

# Patient Safety: It's Not Rocket Science



**James P. Bagian, MD, PE**

Chief Patient Safety and Systems Innovation Officer  
Director, Center for Health Engineering & Patient Safety

University of Michigan

[jbagian@umich.edu](mailto:jbagian@umich.edu)



# IOM Goals

n Safe

n Timely

n Efficient

n Effective

n Equitable

n Patient-Centered



# Patient Safety - The Problem

- n Not New
- n 1964 - Schimmel (Ann. Int. Med.)
- n 1981 - Steel (NEJM)
- n 1991 - Harvard Practice Study (NEJM)
- n 1995 - Family Practice MDs (JFamPrct)
- n 11/99 - IOM Report
  - Deaths due to Preventable Adverse Events greater than MVA, Breast Cancer, or AIDS



# Where Healthcare Was/Is

- n Cottage Industry Mentality
- n Virtually Total Reliance on:
  - Professional/Individual Responsibility
  - Individual Perfection
  - Train and Blame
- n Little Understanding of Systems Relative to People and Processes
  - Ignorance vs Arrogance

**Culturally Different!!!!**



# Typical Approach

- n New Policies, Regulations, Reporting Systems, Training
- n Good First Step But.....
  - Lack of Systems Insight
  - Superficial Solutions (?Answers)
  - Inadequate Follow-Up
  - Lost Opportunity



# Typical Missing Features

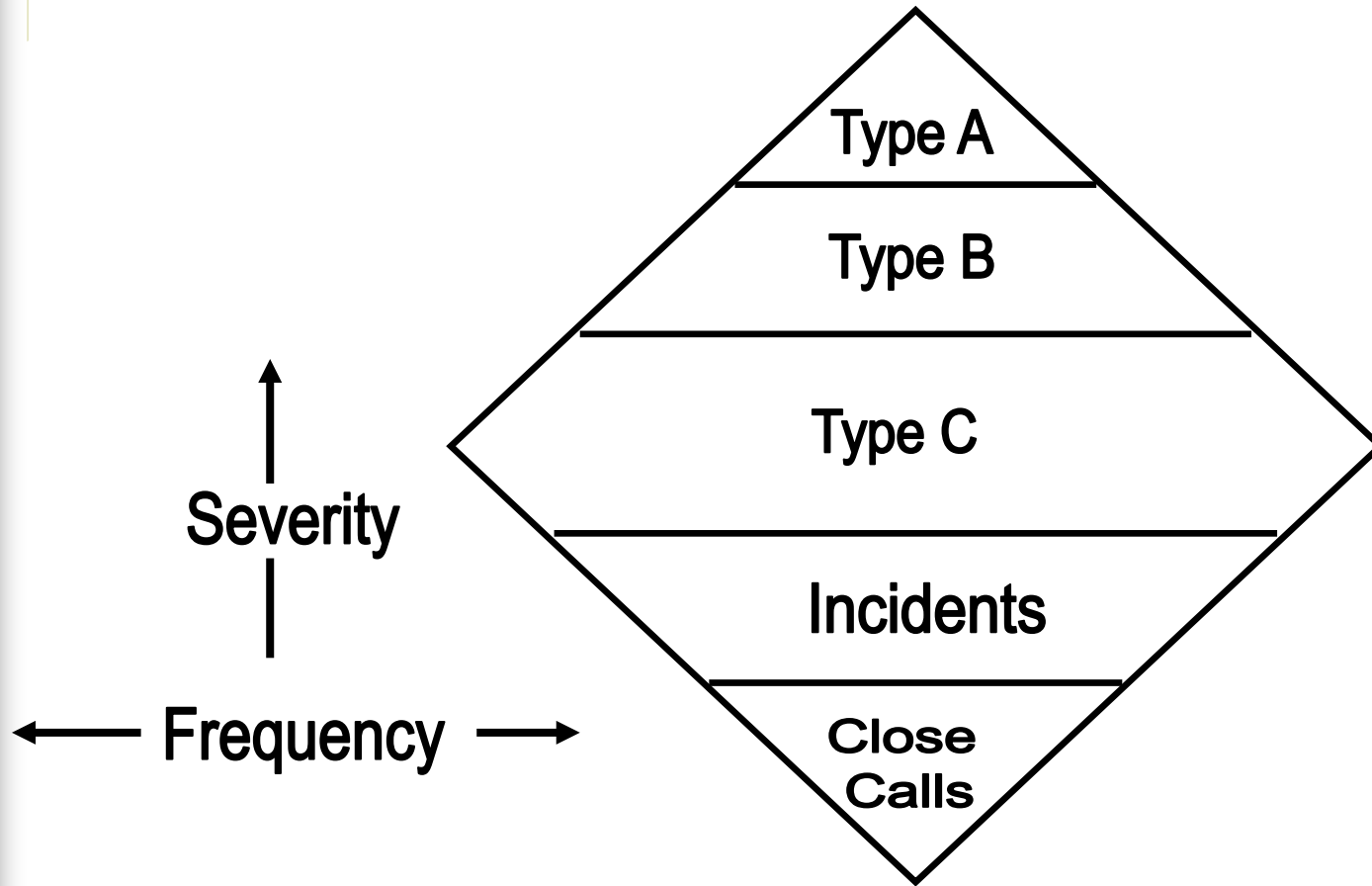
- n Clear Understanding of Goal
- n Preventive Approach
- n Field Understanding & Buy-In
- n Systems Approach
- n Sustainability
- n Trust/Culture of Safety



