VA | U.S. Department of Veterans Affairs

Root Cause Analysis Tools

VA National Center for Patient Safety

NCPS VA National Center for Patient Safety

Safer Systems • Safer Care

Root Cause Analysis Tools

Welcome

Our mission is preventing patient harm.

We look in large part to High-Reliability Organizations (HROs) like aviation and nuclear power for guidance in accomplishing our mission. Both of these industries have very low accident rates in spite of the complex and hazardous nature of their business. Some keys to their success are:

- Mindfulness, an active awareness of the risks at hand and attention to cues signaling that something isn't right.
- Standardized approaches to tasks (e.g., checklists) to ensure consistency regardless of who is doing the task.
- Teamwork that features a common understanding of the task at hand, its intended outcome, rules for communication, and individual roles.
- Seeking out and listening to local experts regardless of rank.
- Resiliency through well-known and rehearsed plans (e.g., drills, simulations) for recovering or rescuing a situation when things go wrong.
- An organizational expectation that employees speak up as soon as a situation seems unsafe.[1]

Organizational openness to and support of employees speaking up with their concerns, constructive criticism and suggestions is fundamental to a **just culture**.[2]

Many HRO strategies are grounded in the science of Human Factors Engineering (HFE). HFE examines how people interact, accomplish work, and respond to surroundings using their thinking, communication and physical abilities (senses, size, strength, etc.) under various personal and environmental conditions (hot/cold, dark/light, quiet/noisy, clear/confusing, focused/distracted, rested/fatigued, etc.). HFE provides evidence-based approaches for improving processes, performance and the places we work, by design.

We can **design in safety**! In other words, we can intentionally make things safer. The strongest designs are permanent and physical (installing a staircase railing) rather than temporary and procedural (warnings to "Watch out for the steps!"). Design may naturally lead us to do the correct thing (three-pronged plugs fit three-pronged sockets) or simplify complicated tasks (adding step-by-step photos to written instructions). HFE strategies aim to put "knowledge in the world" when and where we need it, instead of adding burden to our limited attention span and memory (reminders to "Be careful!" or repetitive training about things we already know). [3]

Each of us comes to work to do our part in providing ideal care for Veterans … not to make a mistake. But, health care is complex and hazardous. Our best intentions are not enough. We must apply the lessons learned and practice the techniques HROs and HFE provide to us.

From a patient safety perspective, when things go wrong it's about design or system failure, not individual fault.* We use a confidential and protected** team-based approach called Root Cause Analysis (RCA) – adapted from aviation – to figure out the answers to four core questions that will help us design safer care:

- **What** happened?
- **Why** did it happen?
- **What** action can we take to prevent it from happening again?
- **How** will we know if the action we took made a difference?

Notice that none of these core questions ask "who" was involved. Our focus is on system failures not individual fault. If **you** make a mistake today, **I** could make the same one tomorrow: unless we speak up, analyze the situation, fix something, and monitor whether our action made a difference.

What you'll find in the rest of this document is a series of questions and technical guidance that will assist you and your team in answering the four core questions and designing and sustaining safer care.

Section 1:

Section 2:

Section 3:

Section 4:

To Recap, Our Mission Is Preventing Patient Harm.

Our methods are described in the language and data of the sciences supporting this mission. Our intent is to cultivate a humanitarian approach in the fullest sense of the word (save lives, alleviate suffering, promote healing, protect human dignity). Health care environments, processes and devices must work well in theory and reality, accommodating the strengths and weaknesses of many different humans: patients, families and significant others, and employees. Communication between employees at all levels and with patients and their loved ones must be open and respectful without intimidation or fear of punishment. Safe health care requires the blending of many fields of science with a humanistic approach. The HRO and HFE strategies described above will provide us with that fine blend.

Thank you

*NOTE: Purposeful or intentional harm (crimes, patient abuse, intentionally unsafe acts, and events involving provider substance abuse) are not a part of patient safety. Intentional harm is handled by administrative processes.

**VHA Directive 2008- 077. "QM and patient safety activities that can generate confidential documents" describes quality improvement processes protected by 38 USC 5705. http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1803

1. Weick, K.E. and Sutcliffe, K.M. *Managing the unexpected: resilient performance in an age of uncertainty*. 2nd ed. San Francisco: Jossey-Bass, 2007.
2. Marx, D. *Patient safety and the "**just culture**": a primer for health care executives.* New York: Columbia University Press, 2001.
3. Norman, D.A. *The design of everyday things.* New York: Doubleday, 1988

Section 1

What Happened?

