

Certification Prep Course

Certified Professional in Patient Safety (CPPS)TM

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Exam Content Areas



January 14	Culture
January 21	Leadership
January 28	Patient Safety Risks & Solutions
February 4	Measuring & Improving Performance
February 11	Systems Thinking & Design

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Objectives

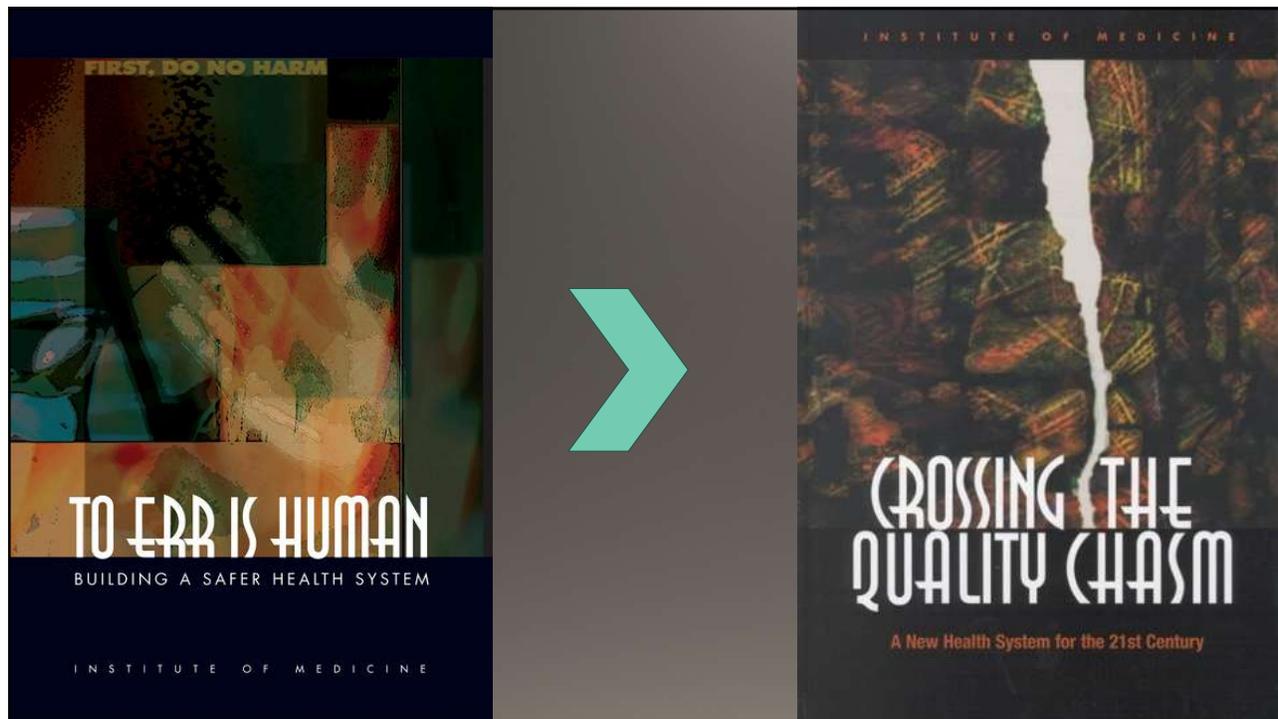
- 01**
Identify common patient safety risks
- 02**
Explain how active and latent failures interact within complex healthcare systems
- 03**
Differentiate between prospective and retrospective risk-assessment tools

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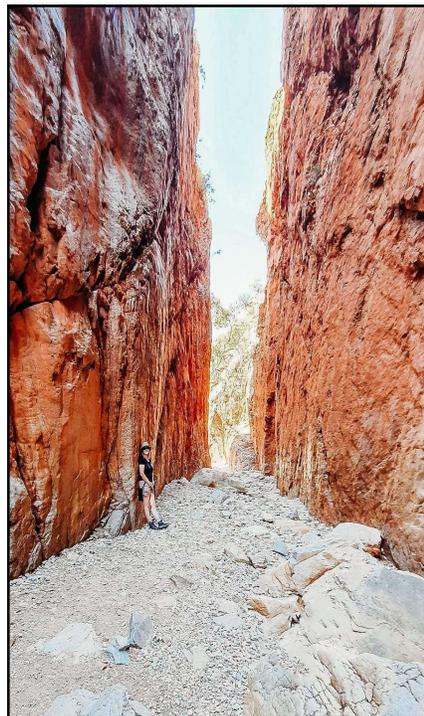
Exam Focus: Patient Safety Risks & Solutions

-  Common risks
-  Evidence-based interventions
-  Risk assessment tools
-  Reporting systems and learning culture

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Crossing the Quality Chasm

- **Safe:** avoiding injuries to patients from the very care that is intended to help them.
- **Timely:** reducing harmful delays for patients and providers.
- **Effective:** providing evidence-based care to those who benefit; avoiding ineffective or harmful care.
- **Efficient:** reduce waste – time, supplies, ideas, energy.
- **Equitable:** ensuring care quality does not vary because of race, language, gender, geography, income, or other factors.
- **Patient-centered:** providing care that is respectful of and responsive to patient preferences, needs, and values.

