

AAMI Conference and Expo
May 14-17th 2005 – Tampa FL

**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

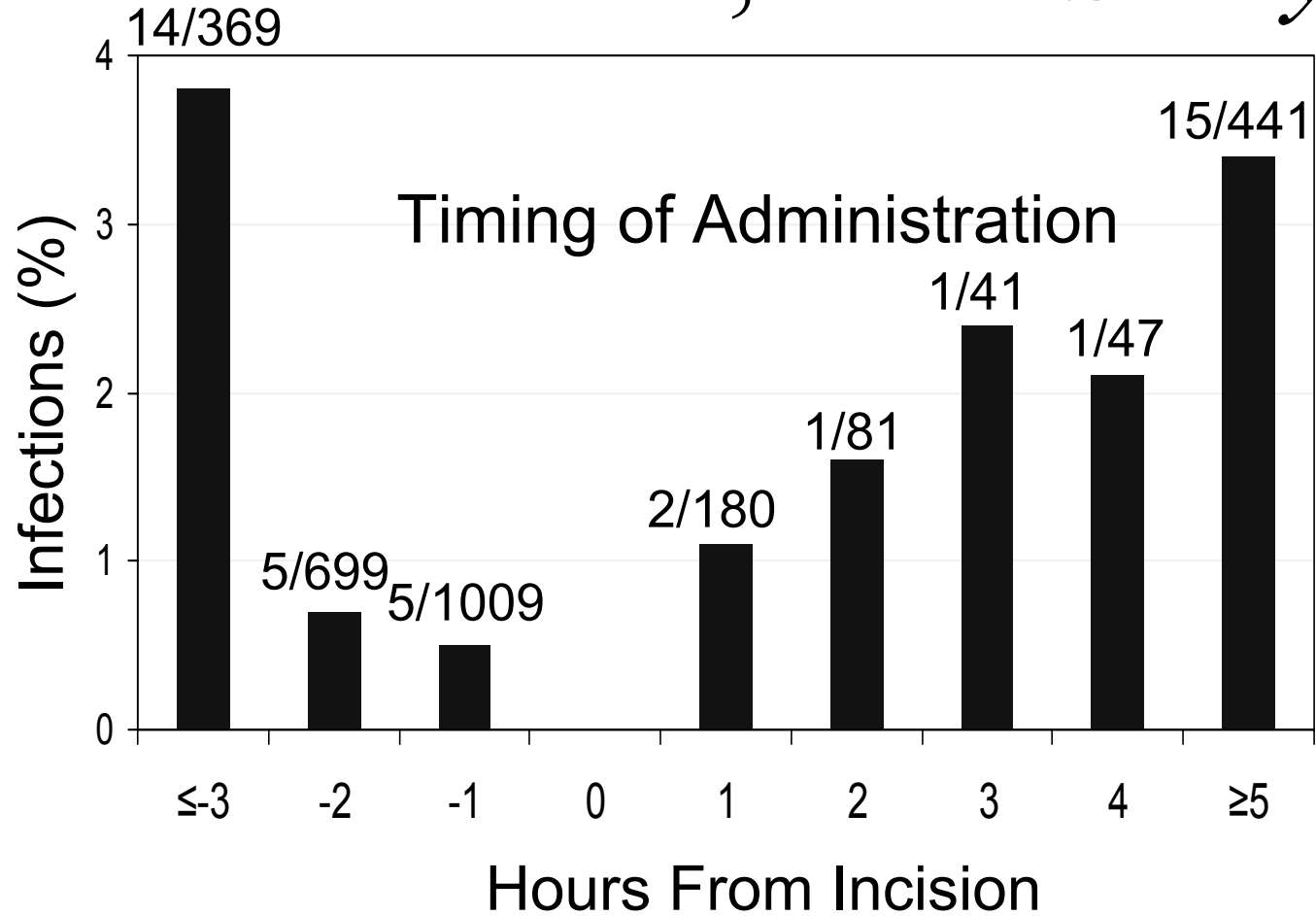