To discover what actually happened and why, RCA teams must keep an open mind, suspend their personal biases, and actively resist jumping to conclusions. Teams pursue objectives, deep questioning about how things are supposed to work (organizational rules) versus how things actually work day-to-day (local norms and work-arounds). The difference teams find between what **should be** and **what is** points them to what needs to be fixed.

Organizations with independent (silo) management and work processes for delivering exceptional service on time to an ever-changing population are constantly at risk for missed opportunities and accidents. This is true for any industry, including health care. James Reason has famously illustrated the defenses (e.g., culture, individual competency, teamwork) and failures (e.g., short staffing, time pressure, clumsy technology) in constant tension with each other in his Swiss Cheese model. [4]

A series of standard questions has been updated* to assist all RCA teams in figuring out what happened and why in a uniform, purposeful way. The questions are designed to reveal vulnerabilities in work processes and systems and prompt the team to review documents, conduct interviews, walk around and observe, and safely simulate or reenact events as needed. Not all questions will be directly relevant or applicable to every situation but they are useful to consider for any event or close call. You will notice some overlap in questions between some sections; it reflects their inter-relatedness in real life. Of course, teams are welcome to develop additional questions of their own.

We begin with questions about what should happen ideally (Rules and Safeguards) and proceed from there to the physical space and tools available to patients and providers (Environment, Equipment, and Information Technology) and conclude with questions that look more closely at how we function as humans in complex situations (Fatigue and Scheduling, Training, and Communication). You will find everything from narrowly focused technical questions to more general cultural questions in this series.

*NCPS Triage Cards for Root Cause Analysis, 2001

4. Reason, J. *The human contribution: unsafe acts, accidents and heroic recoveries.* Burlington, VT: Ashgate Publishing Company, 2008.

Rules (Policies and Procedures)

There are many reasons we don't follow rules: confidence in our own and/or our work group's skills, time pressures and competing priorities, out-of-date or irrelevant rules, and lack of awareness of or access to the rules, etc.

In complex processes involving multiple experts with separate tasks, there are many opportunities for rules to breakdown. A good example is the medication use process which includes: access to medication (availability versus scarcity) using standard or non-standard procurement processes, and; storage, ordering, dispensing, administering, and monitoring the effects of medication. Medication administration alone is fraught with memory-bound rules (e.g., 5 Rights) which are easily derailed if there is look-alike or sound-alike confusion, distraction, and/or use of complicated devices (multi-dose vials, multi-use syringes, smart pumps), etc.

Rule Design and Use

1. Were there current, written policies and procedures that addressed relevant tasks and processes?

2. Were these policies and procedures consistent with relevant federal and VHA policies, standards and regulations?

3. Were these policies and procedures clear, understandable and easily available to all staff?

Rules and Risk Assessment

4. Was there an overall management plan for identifying and addressing risk?

5. Did management have an audit or quality control process to inform them about how key processes related to the event were functioning?

6. Would this problem be detected by current audit or quality control processes?

7. Had a previous RCA or audit been done for a similar event?

8. If a previous RCA or audit had been done for a similar event were effective actions taken on a timely basis and evaluated?

9. Was the care the patient required within the scope of the facility's mission, staffing and support service resources?

Rules Training

10. Was staff involved in the adverse event or close call qualified and trained to perform their tasks?

11. Was staff oriented to the job, facility and relevant unit policies regarding: safety, security, hazardous material management, emergency preparedness, life safety management, medical equipment, and utilities management?

Rules and Culture

12. Were relevant policies and procedures actually used on a day-to-day basis (if not, what got in the way)?

Safeguards (Barriers and Controls)

Safeguards – also known as barriers and controls–are designed to prevent/protect us from encountering a dangerous situation and to minimize or eliminate injury.

Think of **everyday** safeguards, like traffic lights, car air bags, railings, construction barricades, goggles, built-in guards on power tools, easily detectable and recognizable emergency sirens and fire alarms, steel-toed boots, as well as treadmills, coffee pots and curling irons that shut-off automatically if we can't get to them in time (or forget).

Now, think of safeguards we commonly use in **health care**, like requiring two identifiers to determine who a patient is, continuous hand hygiene, cleaning and sterilizing instruments, obtaining informed consent, performing time-outs and site marking, dressing in isolation gowns and masks, applying bed and wheelchair brakes, adjusting the volume on equipment alarms, programming IV pumps, and using bar code scanners.

