Getting the Most Out of Root Cause Analysis

April 29th, 2025

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Course Objectives

- Identify potential pitfalls to avoid when conducting a root cause analysis.
- List the elements of a well-done root cause analysis.
- Describe the components of a multifaceted approach to systems change using a scoring rubric.
- Define a highly effective measurement oversight process.



Distinguished Faculty





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ECRI, the Most Trusted Voice in Healthcare



- Independent, nonprofit, mission focused organization
- Committed to improving the safety, quality, and cost effectiveness of healthcare
- Dedicated to evidence-based research and testing, supply chain intelligence, and collaboration with the healthcare community

Joel J. Nobel, MD, Founder of ECRI in 1968



Implementing evidence-based practice to reduce preventable harm

Value of a Strong PSO Engagement





ECRI: A Total Systems Safety Solution





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The Gold Standard for Safety

ECRI and the Institute for Safe Medication Practices PSO

Members in **over 90%** of the U.S. Supporting **over 500**

hospitals across the U.S.

Supporting **over 200** medical practices across the U.S.







ECRI and the Institute for Safe Medication Practices PSO



Adverse events database with comparative dashboards

Compare your organization's near miss and adverse events to like organizations



Risk, Safety and Quality articles across the continuum of care



Save staff time by accessing patient safety policies and guidelines in one place



Root Cause Analyses collected



Address challenges by through Advisor review of RCA, which includes recommended action plans and solutions



Growing Call for Total Systems Safety







National Action Alliance for Patient and Workforce Safety Commitment

Vision Safe care everywhere, zero preventable harm for all.

Mission

A total systems approach to safety that is focused on culture, leadership, and governance; patient and family engagement; workforce safety and well-being; and learning health system development toward our vision of zero preventable harm.

Commitment

To support the National Action Alliance's vision, we commit to:

- Championing patient and workforce safety. Designating an Executive Lead on safety to directly interface with the highest-ranking person in the organization.
- Performing an organizational safety self-assessment and implementing a safety plan that addresses identified gaps, including in healthcare equity.
- 3. Empowering the patient's voice in all aspects of safety.
- 4. Strengthening safety competencies for all team members.
- Collaborating when it comes to safety. Transparently sharing progress on safety initiatives and lessons learned and leveraging and contributing to safety resources as an active participant of the National Action Alliance.

What is Total Systems Safety?

- Total Systems Approach to Safety builds a programmatic, enterprise safety management program around the needs of the humans.
- "Enterprise safety" is a comprehensive framework that supports leaders to make clinical and operational decisions that support the physical, emotional, and psychological safety for patients, families and healthcare workers.
 - It strengthens the patient safety management program with integrated standard operating procedures, engagement tools, and key performance indicators.
 - It strengthens clinical workflows with human factors engineering and system design tools and methods. (supports clinicians and patients)
 - Aligns safety with operational excellence
- Boost efficiency of patient safety and clinical teams
 - Improve quality of safety processes and outcomes
 - Advance patient and worker safety and move to a goal of zero preventable harm



Common Understanding

- Total systems safety focuses on creating greater efficiency and resilience in clinical and safety operations.
- It incorporates principles of human factors, systems design engineering, health equity and advanced safety solutions to redesign how individual components of a system can be more transparent and aligned.
- This facilitates healthcare teams to deliver safer and more effective care.



Strategies for Improvement





Event Inquiry & Analysis Methodology



Pitfalls to Avoid When Conducting a Root Cause Analysis (RCA)



Pitfalls to Avoid When Conducting a Root Cause Analysis (RCA)

- Define RCA
- Importance of addressing RCA pitfalls
- RCA's role in identifying and preventing adverse events



ISMP: Building Patient Safety Skills: Common Pitfalls in Root Cause Analysis - Patient Safety & Quality Healthcare

- Curriculum & Staff Training
- Failure to Conduct at-Risk Behavior Investigation
- Failure to Identify Deep-Seated Latent Failures
- Failure to Conduct Human Error/Human Factors Investigation
- Failure to Seek Outside Knowledge
- Not Linking the Causation to the Actions
- Selecting Weak Risk-Reduction Strategies
- Failure to Carry Out the Action Plan and Measure Success
- Focus Too Narrow or Too Broad

ISMP: Building Patient Safety Skills: Common Pitfalls in Root Cause Analysis - Patient Safety & Quality Healthcare April 22nd, 2010





Timeline with Task Analysis and Gap Analysis





Did the CNA know that the patient was GBS+ and should be monitored for SROM? Did the CNA ask the patient what she meant by having a rough night?