<https://nap.nationalacademies.org/catalog/10027/crossing-the-quality-chasm-a-new-health-system-for-the>

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“First, do no harm”



Patient safety is defined by the Institute of Medicine (IOM) as the **prevention of harm to patients.**

System of care delivery that:

- Prevents errors
- Learns from the errors that do occur
- Is built on a culture of safety that involves health care professionals, organizations, and patients.

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1 in every 10 patients is harmed in health care.



Medication Errors

Communication Failures

Diagnostic Errors

Hospital-Associated Infections

Falls

Handoff/Discharge Errors

Surgical Errors

Sepsis

Sources:
World Health Organization. Patient Safety. <https://www.who.int/news-room/fact-sheets/detail/patient-safety>

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System Design

A system should be designed so that the safest action is the easiest action.

Supports human decision-making

Reduces unnecessary cognitive load

Standardizes high-risk processes

Minimizes reliance on memory

Builds in redundancies and forcing functions

Anticipates human fallibility rather than relying on perfect performance

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Terminology

Active Failure



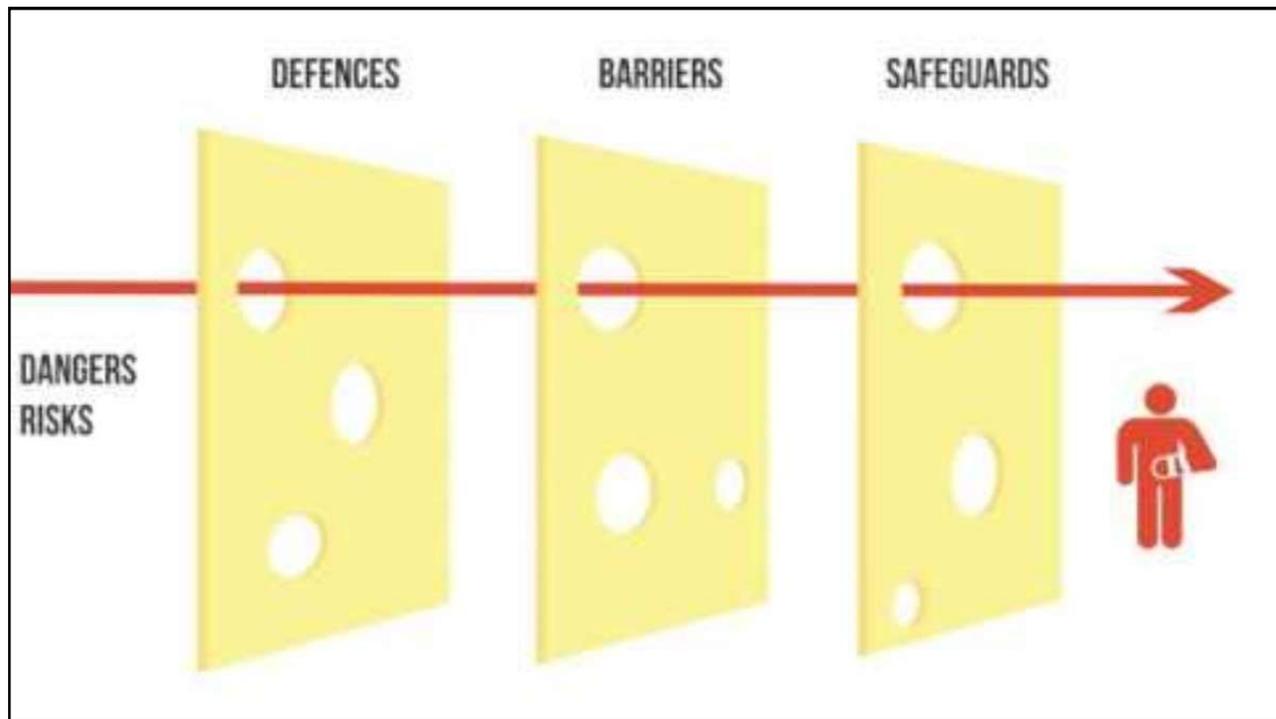
- Unsafe acts committed by individuals.
- Immediate, visible, and often the last step before an event.

Latent Failure



- System-level weaknesses embedded in processes, design, or culture.
- Hidden until triggered by conditions leading to an event.

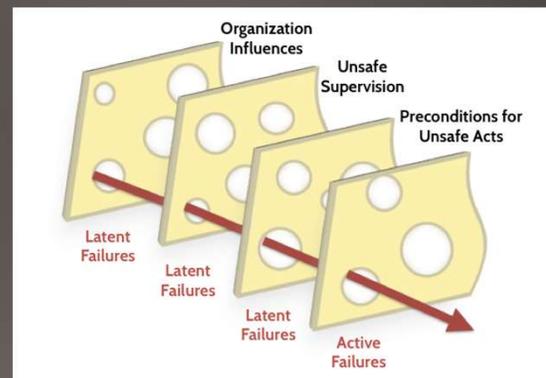
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Swiss Cheese Model

- Framework outlined by James Reason identifies active and latent failures at both the “sharp end” and “blunt end” of a system.
- Sharp End: Activities that occur in the care delivery system that are visible,
- Blunt end: Actions and decisions that occur behind the scenes, at an organizational management level, setting the culture of the organization and work environment.
- Strengthen the system by closing holes.
- Builds safer, more reliable processes.