Did you notice a difference between the two lists?

Many everyday safeguards are permanent and physical. These barriers and controls are either in use or waiting to be triggered for use on behalf of **all of us**, for as long as they are needed and they rarely malfunction. They require very **little thought or work to activate** their preventive and protective functions. When stronger, population-oriented safeguards fail it is often because we work around them for what we thought was a good reason at the time (after all, we're human).

Many health care safeguards rely on complicated or complex temporary and procedural processes. Often, activating these safeguards requires **purposeful thought and decision making, work**, and **time** from **each of us**, **individually**, every time they are used. When these weaker safeguards fail it is often because we forgot to do something – limited capacity for active attention coupled with memory burden – or, we work around them for what we thought was a good reason at the time (after all, we're human).

The challenge for RCA teams is to design stronger safeguards by applying HRO and HFE approaches and techniques. Sometimes our ideas will be futuristic, and may seem far-fetched but that's okay: before pulse oximetry, we had to rely on skin pallor and nail bed capillary refill to assess oxygen saturation (and someday we'll probably use biometrics/biological markers instead of asking patients for their name and birthdate to identify them, etc.).

When working through these questions, remember that a safeguard might be part of the physical environment, a device or a process (or some combination of these things). For example, if we're looking at safeguards that prevent patient elopement, we may find that there is a sally port to control entry and exit, a door alarm, and routine staff rounds to see and count patients on the unit.

Please contact the VA National Center for Patient Safety (NCPS) for help in designing safeguards or to share your innovative and futuristic ideas, any time!

Patient-Centered Safeguards

1. Were patient risks and unintended consequences considered in designing or selecting the safeguard? For example: while sally ports may reduce elopement from locked units, they may also hinder rapid access to the unit in a medical emergency.

2. Was the safeguard intended to protect the patient (or staff, equipment, environment)?

Maintaining and Selecting Safeguards (Physical Plant, Device or Process)

3. If applicable, what safeguard was in use when the event or close call happened?

4. If a safeguard was in place, did it function correctly?

5. (If the safeguard malfunctioned) would the event or close call have been prevented if the safeguard had functioned correctly?

6. If the safeguard was a piece of equipment or device, was it routinely checked and referred for maintenance and repair?

7. If relevant, did selection of the safeguard include evaluation of blueprints, design specifications, installation and maintenance requirements, and consideration of its effects on other processes and tasks?

8. Was the safeguard's performance **tested before** it was put into use (did it reliably do what it was supposed to do)?

9. Before the safeguard was put into use, was a method for **monitoring** its use and effectiveness in place (to identify the results of implementation)?

Safeguards and Culture

10. Was the concept of "fault tolerance" – ensuring that essential tasks continue even when things go wrong – applied in the design and selection of the safeguard? Fault tolerance includes back-up or contingency planning, and is also known as defense-in-depth. For example: Ambu bags are immediately accessible and ready for use in the event of a power outage or other mechanical ventilator failure.

Environment

RCA teams really need to visit the area involved in an adverse event or close call and safely simulate the steps leading up to the event (do not have a second accident!). Walking around in the area and getting an actual sense of the physical layout and how things work in that space will provide the team with a clear understanding of how things could have happened.

Design of the Work Area

1. Was the work area designed for the task (versus temporary or converted space)?

2. Were the tools and equipment staff needed easily accessible to them?

3. Was the level of automation and technology appropriate for the area?

Risk Assessment

4. Did the work area meet current codes, specifications and regulations?

5. Were environmental stressors an obstacle (e.g., distraction, distance, noise, lighting, odors, vibration, temperature, construction, etc.)?

6. Had relevant patient emergency and facility disaster drills been conducted (e.g., cardiac arrest response, MRI suite, fire and weather related evacuation)?

7. Had an environmental risk assessment of the area been done (e.g., Environment of Care Rounds, Annual Workplace Evaluation, Mental Health Environment of Care Checklist, Patient Safety Assessment Tool, etc.)?

Environment and Culture

8. If environmental stressors were known obstacles, had action been taken by leaders/managers to prevent or minimize their impact (did it make things better or worse)? For example: did construction safeguards – signs, barriers, detours – ensure safe and efficient movement for patients, families and staff?

9. Did new or temporary staff (students, floats) receive an orientation to the unit and emergency procedures?

Equipment

There are many kinds of equipment – also known as devices – used in health care settings. The following questions apply to all kinds of equipment used by clinical, administrative and support service staff as well as patients, families and significant others (from telephones and fax machines to MRI machines, from syringes and medication vials to programmable IV pumps, from slippers and beds to patient lift devices, etc.). RCA teams need to examine equipment, request an expert demonstration of how it works, and safely simulate using the equipment to better understand how things happened.