Bias







Why Equity Matters

- "Asian and Hispanic patients hospitalized with acute cardiovascular disease, pneumonia, and major surgery had significantly higher rates of hospital-acquired infections when compared to white non-Hispanic patients."^{4,5}
- "49.1 percent of limited English proficient patient adverse events involved some physical harm whereas only 29.5 percent of adverse events for patients who speak English resulted in physical harm."^{5,6}
- "Racism and gender discrimination have profound impacts on the well-being of Black women." Racial health disparities are evident in Black women's maternal mortality, cardiovascular disease treatment, blood disorders management, and aging-related care.⁷





Claims and Stories

Brooke Smith Delivered stillborn daughter after twice being discharged as "false Labor." She felt doctors and nurses ignored her concerns.⁸ Women veterans experience sexual and gender-based harassment at VA healthcare facilities.¹⁰

Sahana Ramesh died from myocarditis after months of treatment for allergic reaction to prescribed medication. Allegations of "negligence and lack of informed consent rooted in widespread racism."⁹



Equity and Social Determinants of Health Considerations

- Ethnicity
- Race
- Age
- Religion
- Language
- Gender
- Immigrants

- Insurance Status
- Health History
- Socioeconomic Status
- Literacy Level
- Sexual Orientation
- Gender Identity
- Indigenous Peoples

- Disability Status
 - Deaf or hearing impaired
 - Blind or visually impaired
 - Cognitive
 - Mobility
 - Learning disabilities
- Body habitus/composition
- Veterans Status
- Geography (zip code)
- Housing / Homelessness



Equity in Causal Analysis

- Analysis without equity may not address all contributing causes to a patient safety event.¹¹
- Corrective action planning without equity may not provide solutions that will prevent this event from recurring.¹¹





Important Biases to Recognize and Capture

Confirmation bias: A systematic error in thinking that happens when processing information; leads us to accept new information that confirms anything we already believe to be true and minimize any contradicting evidence.

It happens because we want what we think is true, to be true.

Social Biases:

- Identify evidence of bias in the care and treatment of the patient
- Note if bias is related to race or ethnicity
- Identify where in the system the bias occurred: system level (policy, procedure) versus staff level (conscious or unconscious)

Was evidence of racial or ethnic disparities or biases identified?

• Was there evidence of or lack of awareness of or biases related to social determinants of health or language or social barriers?

Was bias identified which may have affected the outcome?

• Was there evidence of bias in the care and treatment, a lack of awareness of a disease pathway or management of the disease pathway identified?

Common Pitfalls





Root Cause Analysis in Aging Services: Considerations for Success



Spaghetti diagram. [internet]. Six-Sigma-Material.com; [accessed 2022 Mar 12]. Available: https://www.six-sigma-material.com/Spaghetti-Diagram.html.

Biggest Challenges

ECRI ISMP PSO PeriOp Collaborative Participant Survey 2022

Describe your biggest challenges to conducting an RCA that relates to a perioperative safety event

• "Honestly, the biggest challenge is scheduling a meeting that will accommodate so many individual schedules. We can easily have 20 RCA team members when there's a multidisciplinary event with several departments involved. The second biggest challenge is ensuring that risk reduction strategies are permanently embedded into everyday workflow."



Phase of the RCA Process

PHASE	QUESTIONS	COLLAB AVG
Immediate of Interim Actions	Questions 1 – 3	4.2
Investigation	Questions 4 – 7	4.2
Analysis	Questions 8 – 9	3.4
Action Planning	Questions 10 – 14	4.2
Monitoring	Questions 15 – 22	3.7



Root-Cause Analysis Techniques





Improving Root Cause Analyses and Actions to Prevent Harm, Version 2. Boston (MA):National Patient Safety Foundation (NPSF); 2016 Jan. Available:https://www.ecri.org/components/PSOCore/Resources/Misc/RCA2_Improving%20Root%20Cause%20Analyses%20and%20Actions%20to%20Prevent%20Harm.pdf

Causal Analysis Fishbone with Equity



Five "Whys"



- Ask, "Why is this a cause of the original problem?"
- For each new answer to the question, ask why again.
- You will usually need to ask why five times. It may be more or less, but it's usually five.
- Beware of channeling your stream of questions down one avenue and thus ignoring other potential contributing root causes of the same problem



Five Rules of Causation: Causal Statements (for writing root-cause statements)



safety terms. [cited 2021 Sep 16] https://www.patientsafety.va.gov/professionals/publications/glossary.asp

Identify Problem: A CABG patient experienced a surgical site infection



- 1. Why did this happen? S. aureus normally found in skin flora entered wound site.
- 2. Why did this happen? The patient did not receive ordered chlorhexidine scrub pre-operatively.
- 3. Why did this happen? There were no pre-packaged scrubs available to nursing staff during the off shift.
- 4. Why did this happen? Supply chain distribution does not restock PAR after 1800.
- 5. Why did this happen? Leadership not aware of need for supply of scrub for evening baths.



Sample Causal Analysis Statements

Format: Cause – Effect – Event; The cause led to the effect which resulted in the event.

The requirement for the pharmacist to simultaneously dispense medications and carry out administrative duties led to multiple interruptions and distractions during the medication dispensing process which increased the likelihood that an inappropriate dose would be selected. The pump's user instructions were in an 8-point font and provided no visual cues / images which led to nursing staff rarely using the instructions thus increasing the likelihood that the pump would be programmed incorrectly.



