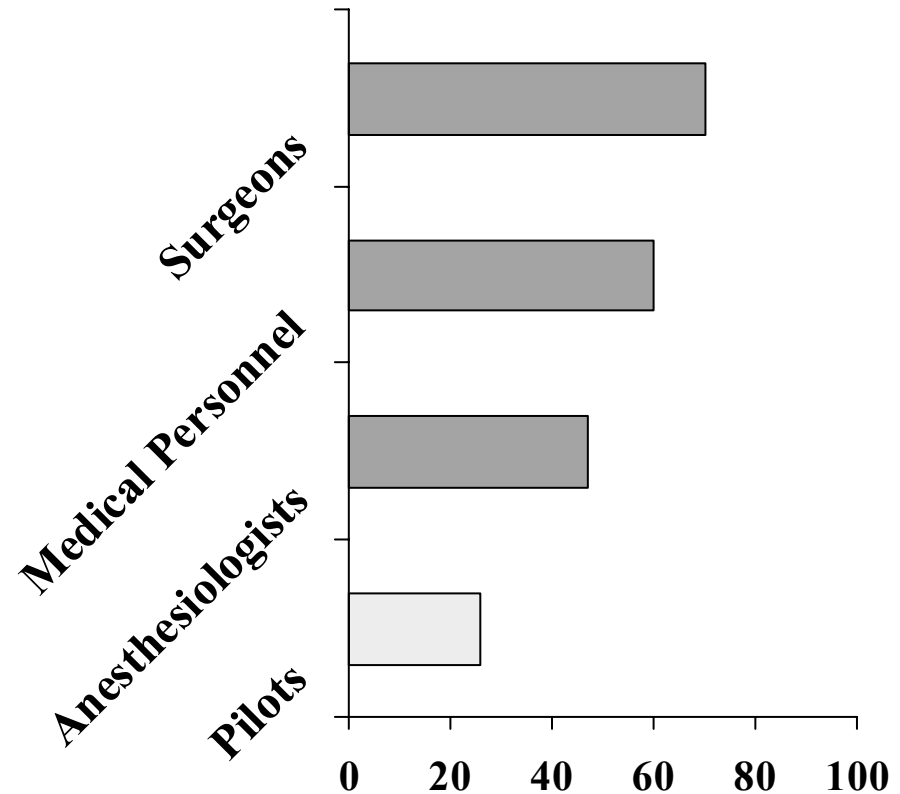
# Fatigue as a Threat

- 24 hours of sleep deprivation have performance effects comparable to blood alcohol level of 0.1%

Nature 1997

# Perceptions of stress and fatigue

- % likely to deny effects of fatigue on performance



# Limiting interns to working <16 hours in ICU reduces attention deficits and serious medical errors

- Interns working more than 16 hrs continuously
  - 50% more attention failures\*
  - 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

# Interns working longer than 24 hours at risk of car crash

- Medical interns working  $> 24$  hours:
  - 2X more likely to have car crash
  - 5X more likely to have a "near miss" incident on the road

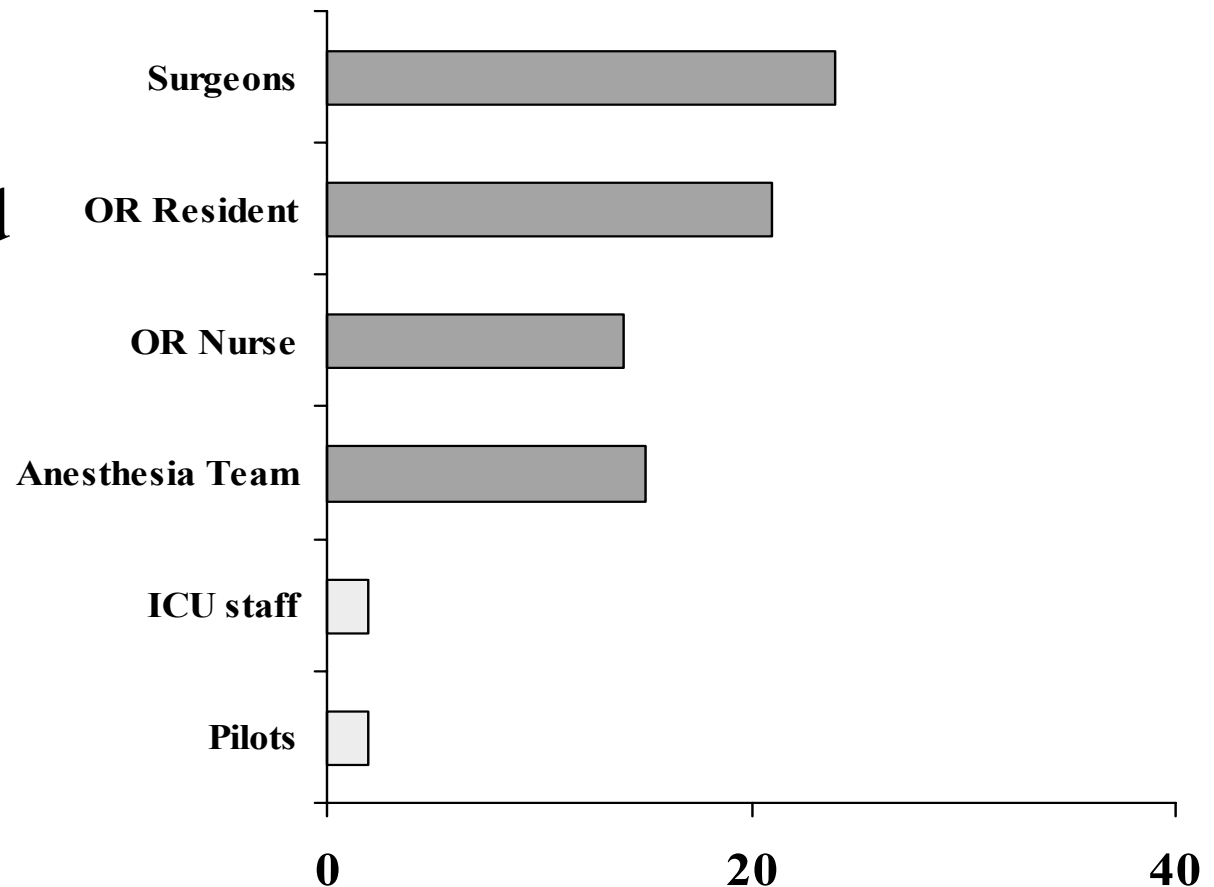
FROM: Barger LK, New Engl J Med; Jan 13, 2005: 125-34

