Risk Management 103: Patient Safety and Adverse Event Analysis

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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

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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

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

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Why Errors Happen

Reason's Swiss Cheese model

Generic Error Modeling System (GEMS)

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

Source: Reason 1990

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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

Joint Commission Outlines 11 Tenets of a Safety Culture

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"

Joint Commission Outlines 11 Tenets of a Safety Culture *(con't)*

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"

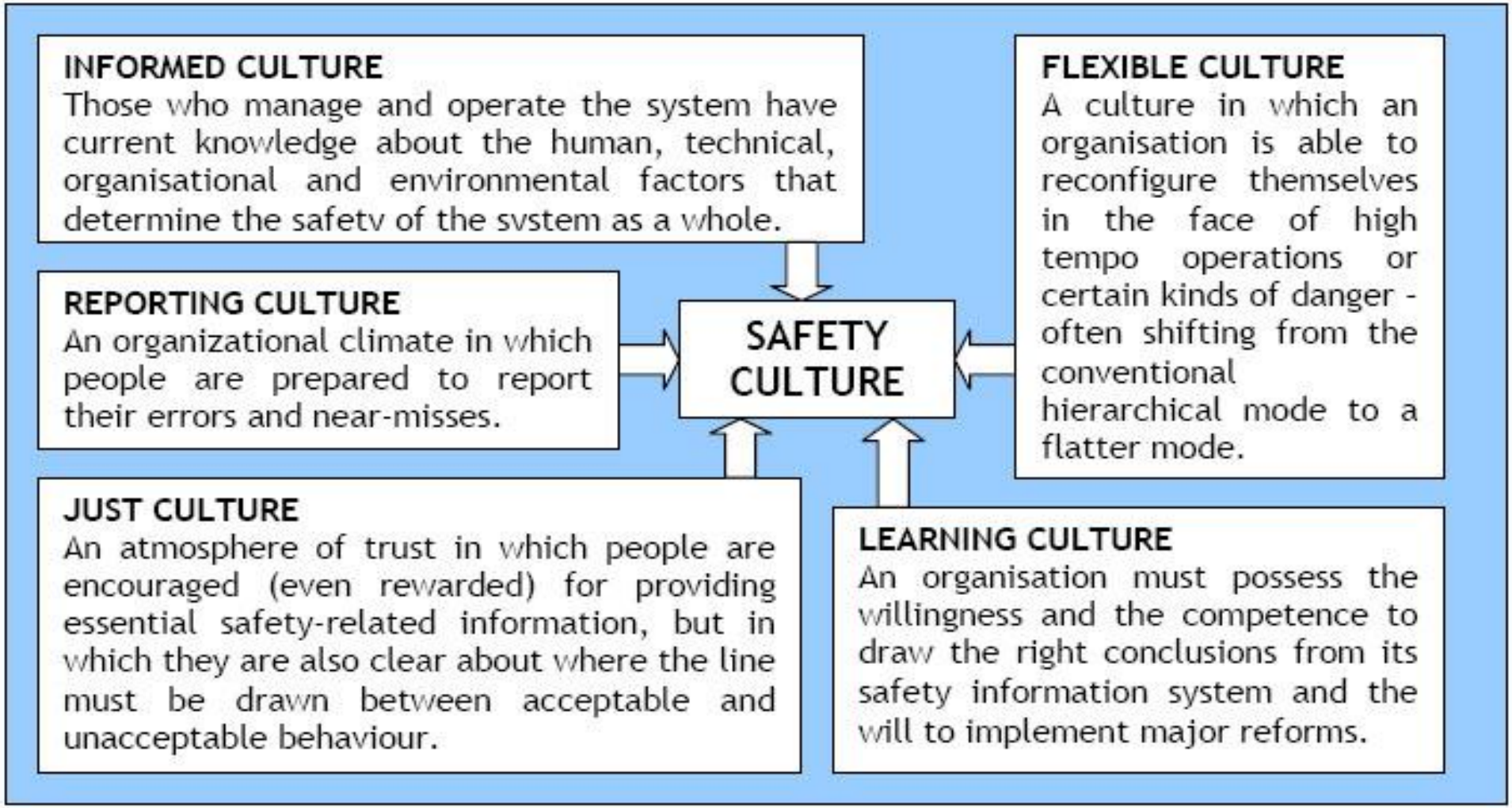
Culture of Patient Safety Survey

- 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

- **AHRQ Medical Office Survey website:** https://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/medical-office/index.html
- **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