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Human Factors



Physical

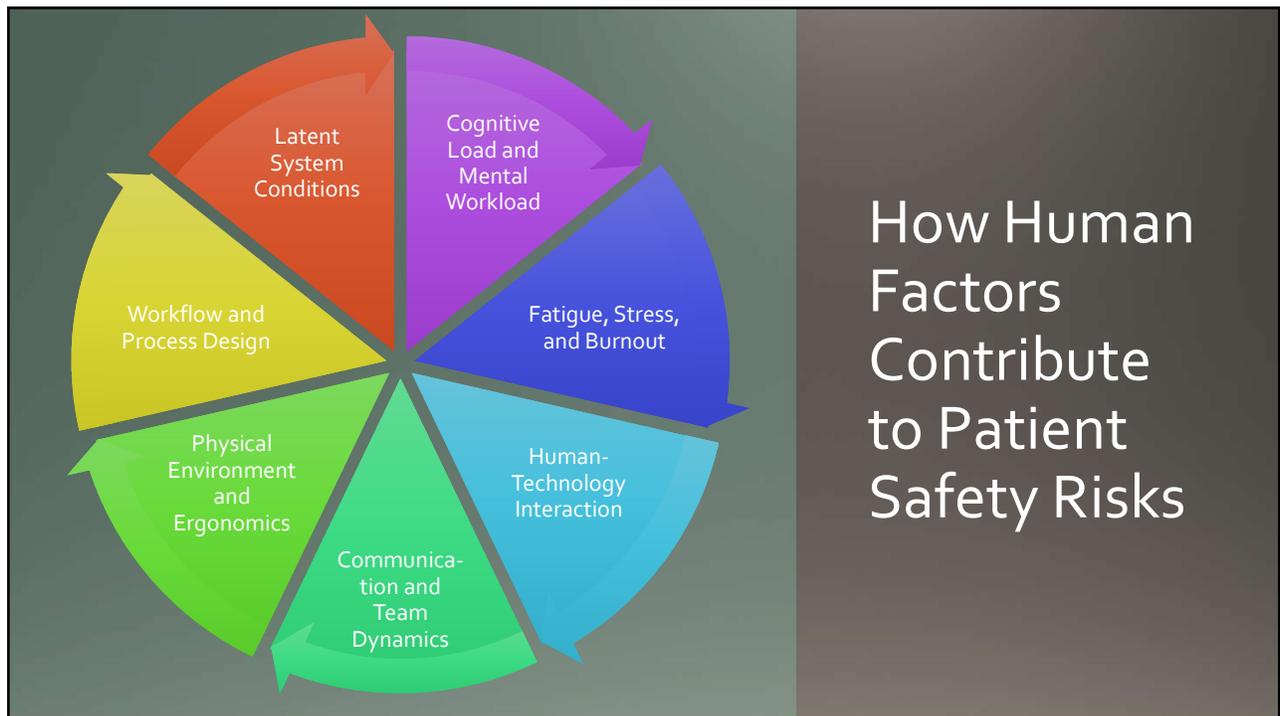


Cognitive



Organizational

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Human Factors in System Design

- Safer workflows
- Fewer errors
- Better teamwork
- Improved patient outcomes

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Capturing Front-Line Safety Concerns



Provides an internal data set that identifies priorities in patient safety improvement needs



Supports psychological safety by assuring non-punitive approach to reporting



Provides feedback and recognition of reporters to encourage robust reporting and near miss reporting

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How Do We Capture Safety Concerns?

Voluntary Reporting Systems

Learning Boards

Patient Safety Leadership Rounds

Patient complaints and concerns

Product recalls and vendor alerts

FMEA, RCA, other process analyses

Eliciting concerns from patients and families

Safety reporting systems

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From Safety Concerns to Risk Assessment

Prospective

help us identify where harm could occur *before* it happens

Retrospective

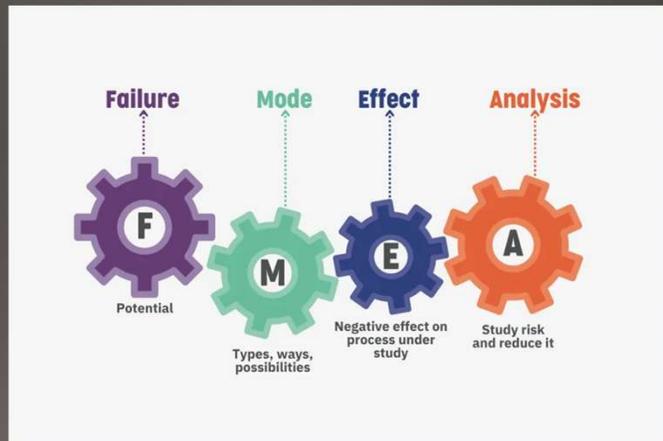
help us learn from events *after* they occur

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Prospective Risk Assessments

Failure, Mode and Effect Analysis

Systematic, proactive method to assess risk of failure and harm in processes and to identify the most key areas for process improvements.



