Risk Management 103: Patient Safety and Adverse Event Analysis

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Patricia Stahura, RN, MSN
Senior Patient Safety Analyst
ECRI Institute
Learning Objectives

• Review primary care patient safety initiatives
• Examine elements of a patient safety program
• Identify barriers to event identification and reporting
• Simulate a root-cause analysis
• Describe the steps from analysis to action
• Recommend measures to ensure sustained improvements
Patient Safety in Primary Care
Primary Care Visits

1 billion ambulatory visits occur annually in the United States

Over 90 million clinic visits to health centers occur annually in the United States

Sources: NCHS; BPHC
Challenges

• Patient safety is a young discipline
• Most studies focus on hospital care
• Primary care safety has different issues than care in hospital settings
• Primary care studies focus on access and overall quality
• System vulnerabilities and safety issues are not investigated
• People are living longer, with chronic conditions, community care
• Knowledge and skills are required from providers
• Patient autonomy is paramount

Source: Bishop et al.
Research in Ambulatory Patient Safety: A 10-Year Review

- More diverse population of patients
- Healthy; chronic conditions; or acute need of hospitalization
- Organizational structures
- Challenging information exchange
- Transitions between primary care, specialist, home care, pharmacy, laboratory
- Patient responsibility

Source: American Medical Association
AHRQ Report: Patient Safety in Ambulatory Care

- Adverse harm from medical or patient self-management
- Possibility of patient errors
- Electronic health records (EHRs) and other technological tools
- Utilize different, and noninteroperable, electronic platforms
- Short visits, long interval between visits or referrals or diagnostic studies
- Intense time pressure
- Coordination of care
- Presence and composition of team

Source: AHRQ

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NPSF: 8 Recommendations for Achieving Total System Safety

1. Establish and maintain a safety culture
2. Centralize and coordinate oversight of patient safety
3. Establish a common set of patient safety metrics
4. Improve funding in order to better understand and prevent safety hazards
5. Deliver safety across the entire continuum
6. Support the health care workforce (e.g., providers, nurses, medical assistants)
7. Partner with patients and families to ensure safe care
8. Ensure technology is safe and optimized

Source: NPSF “Free from Harm”
Brainstorm Activity
Top 10 Patient Safety List

• Write down your top 10 list of patient safety concerns
  • What keeps you awake at night?
• Be prepared to tell the group
• Compare it to research and literature
Concepts, Theories, and Program Development
What Is Patient Safety?

- **Prevention of errors** (World Health Organization)
- **Avoidance, prevention, and amelioration** (National Patient Safety Foundation)
- **Freedom from accidental injury** (Institute of Medicine)
- **Absence of harm** (AHRQ)

**Sources:** WHO; NPSF “Free from Harm”; IOM; AHRQ
Why Errors Happen

Reason’s Swiss Cheese model
## Generic Error Modeling System (GEMS)

<table>
<thead>
<tr>
<th>Skill-based error</th>
<th>Rule-based error</th>
<th>Knowledge-based error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1,000</td>
<td>1/100</td>
<td>3/10</td>
</tr>
<tr>
<td><strong>Slip or lapse when performing a familiar task</strong></td>
<td>Sequence of preestablished steps results in a decision-making error</td>
<td>Figuring it out without rules or experience results in a problem-solving error</td>
</tr>
<tr>
<td><strong>Unintentional deviation from planned or routine action</strong></td>
<td>Rules from training experience or procedure that is known are misapplied or not followed</td>
<td>Follows an analytical or logical thought process, because specific rule to follow is unknown</td>
</tr>
<tr>
<td>Autopilot</td>
<td>Follow the rules</td>
<td>Don’t go there alone</td>
</tr>
</tbody>
</table>

**Source:** Reason 1990
Elements of a Safety Program

• Safety culture
• Design safe and reliable processes and systems
• Oversight of program
• Coordination
• Reporting and analysis
• Meaningful metrics
• Elements from across the continuum
Goals for Safety Program