Source: Based on Reason 1997

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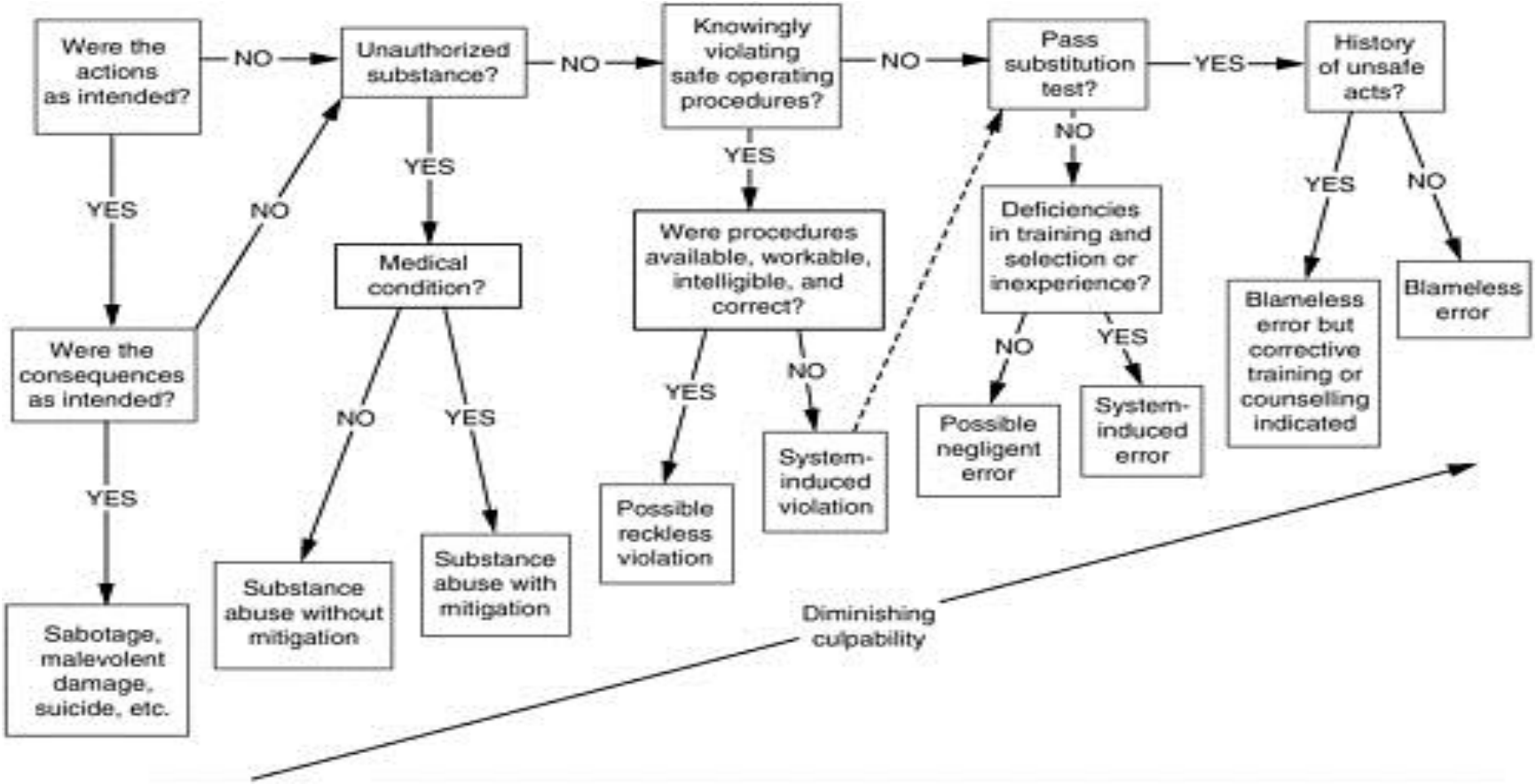
Just Culture