Action Strength: Hierarchy of Risk Reduction Strategies

• The best at removing the dependence on the human to "get it right" (they are physical and permanent, rather than procedural and temporary)

• Reduce the reliance on the human to get it right, but do not fully control for human error

• Support/clarify the process, but rely solely on the human; these

actions do not necessarily prevent the event/cause from occurring

Low

Medium

High



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Exercise

Implementing policies



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Let's Debrief

- How many of you ended up with paper projects that were exactly the same?
- Why were you unable to end up with exactly the same cut-outs?
- What instructions were the least helpful and why?
- How could these instructions have been made clearer?
- What clarifying questions would you have asked if permitted to clarify the instructions?
- What additional tools or devices would help the reliability of the instructions and fullness of understanding?



Let's Try Again

Reducing variability



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Elements of a Well-Done RCA



Elements of a Well-Done RCA

- Total Systems Approach
- Psychological Safety
- Patient and Family Engagement
- Health Equity
- Leadership and Board Awareness



ECRI's Total Systems Safety | The Path to Eliminating Preventable Harm



A Healthy System Supports a Healthy Culture of Safety

- Physical Environment the work environment in which team members provide care and serve patients.
- **Tasks & Processes** the steps used to conduct safe and effective patient care and service delivery.
- **Tools & Technology** the use of technology and devices to create efficiencies and improve better outcomes.
- **Organization** other factors that can impact care delivery and a safe environment for the team members.
- **People** the team members, patients, families, and caregivers involved in all aspects of the patient care experience.
- **External Environment-** an aligned internal environment supports better integration with external factors.



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*Serious events reported immediately to supervisor and risk manager

Rose VL, Lucas SR, Wergin J. *Incident identification and notifications in aging: a systems thinking approach*. White paper. ECRI. May 2020. Incident Identification and Notifications in Aging Services

Medication Practices

Importance of Communicating with the Patient and Family







Principles of Communication, Apology, and Resolution





Communication and Resolution

	High Reliability Principles				
	Preoccupation with	Reluctance to	Sensitivity to	Commitment to	Deference to
	Failure	simplify	operations	resilience	expertise
Communication and Resolution of Unanticipated Patient Outcomes	Open communication with patients and families about harm events helps to reduce financial impact of future claims	Assure patients and families that the cause of the unanticipated outcome will be determined and communicated to them	Leaders are made aware of a serious safety event and expect the inclusion of the patient and family in the conversation	The communication and resolution process is initiated quickly when an unanticipated outcome occurs	Individuals involved in communication and resolution of unanticipated outcomes are trained and supported by leaders to communicate with patients and families

Communication Resolution Programs: Reshaping Response to Patient Harm | Bree Collaborative



IHI National Action Plan: Patient and Family Engagement

Recommendation 9. Promote a culture of trust and respect for patients, families, and care

partners.

Key Influencers	Implementation Tactics			
Governance bodies	Tactic 9a. Transparently provide information related to the			
Senior leaders	organization's safety and quality performance with patients, families,			
Safety and quality leaders	and care partners during the informed consent process.			
Senior leaders	Tactic 9b. Implement and maintain programs for providing appropriate			
Safety and quality leaders	ongoing support in the aftermath of harm. When preventable harm			
Accreditors/regulators	occurs, interview the patient and family and include them, as			
J J	appropriate, in root cause analyses. Openly and honestly disclose when			
	the standard of care is breached, apologize, address physical and			
	psychological harm, and offer the opportunity to discuss appropriate			
	remedies.			
Governance bodies	Tactic 9c. Institute communication and resolution programs for patients,			
Senior leaders	families, and care partners and encourage them to obtain and consult			
 Safety and guality leaders 	with their own legal counsel. Do not impose or permit gag and			
	confidentiality clauses to be included in post-harm legal agreements			
	with patients, families, and care partners.			
Governance bodies	Tactic 9d. Ensure that preventable harm events and lessons learned are			
Senior leaders	shared with patients, families, and care partners and within and among			
	health care facilities.			
Senior leaders	Tactic 9e. Apply rigorous safety and quality approaches to track and			
Safety and quality leaders	prevent nonphysical harm events such as emotional harm and			
Health care professionals	disrespect, analyze these events, and promote corrective actions to			
Human resources leaders	deter recurrences.			



National Steering Committee for Patient Safety. Safer Together: A National Action Plan to Advance Patient Safety. Boston, Massachusetts: Institute for Healthcare Improvement; 2020. (Available at www.ihi.org/SafetyActionPlan)

Peer Support Is an Essential Part of the Safety Management Program

Total Systems Safety



Enterprise Safety Management[™]

Peer Support for Team Members

- Communication, Apology, Review, and Resolution with Patients and Families
- Root Cause Analysis of Harm Events and Near Misses
- Great Catch Reporting and Recognition

- Patient Reported Safety Concerns: Reporting, Response, and Action
- Safety Event Reporting
- Tiered Safety Huddles
- Supply and Equipment Recall and Hazard Response

Importance of a Peer Support Program

Fosters a culture in which all employees are resilient and mutually supportive before, during, and after stressful events.