Equipment Design and Use

1. Had this equipment worked correctly in the past?

2. Was the equipment designed for the task?

3. Did equipment work ideally in terms of: staff needs and expertise, workload (enough equipment on hand as needed), and physical space?

4. Was the equipment designed so that it **could be used incorrectly**?

5. Did staff use “work-arounds” when using this equipment?

6. Did the equipment detect malfunctions and make them obvious in a timely manner (e.g., alarms, warning, color changes, etc.)?

7. Were equipment displays (screens) and controls (dials, switches, knobs) easy to understand and use?

8. Did equipment displays and controls work correctly?

Equipment Maintenance

9. Was an NCPS Alert, Advisory or Recall associated with this equipment?

10. Was there a routine maintenance program in place to ensure equipment stayed in good working condition (checking expiration dates and no use if expired, proper cleaning and sterilization, no missing or damaged parts, etc.)?

11. If there was a maintenance program, did the most recent inspection indicate the equipment was working properly?

12. If the previous inspection pointed to equipment problems, what corrective actions were taken and were they effective?

Equipment Training

13. Was staff properly trained to operate the equipment before using it?

Equipment Policy

14. Did the equipment meet current codes, specifications and regulations?

15. If a vendor/manufacturer brought in equipment for use, was VHA policy followed (or was the equipment obtained through a non-standard process)?

16. If equipment was re-used, was it supposed to be re-used (not a single use device)?

Equipment and Culture

17. If problems were identified previously, were adequate time and resources provided for relevant physical plant and equipment upgrades?

18. Were emergency supplies and back-up systems available on-demand in case of equipment failure?

Information Technology

Information Technology (IT) includes a wide variety of products that employees use in the delivery of care (e.g., CPRS, VistA, VistA Imaging, BCMA, etc.). The questions in this section apply to any such electronic products. RCA teams need a safe demonstration of the product involved in an adverse event or close call to better understand how things happened.

Please request that IT support staff enter a remedy ticket for all IT malfunctions. In particular, remedy tickets should note "potential patient safety issue" to ensure that the Informatics Patient Safety Office is notified in a timely manner. (Consider interim measures that may be taken while awaiting a national fix: communication, training, safeguards, etc.)

Information Technology Design and Use

1. Was the electronic health record up and running and available as needed? (If not, did contingency plans work effectively and efficiently?)

2. Once the screen or report information was accessed, was it difficult for staff to read or interpret it?

3. Was the intended patient record selected correctly?

4. Was the most recently available information displayed?

5. Was correct information displayed, but misinterpreted?

6. Was incorrect information displayed?

7. Did automatic order checks/alerts/flags function correctly?

8. If there was a mistake in the IT system, where in the process was it detected? For example: an overdose was undetected during order entry, and caught by a nurse before it was given.

9. If two or more IT systems were used was the information displayed in the same way?

10. Did an “error” message appear?

Information Technology Training

11. Did staff know how to use the hardware and software in order to access the screen or report information they needed?

12. Did staff know what the software can and cannot do?

13. Did IT policies, procedures or training have an effect on the event or close call?

Fatigue and Scheduling

Fatigue

1. Was staff fatigue a factor in the adverse event or close call?

2. Did scheduling allow personnel to get adequate sleep?

3. Was there a process in place to minimize the effects of fatigue (e.g., strategic naps, modification of assignments, etc.)?

Patients and Scheduling

4. Was the patient informed of and properly prepared for tests and procedures in a timely manner?

5. If relevant was the patient actively engaged in unit level treatment programs and activities?

Scheduling and Support Services

6. Were staff roles and tasks clearly defined and assigned?

7. Was the mix of staff (clinical, administrative, support) adequate for the workload?

8. Was there sufficient staff on hand for the clinical care workload?

9. Was there sufficient staff on hand for the administrative workload (logistics, phone calls, patient transport, etc.)?

Scheduling and Culture

10. Were other clinical and support service staff/teams available on-demand to assist with clinical and administrative tasks (e.g., rapid response/code team, consults, biomedical engineering, environmental management, etc.)?