Causes of Quality-Safety Problems

- 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*



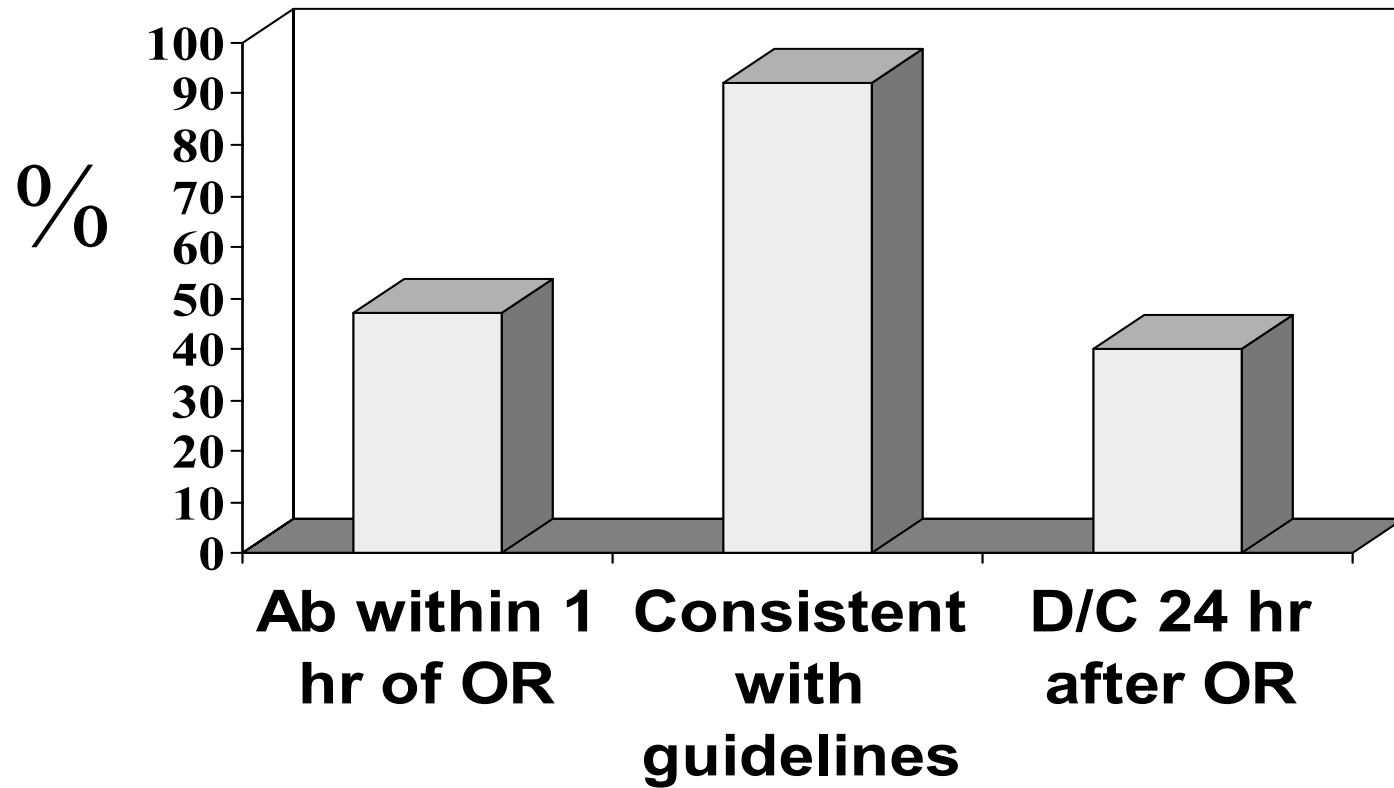
Classen. NEJM. 1992;328:281.