# Safety System Design

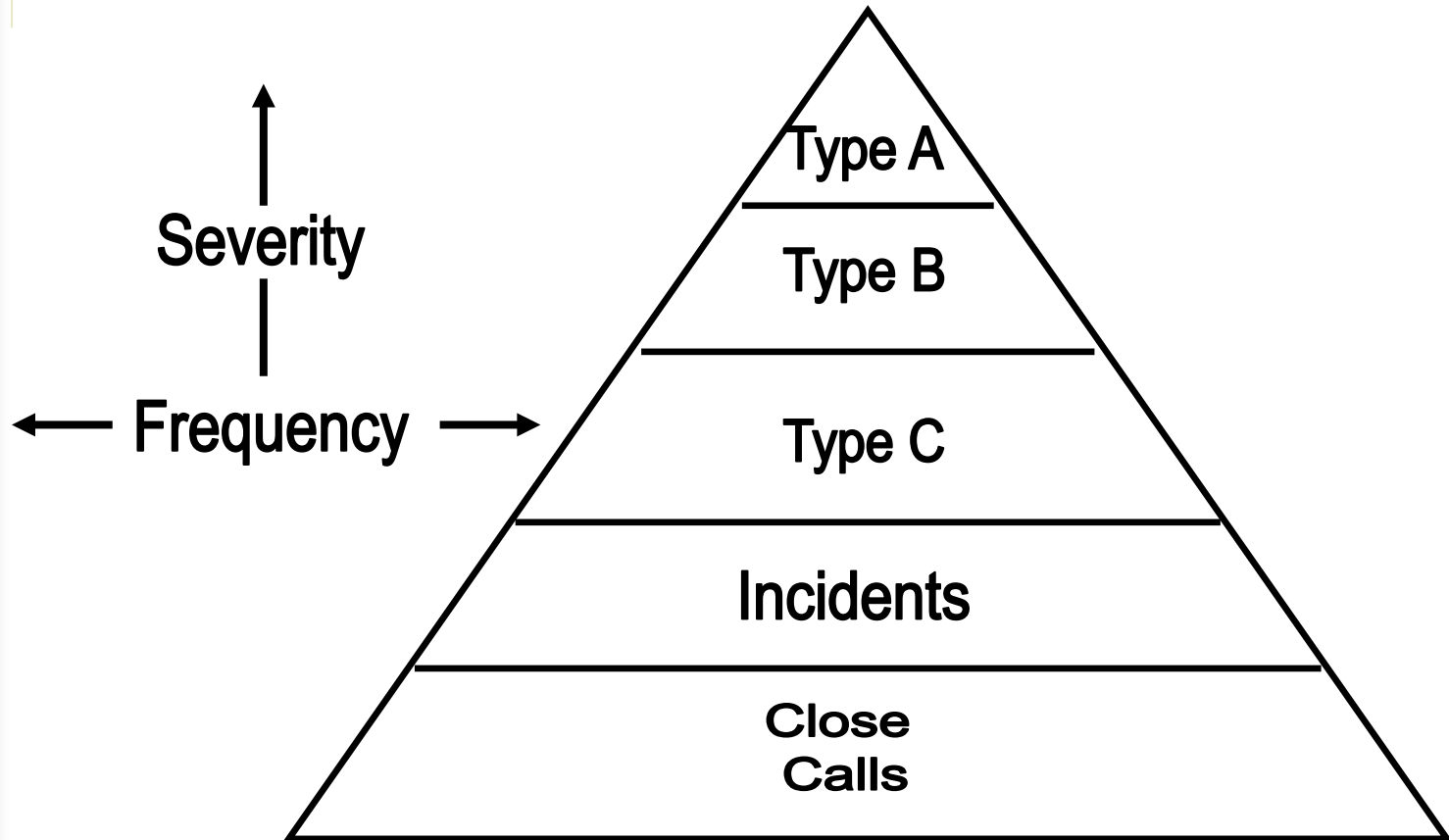
- n High Reliability Organizations
- n Role of Reporting
  - Learning or Accountability
- n Systems-Based Solutions
  - Patient Centered – DUH!!!!
- n Importance of Close Calls