# Challenge # 6

Create a culture that allows a  
“call out’ of  
incorrect information or actions  
without fear of reprimand

# Attitudes to teamwork & hierarchy

- % agree that junior team members should not question decisions by senior team



# Teamwork To Reduce Errors

## Business Case

- Review of 54 legal cases in 8 hospitals
    - Analysis of 48 components of teamwork
  - Four major failures
    - Identify established protocol or developed a plan
    - Advocate and assert a position
    - Prioritize and/or understand tasks/plan for patient
    - Cross monitor action (watch each other for simple mistakes)
  - Estimated avoidable legal costs \$16 million or \$560,479 per case
- Risser D Ann Int Med 1999

# Intimidation of Health Care Workers

## Who Question Potential Errors

	Often	Sometimes
• Refusal to answer calls		
– MDs	20%	40%
– Non MDs	22%	41%
• Condescending language		
– MDs	28%	39%
– Non MDs	32%	36%
• Verbal abuse	6%	16%

*We pick the best people to be  
healthcare professionals, train them,  
set standards, certify them, insist on  
perfection, and then punish them if  
they fail*

Lucian L. Leape, MD 2000

# Survey of healthcare worker's attitude about a non-punitive culture N= 1225 8/01

- Can't weed out "bad apples:" 20%
- Tolerates failure: 15%
- excuses poor performance - 15%
- Increases carelessness - 21%

# When to Blame or Punish



- Was the Unsafe Act Intended? and
- Was the Bad Outcome Intended?

AHRQ  
Agency for Healthcare  
Research and Quality

AHRQ



Agency for Healthcare Research  
and Quality

*Making Healthcare Safer: A Critical Analysis of  
79 Patient Safety Practices, 2001*

*Chapter 41*

*Human Factors and Medical Devices*

# AHRQ Eleven of 79 Practices

Rated Highest with Evidence Supporting Widespread Implementation

- Ultrasound guidance for IV catheter insertions
- Sterile barriers for IV catheter insertions
- Pre-operative antibiotic prophylaxis
- Antibiotic-impregnated IV catheters
- Prevent venous thromboembolism
- Peri-operative beta-blockers
- Informed Consent
- Bedding to prevent pressure ulcers
- Patient self-management for (Coumadin™)
- Enteral nutrition in critically ill patients

Download AHRQ patient safety  
practices at

[www.premierinc.com/safety](http://www.premierinc.com/safety)

# Challenge # 7

**Stop worrying ....**

just start collecting data on  
quality and safety measures  
for

- reimbursement
- tracking improvement

# CMS Safety and Quality Initiatives 2005



- *Pay for Reporting*
  - *Hospital Quality Alliance*
- *Pay for Performance*
  - *CMS-Premier demo*

# Hospital Quality ~~Initiative~~ Alliance *aka* *National Voluntary Hospital Reporting Initiative*

- Collaboration of
  - AHA, FAH, AAMC, CMS
  - JCAHO, AHRQ, NQF, AARP, AFL-CIO
- Starter Set of 10 measures to be reported by to receive full Medicare payment
  - CHF (congestive heart failure)
  - AMI (acute myocardial infarction)
  - CAP (community acquired pneumonia)
- Aligned with measures from JCAHO, CMS, NQF

# First Ten Quality Measures\*

AHA, JCAHO, NQF with CMS

Condition	Measure
<b>AMI</b>	Aspirin at arrival Aspirin at discharge Beta blocker at arrival Beta blocker at discharge ACE inhibitor for LVSD
<b>CHF</b>	L ventricular function assessment ACE inhibitor for LVSD
<b>CAP</b>	Initial antibiotic timing Pneumococcal vaccination Oxygen Assessment

\*Feasible, practical, validated

Comparative data on CMS web site  
[www.cms.gov/quality/hospital](http://www.cms.gov/quality/hospital) rev

# CMS/Premier Hospital Quality Incentive Demonstration Project

- 3-year demo- links payment with quality and safety measures
- Top performers identified in five clinical areas
  - Acute Myocardial Infarction
  - Congestive Heart Failure
  - Coronary Artery Bypass Graft
  - Hip and Knee Replacement
  - Pneumonia
- 278 participating hospitals

# CMS - Premier Project

## Pay Hospitals for Performance in Safety and Quality

- Top 10<sup>th</sup> percentile  
*(additional 2% Medicare)*
- Top 20<sup>th</sup> percentile (1%)

# Challenge # 8

- Keeping the public accurately informed of quality and safety of care in each hospital

CMS Web site for Consumers

[www.hospitalcompare.hhs.gov](http://www.hospitalcompare.hhs.gov)