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

Culpability



Accountability

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

Case Study 2: Allergies

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

Case Study 2: Allergies *(con't)*

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

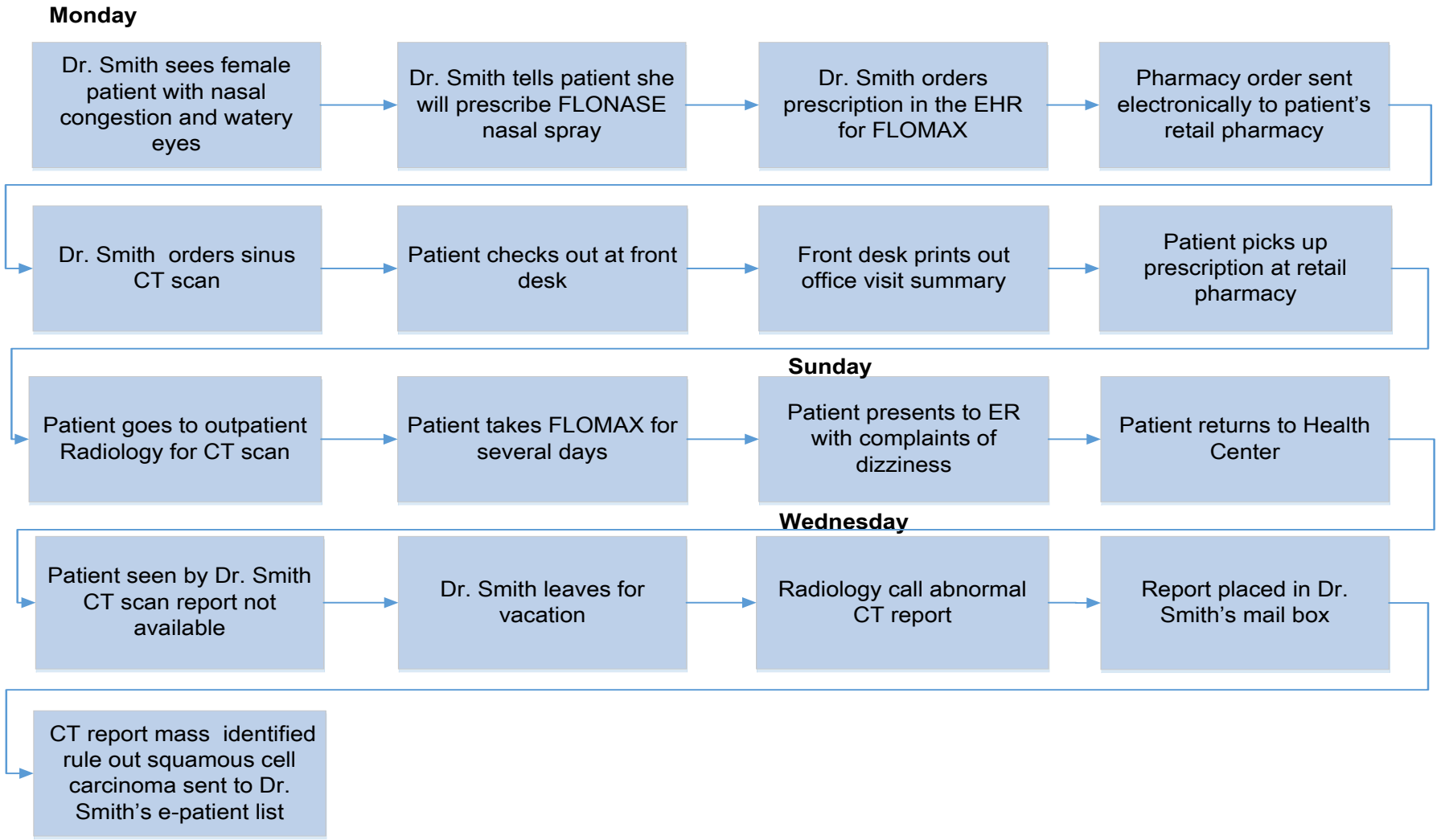
- Design to prevent, intercept, and alleviate errors
- Reduce complexity
- Automate
- Impose constraints, hard stops
- Optimize technology
- Implement barriers or safeguards
- Use alerts, alarms

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

Flow Chart Example



Swim Lane Map

Urine testing process

Provider	Medical Assistant	Patient	Laboratory
Orders Urine Test in EHR			
	Receives notice on task list		
	Identifies patient		
	Instructs patient on collection		
	Writes initials on cup		
		Patient voids	
		Leaves specimen in bathroom	
	Retrieves specimen		
	Labels specimen		
	Places specimen in bag with a requisition		
	Stores specimen for pick up		
			Courier picks up specimen
			Prepare specimen for testing
			Urine tested
			Results entered into EHR
Results posted in EHR			
Calls results		Receives test results	
Documents treatment plan			