# THE "MISHAP DIAMOND"



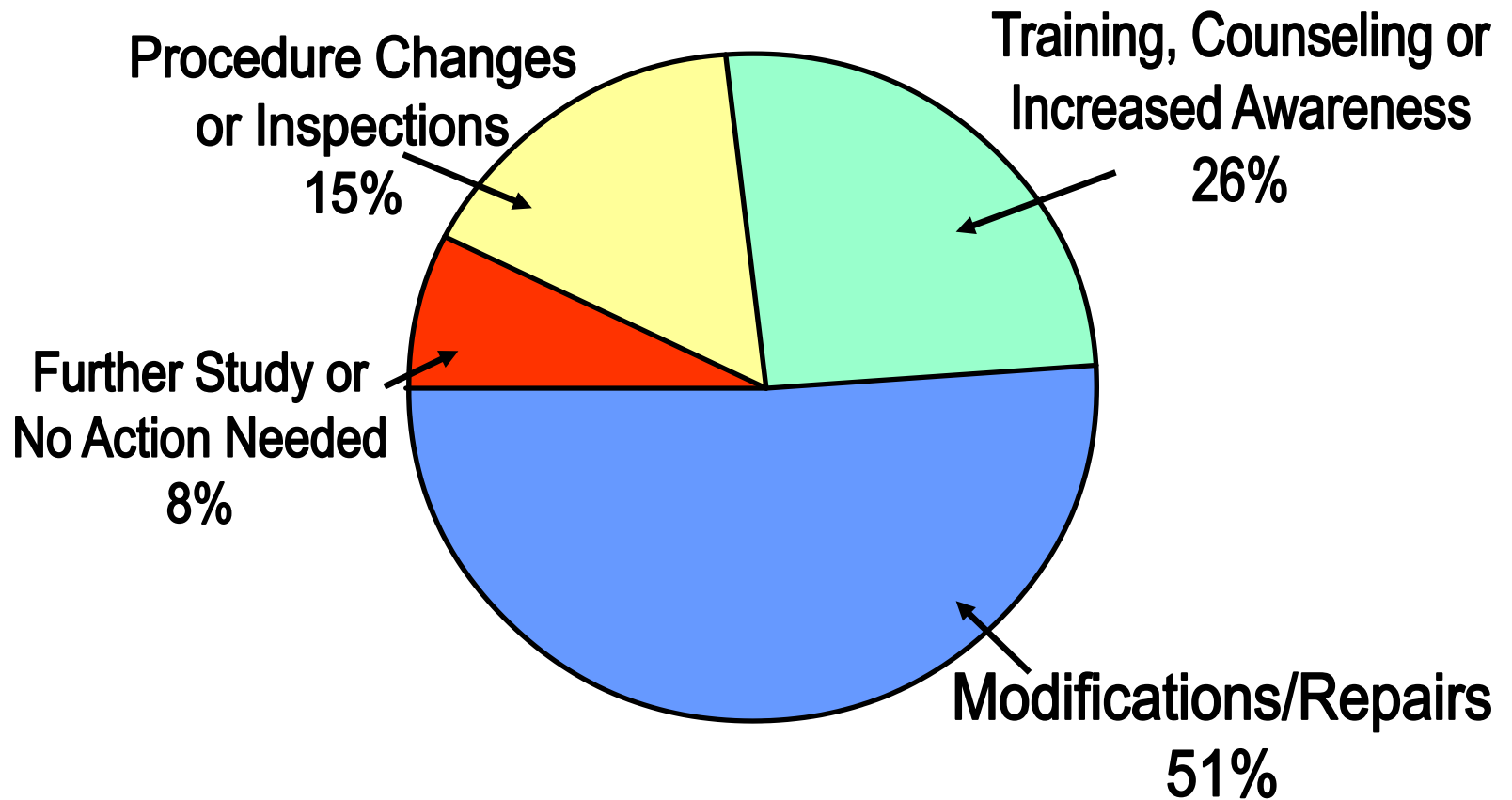
Weak Program Model

# THE "MISHAP PYRAMID"



Strong Program Model

# Corrective Actions from Close Call Reports





# Guiding Principles For Patient Safety System

## § *Learning, Not Accountability System*

### § Reporting System Characteristics

- Non-punitive - Confidential and De-identified
- Internal and External

### § Importance of Close Call

### § Reports Should Emphasize Narratives

### § Interdisciplinary Review Teams

### § About Identifying Vulnerabilities **NOT** Statistics

### § Prompt Feedback

### § Open to All Comers



# Safety & Human Error: Challenges

- n Healthcare Views Errors as Failings Which Deserve Blame - Fault
- n Train and Blame Mentality
- n Blind Adherence To Rules
- n Corrective Actions Focusing on Individual
- n No Blood No Foul Philosophy



# Safety & Human Error: Cornerstones

- n People Don't Come to Work to Hurt Someone or Make a Mistake
- n Must Keep Asking "Why?"

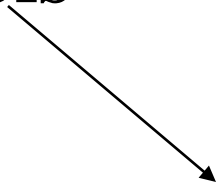


# Patient Safety - Strategy

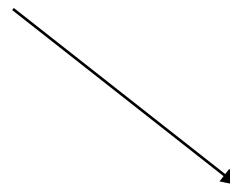
- n Invite People to Play
  - Problem Recognition
  - Remove Barriers (Punitive, Difficulty, Black Hole Effect)
  - Learning **NOT** Accountability System
- n Importance of Close Call
- n ***Blameworthy Definition***
- n Training (Middle thru Top Management)
  - Leadership At All Levels
- n Human Factors Approach
  - Tools That Guide Behavior

# Changing Culture

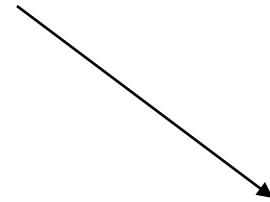
**Tools**



**Behavior**



**Attitude**



**CULTURE!!!**



# Prioritize

## n Risk Based

- Severity