Impact of Traumatic Events on Healthcare Workers

- Healthcare workers involved in an unanticipated adverse patient event, a medical error, and/or a patient-related injury can become traumatized.
- They can experience both a professional and personal impact.
- They may feel loss of self-confidence, fear of litigation or reputational damage, guilt, anger, and fear.
- The impact of medical errors on clinicians has been termed the second victim phenomenon.
- Without peer support, clinicians may suffer in silence.

PSO

Source: Wu; Scott et al

Impact of Traumatic Events on Healthcare Staff

Symptoms

- 81% Troubling memories
- 76% Anxiety/concern
- 75% Anger toward themselves
- 72% Regret/remorse
- 70% Distress
- 56% Fear of future errors
- 52% Embarrassment
- 51% Guilt
- 35% Sleeping difficulties



Concerns

- Is the patient/family okay?
- Will I be fired?
- Will I be sued?
- Will I lose my license?
- What will my colleagues think?
- Will I ever be trusted again?
- What happens next?



Three Tiers of Support

Tier 1 Support

- Unit- or department-level support
- Manager and colleagues
- Empathy, listening, affirmation



- Trained Peer Support Program team response
- Individual support or group support
- Trained in Psychological First Aid

Tier 3 Support

- Professional counseling
- Referral to Employee Assistance Plan
- Other resources to support team members deeply impacted by stressful events



PSYCHOLOGICAL 1ST AID

- **1** One on One
- **ST** Safe Space to Triage and Talk
- A Acknowledge and Assess
- I Identify and Intervene
- D Determination and Debrief



Key Questions to Ask

- Does your senior leadership and board have a baseline understanding of quality and safety principles?
- Does the organizational mission statement meaningfully address quality and safety?
- Do they know the right questions to ask to uncover critical issues?





Opportunities to Engage and Educate the Board

- 50% of healthcare boards rate "quality of care" among their top two priorities.
- 37% of boards fail to include quality performance reviews on every agenda.
- 58% of boards dedicate less than 20 percent of their time to quality, despite accountability for patient safety and quality falling heavily in their care.
- 61% of boards said they have no requirements for continuing education.
- Only about 24% of board members have clinical backgrounds.

Source: American Hospital Association



Across the Spectrum: Board Maturity Levels

17% are beginning focus is only on regulatory compliance 55% are developing limited to hearing reports from its quality committee 8% are advancing creating quality goals and plans, reviewing adverse events

28% are approaching committed to the goal of high reliability for all clinical services

Source: The Joint Commission



CMS Conditions of Participation

- Executive Responsibilities
- Governing Body (Board), medical staff, and administrative officials are responsible and accountable for ensuring:
 - Ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.
 - QAPI efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated.
 - That clear expectations for safety are established.
 - Determining number of distinct improvement projects.

DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: OSO-23-09-Hospital DATE: March 9, 2023 TO: State Survey Agency Directors FROM: Director, Quality, Safety & Oversight Group (QSOG) Revision to State Operations Manual (SOM), Hospital Appendix A - Interpretive SUBJECT: Guidelines for 42 CFR 482.21, Quality Assessment & Performance Improvement (QAPI) Program

Memorandum Summary

 CMS is committed to consistent implementation and oversight of the QAPI requirements as a part of our patient safety initiative.

- · QAPI Guidance Released: CMS is releasing the updated interpretive guidance for State Operations Manual (SOM) Hospital Appendix A for the QAPI CoP
- The QAPI CoP requires a hospital to "maintain and demonstrate evidence of its QAPI program for review by CMS, as well as the governing body oversight of the program in an effort to deliver safe, quality patient care and prevent adverse events and patient harm." (42 CFR 482.21)

Source: CMS "Revision"



Key Leadership Behaviors for Root Cause Analysis

- Set expectation that the executive leader and board will be notified within 3 business days of the identification of a serious safety event.
- Clearly communicate expectation that all key stakeholders in the causal-analysis process play a significant role and that it is critical that they dedicate time to fulfill their roles in the process.
- Promote the importance of taking a systems approach to identifying contributing factors related to the organization, the environment, human error, and those factors related to social determinants of health and barriers to health equity.
- Review and approve action plans for selected serious safety events—guiding causal team members to identify robust action items.
- Ensure that all leaders are accountable for action plans assigned to their unit or department, developed as a result of causal analysis. Take action when there is a failure to follow through on action planning.
- Convey the importance of a learning system for safety by sharing lessons openly and frequently from all types of causal analyses.



System-Wide Assessment on Safety

- Our hospital leaders, including C-suite executives, place patient safety as a core institutional value.
 One or more C-suite leaders oversee a systemwide assessment on safety, and the execution of patient safety initiatives and operations, with specific improvement plans and metrics.
- These plans and metrics are widely shared across the hospital and governing board.