Process Map References

- **American Academy of Family Physicians. Process mapping: a how-to primer.** http://www.aafp.org/dam/AAFP/documents/practice_management/pcmh/patientcare/PSMSProcessMapping.pdf

- **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

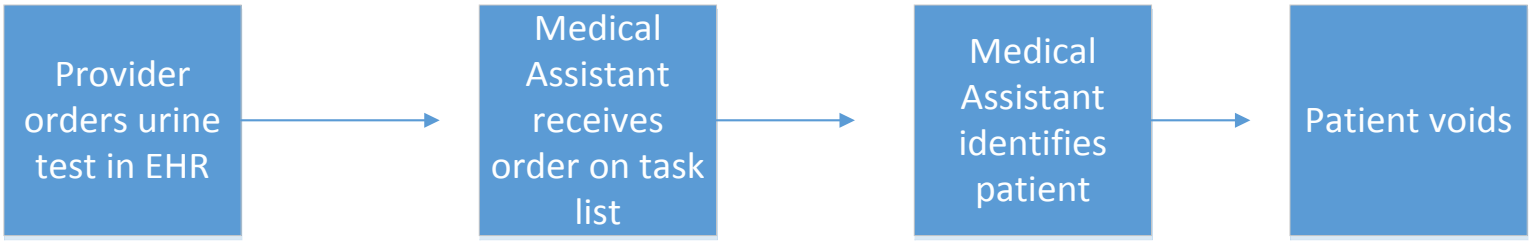
- **Guidance for performing failure mode and effects analysis with performance improvement projects.** https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/GuidanceForFMEA.pdf
- **VA National Patient Safety Center. The basics of healthcare failure mode and effect analysis.** https://www.patientsafety.va.gov/docs/hfmea/FMEA2.pdf
- **Institute for Healthcare Improvement. Interactive FMEA Tool.*** http://app.ihi.org/Workspace/tools/fmea/CreateTool.aspx?TemplateProcessId=1&Category=10

*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.

5. Step of link in process	6. List all potential failure modes	7. Potential effect	8. Severity of effect	9. Frequency of failure	10. Detectability	11. RPN* (8×9×10)	12. Possible causes (from RCA)	13. Recommended redesign
			Severity ratings	Occurrence ratings	Detectability ratings	RPNs		

*RPN = risk priority number

Risk Assessment

- Self-assessments
- Informal patient safety walkround
- Commercially available
- Insurance carriers