• Improve the culture of safety

• Improve processes and systems
1. Report and learn from adverse events
2. Distinguish human and system errors from unsafe, blameworthy actions
3. Ensure that leaders model appropriate behavior and champion efforts
4. Enforce and communicate policies that support culture as well as reporting adverse events, close calls, and unsafe conditions

Source: Joint Commission “Sentinel Event Alert 57”
5. Recognize team members who report or who have good safety suggestions

6. Determine safety culture baseline with reliable tool

7. Analyze survey results to find opportunities

8. Unit-based initiatives (work station)

9. Team training

10. Assess system strengths and vulnerabilities

11. Repeat culture of safety assessment every 18–24 months

Source: Joint Commission “Sentinel Event Alert 57”
Culture of Patient Safety Survey

- Points to conditions that can result in adverse events
- Increases staff awareness
- Assesses patient safety culture
- Identifies strengths and weaknesses
- Measures improvement over time
- Helps to prioritize and focus
Safety Survey Resources


• ECRI Institute Clinical Risk Management Program:
  • Get Safe! and Practice Alert resources
  • Safety Attitudes Questionnaire (Ambulatory Program): https://www.ecri.org/components/HRSA/Pages/PSRMPol1.aspx
Safety Culture

**INFORMED CULTURE**
Those who manage and operate the system have current knowledge about the human, technical, organisational and environmental factors that determine the safety of the system as a whole.

**REPORTING CULTURE**
An organizational climate in which people are prepared to report their errors and near-misses.

**JUST CULTURE**
An atmosphere of trust in which people are encouraged (even rewarded) for providing essential safety-related information, but in which they are also clear about where the line must be drawn between acceptable and unacceptable behaviour.

**FLEXIBLE CULTURE**
A culture in which an organisation is able to reconfigure themselves in the face of high tempo operations or certain kinds of danger - often shifting from the conventional hierarchical mode to a flatter mode.

**LEARNING CULTURE**
An organisation must possess the willingness and the competence to draw the right conclusions from its safety information system and the will to implement major reforms.

Source: Based on Reason 1997
Just Culture

- Emphasizes creating reliable and safe systems and processes
- Just, but not blame-free
- Accountability and culpability
Culpability

- Were the actions as intended?
  - NO → Unauthorized substance?
    - NO → Medical condition?
      - NO → Substance abuse with mitigation
      - YES → Substance abuse without mitigation
    - YES → System-induced violation
  - YES → Sabotage, malevolent damage, suicide, etc.

- Were the consequences as intended?
  - NO → Unavailable procedures available, workable, intelligible, and correct?
    - NO → System-induced error
    - YES → Possible negligent error
  - YES → Diminishing culpability

- Knowingly violating safe operating procedures?
  - NO → Pass substitution test?
    - YES → History of unsafe acts?
      - YES → Blameless error
      - NO → Blameless error but corrective training or counseling indicated
    - NO → Deficiencies in training and selection or inexperience?
      - YES → System-induced error
      - NO → Possible negligent error
## Accountability

<table>
<thead>
<tr>
<th>Human error</th>
<th>At-risk behavior</th>
<th>Reckless behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td>A product of our current system design and our behavioral choices</td>
<td>A choice in which the risk is believed to be insignificant or justified</td>
<td>A conscious disregard for a substantial and unjustified risk</td>
</tr>
<tr>
<td>Manage through changes in:</td>
<td>Manage through:</td>
<td>Manage through:</td>
</tr>
<tr>
<td>○ Choices</td>
<td>○ Removing incentives for the behavior</td>
<td>○ Remedial action</td>
</tr>
<tr>
<td>○ Processes</td>
<td>○ Creating incentives for better choices</td>
<td>○ Punitive action</td>
</tr>
<tr>
<td>○ Procedures</td>
<td>○ Increasing situational awareness</td>
<td></td>
</tr>
<tr>
<td>○ Training</td>
<td></td>
<td></td>
</tr>
<tr>
<td>○ Environment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>○ Design</td>
<td></td>
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</tr>
</tbody>
</table>

**Console**

**Coach**

**Punish**
Group Discussion: Culpability and Accountability Case Studies
Case Study 1: Documentation

On Friday at 4 p.m., a walk-in patient complained that the wound on his foot was very painful and had yellow drainage. The provider prescribed a topical antibiotic and a nonsteroidal anti-inflammatory. The provider was in a hurry and didn’t document the visit.
Case Study 1: Documentation (con’t)

Over the weekend, the wound worsened, the patient was admitted to the hospital, and eventually a toe was amputated.