Summary

- Senior leaders and the board must understand their role in making safety a top organizational priority
- Safety leaders should implement strategies to involve senior leaders and boards as partners in planning to eliminate preventable harm
- Leaders can assess the state of the organizational maturity using the Total Systems Safety Organizational Self-Assessment

Components of a Multifaceted Approach to Systems Change

Components of a Multifaceted Approach to Systems Change

- Using systems thinking as an approach to action strategy sustainability.
- Systems Change Hierarchy.
- HI-IMPACT Tool.

WHO Global Patient Safety Action Plan 2021-2030

- Towards Eliminating Avoidable Harm in Health Care
- <u>https://www.who.int/teams/integrat</u> <u>ed-health-services/patient-</u> <u>safety/policy/global-patient-safety-</u> <u>action-plan</u>
- Framework for action: 7 strategic objectives and 35 strategies!

Framework for Action

1. Policies to eliminate avoidable harm

- 2. High-reliability systems
- **3.** Safety of clinical processes
- 4. Patient and family engagement
- 5. Health worker education, skills and safety
- 6. Information, research and risk management
- 7. Synergy, partnership and solidarity

Healthcare: *Complex, Adaptive, Sociotechnical* System

- Systems are made of components.
- Each can lead to success or failure.
- People are integral. We influence and we are influenced.
- There is an external environment that cannot be controlled but must be accounted for.

Model of Sustainability

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Action Hierarchy Limitations

Corrective Action Hierarchy / Hierarchy of Intervention Effectiveness

- Strong corrective actions, such as forcing functions, improve patient safety by preventing the occurrence of active failures or reducing their consequences.
- Incremental fixes one event at a time is insufficient.^{Wood&Wiegmann}
- Lack of emphasis on transforming **systems**.
- Focused on active failures.

Wood LJ and Wiegmann DA. Beyond the corrective action hierarchy: a systems approach to organizational change. Int J Qual Health Care. 2020;438-444.

A Broader Systems Approach

Proposed

- A multifaceted definition of 'systems change'
- A rubric for determining the extent to which a specific corrective action reflects a 'systems change' is provided.

Outcome

- For interventions to be considered "strong", they would have to make a system impact
- Interventions that address the specific issue but do not consider the system are considered "weak" because they do not correct the system issues that lead to the event

International Journal for Quality in Health Care, 2020, 438–444 doi: 10.1093/intqhc/mzaa068 Advance Access Publication: 24 June 2020 Methodology Article

OXFORD

Methodology Article

Beyond the corrective action hierarchy: A systems approach to organizational change LAURA J. WOOD, and DOUGLAS A. WIEGMANN

Department of Industrial and Systems Engineering, University of Wisconsin-Madison, 1513 University Ave, Madison, WI 53706 USA

Case Scenario: What's Causing the Underlying Problem?

A respiratory therapist (RT), working in a crowded space while under high stress and time pressure, inadvertently hooks up a patient's oxygen mask to an air flowmeter rather than the appropriate oxygen flowmeter. The patient's hypotension and shortness of breath subsequently worsen. A chest X-ray indicates acute respiratory distress syndrome, and the patient is intubated for type I (hypoxemic) respiratory failure.

The physician again orders the patient to be placed on high-flow oxygen; however, the same tubing connected to the air flowmeter is used. Shortly thereafter, the RT returns to check on the patient and notices she had mistakenly connected the oxygen mask to the air flowmeter. She connects the tube to the appropriate oxygen flowmeter and reports the incident to her supervisor.

Case Scenario: What's Causing the Underlying Problem?

Deeper analysis of this event (e.g. RCA) reveals that the hospital gas supply delivers gas under pressure to outlets that are typically on wall panels at the head of the bed. The working pressure for outlets is too high to deliver gas directly to masks and bags, so a flowmeter is connected to the outlet to adjust the flow rate. These flowmeters look nearly identical and are used to provide gas to the same ventilatory devices (e.g. masks). Furthermore, the same tubing is used interchangeably for both the air and oxygen flowmeter nozzles.

One weaker action would be to warn RTs that many connectors and tubes work and look alike, so there is a risk of hooking up devices to the wrong flowmeter; consequently, they should be mindful of these risks. Another weaker action would be to place colored labels on each flowmeter to decrease the chance of confusion. In contrast, a stronger action would be to redesign the flowmeter connectors and device tubing to make it physically impossible to attach a device to the wrong flowmeter. The latter is a stronger action because it incorporates forcing functions and does not rely on memory or willingness to comply.
Case Scenario: What's Causing the Underlying Problem?

Redesigning the connectors and tubing is, indeed, a good idea. Given the problem exists elsewhere (e.g. emergency department (ED) and other intensive care units (ICU)), we would advocate implementing the redesign across the enterprise.