- Probability

## n Must Make Sense

- Business Processes
- Regulatory Environment

# Causation/Actions:

## Who vs. What & Why

### n Who

- ‘Whose Fault Is This?’
- Actions focused on correcting individual
- ‘Corrects’ only after problem occurs
- Limited scope of action and generalizability

### n What & Why

- Actions focus on systems level causation
- Widespread applicability
- Stronger preventive strategy



# Systematic

- n Cause and Effect
- n Human Error Must Have Preceding Cause
- n Failure to Follow Procedure By Itself Is **NOT** a Root Cause
- n Negative Descriptors Aren't Actionable
- n Failure To Act Is **Not** A Cause Without Pre-existing Requirement To Act
- n Why, Why, Why



# Human Factors Engineering and “Actions”

- n **Warnings and labels** (watch out!)
- n **Training** (don't do that)
- n **Procedure changes** (work around that)
- n **Interlock, lock-in, lock-out**, etc (let me design it so you can not do that – forcing functions)
- n **Is there one right action???**

Weaker

Stronger



# Action Assessment

## n Characteristics of Actions

- Temporary vs. Permanent
- Procedural vs. Physical

## n Action Evaluation

- Process
- Outcome




# Communication

- n Communication Identified As Principal Factor >70% Of RCAs
- n Medical Team Training (MTT) Developed To Improve Results
  - Crew Resource Management Principles  
**AND**
  - ***Briefings and De-Briefings***

# Checklist-Driven Preoperative Briefing

VETERANS HEALTH ADMINISTRATION  
**Preoperative Briefing Guide for Use in the Operating Room**  
 ✓ Read and Verify Checklist, Local Facilities Decide When Checklist Completed.