Three months later when a claim was made, the provider entered a note in the EHR, writing in great detail that the patient refused hospitalization and that an oral antibiotic was prescribed.
How culpable is the provider?

How accountable is the provider?
Patient went for a computed tomography (CT) scan, and the technician checked the EHR for allergies but none were documented.

The tech asked the patient if she had ever had a reaction to contrast media or dyes in the past. The patient said she did get hives, and she was therefore premedicated before the CT scan.

Source: Adapted from PSNET.AHRQ.gov
During her follow-up at the health center, the patient asked the medical assistant if the allergy to contrast agent had been entered into her EHR. It was not.

Upon investigation the allergy had been removed from the patient’s allergy list. The medical assistant had removed the contrast intolerance from the allergy list because it is not a “true” allergy. She intended to find out where to document an intolerance in the EHR but forgot to ask.

Source: Adapted from PSNET.AHRQ.gov
How culpable is the provider?

How accountable is the provider?
Design Safe and Reliable Systems

- Design to prevent, intercept, and alleviate errors
- Reduce complexity
- Automate
- Impose constraints, hard stops
- Optimize technology
- Implement barriers or safeguards
- Use alerts, alarms
The Tools: People, Process, and Technology
Tools to Design Safe and Reliable Systems

• Flowcharts
• Process maps
• Failure mode and effects analysis (FMEA)
• Risk assessments
• Behavior-based safety
• 5 S’s
• Team training
• Technology
Monday

Dr. Smith sees female patient with nasal congestion and watery eyes

Dr. Smith tells patient she will prescribe FLONASE nasal spray

Dr. Smith orders prescription in the EHR for FLOMAX

Pharmacy order sent electronically to patient’s retail pharmacy

Dr. Smith orders sinus CT scan

Patient checks out at front desk

Front desk prints out office visit summary

Patient picks up prescription at retail pharmacy

Patient goes to outpatient Radiology for CT scan

Patient takes FLOMAX for several days

Patient presents to ER with complaints of dizziness

Patient returns to Health Center

Sunday

Monday

Patient seen by Dr. Smith CT scan report not available

Dr. Smith leaves for vacation

Radiology call abnormal CT report

Report placed in Dr. Smith’s mail box

CT report mass identified rule out squamous cell carcinoma sent to Dr. Smith’s e-patient list

Wednesday
### Urine testing process

<table>
<thead>
<tr>
<th>Provider</th>
<th>Medical Assistant</th>
<th>Patient</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orders Urine Test in EHR</td>
<td>Receives notice on task list</td>
<td>Patient voids</td>
<td>Courier picks up specimen</td>
</tr>
<tr>
<td></td>
<td>Identifies patient</td>
<td>Leaves specimen in bathroom</td>
<td>Prepare specimen for testing</td>
</tr>
<tr>
<td></td>
<td>Instructs patient on collection</td>
<td></td>
<td>Urine tested</td>
</tr>
<tr>
<td></td>
<td>Writes initials on cup</td>
<td></td>
<td>Results entered into EHR</td>
</tr>
<tr>
<td></td>
<td>Retrieves specimen</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Labels specimen</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Places specimen in bag with a requisition</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stores specimen for pick up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Results posted in EHR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calls results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documents treatment plan</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Process Map References

• American Academy of Family Physicians. Process mapping: a how-to primer.