However, just because a corrective action is implemented system-wide does not make it a 'systems fix'. Thus, implementation of this 'strong' intervention will have a nominal impact on the organization's overall patient harm rate, because it does not address the underlying latent conditions that promoted the active failure (i.e. hooking the tube to the wrong flowmeter).

Corrective actions aimed at preventing active failures only target the 'symptoms' of underlying latent conditions.

What's Really Causing the Underlying Problem?



- Working in crowded space.
- Under high stress and time pressure.
- Unit understaffed.
- Monitoring a new hire.
- Hour 10 of a 12-hour shift (4am).
- Previous occurrences immediately detected and corrected.
- RTs reluctant to report near misses.

Systems Change Defined



• Systems approach to safety: functional interactions



Taking Action Planning One Step Further: Create System Change

- Take change from a singular focus to one that has system impact
- Four fundamental dimensions of systems change: scope, breadth, depth and degree
- Use a matrix to assess ability to impact system change
- Rate action using each criteria on a scale from 1 – 5 and sum the scores.



Corrective Actions: System Change Rubric and Hierarchy Scoring Tool

Rate your corrective action (s) using each of the four criteria and sum the scores. Scores can range from 4-20. High scores (16-20) indicate that the corrective action is a **major systems change**. Low scores (4-9) indicate the corrective action represents a **nominal systems change**. Score that lie in-between (10-15) indicate that the corrective action represents a **moderate systems change**.

Criteria	Low	Medium	High
	Score 1-2	Score 3	Score 4-5
Scope (Is the fix local or enterprise wide?)	The goal of the change is to address a hazard or threat to patient safety solely within the care setting which the patient harm event occurred.	The goal of the change is to address a hazard specific threat to patient safety within a limited number of locations outside the care setting in which the patient harm event occurred.	The goal of the change is to produce a collective improvement in patient safety across different, often heterogenous, healthcare settings throughout the enterprise.
Breadth (Does the fix focus on multiple roles?)	The purpose of the change is to fix a gap in clinical practice associated with a specific provider role (e.g., nursing).	The change targets the performance of a few different clinical/operational stakeholders, not just a single provider role (e.g., nursing).	The change targets the performance of numerous operational stakeholders and clinical specialties throughout the enterprise.
Depth (Does the fix cut across organizational levels?)	The change only targets the performance of stakeholders who provide services or deliver care (i.e., it does not address behavior or performance at the supervisory or organizational levels).	The change targets operational processes and performance at the supervisory/middle management levels, either separately or in addition to stakeholders at the care delivery level. However, it does not directly target factors or stakeholders at leadership levels.	The change targets organizational factors and the performance of stakeholders at the leadership level, separately or in addition to middle managers and stakeholders who provide services/deliver care.
Degree (Does the fix reflect a fundamental change in the way the organization operates?)	The change focuses on reducing the occurrence and/or consequence of a specific erroneous action or active failure through engineering and design modifications (e.g., forcing functions).	The change focuses on making sure things are done right through incremental improvements within existing modes of practice (i.e., doing the same things better).	The change fundamentally alters how things get done within the targeted context. It reflects a paradigm shift in how the problem is perceived and the strategies used to address it (e.g., viewing and doing things differently).

System Change Rubric: Statements to Rate About the Change (adapted from Wood and Wiegmann, 2020)

Criteria	Low	Medium	High		
		3	4 5		
Scope Is the fix local or enterprise wide?	Goal is to address a hazard or threat to patient safety solely within the care setting in which the patient harm event occurred.	Goal is to address a hazard specific threat to patient safety within a limited number of locations outside the care setting in which the patient harm event occurred.	Goal is to produce a collective improvement in patient safety across different, often heterogenous, healthcare settings throughout the enterprise.		
Breadth Does the fix focus on multiple roles?	Purpose is to fix a gap in clinical practice associated with a specific provider role (e.g., nursing).	Targets the performance of a few different clinical/operational stakeholders, not just a single provider role (e.g., nursing).	Targets the performance of numerous operational stakeholders and clinical specialties throughout the enterprise.		
Depth Does the fix cut across organizational levels?	Only targets the performance of stakeholders who provide services or deliver care (i.e., it does not address behavior or performance at the supervisory organizational levels).	Targets operational processes and performance at the supervisory/middle management levels, either separately or in addition to stakeholders at the care delivery level. However, it does not directly target factors or stakeholders at leadership levels.	Targets organizational factors and the performance of stakeholders at the leadership level, separately or in addition to middle managers and stakeholders who provide services/deliver care.		
Degree Does the fix reflect a fundamental change in organizational operation?	Focuses on reducing the occurrence and/or consequences of a specific erroneous action or active failure through engineering and design modifications (e.g., forcing functions).	Focuses on making sure things are done right through incremental improvements within existing modes of practice (i.e., doing the same things better).	Fundamentally alters how things get done within the targeted context. It reflects a paradigm shift in how the problem is perceived and the strategies used to address it (e.g., viewing and doing things differently).		