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

3 → ○

(Democrat)

Al Gore -President
Joe Lieberman - Vice President

5 → ○

(Libertarian)

Harry Brown- President
Art Oliver- Vice President

7 → ○

(Reform)

Pat Buchanan-President
Ezola Foster- Vice President

○ ← 4

(Socialist)

David McReynolds- President
Mary Cal Holeb- Vice President

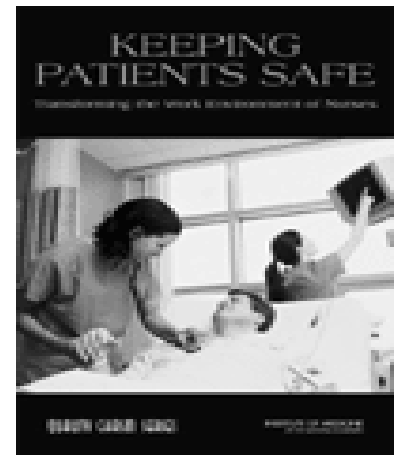
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IOM: Keeping Patients Safe

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

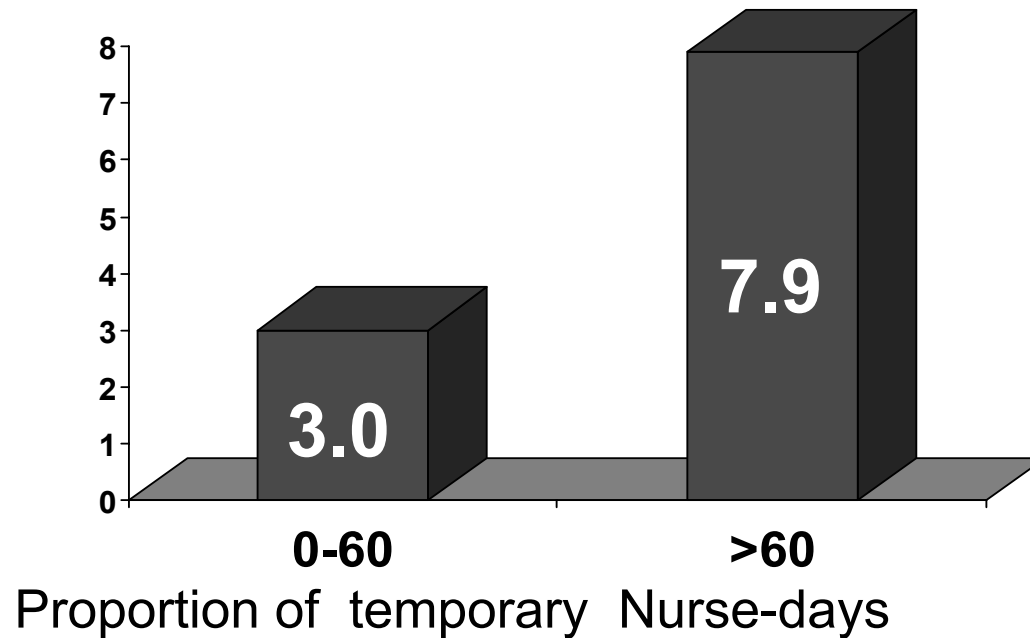
“..lower nurse staffing
linked with
higher 30-day risk-adjusted
mortality”