• Minnesota Department of Health. Swim lane map.
  http://www.health.state.mn.us/divs/opi/qi/toolbox/swimlane.html
FMEA

- Proactive
- Structured, systematic approach
- Identifies problems or defects in a process or a service
- Severity
- Detectability
- Probability
- Variety of methodologies and work sheets
Why FMEA?

• Failure modes—What could go wrong?
• Failure cause—Why would a failure occur?
• Failure effects—What would be the outcome of the failure?
FMEA References

• Guidance for performing failure mode and effects analysis with performance improvement projects. 

• VA National Patient Safety Center. The basics of healthcare failure mode and effect analysis. 
  https://www.patientsafety.va.gov/docs/hfmea/FMEA2.pdf

• Institute for Healthcare Improvement. Interactive FMEA Tool.* 

*Requires registration
FMEA Steps

1. Select a topic to analyze
2. Form a team
3. Create a diagram or visual
4. Conduct the analysis, find the failures
5. Identify causes and action
6. Design a change
7. Measure success
What Could Go Wrong?

1. Selects wrong patient
2. Selects wrong test
3. Selects routine vs. stat
4. Doesn’t select call results
5. Doesn’t specify phone number

1. Not at computer
2. Pt. not assigned to MA
3. Busy with procedure

1. Used one identifier
2. Calls out a name and patient responds
3. Uses exam room number not name

1. Inadequate amount
2. Unable to urinate
3. Several patients provide specimens at the same time
4. No initials on cup
5. Initials get wet
6. Puts toilet tissue in cup
FMEA Worksheet

Enter ratings and RPN values in respective columns.

1. Flowchart the selected process as it is designed.
2. Flowchart the selected process as it is routinely conducted (the actual process).
3. List each step and each link between the steps of the intended process in column 5 below.
4. Include discrepancies between the flowcharts (steps 1 and 2) in column 6 below.

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Severity ratings</td>
<td>Occurrence ratings</td>
<td>Detectability ratings</td>
<td>RPNs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*RPN = risk priority number
Risk Assessment

- Self-assessments
- Informal patient safety walkthrough
- Commercially available
- Insurance carriers
## Behavior-Based Safety Expectations and Error Prevention Tools

<table>
<thead>
<tr>
<th>Behavior-based expectations</th>
<th>Error prevention tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pay attention to detail</td>
<td>➤ STAR (Stop-Think-Act-Review)</td>
</tr>
<tr>
<td>Communicate clearly</td>
<td>➤ Repeat backs&lt;br&gt;➤ Clarifying question&lt;br&gt;➤ Phonetic and numeric clarifications</td>
</tr>
<tr>
<td>Have a questioning attitude</td>
<td>➤ Validate and verify, ask why</td>
</tr>
<tr>
<td>Hand off effectively</td>
<td>➤ Patient/project, plan, purpose, problems, precautions</td>
</tr>
<tr>
<td>Look out for your coworkers</td>
<td>➤ Peer checking&lt;br&gt;➤ Peer coaching&lt;br&gt;➤ Escalate your concerns</td>
</tr>
</tbody>
</table>
## 5 S’s For Success

<table>
<thead>
<tr>
<th>Sort</th>
<th>• Determine what is needed, what is not needed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Eliminate obstacles</td>
</tr>
<tr>
<td><strong>Set in order—systematize</strong></td>
<td>• Organize, arrange logically</td>
</tr>
<tr>
<td></td>
<td>• Make workflow easy</td>
</tr>
<tr>
<td><strong>Shine—sanitize</strong></td>
<td>• Clean</td>
</tr>
<tr>
<td></td>
<td>• Replace, restore broken</td>
</tr>
<tr>
<td><strong>Standardize</strong></td>
<td>• Use best practices</td>
</tr>
<tr>
<td></td>
<td>• Maintain order</td>
</tr>
<tr>
<td><strong>Sustain</strong></td>
<td>• Keep the order</td>
</tr>
<tr>
<td></td>
<td>• Perform audits</td>
</tr>
</tbody>
</table>

**Source:** Adapted from Young
TeamSTEPPS® for Office-Based Care Version

TeamSTEPPS® for Office-Based Care offers techniques, tools, and strategies to assist health care professionals in developing and optimizing team knowledge and performance in an office-based care setting. The course is intended for practice facilitators—individuals who play a key role in leading and assisting practices with their quality improvement and practice transformation efforts.