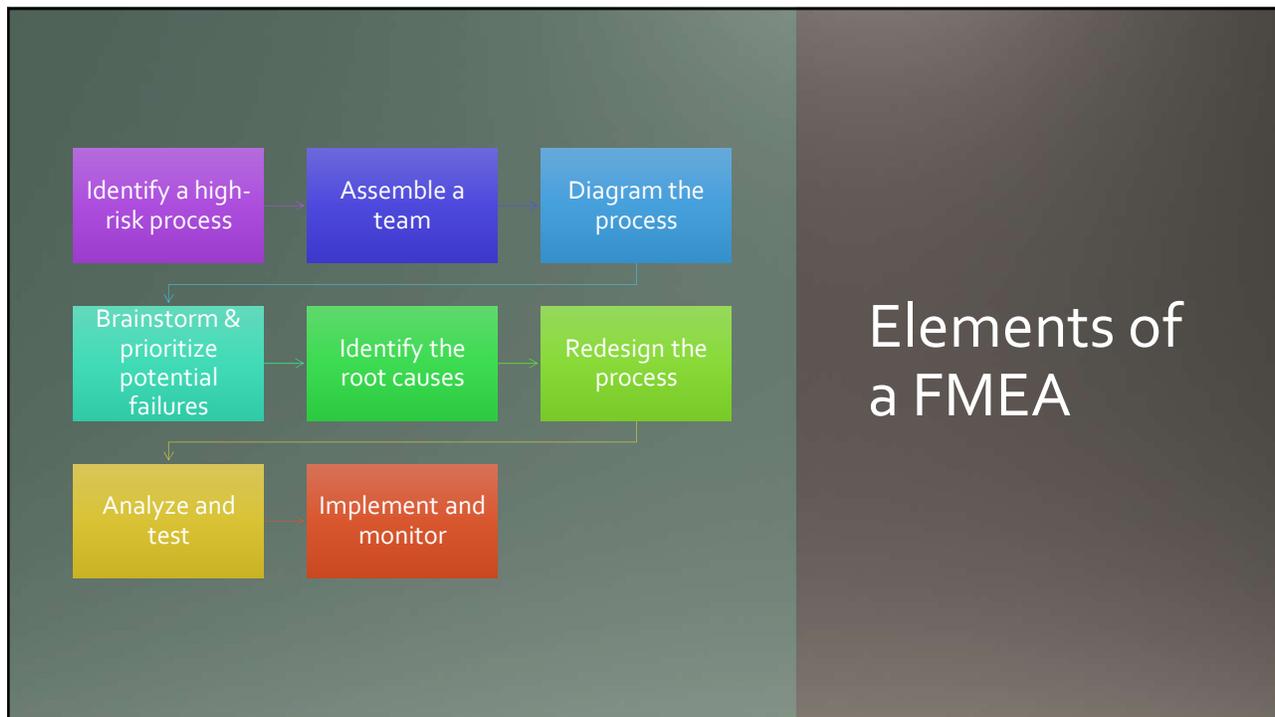
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FMEA Triggers

- Introducing a new process, workflow, or technology
- Redesigning or changing an existing process
- Identifying a high-risk or high-volume process
- Noticing early warning signs or "weak signals"
- Preparing for regulatory, accreditation, or safety-critical programs
- After recognizing latent system vulnerabilities

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Elements of a FMEA

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Institute for Safe Medication Practices

Example of a Health Care Failure Mode and Effects Analysis for IV Patient Controlled Analgesia (PCA)

Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Prescribing							
Assess patient	Inaccurate pain assessment	Cultural influences; patient unable to articulate	Poor pain control	2	4	8	Standard scale to help assess pain; training on cultural influences
Choose analgesic/mode of delivery	Wrong analgesic selected	Clinical situation not considered (age, renal function, allergies, etc.); tolerance to opiates not considered; standard PCA protocols not followed (or not available); concomitant use of other analgesics not considered; drug shortage; knowledge deficit; improper selection of patients appropriate for PCA	Improper dosing; improper drug; allergic response; improper use of substitute drug	4	3	12	CPOE with decision support, clinical pharmacy program; standard PCA protocol with education on use; point-of-use access to drug information; feedback mechanism on drug shortages with information on substitute drugs available; selection criteria for PCA patients
Prescribe analgesic	Wrong dose (loading, PCA, constant, lock-out), route, frequency	Knowledge deficit; mental slip; wrong selection from list; information about drug not available	Overdose; under-dose; ADR	4	3	12	CPOE with decision support; clinical pharmacy program; standard PCA protocols
	Proper patient monitoring not ordered	Knowledge deficit; mental slip	Failure to detect problems early to prevent harm	4	3	12	Standard PCA order sets with monitoring guidelines
	Prescribed on wrong patient	Similar patient names; patient identifier not clear; name does not appear on screen when ordering medications	Wrong patient receives inappropriate drug and dose; ADR; allergic response	3	3	9	Match therapy to patient condition; alerts for look-alike patient names; visible demographic information on