Behavior-Based Safety Expectations and Error Prevention Tools

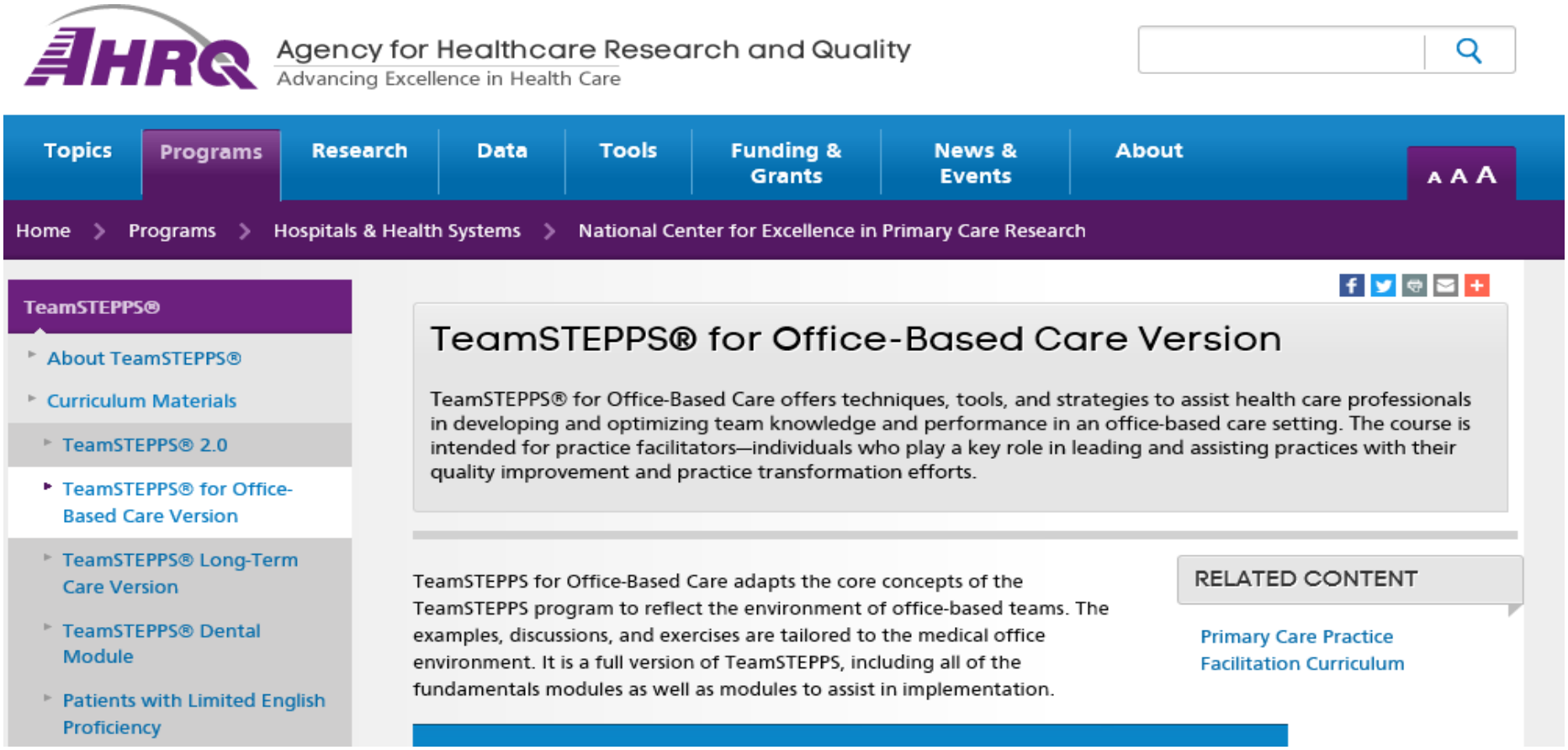
Behavior-based expectations	Error prevention tools
Pay attention to detail	▶ STAR (Stop-Think-Act-Review)
Communicate clearly	▶ Repeat backs ▶ Clarifying question ▶ Phonetic and numeric clarifications
Have a questioning attitude	▶ Validate and verify, ask why
Hand off effectively	▶ Patient/project, plan, purpose, problems, precautions
Look out for your coworkers	▶ Peer checking ▶ Peer coaching ▶ Escalate your concerns

5 S's For Success

Sort	• Determine what is needed, what is not needed • Eliminate obstacles
Set in order—systematize	• Organize, arrange logically • Make workflow easy
Shine—sanitize	• Clean • Replace, restore broken
Standardize	• Use best practices • Maintain order
Sustain	• Keep the order • Perform audits

Source: Adapted from Young

Team Training



AHRQ TeamSTEPPS for Office-Based Care Version:
https://www.ahrq.gov/teamstepps/officebasedcare/index.html

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Safety Benefits of Technology

Drug alerts	Standard orders
Online references	Alerts preventive care
E-prescribing	Automatic recalls
Medication reconciliation	Enhanced communication
Clinical decision support	Rapid deployment of best practices
Test and referral tracking	Quality reports
Abnormal result alerts	Measure clinical performance
Electronic imaging	Drop-down menus
Decrease duplication of tests	Forced functions

Group Discussion:
Patient Safety Program

What are the two key elements of a patient safety program?