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

Omission 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

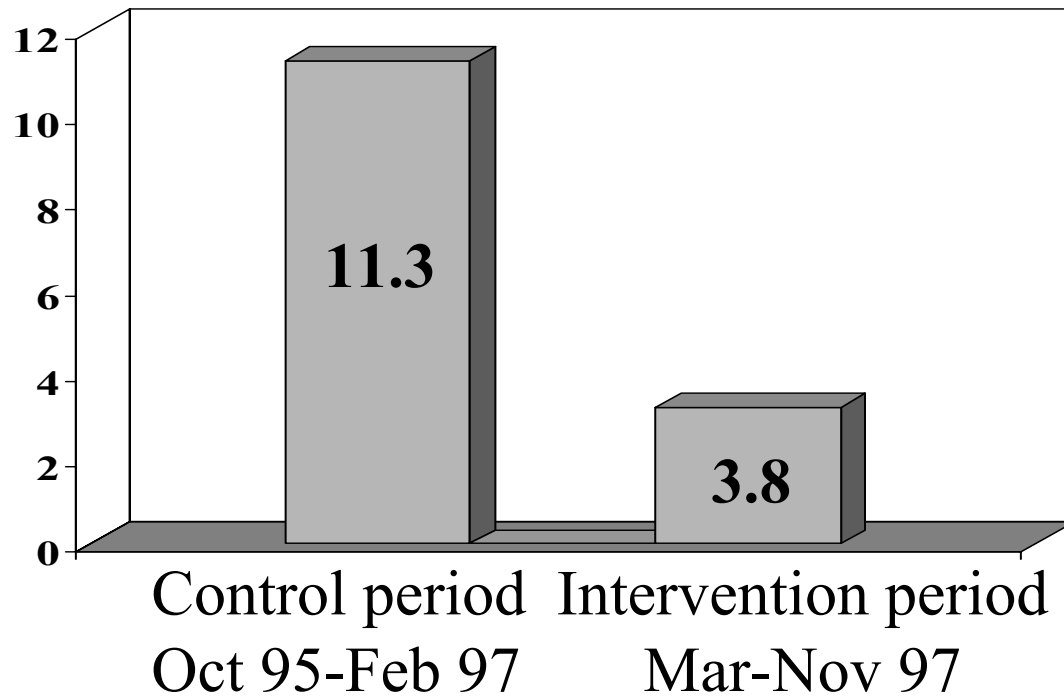
Standardize the process

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 ≥ 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

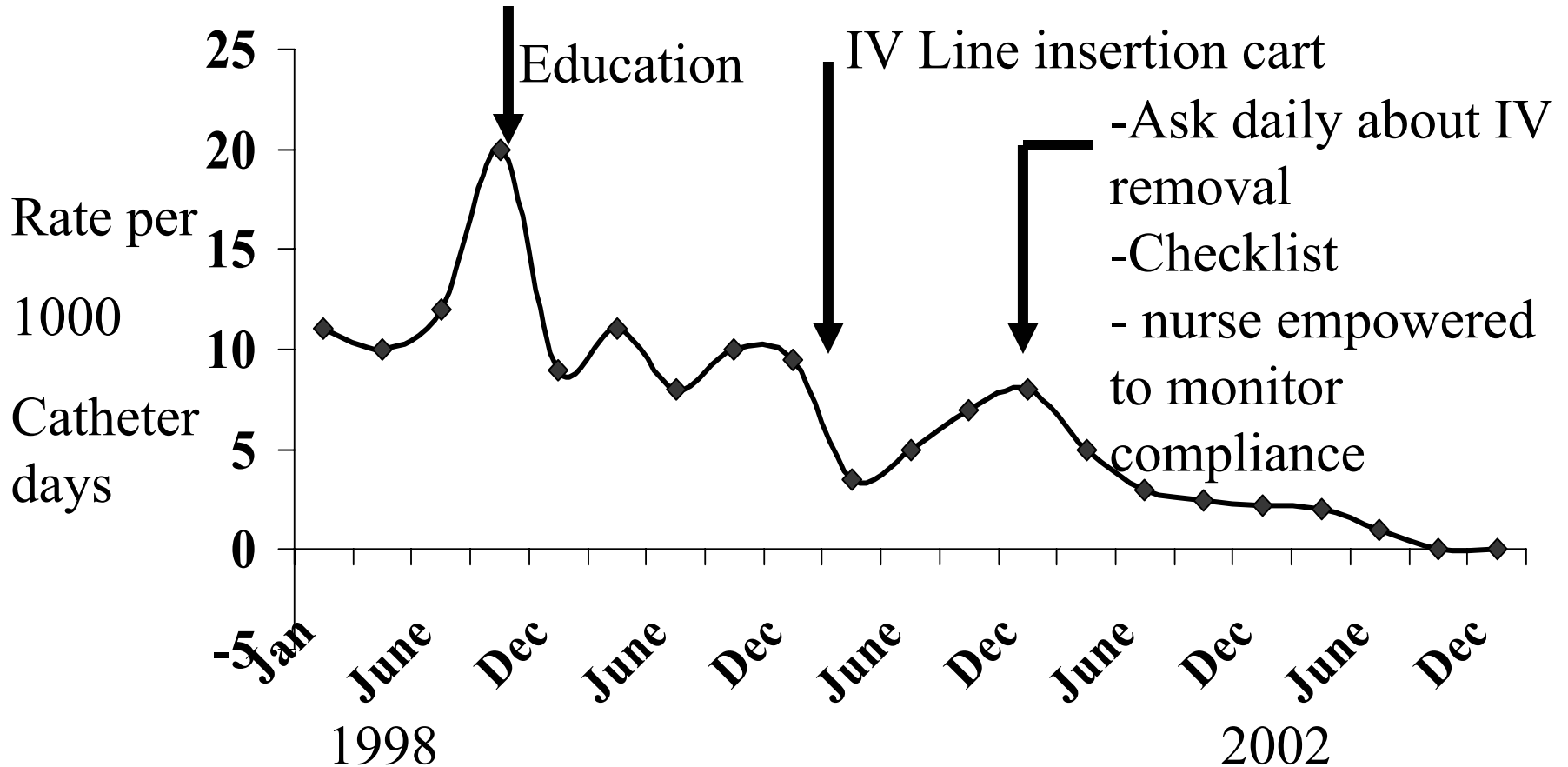
Combined simple and inexpensive interventions to eliminate catheter-related bloodstream infections

