Patient Safety: It’s Not Rocket Science

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IOM Goals

- Safe
- Timely
- Efficient
- Effective
- Equitable
- Patient-Centered
Patient Safety - The Problem

- Not New
- 1981 - Steel (NEJM)
- 1991 - Harvard Practice Study (NEJM)
- 1995 - Family Practice MDs (J Fam Prc) rct
- 11/99 - IOM Report
  - Deaths due to Preventable Adverse Events greater than MVA, Breast Cancer, or AIDS
Where Healthcare Was/Is

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

Culturally Different!!!!
Typical Approach

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

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

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

Severity

Frequency

Type A

Type B

Type C

Incidents

Close Calls

Weak Program Model
THE "MISHAP PYRAMID"

Strong Program Model

Severity

Frequency

Type A

Type B

Type C

Incidents

Close Calls
Corrective Actions from Close Call Reports

- Modifications/Repairs: 51%
- Training, Counseling or Increased Awareness: 26%
- Procedure Changes or Inspections: 15%
- Further Study or No Action Needed: 8%
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

- Healthcare Views Errors as Failings Which Deserve Blame - Fault
- Train and Blame Mentality
- Blind Adherence To Rules
- Corrective Actions Focusing on Individual
- No Blood No Foul Philosophy
Safety & Human Error: Cornerstones

- People Don’t Come to Work to Hurt Someone or Make a Mistake
- Must Keep Asking “Why?”
Patient Safety - Strategy

- Invite People to Play
  - Problem Recognition
  - Remove Barriers (Punitive, Difficulty, Black Hole Effect)
  - Learning **NOT** Accountability System

- Importance of Close Call

- **Blameworthy Definition**

- Training (Middle thru Top Management)
  - Leadership At All Levels

- Human Factors Approach
  - Tools That Guide Behavior
Changing Culture

- Tools
- Behavior
- Attitude

CULTURE!!!
Prioritize

- Risk Based
  - Severity
  - Probability

- Must Make Sense
  - Business Processes
  - Regulatory Environment
Causation/Actions: Who vs. What & Why

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

- **What & Why**
  - Actions focus on systems level causation
  - Widespread applicability
  - Stronger preventive strategy
Systematic

- Cause and Effect
- Human Error Must Have Preceding Cause
- Failure to Follow Procedure By Itself Is NOT a Root Cause
- Negative Descriptors Aren’t Actionable
- Failure To Act Is NOT A Cause Without Pre-existing Requirement To Act
- Why, Why, Why
Human Factors Engineering and “Actions”

- **Warnings and labels** (watch out!)
- **Training** (don’t do that)
- **Procedure changes** (work around that)
- **Interlock, lock-in, lock-out**, etc (let me design it so you can not do that – forcing functions)

- **Is there one right action??**
Action Assessment

- Characteristics of Actions
  - Temporary vs. Permanent
  - Procedural vs. Physical

- Action Evaluation
  - Process
  - Outcome
Communication

- Communication Identified As Principal Factor >70% Of RCAs
- 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.