Adverse Event Reporting and Data Gathering

ECRI Institute Clinical Risk Management Program Toolkits

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

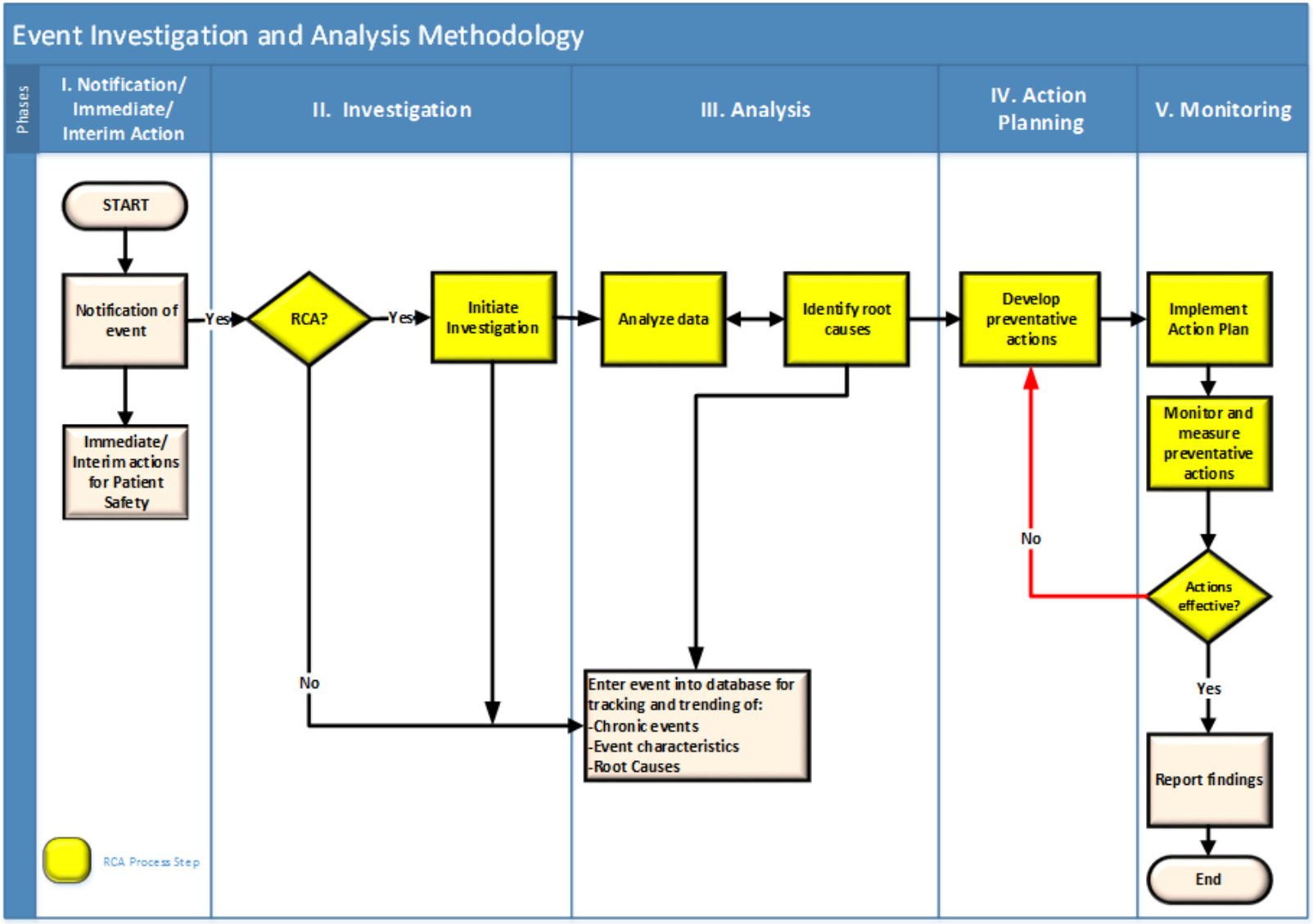
- **Event reporting toolkit.** https://www.ecri.org/Components/HRSA/Pages/EventReportToolkit.aspx