<ul style="list-style-type: none"> <li><input type="checkbox"/> Patient Name<sup>1-4</sup></li> <li><input type="checkbox"/> Social Security #, Birthdate, or Other VA-Approved Identifier<sup>1</sup></li> <li><input type="checkbox"/> Names &amp; Roles of Team Members<sup>2</sup></li> <li><input type="checkbox"/> Procedure<sup>1-4</sup></li> <li><input type="checkbox"/> Surgical Site<sup>1-4</sup> <ul style="list-style-type: none"> <li><input type="checkbox"/> Marked or on Wristband</li> </ul> </li> <li><input type="checkbox"/> Laterality/Side<sup>1-4</sup></li> <li><input type="checkbox"/> Known Allergy<sup>2</sup> <ul style="list-style-type: none"> <li><input type="checkbox"/> No</li> <li><input type="checkbox"/> Yes</li> </ul> </li> <li><input type="checkbox"/> Anesthesia<sup>2</sup> <ul style="list-style-type: none"> <li><input type="checkbox"/> Difficult Airway, Aspiration Risk?                             <ul style="list-style-type: none"> <li><input type="checkbox"/> No</li> <li><input type="checkbox"/> Yes</li> </ul> </li> <li><input type="checkbox"/> If Yes, Equipment &amp; Assistance Available</li> <li><input type="checkbox"/> Safety Check Completed</li> <li><input type="checkbox"/> Pulse Oximetry</li> </ul> </li> <li><input type="checkbox"/> Instruments &amp; Special Equipment<sup>2-4</sup> <ul style="list-style-type: none"> <li><input type="checkbox"/> N/A</li> <li><input type="checkbox"/> Yes</li> </ul> </li> <li><input type="checkbox"/> Implant (s)<sup>1-4</sup> <ul style="list-style-type: none"> <li><input type="checkbox"/> N/A</li> <li><input type="checkbox"/> Yes</li> <li><input type="checkbox"/> If Yes, Specifics</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Pertinent Lab Results</li> <li><input type="checkbox"/> Risk of &gt;500 ml Blood Loss<sup>2,4</sup> <ul style="list-style-type: none"> <li><input type="checkbox"/> No</li> <li><input type="checkbox"/> Yes, and adequate IV access and fluids planned, and blood availability confirmed</li> </ul> </li> <li><input type="checkbox"/> If Yes,                             <ul style="list-style-type: none"> <li><input type="checkbox"/> Type &amp; Screen</li> </ul> </li> </ul> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Type &amp; Cross</li> </ul>	<div style="border: 2px solid red; padding: 5px; text-align: center;">  <p><b>TIME OUT!</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Name of Patient &amp; SS# or birthdate</li> <li><input type="checkbox"/> Procedure to be performed</li> <li><input type="checkbox"/> Position</li> <li><input type="checkbox"/> Consent form checked (patient, procedure, site/side, reason)</li> <li><input type="checkbox"/> Check that surgical site marked (and visible after draping) and/or wristband confirmed</li> <li><input type="checkbox"/> Implant to be used (if applicable)</li> <li><input type="checkbox"/> Two members confirm imaging studies available, correct, properly labeled, presented                             <ul style="list-style-type: none"> <li><input type="checkbox"/> Yes</li> <li><input type="checkbox"/> N/A</li> </ul> </li> </ul> </div>
<ul style="list-style-type: none"> <li><input type="checkbox"/> Prophylactic Antibiotics Given Within 60 Minutes of Incision<sup>2-4</sup> <ul style="list-style-type: none"> <li><input type="checkbox"/> Yes</li> <li><input type="checkbox"/> N/A</li> </ul> </li> <li><input type="checkbox"/> DVT Prophylaxis<sup>4</sup> <ul style="list-style-type: none"> <li><input type="checkbox"/> Yes</li> <li><input type="checkbox"/> N/A</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Anticipated Critical Events<sup>2</sup> <ul style="list-style-type: none"> <li><input type="checkbox"/> Surgeon</li> <li><input type="checkbox"/> Anesthesia</li> <li><input type="checkbox"/> Nursing</li> </ul> </li> <li><input type="checkbox"/> Postop Disposition &amp; Bed Availability<sup>4</sup></li> </ul>	