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FMEA Weaknesses

- RPN scoring can be influenced by team bias
- Risk scores are subjective and often inconsistent
- Creates a false sense of mathematical precision

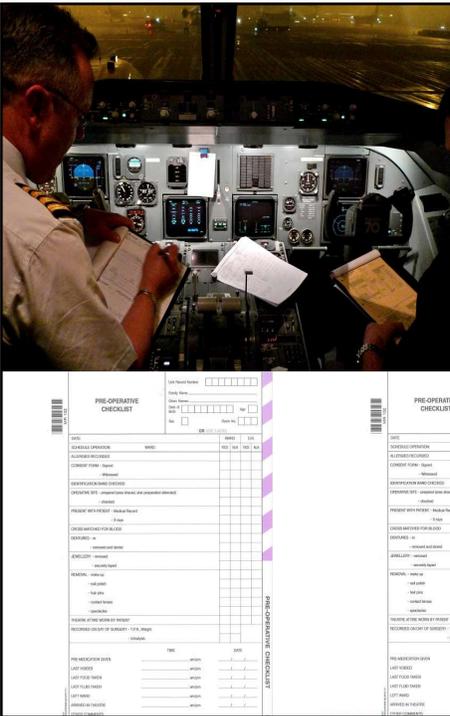


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Safety Checklists

- Improve communication
- Strengthen adherence to guidelines
- Improve human factors
- Reduce the incidence of adverse events
- Decrease mortality and morbidity



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Other Prospective Risk Assessments

- Safety rounding
- Communication with frontline staff & patients
- Gap analysis to identify improvement needs
- Monitoring adherence to evidence-based best practices in high-risk areas

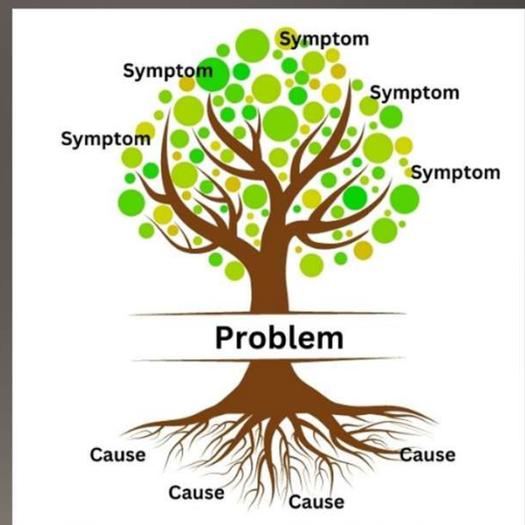


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Root Cause Analysis

Root Cause Analysis (RCA)
and
Root Cause Analysis & Action (RCA2)

Image source: [Workfellow](#)



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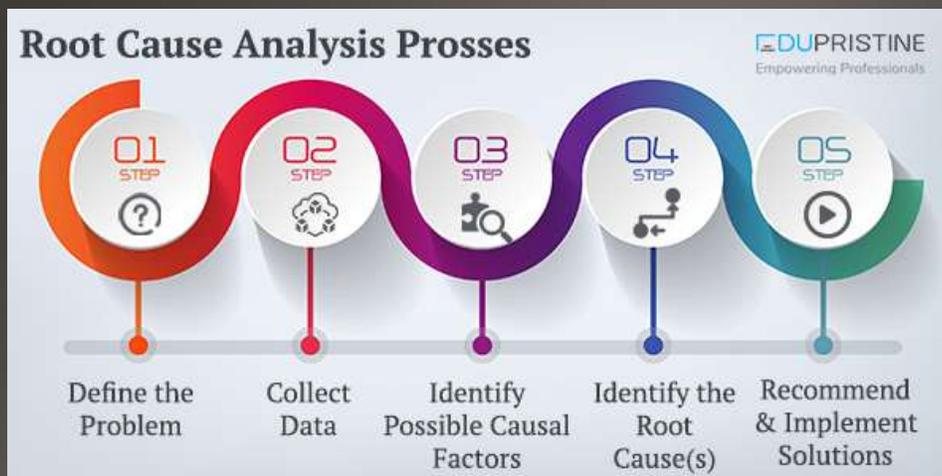
RCA Triggers

- Sentinel or “never” events
- Serious harm events
- Recurrent or clustered events
- High-risk near misses
- Trending risks in reporting data
- Latent system concerns
- Leadership or frontline concern

Image Source: <https://www.intelycare.com/facilities/resources/what-is-a-sentinel-event-in-healthcare-overview-and-faq/>

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Components of a Root Cause Analysis



Source: <https://www.edupristine.com/blog/root-cause-analysis/>

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Effective Root Cause Analyses

- Use structure and tools to clarify the timeline and contributing factors
- Compare the process *as designed vs. as actually performed*
- Analyze differences through a human-factors lens
- Focus on process causation, not individual blame
- Identify actionable improvements to reduce risk