TeamSTEPPS for Office-Based Care adapts the core concepts of the TeamSTEPPS program to reflect the environment of office-based teams. The examples, discussions, and exercises are tailored to the medical office environment. It is a full version of TeamSTEPPS, including all of the fundamentals modules as well as modules to assist in implementation.
## Safety Benefits of Technology

<table>
<thead>
<tr>
<th>Drug alerts</th>
<th>Standard orders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online references</td>
<td>Alerts preventive care</td>
</tr>
<tr>
<td>E-prescribing</td>
<td>Automatic recalls</td>
</tr>
<tr>
<td>Medication reconciliation</td>
<td>Enhanced communication</td>
</tr>
<tr>
<td>Clinical decision support</td>
<td>Rapid deployment of best practices</td>
</tr>
<tr>
<td>Test and referral tracking</td>
<td>Quality reports</td>
</tr>
<tr>
<td>Abnormal result alerts</td>
<td>Measure clinical performance</td>
</tr>
<tr>
<td>Electronic imaging</td>
<td>Drop-down menus</td>
</tr>
<tr>
<td>Decrease duplication of tests</td>
<td>Forced functions</td>
</tr>
</tbody>
</table>
Group Discussion: Patient Safety Program
What are the two key elements of a patient safety program?
Adverse Event Reporting and Data Gathering
Clinical Risk Management Services - Tools

Event Reporting Toolkit

Published 12/14/2016

This toolkit provides a model policy on adverse event and near miss reporting, sample event report narrative and data collection forms, an event summary tool, a sample action plan template, and an overview of barriers to event reporting with suggested strategies to overcome barriers that can be used as resources for improving systems for risk identification and analysis.

Toolkit Resources

- Sample Event-Reporting Policy
- Event Reporting Barriers and Strategies
- Event Summary Tool
- Flow of Information Diagram
- Sample Action Plan Template
- Confidential Event Form
- Sample Event Report Narrative
- Event-Report Interview Guidelines
Event Toolkit References

• **Event reporting toolkit.**

• **Event response toolkit.**
  https://www.ecri.org/components/HRSA/Pages/EventResponseToolkit.aspx
Adverse Event: What Were They Thinking?

We know that:

• Systems break down
• Humans make mistakes
Event Investigation and Analysis Methodology

<table>
<thead>
<tr>
<th>Phases</th>
<th>I. Notification/Immediate/Interim Action</th>
<th>II. Investigation</th>
<th>III. Analysis</th>
<th>IV. Action Planning</th>
<th>V. Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>START</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Notification of event</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCA?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Immediate/Interim actions for Patient Safety</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

II. Investigation
- Initiate Investigation
- Analyze data
- Identify root causes
- Develop preventative actions

III. Analysis
- Enter event into database for tracking and trending of:
  - Chronic events
  - Event characteristics
  - Root Causes

IV. Action Planning
- Implement Action Plan
- Monitor and measure preventative actions
- Actions effective?
- Yes
  - Report findings
  - End
- No

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Event Investigation and Analysis Methodology

<table>
<thead>
<tr>
<th>Phases</th>
<th>I. Notification/Immediate/Interim Action</th>
<th>II. Investigation</th>
<th>III. Analysis</th>
<th>IV. Action Planning</th>
<th>V. Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>START</td>
<td>Initiate</td>
<td>Identify root action</td>
<td>Develop actions</td>
<td>Implement Action Plan</td>
</tr>
<tr>
<td></td>
<td>Notification of event</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Immediate/Interim actions for Patient Safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Enter event into database for tracking and trending of:
  - Chronic events
  - Event characteristics
  - Root Causes

- Assess effect size?