Systems Change Hierarchy: 4-9 = nominal systems change; 10-15 = moderate systems change; 16-20 = major systems change

Corrective Action Strategies



- Redesign connectors and device tubing throughout the system.
- Improve RT supervisor's staffing and scheduling processes.
- Implement inclusive leadership program fosters psychological safety across the system.

Scoring Using the Systems Change Hierarchy

Corrective Action Strategy	Systems Change Criteria								
Confective Action Strategy	Scope	Breadth	Depth	Degree	Sum				
Redesign connectors and tubing throughout the healthcare system to make it physically impossible for personnel to attach a device to the wrong flowmeter.	2	2	1	1	6				
Revise supervisors' processes associated with staffing and scheduling to better manage RT workload and competing priorities, such as mentoring new RTs, responding to codes, handing off patients, etc.	3	1	3	3	10				
Implement an inclusive leadership program that fosters a sense of psychological safety among staff throughout the healthcare system, so they are more willing to self-report errors or other hazards before they cause harm.	5	5	4	4	18				



HI-IMPACT





HI-IMPACT Tool

Will the practice change.....



- H: be assessed to consider potential impacts on the **human users**?
- I: reflect **input from frontline staff** in all relevant departments?
- I: reduce the risk of **inequities and disparities** in care?
- M: be **measured** for strength and impact across systems?
- P: reflect patient and family values or preferences?
- A: be supported by an **appraisal of evidence** to ensure it is evidence-based?
- C: be cost-effective when considering both monetary and nonmonetary costs?
- **T**: Will any changes that include **technology be assessed** for usability?



HI-IMPACT Example

Practice Change	<u>Human</u> <u>Users</u>	<u>Input</u> from <u>Frontline</u> <u>Staff</u>	Inequities and Disparities in Care	<u>Measure for</u> <u>Strength</u> <u>and</u> <u>System</u> <u>Impact</u>	<u>Patient and</u> <u>Family</u> <u>Values or</u> <u>Preferences</u>	<u>Appraisal</u> <u>of</u> Evidence	<u>Cost-</u> <u>Effectiveness</u>	<u>Technology</u> <u>Assessment</u>	<u>Total</u> <u>Score</u>
Implementing virtual observation technology to prevent falls	5	4	4	4	2	4	3	4	30
New signage for patients	1	2	1	1	1	1	5	NA	12



Highly Effective Measurement Oversight Process



Highly Effective Measurement Oversight Process

- "What gets measured gets managed." *Peter F. Drucker*
- Oversight strategies for individual RCA action strategies.
- Key indicators for the entire RCA program.



Action Strategy Outcomes

- Systems to ensure implementation of action strategies.
- Completed action strategies not sustained = safety event reoccurrence.

Methods

- Multidisciplinary hospital-level safety review,
- Contributing factors & action strategies from 2020-2021.
- Tracked to completion through 2023.

The Joint Commission Journal on Quality and Patient Safety 2024; 50:492-499

Putting the "Action" in RCA²: An Analysis of Intervention Strength After Adverse Events

Jessica A. Zerillo, MD, MPH; Sarah A. Tardiff, BSN, RN; Dorothy Flood, BSN, RN; Lauge Sokol-Hessner, MD, CPPS; Anthony Weiss, MD, MBA





Action Strategy Results and Potential Key Performance Indicators (KPIs)³





67 Events

• 85% - more than one action

148 Actions and *completion rate*:

- 57% = weak 98%
- 24% = intermediate *81%*
- 10% = strong 73%
- 9% = more information needed

Overall completion rate = 85%

Zerillo JA, Tardiff SA, Flood D, Sokol-Hessner L, and Weiss A. Putting the "action" in RCA²: an analysis of intervention strength after adverse events. 2024;50(7):492-503.

Measurement Oversight (1)

Who Owns the Process?





Measurement Oversight (2)

Defined Key Components (Measure Specifics)

- Measure name / focus
- Measure type: structure, process, or outcome
 - Numerator and denominator
- Goal or target
- Collection method
- Frequency and duration
- Responsible party
- Due date
- Evaluation dates or frequency
- Oversight committee or council



Measurement Oversight (2 continued)

Contributing Easter(s) Action	Action	Manaura of	Massura of	Beenensible	Evaluation
Contributing Factor(s) Action	Action		iveasure of	Responsible	Evaluation
to event Plan/Str	rategy Strength	Effectiveness/Change	Effectiveness/Change cont.	Party & Due	Oversight
List out all of the Write an	n action plan	(Include measure focus,	(Include frequency and duration	Date	Committee
contributing factors or strate	egy that will High	goal/target, and collection	of monitoring, type of measure		and Frequency
for this root cause decrease	e or Moderate	method)	(Structure (S), Process (P) or		(Include
eliminat	te the root Low		Outcome (O) and actual metric		committee
cause			used indicated by date achieved		responsible for
	Select one		or ratio % using numerator and		receiving
	per action		denominator)		reports and
					frequency e.g.
					quarterly)
Use Blue Font Use Blue	e Font Use Blue	Measure Focus:	Frequency and Duration of	Who?	Will be
	Font	Use Blue Font	Monitoring:	Use Blue	evaluated by:
			Use Blue Font	Font	Use Blue Font
		Goal/target:			
		Use Blue Font	Type of Measure: Use Blue Font	Due by	
				Use Blue	Frequency:
		Data Collection Method(s):	Numerator: Use Blue Font	Font	Use Blue Font
		Use Blue Font			
			Denominator: Use Blue Font		



Measurement Oversight (2 continued)

Action Strategy 1

Design process for pharmacy staff oversight of all epidural medication cart distribution and medication PAR levels.