- 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

Effect of Medical Emergency Teams

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

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 list¹”

- 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⁻²”

- 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???”

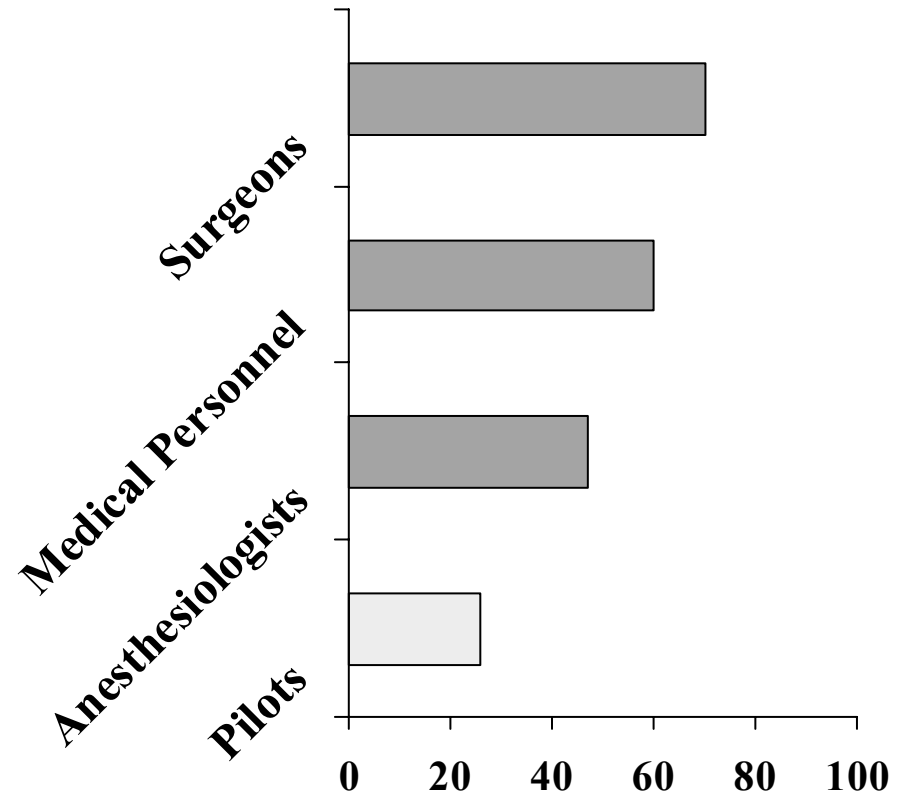
Fatigue as a Threat

- 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

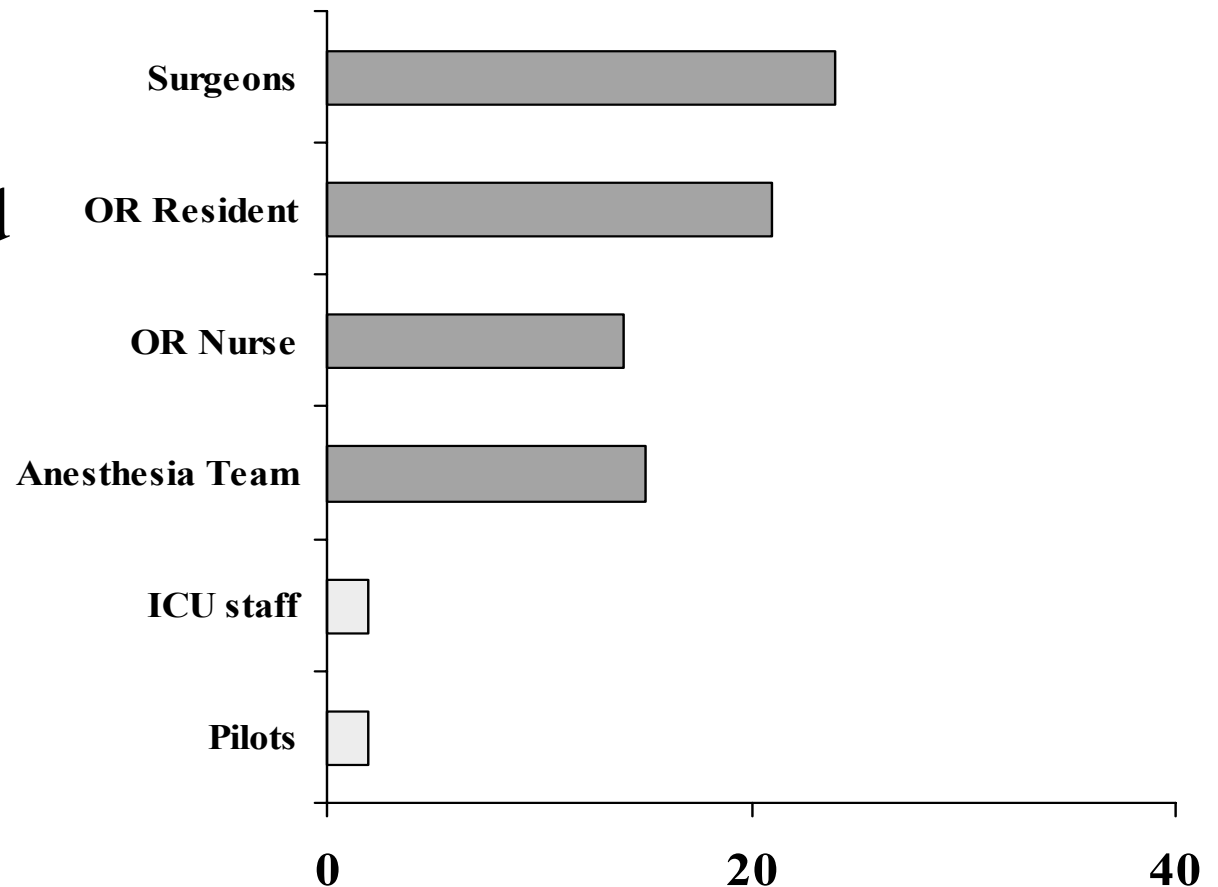
FROM: Barger LK, New Engl J Med; Jan 13, 2005: 125-34

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

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

*Feasible, practical, validated

Comparative data on CMS web site
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 10th percentile
(additional 2% Medicare)
- Top 20th 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