- Report findings

- No

- Implement preventive actions

- End
Remove Barriers to Event Reporting

• Policy and procedure
• Reporting systems in place
• Make it easy (short form)
• Nonpunitive
• Trust
• Follow up with reporter
• Make it a “value add”
• Anonymous reporting
Identifying Adverse Events in Primary Care

- Provider reported
- Pharmacist reported
- Patient reported
- Random chart sample
- Assessment of deceased patient records

Source: Vincent and Amalberti
“We Don’t Have Events to Report”

- Your top 10 worst concerns
- Global trigger tool (Institute for Healthcare Improvement)
- FMEA
- Patient safety indicators (AHRQ)
- Complications, complaints, claims
- Quality measures
- Clinical safety rounds
- Regulatory, accreditation
Investigation

• Take immediate action
• Initiate interview process
• Review documents
• Map timeline and process
Interview Process

- Prepare questions
- Prefer in person (private but familiar)
- Ask staff not to discuss among themselves
- Speak with one person at a time
- Be sensitive to staff involved in the adverse event
- Request permission to take notes
- Stress the purpose is to identify system issues
- Practice active listening
- Describe what you normally do when completing the task
Analysis to Action
• You can’t fix *what* happened
• You need to know *why* it happened
Causal Analysis

- Root cause
- Apparent cause
- Common cause
When Should I Conduct an RCA?

- Sentinel events
- Safety assessment code (SAC) matrix
- Significant, serious
- Blameworthy events
- Your worst event or near miss
- Severity
- Frequency
- Trends
<table>
<thead>
<tr>
<th>SAC</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Catastrophic</strong></td>
<td>Patients with actual or potential: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) <strong>not related to the natural course of the patient's illness or underlying condition</strong> (i.e., acts of commission or omission). This includes outcomes that are a direct result of injuries sustained in a fall; or associated with an unauthorized departure from an around-the-clock treatment setting; or the result of an assault or other crime. Any of the adverse events defined by the Joint Commission as reviewable “Sentinel Events” should also be considered in this category (see App. A, subpar. 1b).</td>
<td>Catastrophic events include death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition.</td>
</tr>
<tr>
<td><strong>Major</strong></td>
<td>Patients with actual or potential: Permanent <strong>lessening</strong> of bodily functioning (sensory, motor, physiologic, or intellectual) <strong>not related to the natural course of the patient's illness or underlying condition</strong> (i.e., acts of commission or omission) or any of the following:</td>
<td>Major events include permanent lessening of bodily functioning not related to the natural course of the patient's illness or underlying condition, along with the following conditions:</td>
</tr>
<tr>
<td></td>
<td>1. Disfigurement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Surgical intervention required</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Increased length of stay for three or more patients</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Increased level of care for three or more patients</td>
<td></td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>Patients with actual or potential: Increased length of stay or increased level of care for one or two patients</td>
<td>Moderate events include increased length of stay or increased level of care for one or two patients.</td>
</tr>
<tr>
<td><strong>Minor</strong></td>
<td>Patients with actual or potential: No injury, nor increased length of stay nor increased level of care</td>
<td>Minor events include no injury, nor increased length of stay, nor increased level of care.</td>
</tr>
</tbody>
</table>

**Source:** VA National Center for Patient Safety “Safety Assessment Code”
Root-Cause Analysis

- What happened?
- Why did it happen?
- What are we going to do about it?
Types of Root-Cause Analysis

- Joint Commission
- SWARM
- 5 Why’s
- Human Factors Analysis Classification System (HFACS)

