More Than Root Cause Analysis: Implementing Actions to Prevent Harm

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Overview

• Definitions
• The Problem
• Historical Perspective
• Cultural Factors
• Systems-Based Approach
• Prioritization/Risk
• Causes and Actions
• Conclusions
Definitions

• Quality – The extent to which a service or product produces a desired outcome(s).
• Safety – Prevention or moderation of hazard induced harm.
• Hazard – A circumstance or agent that can lead to harm, damage, or loss.
• Risk – The chance of a specific event occurring. Measured in terms of consequences and likelihood.
What Is A System?

• A collection of elements whose operation is interdependent.
• Systems obey rules that cannot be understood by breaking them into parts, and stop functioning (or malfunction) when an element is removed or altered significantly.
• Systems provide a coherent and unified way of viewing, interpreting and of organizing our thoughts about the world.
IOM Goals

• Safe
• Timely
• Efficient
• Effective
• Equitable
• Patient Centered
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
Program Elements

• Goal – Prevent Inadvertent Harm To Patient While Under Our Care
• Culture Not Compliance
• Identify Barriers
Awareness and Shame May be Largest Hurdles

• Survey at VHA and Data From Other Private Healthcare Organizations
  – Only 27% Agreed that Errors were a Serious Problem
  – 49% “Ashamed” by Error

• IOM report concurs
Combating Shame: Blameworthy Concept

- Safety Reports Are Only For Systems Improvement
- Reports Kept Confidential/Nonpunitive As Long As Not Deemed ‘Intentionally Unsafe’
  - Criminal Act
  - Under Influence of Alcohol or Illicit Drugs
  - Purposely Unsafe
- Supervisory System Is A Parallel Process
  - May Not Use Identified Info From Safety Report
Program Elements

• Goal – Prevent Inadvertent Harm To Patient While Under Our Care
• Culture Not Compliance
• Identify Barriers
• Reporting Systems
Safety System Design

- High Reliability Organizations
- Role of Reporting
  - Learning or Accountability
Patient Safety System Design

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

THE "MISHAP DIAMOND"

Type A
Type B
Type C
Incidents
Close Calls

Weak Program Model

Severity

Frequency
THE "MISHAP PYRAMID"

Severity
Frequency

Type A
Type B
Type C
Incidents
Close Calls

Strong Program Model
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%
Program Elements

• Goal – Prevent Inadvertent Harm To Patient While Under Our Care
• Culture Not Compliance
• Identify Barriers
• Reporting Systems
  – Identify Vulnerabilities, Not for Counting
• Systems-Based Solutions
Safety & Human Error: Challenges

- Healthcare Views Errors as Failings Which Deserve Blame - Fault
- Train and Blame Mentality vs Systems-Based
- 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?”
Changing Culture

Tools → Behavior → Attitude → CULTURE!!!
Prioritize

• Risk Based
  – Severity
  – Probability

• Must Make Sense
  – Business Processes
  – Regulatory Environment
Safety Assessment Code (SAC)
## Safety Assessment Code (SAC)

### Actual SAC

#### Probability

<table>
<thead>
<tr>
<th></th>
<th>Catastrophic</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
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<tr>
<td>Frequent</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
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<tr>
<td>Occasional</td>
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<tr>
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<td>1</td>
</tr>
<tr>
<td>Remote</td>
<td>3</td>
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</table>

### Potential SAC

#### Probability

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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
• 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** (design it so you cannot do that – forcing functions)
- **Is there one right action??**
# Action Hierarchy