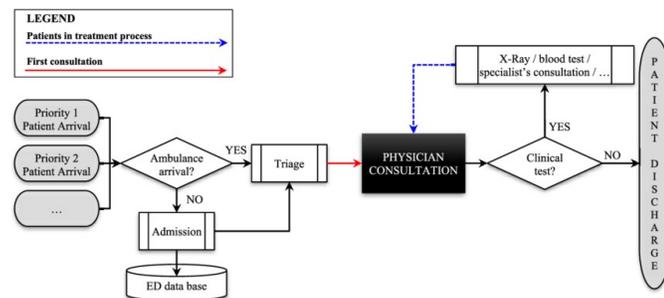
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RCA Tools & Structures

Flowcharting

mapping the timeline and actual vs. ideal process

https://www.researchgate.net/figure/Patient-flowchart-in-the-ED-For-interpretation-of-the-references-to-colour-in-this_fig1_336820286



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RCA Tools & Structures

The 5 Whys

drilling down to contributing factors

<https://www.designorate.com/how-to-apply-root-cause-analysis-using-5-whys/>

Problem	Patients don't attend their doctor appointment
↳ Why	The appointment message doesn't alert them before the doctor session
↳ Why	The messages don't have an alert feature
↳ Why	The system doesn't allow repeated messages or link appointment to patient's calendar
↳ Why	The system doesn't include an alerting or follow-up feature

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RCA Tools & Structures

Fishbone/Ishikawa diagrams

categorizing causes into system areas

<https://easyrca.com/blog/improving-patient-safety-with-fishbone-diagrams/>

The diagram is a fishbone-style Ishikawa diagram with a central horizontal spine pointing to a rounded rectangle on the right labeled "High patient wait times". Five main categories are shown in boxes above and below the spine, with arrows pointing to specific causes:

- People** (top left):
 - Skill Levels: Variability in skill levels among staff, leading to inefficiencies.
 - Training: New staff not adequately trained on the electronic health record (HER) system, causing slow data entry.
- Environment** (top right):
 - Cleanliness: Rooms not cleaned and prepared in a timely manner, delaying patient admission.
 - Lighting: Inadequate lighting in examinations rooms, making it difficult for precise assessments.
- Policies** (bottom left):
 - Guidelines: Lack of clear guidelines for prioritizing patients based on urgency, causing treatment delays.
- Processes** (bottom center):
 - Protocols: Absence of fast-track protocols for minor ailments.
- Materials** (bottom right):
 - Storage: Disorganized storage areas, making it hard to find necessary supplies quickly.

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Weaknesses & Pitfalls of the RCA Process

- Resource- and time-intensive
- Team composition can introduce bias
- Can feel like “just another requirement”
- Sentinel event criteria exclude near misses
- Many contributory factors—not always a single “root cause”
- May miss deeper system and human-factors issues
- Weak or vague risk-reduction strategies
- No follow-through on action plans
- Failure to connect causes to actions
- Focus too narrow or too broad
- Punitive culture undermining learning

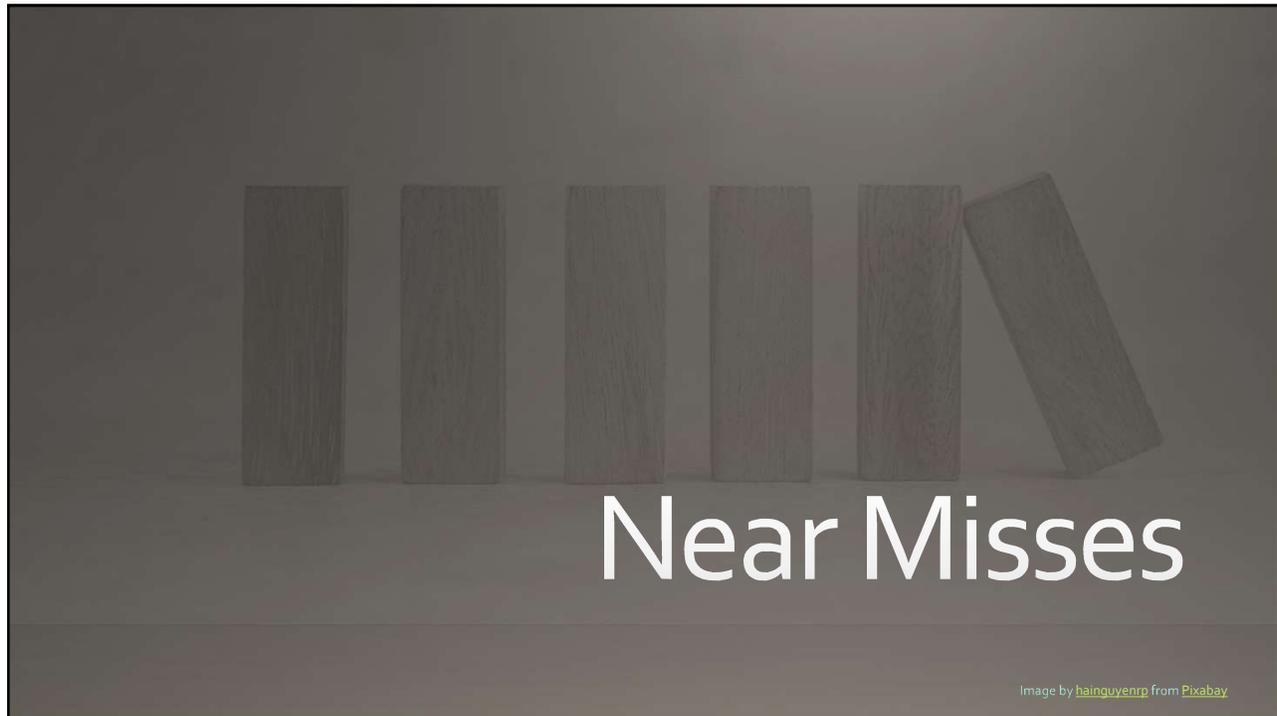
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Other Retrospective Risk Assessments