Sources: Li et al.; Joint Commission “Framework”
### 5 Why’s

<table>
<thead>
<tr>
<th>Problem Statement</th>
<th>(One-sentence description of event or problem) Patient’s abnormal sinus CT scan report was delayed for more than 14 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why?</td>
<td>Ordering physician was on vacation and radiology center entered the abnormal test results to the patient’s EHR and flagged the ordering physician’s task list</td>
</tr>
<tr>
<td>Why?</td>
<td>Ordering physician and covering provider were trained that test results would automatically default to covering provider’s task list for follow-up</td>
</tr>
<tr>
<td>Why?</td>
<td>The sinus CT scan report did not automatically default to the covering provider</td>
</tr>
<tr>
<td>Why?</td>
<td>There was an EHR upgrade; the automatic default malfunctioned and was turned off</td>
</tr>
<tr>
<td>Why?</td>
<td>The test results module and interface were not tested following the upgrade</td>
</tr>
</tbody>
</table>
| Root cause(s)     | 1. Malfunction after EHR upgrade went unnoticed  
2. No failsafe process to monitor that test results are being reviewed by provider or covering providers |

**Source:** Adapted from CMS
Using Human Factors Analysis and Classification System (HFACS)

<table>
<thead>
<tr>
<th># Nanocodes</th>
<th>Nanocode short description</th>
<th>Subcategory</th>
<th>Category</th>
<th># Nanocodes/ category</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Skill-based error</td>
<td></td>
<td>Error</td>
<td>Unsafe acts</td>
</tr>
<tr>
<td></td>
<td>Judgment/decision making</td>
<td></td>
<td>Violations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Misperception</td>
<td></td>
<td>Environmental factors</td>
<td>Preconditions for unsafe acts</td>
</tr>
<tr>
<td></td>
<td>Routine (bending rules)</td>
<td></td>
<td>Condition of the operator</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exceptional (breaking rules)</td>
<td></td>
<td>Personnel factors</td>
<td></td>
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<tr>
<td></td>
<td>Physical factors</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Technological factors</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Adverse mental states</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Adverse physiological state</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Chronic performance limitations</td>
<td></td>
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<tr>
<td></td>
<td>Communication/coordination/planning</td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>Fitness for duty</td>
<td></td>
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<tr>
<td></td>
<td>Inadequate supervision</td>
<td></td>
<td></td>
<td>Supervision</td>
</tr>
<tr>
<td></td>
<td>Planned inappropriate operations</td>
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<tr>
<td></td>
<td>Failure to address known problem</td>
<td></td>
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<tr>
<td></td>
<td>Supervisory violations</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Resource/acquisition management</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Organizational climate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Organizational processes</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

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Human Factors Analysis Classification System (HFACS) Framework

- Organizational Influences
  - Resource Management
  - Organizational Climate
  - Organizational Process

- Supervision
  - Inadequate Supervision
  - Inappropriate Planned Operations
  - Failure to Address a Known Problem
  - Supervisory Violation

- Preconditions for Unsafe Acts
  - Environmental Factors
    - Physical Environment
    - Technological Environment
    - Communication / Coordination / Planning
  - Personnel Factors
    - Fitness for Duty
  - Conditions of the Operator
    - Adverse Mental State
    - Adverse Physiological State
    - Chronic Performance Limitation

- Unsafe Act
  - Errors
    - Skill-Based Error
    - Decision Error
    - Perceptual Error
  - Violations
    - Routine
    - Exceptional
Root-Cause Analysis References

  https://www.jointcommission.org/framework_for_conducting_a_root_cause_analysis_and_action_plan/

- SWARM:

Group Activity: Actions to Take to Prevent Recurrence

How do we know what actions to take?
Action Plans

• Linked to the identified cause
• One action item for each root cause
• Redesign using best practices and established science
• Select strong or weak interventions
• Track who, what, when, where, how
• Implement
• Measure
Action Plan

- Assign an individual to implement action plan
- This individual should have authority to effect change
- Permanent
- Resources
- Timeframes
Types of Actions

- Remedial actions—don’t necessarily address the cause
- Interim actions—short-term actions to reduce risk during implementation of long-term actions
- Corrective actions—address the root cause, and as a result, prevent recurrence of the event
# Hierarchy of Error Reduction Strategies