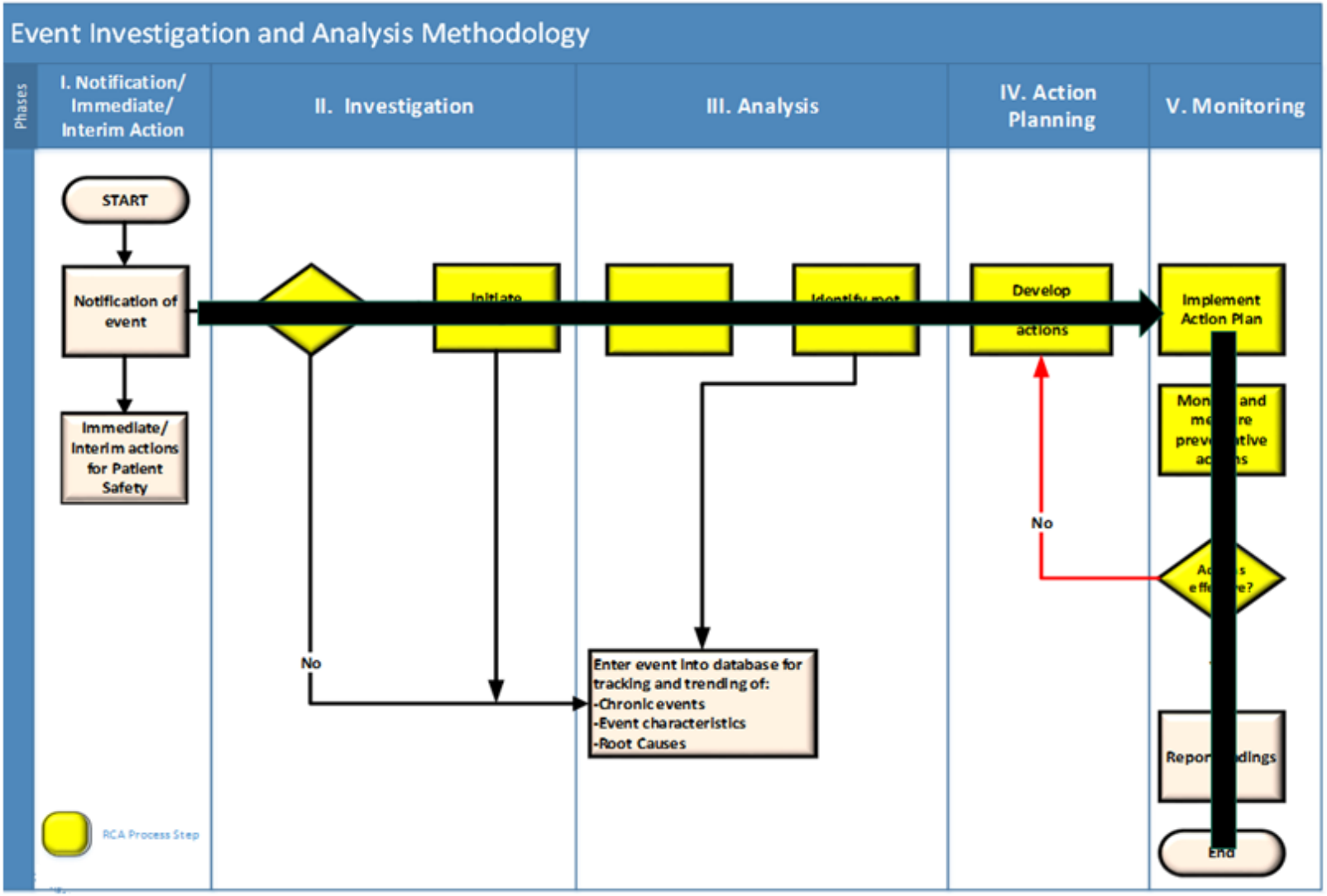
- **Event response toolkit.** https://www.ecri.org/components/HRSA/Pages/EventResponseToolkit.aspx

Adverse Event: What Were They Thinking?

We know that:

- **Systems break down**
- **Humans make mistakes**





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

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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

Analysis

- 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

VA National Center for Patient Safety: Safety Assessment Code (SAC) Matrix

Catastrophic

Patients with actual or potential:
Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) **not related to the natural course of the patient's illness or underlying condition** (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).

Major

Patients with actual or potential:
Permanent **lessening** of bodily functioning (sensory, motor, physiologic, or intellectual) **not related to the natural course of the patient's illness or underlying conditions** (i.e., acts of commission or omission) or any of the following:

1. Disfigurement
2. Surgical intervention required
3. Increased length of stay for three or more patients
4. Increased level of care for three or more patients

Moderate

Patients with actual or potential:
Increased length of stay **or** increased level of care for one or two patients

Minor

Patients with actual or potential:
No injury, nor increased length of stay nor increased level of care