- Incident Reporting Systems
- Case Reviews
- Analytic tools within RCA
- Mortality & Morbidity Reviews
- Trigger Tools
- Discovery Tools



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Terminology

<h3>Near Miss</h3> <ul style="list-style-type: none">• An event that did not reach the patient but could have resulted in harm if circumstances were slightly different.• Signals system vulnerabilities and opportunities for learning.	<h3>Sentinel Event</h3> <ul style="list-style-type: none">• A serious patient safety event resulting in death, permanent harm, or severe temporary harm either physically or psychologically.• Requires immediate investigation and response.
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Importance of Near Misses



- Early warning signals that reveal system vulnerabilities before harm occurs.
- High-value learning opportunities that allow proactive improvement.
- Near misses expose “holes in the Swiss cheese”—process and system defects.
- Fixing these weaknesses strengthens defenses, improves reliability, and prevents future harm.
- Reporting near misses supports psychological safety and a strong safety culture.

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Underreporting of Near Misses

Perception

Fear of Blame or Punishment

Reporting System Barriers

Lack of feedback

Normalized as workarounds

Unclear definitions or expectations

Underestimation of system-level risk.

Cultural barriers to speaking up

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Patient Safety Solutions and Evidence-Based Safety Practices

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Care Bundles

- Structured way to improve care processes and patient outcomes.
- Small, straightforward set of evidence-based practices that, when performed collectively and reliably, has been shown to improve outcomes.
- The power of the bundle lies not in individual elements, but in performing all elements together, every time.



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Simulation



High Fidelity Simulation

Used for task-based, time-sensitive clinical skills

Supports training for emergencies (e.g., codes, airway management)

Mimics real physiology and scenarios for team performance



Low Fidelity Simulation

Testing new equipment, workflows, or procedures

Supporting FMEA by walking through steps in real time

Practicing communication and teamwork skills

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Checklists



A memory tool for complex processes



Effective in industries with hardwired safety culture (e.g., aviation)



Checklist effectiveness in healthcare has been variable



Success depends heavily on organizational culture

Reasons for Checklist Failure:

- Lack of ownership by physicians and other leaders
- Checklist is illogical or inappropriate for a particular clinical setting
- Perception that the process wastes time and resources

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Health Information Technology

Benefits of Health IT

- Reduces medication errors
- Eliminates illegible handwriting
- Enables computerized provider order entry (CPOE)
- Supports best practices with Clinical Decision Support (CDS)

Unintended Consequences of HIT

- Creates more or new types of work for clinicians
- Changes communication patterns and workflows
- Generates new types of errors (e.g., copy-paste, alert fatigue)

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Alerts and decision support



Provides real-time prompts that help clinicians make safer decisions.



Reduces errors by flagging risks before harm occurs.



Integrates evidence-based guidance directly into workflow.

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Standardization



Creates consistent processes so safety is built into everyday practice.



Reduces variation and eliminates unnecessary complexity.



Ensures all staff follow the same best-practice steps.

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Forcing Functions

System design that makes the correct action the only possible action.

Prevents high-risk errors by physically or technologically blocking unsafe steps.

Removes reliance on memory or vigilance.

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Double-Checks and Redundancies



Adds an extra layer of verification to catch errors before they reach the patient.



Improves reliability for high-risk tasks or medications.



Uses independent checks or automated backup systems.