<table>
<thead>
<tr>
<th><strong>STOP</strong></th>
<th><strong>TIME OUT!</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>q Antibiotic Prophylaxis</td>
<td>q DVT Prophylaxis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Patient Name</strong></th>
<th><strong>Antibiotic Prophylaxis</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Social Security #, Birthday, or Other VA-Approved Identifier</strong></td>
<td><strong>DVT Prophylaxis</strong></td>
</tr>
<tr>
<td><strong>Names &amp; Roles of Team Members</strong></td>
<td></td>
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<tr>
<td><strong>Procedure</strong></td>
<td></td>
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<tr>
<td><strong>Surgical Site</strong></td>
<td></td>
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<tr>
<td><strong>Laterality/Side</strong></td>
<td></td>
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<tr>
<td><strong>Known Allergy</strong></td>
<td></td>
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<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Anesthesia</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Difficult Airway, Aspiration Risk?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No</strong></td>
<td></td>
</tr>
<tr>
<td><strong>If Yes, Equipment &amp; Assistance Available</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Safety Check Completed</strong></td>
<td></td>
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<tr>
<td><strong>Pulse Oximetry</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Instruments &amp; Special Equipment</strong></td>
<td></td>
</tr>
<tr>
<td><strong>NA</strong></td>
<td></td>
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<tr>
<td><strong>Yes</strong></td>
<td></td>
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<tr>
<td><strong>Implant (s)</strong></td>
<td></td>
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<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>If Yes, Specific</strong></td>
<td></td>
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<tr>
<td><strong>Perioperative Lab Results</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Risk of &gt;500 ml Blood Loss</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No</strong></td>
<td></td>
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<tr>
<td><strong>Yes, and adequate IV access and fluids planned, and blood availability confirmed</strong></td>
<td></td>
</tr>
<tr>
<td><strong>If Yes,</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Type &amp; Screen</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Type &amp; Cross</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Prophylactic Antibiotics Given Within 60 Minutes of Incision</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>NA</strong></td>
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<tr>
<td><strong>DVT Prophylaxis</strong></td>
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<tr>
<td><strong>Yes</strong></td>
<td></td>
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<tr>
<td><strong>NA</strong></td>
<td></td>
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<tr>
<td><strong>Anticipated Critical Events</strong></td>
<td></td>
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<tr>
<td><strong>Surgery</strong></td>
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<tr>
<td><strong>Anesthesia</strong></td>
<td></td>
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<tr>
<td><strong>Nursing</strong></td>
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<tr>
<td><strong>Postop Disposition &amp; Bed Availability</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>NA</strong></td>
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</tbody>
</table>

*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 VA. The WHO Surgical Safety Checklist is available at [http://www.who.int/patientsafety/checklists-and-tools/checklist-anaesthesia.pdf](http://www.who.int/patientsafety/checklists-and-tools/checklist-anaesthesia.pdf)*

*VA Policy/Directive, *WHO Checklist, Joint Commission, Medical Team Training*
### VETERANS HEALTH ADMINISTRATION

**Postoperative Briefing Guide for Use in the Operating Room**

*Provide Comments as Appropriate*

<table>
<thead>
<tr>
<th>Role</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon</td>
<td>Unsatisfactory</td>
<td>Satisfactory</td>
<td>Excellent</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anesthesiologist/CRNA</td>
<td>Unsatisfactory</td>
<td>Satisfactory</td>
<td>Excellent</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse(s)</td>
<td>Unsatisfactory</td>
<td>Satisfactory</td>
<td>Excellent</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

- ☐ Instruments, Sponge, Needle Count Correct²
  - ☐ Yes
  - ☐ No
  - ☐ If No, Explain

- ☐ Delays⁴
  - ☐ No
  - ☐ Yes
  - ☐ If Yes, Specify

- ☐ Equipment Issues²
  - ☐ No
  - ☐ Yes
  - ☐ If Yes, Specify

- ☐ Name of Procedure Recorded²

- ☐ Specimen Labeled Properly²

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

☐ **Comments**

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¹This 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/sol checklist finalium08 pdf](http://www safesurg org/uploads/1/0/9/0/1090835/sol checklist finalium08 pdf)

²VHA Policy/Directive, ³WHO Checklist, ⁴Joint Commission, ⁵Medical Team Training
Association Between Implementation of a Medical Team Training Program and Surgical Mortality

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ADVERSE EVENTS RELATED TO surgery continue to occur despite the best efforts of clinicians. Teamwork and effective communication are known determinants of surgical safety. Previous efforts at demonstrating the efficacy of patient safety initiatives have been limited because of the inability to study a control group. 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.

The Veterans Health Administration (VHA) is the largest national integrated health care system in the United States, with 133 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 nontraining 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.
What Have We Learned?

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

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

- Problem Identification
- Clear Goal Definition
- Involvement Of All Sectors
- Identify Systems Influences
- Identify Systems Controls
- Identify Constraints
- Critique - Go To Worst Critics Early On
- Pilot - Volunteers First Then Others
- Evaluate
Leadership - What Can You Do Right Now?

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

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

**Safety is the Foundation Upon which Quality is Built**
Bibliography