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

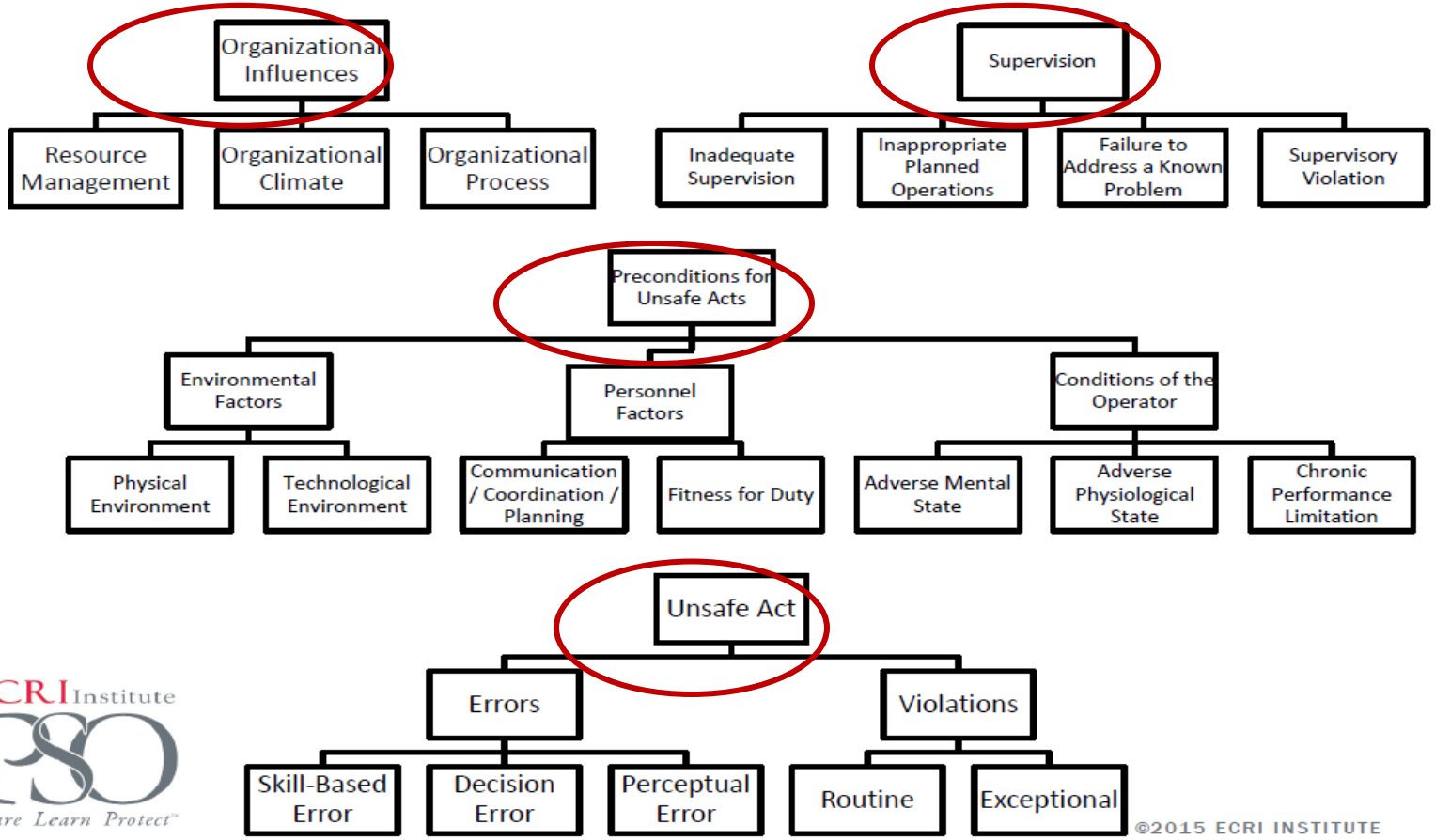
Problem Statement	(One-sentence description of event or problem) Patient's abnormal sinus CT scan report was delayed for more than 14 days
Why?	Ordering physician was on vacation and radiology center entered the abnormal test results to the patient's EHR and flagged the ordering physician's task list
Why?	Ordering physician and covering provider were trained that test results would automatically default to covering provider's task list for follow-up
Why?	The sinus CT scan report did not automatically default to the covering provider
Why?	There was an EHR upgrade; the automatic default malfunctioned and was turned off
Why?	The test results module and interface were not tested following the upgrade
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)

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

Human Factors Analysis Classification System (HFACS) Framework



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Root-Cause Analysis References

- **Joint Commission. Framework for conducting a root cause analysis and action plan.** https://www.jointcommission.org/framework_for_conducting_a_root_cause_analysis_and_action_plan/
- **SWARM:**

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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

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

Source: Adapted from VA National Center for Patient Safety "Root Cause Analysis"

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Examples of Error Reduction Actions

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

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

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Thank You

Additional Questions?

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HRSA Health Center Program

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