•	Measure of Effectiveness/Change (Include measure focus, goal/target, and collection method)	Measure of Effectiveness/Change cont. (Include frequency and duration of monitoring, type of measure (Structure (S), Process (P) or Outcome (O) and actual metric used indicated by date achieved or ratio % using numerator and denominator)	Responsible Party & Due Date	Evaluation Date and Comment (Include frequency e.g. quarterly)
	Measure Focus : Pharmacy oversight of Anesthesia epidural cart PAR levels in Women's Health	Frequency and Duration of Monitoring: Weekly review until completed	Director of Pharmacy	Will be evaluated quarterly (e.g., June,
•	Goal/target: 100% oversight of epidural carts by pharmacy department	Structure Measure: Documentation of organizational confirmation of Pharmacy oversight of all medications, including epidural carts in Women's Health evidenced	Due: September 22, 2023	Sept., Jan., and April)
ECI	Collection Method: Meeting Minutes/Email communications	by meeting minutes and emails; supported by policy		

Measurement Oversight (3)

Discussion and Decision Considerations

- Who oversees the whole process?
- Who is responsible for implementing the action strategies?
- Who is responsible for collecting the measure data?
- Who is responsible for validating collected measure data?
- Who is responsible to address under performance?



Measurement Oversight (4)

Use Existing Committees and Processes for Oversight

- Accountability should lie with a given department's quality improvement structure .
- Patient safety committee, quality committee, board quality.
- Start with a minimum of monthly report outs.
- Suggest PowerPoints or methods for submitting results.



Sample Tracking Template

MEASURES OF EFFECTIVENESS, SUCCESS										
Measure Focus (area the measure is assessing)	Goal/Target Method of Frequency Data of Collection Monitoring		Duration of Type of Monitoring Measure		Sample Size					

	METRICS	
Actual Completion Date	Numerator (if used/needed - for process- outcome measures)	Denominator (if used/needed for process- outcome measures)
	l	

ACCOUNTABILITY									
Part of Dept QI Plan/Process Hospital Dept	Part of Dept QI Plan/Process Medical Staff Dept	Main Committee Report-Outs	Frequency	Other Committee Report-Outs	Frequency				



Example: Decrease Possible Ventilator-Associated Pneumonia (PVAP) and Ventilator Associated Pneumonia (VAP) Rates in intensive care units (ICUs)

- Baseline evaluate actual PVAP/VAP rates for each ICU for a period of time, e.g., the last six months.
- Benchmark identify a best performer or recommended rate, e.g., national target.
- Target (goal) decrease the PVAP/VAP rate per 1,000 ventilator days by 50% within 12 months.
- Thresholds set ranges of performance—desirable and otherwise.
- Color coding track progress over time and code according to thresholds.



Semmelweis Univ	ersity N	ledical (Center*			>90%	84-90	<84%					
% PVAP/VAP Bun	dle Com	pliance		CY 202	3								
Target > 90%	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	CYTD
CARDIAC ICU	92	93	93	94	95	96	97	98	98				95
NEONATAL ICU	88	75	79	75	90	91	92	91	95				86
NEURO ICU	56	58	68	88	88	89	91	86	80				78
TRAUMA ICU	95	96	97	90	87	93	94	87	95				93
OVERALL	83	81	84	87	90	92	94	91	92				88

Managing with KPIs continued





*Fictitious hospital and data

Key Performance Indicators for RCA Program

- Proportion of events with a strong action.
- Proportion of events with a strong and intermediate strength action.
- Proportion of events with intermediate or strong action to the proportion of events with only weak actions.
- Completion of actions by intervention strength and comparison of intermediate/strong and strong actions for preventable vs. non-preventable events using two-sided chi-squared test w significance of p ≥ 0.05.
- Of 67 events 82% considered preventable.
- Of 67 events 85% had more than 1 action (median of 2 actions per event).
- Completion rate for preventable events = 88%.
- Completion rate for non-preventable events = 72%.





Leadership is then about mobilizing and engaging the people with the problem rather than trying to anesthetize them so that you can just go off and solve it on your own.



I HARVARD BUSINESS PRESS I

The Practice of



Heifetz RA, Grashow A, Linsky M. The practice of adaptive leadership: tools and tactics for changing your organization and the world. Boston (MA): Harvard Business Press; 2009.





Thank you!

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