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Measurement and Monitoring



KPIs for harm reduction

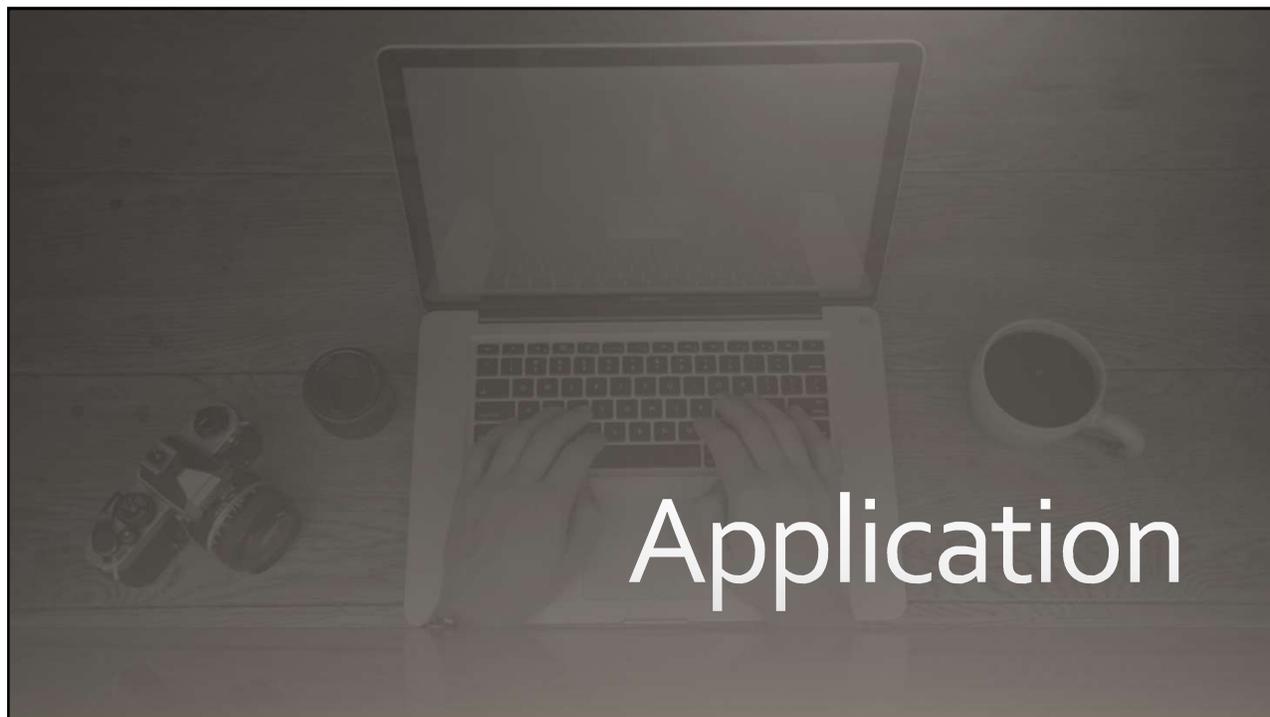


Compliance audits



Feedback loops

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Background

Key Risk Signals:

- Frequent interruptions (ED calls, dual-role coverage)
- Look-alike vials stored together
- High cognitive load from thin staffing
- Inconsistent barcode scanning
- Medication prep in a high-traffic area

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Risk Identification

Prospective Work (FMEA):

- Highest-risk failure: **interruptions**
- Identified gaps in process, environment, and staffing

Retrospective Work (RCA²):

- Flowcharting actual vs. intended workflow
- Fishbone + 5 Whys revealed multiple latent conditions

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Improvements and Solutions

System Improvements:

- **Forcing function:** required barcode scanning
- **Standardization:** simplified antibiotic order sets; separated look-alike vials
- **Redesign:** small “no-interruption” med-prep room
- **Simulation:** low-fidelity run-through before rollout

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Summary & Key Takeaways

- Patient safety is a systems issue, not an individual issue.
- Understand the core frameworks: To Err Is Human, STEEEP, and the Swiss Cheese Model.
- Human factors drive safety.
- Use both prospective and retrospective tools to find and fix risks.
- Near misses have enormous value.
- Effective safety systems rely on design, not vigilance.

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Practice Questions

Which tool should be used to prevent harm before it occurs?

A: Root Cause Analysis (RCA)

B: Failure Mode and Effects Analysis (FMEA)

C: Mortality & Morbidity Review

D: Incident Reporting System

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Practice Questions

What is the best intervention for reducing CLABSI risk?

A. Increasing surveillance cultures

B. Using chlorhexidine skin prep and maximal sterile barriers

C. Replacing central lines every 72 hours

D. Relying on nurse reminders

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Practice Questions

A nurse reports a near miss involving a look-alike medication vial. What is the most important leadership action?

- A. Remind staff to be more careful
- B. File the report and take no action because no harm occurred
- C. Redesign storage and labeling processes in the medication area
- D. Ask the nurse to complete additional training

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Practice Questions

A medication error occurs because a nurse was interrupted repeatedly during preparation. Which safety strategy best addresses this?

- A. Re-educating the nurse about distractions
- B. Creating a “no-interruption zone” for medication preparation
- C. Asking the nurse manager to monitor the nurse more closely
- D. Adding another required documentation field

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Practice Questions

You reviews three recent falls on the night shift. All patients were on different units and had different diagnoses. What is the BEST next step?

A. Conduct separate RCAs for each fall

B. Perform an aggregate review to identify system-level patterns

C. Retrain all night-shift staff on fall prevention measures

D. Increase rounding frequency on all units

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Practice Questions

A physician overrides an important EHR warning because they receive dozens of alerts per day. What patient-safety concept does this illustrate?

A. Standardization

B. Alert fatigue

C. Forcing function

D. Near-miss analysis

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Practice Questions

A team is investigating a wrong-dose near miss. They discover the MAR process is inconsistent with how staff actually prepare medications. What tool supports this finding?

A. Flowcharting “as designed” vs. “as performed”

B. Safety checklist audit

C. Simulation of the new workflow

D. Audit of patient charts

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Wrap Up



Next Session:

Measuring & Improving Performance
February 04

Contact:

Jennifer Wagner

jwagner@convergencehealth.org

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