<table>
<thead>
<tr>
<th>Action Level</th>
<th>Actions</th>
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</thead>
<tbody>
<tr>
<td><strong>Stronger Actions</strong></td>
<td>Architectural/physical plant changes</td>
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<tr>
<td></td>
<td>New devices with usability testing before purchasing</td>
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<tr>
<td></td>
<td>Engineering control or interlock (forcing functions)</td>
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<tr>
<td></td>
<td>Simplify the process and remove unnecessary steps</td>
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<tr>
<td></td>
<td>Standardize on equipment or process</td>
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<td></td>
<td>Tangible involvement and action by leadership in support of patient safety</td>
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<tr>
<td><strong>Intermediate Actions</strong></td>
<td>Redundancy</td>
</tr>
<tr>
<td></td>
<td>Increase in staffing/decrease in workload</td>
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<tr>
<td></td>
<td>Software enhancements/modifications</td>
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<td></td>
<td>Education using simulation-based learning with a competency assessment completed on a recurring basis</td>
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<tr>
<td></td>
<td>Eliminate/reduce distractions (sterile medical environment)</td>
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<td></td>
<td>Checklist/cognitive aid</td>
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<tr>
<td></td>
<td>Eliminate look and sound-alikes</td>
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<td></td>
<td>Repeat-back/Read-back</td>
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<tr>
<td></td>
<td>Enhanced documentation/communication</td>
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<tr>
<td><strong>Weaker Actions</strong></td>
<td>Double checks</td>
</tr>
<tr>
<td></td>
<td>Warnings and labels</td>
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<tr>
<td></td>
<td>New procedure/memorandum/policy</td>
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<td></td>
<td>Traditional training</td>
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<td></td>
<td>Additional study/analysis</td>
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Action Assessment

• Characteristics of Actions
  – Temporary vs. Permanent
  – Procedural vs. Physical

• Action Evaluation
  – Process
  – Outcome
Management Involvement

• Formalized, Not Ad Hoc
  – Regular Part of Agenda For All Levels
• Safety Permeates the Fabric of All Activities
• Relentless
Warning Signs of an Ineffective RCA² - “Red Flags”

- Contributing factors absent, lack supporting data or information.
- Human error identified as causing the event.
- Causal statements do not comply with Five Rules of Causation.
- No stronger or intermediate strength actions are identified.
- No corrective actions are identified, or the corrective actions do not address identified system vulnerabilities.
- Action follow-up is assigned to a group and not to an individual.
- Actions do not have completion dates or meaningful measures.
- The event review took longer than 45 days to complete.
- There is little confidence that corrective action will significantly reduce the risk of future occurrences of similar events.
RCA²
Improving Root Cause Analyses and Actions to Prevent Harm
Is There A Business Case?

• YOU BET!!!

• Examples:
  – “Easy CAP” CO₂ Detector
    • $125/detected esophageal intubation
  – Ventilator Humidification System
    • $114k/facility/yr and reduced risk
• RCA/40person-hrs X 12RCA/yr = 0.25FTEE
Leadership & Boards

• Leadership support critical to success
  – Who?
   • CEO and Board
  – What?
   • Approval of actions
   • Rationale for actions not approved
     • Transparent Acceptance of Risk
     • Determining organization-wide applicability
  – How?
    • Assess actions against Hierarchy
    • Be cognizant of “Red Flags”
Leadership - What Can Be Done 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
• Part of Every Agenda

• **What Happened?**, **What Should Have Happened?**, **What Usually Happens?**
Leadership - Key Points

• Transparent Risk-Based Prioritization Methodology
• Emphasize Systems-Based Solutions
  – Determination of Real Underlying Causes
  – Seek Out Stronger Solutions
• Emphasize Formal Scrutiny of Close-Calls
• **Interventions Must Go Farther Than Simply Training and Policy**
Professionalism:
A Personal Litmus Test

• I am proud to have any clinical decision I make published on the front page of the newspaper for all of my friends, colleagues, and patients to read.

• The clinical care and the manner in which I treat my patients is the same that I would choose for someone I love.

• If I witness any patient receiving care that doesn’t comport with the two criteria above it is my DUTY and OBLIGATION to take action.
Closing Thoughts

• It’s Everyone’s Job
• 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**