<table>
<thead>
<tr>
<th>Strong actions</th>
<th>Intermediate actions</th>
<th>Weaker actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not dependent on humans to get it right</td>
<td>Doesn’t fully control for human error</td>
<td>Relies solely on human action</td>
</tr>
<tr>
<td>Physical</td>
<td>Cognitive</td>
<td>Information</td>
</tr>
<tr>
<td>Permanent</td>
<td>Procedural</td>
<td>Temporary</td>
</tr>
<tr>
<td>Forces the person to get it right</td>
<td>Helps the person remember</td>
<td>Informs, alerts, prompts the person</td>
</tr>
<tr>
<td>Eliminates the chance to choose the wrong option</td>
<td>Serves as a guide</td>
<td>Action left up to personal interpretation</td>
</tr>
</tbody>
</table>

**Source:** Adapted from VA National Center for Patient Safety “Root Cause Analysis”

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## Examples of Error Reduction Actions

<table>
<thead>
<tr>
<th>Strong actions</th>
<th>Intermediate actions</th>
<th>Weaker actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forced functions</td>
<td>Redundancy</td>
<td>Warning signs and labels</td>
</tr>
<tr>
<td>Automation/technology</td>
<td>Checklists/reminders</td>
<td>New or longer policies</td>
</tr>
<tr>
<td>Physical</td>
<td>Eliminate look-alikes/sound-alikes</td>
<td>New procedures or rules</td>
</tr>
<tr>
<td>Simplify the process</td>
<td>Enhanced communication</td>
<td>Training</td>
</tr>
<tr>
<td>Remove unnecessary</td>
<td>Software enhancement</td>
<td>Additional analysis/study</td>
</tr>
<tr>
<td>Standardize equipment</td>
<td>Eliminate distractions</td>
<td>Memos</td>
</tr>
<tr>
<td>Failsafe mechanisms</td>
<td>Minimize choices</td>
<td>Be more careful</td>
</tr>
<tr>
<td>Architectural</td>
<td>Increase detectability</td>
<td>Documentation</td>
</tr>
</tbody>
</table>

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How Will We Know Whether the Action We Took Makes a Difference?

- Collect measures of intended outcome
- Determine which method
- Determine frequency of measurement/data collection
- Monitor for a predetermined period
- Define reporting hierarchy
Measures of Effectiveness

- Ensures the new process is carried out as planned
- Process measure: how you know that the action is actually taking place
- Outcomes measure: the effectiveness of the action in achieving the expected results
Sustaining Improvements

• Formal follow-up process of RCA recommendations
• Patient involvement
• Metrics/measures
• Technology
• Board involvement
• Walkrounds/visibility
• Simulations and drills
• New top 10 list
Communication and Monitoring

- Huddle (stand-up meetings)
- Safety message boards
- Interactive sessions with staff
- Tell stories about patient/staff (voice of the customer)
- Opportunities to relive accomplishments
- Patient newsletter/education
- Formal report to risk management committee
Summary

- Identify your top 10 patient safety concerns
- After analysis, take action
- Opt for strong actions over weak
- Measure for success and sustainability
- Share this information with 3 people
References


- Institute of Medicine. To Err Is Human.
References (con’t)

- Joint Commission:
  11 Tenets of a safety culture. [Link](https://www.jointcommission.org/assets/1/6/SEA_57_infographic_11_tenets_safety_culture.pdf)
  Framework for conducting a root cause analysis and action plan. 2013. [Link](https://www.jointcommission.org/framework_for_conducting_a_root_cause_analysis_and_action_plan/)
  Sentinel event alert 57. The essential role of leadership in developing a safety culture. 2017. [Link](https://www.jointcommission.org/sea_issue_57/)


- National Patient Safety Foundation (NPSF):
  RCA2: improving root cause analyses and actions to prevent harm. 2016. [Link](http://www.npsf.org/?RCA2)

References (con’t)

• VA National Center for Patient Safety, U.S. Department of Veterans Affairs:
Thank You

Additional Questions?

BPHC Helpdesk:
1-877-974-BPHC (2742)
https://www.hrsa.gov/about/contact/bphc.aspx
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