- q Antibiotic Prophylaxis
- q DVT Prophylaxis

<sup>1</sup>This checklist contains the elements of the WHO checklist and also includes a sampling of the majority of elements as suggested by frontline OR teams from the VHA. The WHO Surgical Safety Checklist is available at [http://www.safesurg.org/uploads/1/0/9/0/1090835/sss1\\_checklist\\_finaljun08.pdf](http://www.safesurg.org/uploads/1/0/9/0/1090835/sss1_checklist_finaljun08.pdf)  
<sup>2</sup>VHA Policy Directive, <sup>3</sup>WHO Checklist, <sup>4</sup>Joint Commission, <sup>5</sup>Medical Team Training

**VETERANS HEALTH ADMINISTRATION**  
**Postoperative Briefing Guide for Use in the Operating Room\***  
 ✓ Provide Comments as Appropriate



<b>Surgeon</b>	<b>1</b>	<b>2</b>	<b>3</b>
	Unsatisfactory	Satisfactory	Excellent

Comments:

<b>Anesthesiologist/CRNA</b>	<b>1</b>	<b>2</b>	<b>3</b>
	Unsatisfactory	Satisfactory	Excellent

Comments:

<b>Nurse (s)</b>	<b>1</b>	<b>2</b>	<b>3</b>
	Unsatisfactory	Satisfactory	Excellent

Comments:

**Areas for Improvement/Safety Issues/Action Items**

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> <b>Instruments, Sponge, Needle Count Correct<sup>2</sup></b><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> If No, Explain | <input type="checkbox"/> <b>Delays<sup>4</sup></b><br><input type="checkbox"/> No<br><input type="checkbox"/> Yes<br><input type="checkbox"/> If Yes, Specify<br><input type="checkbox"/> <b>Name of Procedure Recorded<sup>2</sup></b> | <input type="checkbox"/> <b>Equipment Issues<sup>2,4</sup></b><br><input type="checkbox"/> No<br><input type="checkbox"/> Yes<br><input type="checkbox"/> If Yes, Specify<br><input type="checkbox"/> <b>Specimen Labeled Properly<sup>2</sup></b> |
|---|---|--|

**Concerns for Postoperative Course [Surgeon, Anesthesiologist/CRNA, Nurse (s)]**

**Comments**

\*This checklist contains the elements of the WHO checklist and also includes a sampling of the majority of elements as suggested by frontline OR teams from the VHA. The WHO Surgical Safety Checklist is available at [http://www.safesurg.org/uploads/1/0/9/0/1090835/ssl\\_checklist\\_finaljun08.pdf](http://www.safesurg.org/uploads/1/0/9/0/1090835/ssl_checklist_finaljun08.pdf)

<sup>1</sup>VHA Policy/Directive, <sup>2</sup>WHO Checklist, <sup>3</sup>Joint Commission, <sup>4</sup>Medical Team Training

# Association Between Implementation of a Medical Team Training Program and Surgical Mortality

Julia Neily, RN, MS, MPH

Peter D. Mills, PhD, MS

Yinong Young-Xu, ScD, MA, MS

Brian T. Carney, MD

Priscilla West, MPH

David H. Berger, MD, MHCM

Lisa M. Mazzia, MD

Douglas E. Paull, MD

James P. Bagian, MD, PE

**A**DVERSE EVENTS RELATED TO surgery continue to occur despite the best efforts of clinicians.<sup>1</sup> Teamwork and effective communication are known determinates of surgical safety.<sup>2-6</sup> Previous efforts at demonstrating the efficacy of patient safety initiatives have been limited because of the inability to study a control group.<sup>7</sup> For example, the use of the World Health Organization Safe Surgery checklist has been evaluated, but its overall efficacy remains uncertain because no control group was studied to clearly demonstrate this instrument's effectiveness.<sup>8</sup>

The Veterans Health Administration (VHA) is the largest national integrated health care system in the United States, with 153 hospitals, 130 of which provide surgical services. The VHA implemented a national team

**Context** There is insufficient information about the effectiveness of medical team training on surgical outcomes. The Veterans Health Administration (VHA) implemented a formalized medical team training program for operating room personnel on a national level.

**Objective** To determine whether an association existed between the VHA Medical Team Training program and surgical outcomes.

**Design, Setting, and Participants** A retrospective health services study with a contemporaneous control group was conducted. Outcome data were obtained from the VHA Surgical Quality Improvement Program (VASQIP) and from structured interviews in fiscal years 2006 to 2008. The analysis included 182 409 sampled procedures from 108 VHA facilities that provided care to veterans. The VHA's nationwide training program required briefings and debriefings in the operating room and included checklists as an integral part of this process. The training included 2 months of preparation, a 1-day conference, and 1 year of quarterly coaching interviews

**Main Outcome Measure** The rate of change in the mortality rate 1 year after facilities enrolled in the training program compared with the year before and with non-training sites.

**Results** The 74 facilities in the training program experienced an 18% reduction in annual mortality (rate ratio [RR], 0.82; 95% confidence interval [CI], 0.76-0.91;  $P = .01$ ) compared with a 7% decrease among the 34 facilities that had not yet undergone training (RR, 0.93; 95% CI, 0.80-1.06;  $P = .59$ ). The risk-adjusted mortality rates at baseline were 17 per 1000 procedures per year for the trained facilities and 15 per 1000 procedures per year for the nontrained facilities. At the end of the study, the rates were 14 per 1000 procedures per year for both groups. Propensity matching of the trained and nontrained groups demonstrated that the decline in the risk-adjusted surgical mortality rate was about 50% greater in the training group (RR, 1.49; 95% CI, 1.10-2.07;  $P = .01$ ) than in the nontraining group. A dose-response relationship for additional quarters of the training program was also demonstrated: for every quarter of the training program, a reduction of 0.5 deaths per 1000 procedures occurred (95% CI, 0.2-1.0;  $P = .001$ ).

**Conclusion** Participation in the VHA Medical Team Training program was associated with lower surgical mortality.

JAMA. 2010;304(15):1693-1700

www.jama.com



# What Have We Learned?

- n Actions needed well before entering the OR
  - Timeout period is too late in many cases
  - Systems-based approaches beyond individual
- n Involvement of all disciplines
- n Structured communication that drives discussion
  - Briefings & debriefings, **Medical Team Training** essential



# Management Involvement

- n Formalized, Not Ad Hoc
  - Regular Part of Agenda For All Levels
- n Safety Permeates the Fabric of All Activities
- n Relentless



# Sustainable Systems Approach

- n Problem Identification
- n Clear Goal Definition
- n Involvement Of All Sectors
- n Identify Systems Influences
- n Identify Systems Controls
- n Identify Constraints
- n ***Critique – Go To Worst Critics Early On***
- n Pilot – Volunteers First Then Others
- n Evaluate



# Leadership - What Can You Do Right Now?

- n Lead by Example
- n Relentless Drumbeat
- n Eliminate 'Whose fault is it?'
- n Encourage Skepticism
  - Devil's Advocate is Valued
- n Distinguish **Real** Priorities From Official Priorities
- n ***What Happened?, What Should Have Happened?, What Usually Happens?***
- n Part of Every Agenda

# Closing Thoughts

- n Not About Errors!!!
- n Counting reports is not the objective, identifying Vulnerabilities is
  - Hope they increase
  - **Analysis, Action, & Feedback are the key**
- n Prevention NOT Punishment
- n Cultural change is the key – takes time
- n ***Safety is the Foundation Upon which Quality is Built***



# Bibliography

- Bagian JP. Patient safety: What is really at issue? *Front Health Serv Manage.* 2005 Fall;22(1):3-16.
- Bagian JP, Lee CZ, et al. Development and Deployment of a Patient Safety Program In a Large Health Care Delivery System or You Can't Fix What You Don't Know About. *J Quality Improvement.* 2001; 27:522-532.
- Bagian JP, Gosbee J, Lee CZ, Williams L, McKnight SD, Mannos DM. The Veterans Affairs Root Cause Analysis System In Action. *J Quality Improvement.* 2002; 28: 531-545.
- Derosier J, Stalhandske E, Bagian JP, Nudell T. Using Health Care Failure Mode and Effect Analysis™: The VA National Center for Patient Safety's Prospective Risk Analysis System. *J Quality Improvement.* 2002; 28: 248-67.
- Weeks WB, Bagian JP. Bad Outcomes of Questionable Medical Decisions. *Ann Intern Med* 2003 Mar 18;138(6):520
- Weeks WB, Bagian JP. The business case for patient safety. *J Quality Improvement.* 2003;29(1):51-54.