Training

As adults, we learn in many different ways, and our preferences vary. Some people learn best by listening to information, some by reading documents, some by writing down what they hear and see, and some by watching a demonstration followed by their own return demonstration, etc. The modalities available for teaching adult learners are equally varied: spoken instruction, discussion, coaching, scholarly papers, posters, videos, computer-based training modules with embedded tests, low- or high-fidelity simulation, etc. It is important to know how each learner learns best, and to pair that preference with the most effective training modality available.

Training for Patients

1. Did the patient and family/significant others receive necessary education in a timely manner?

2. If relevant, were the patient and family/significant others trained in the use of medical devices and treatments (e.g., oxygen, patient controlled analgesia, hand hygiene, etc.)?

Assessing the Need for Staff Training

3. Was there an educational assessment to determine what training staff actually needed?

4. Was training designed with the intent of helping staff perform tasks correctly using a HFE approach? For example: practice scenarios, drills, simulation, etc.

5. Was the level of staff experience, training, scope of practice and competency consistent with their tasks?

6. Was the level of staff supervision appropriate?

Training Content

7. Was staff trained in the use of safeguards and back-up/contingency plans in case their task did not proceed as planned?

8. Was staff trained in how to report adverse events and close calls, calling for help, and hand-off communications?

Training Effectiveness

9. Was relevant training provided before the task started?

10. Were the results of training monitored over time?

11. Did the results of training show that it was effective and successful?

Training and Culture

12. Did the work area promote speaking up, reporting adverse events and close calls, and learning from those situations (lessons learned)?

Communication

Communication With Patients

1. Was the patient identified correctly?

2. Were the patient and their family/significant others actively involved in assessment and treatment decisions?

Communication About Patients

3. If applicable, did the patient receive the correct medications?

4. If applicable, did the patient have the correct procedure?

5. If applicable, were the laboratory or diagnostic specimens or results labeled correctly?

6. Was communication between managers/supervisors and front-line staff adequate (accurate, no jargon or slang, unambiguous)?

7. Was communication between front-line staff **within** the patient care area adequate?

8. Was communication **across** patient care areas adequate (e.g., transfers, consults)?

9. If the patient had a life threatening condition was it communicated effectively with urgency?

Communication by Documentation

10. Were patient assessments from relevant disciplines available and used by the treatment team in a timely manner?

11. Did the patient's record give a clear picture of his/her work-up, treatment plan, and response to treatment?

12. Were relevant policies and procedures available and communicated adequately to the people who needed them?

13. Was there an existing recall/alert/bulletin related to the event or close call? Did relevant staff know about it?

14. Did information technology (CPRS, BCMA, VistA, etc.) adequately support communication about the patient and their plan of care?

Communication and Culture

15. If the patient had an invasive procedure did a "time out" occur?

16. Were standardized communication tools and techniques used within and across disciplines (e.g., checklists, read-back, hand-off templates, briefings, debriefings, time-out procedures, etc.)?

17. Were there any obstacles to relaying or talking about safety risks?

18. Did relevant work areas welcome staff to speak up about risks and offer suggestions for reducing or eliminating risk?

19. Does the organization promote a just culture by openly encouraging and rewarding staff when they report actual or potential mistakes?

Section 2

Why Did It Happen?

Root Causes and Contributing Factors

Once the RCA team fully understands what happened and why, they come to a critical step: clearly describing how the root cause(s) or contributing factor(s) led to the event or close call. We call these descriptions root cause/contributing factor statements.

David Marx's research and findings describing why things go wrong during airplane maintenance is our inspiration for health care root cause/contributing factor statements.[5] With the help of colleagues in the aviation community, David found that accurate, precise and unemotional HFE-based descriptions of what happened led to deeper, more thorough understanding. This is important, because the better we understand why things happened, the better we can develop and implement remedies to fix or minimize future problems. David developed seven **rules of causation**, and we have adopted five of those rules.

A scenario followed by an example of the correct and incorrect use of each of the five rules of causation follows. You will see how these rules enable us to pinpoint the things that need to be fixed. There is a 1-2-3 rhythm to these statements: 1 - something (a system breakdown or gap), 2 - led to/caused/increased the likelihood of, 3- something (close call or adverse event). You can see that these statements point us to fixing system breakdowns or gaps in order to prevent or minimize the close call or adverse event in the future.

Rule 1 – Clearly link and describe the "cause and effect"

Scenario:

Programming IV pumps is complicated. It's even harder to do if we are sleep deprived. If we are sleep deprived enough, our cognitive and motor abilities are measurably impaired; it is not a matter of will power. In this scenario, a nurse who worked a double shift made a programming mistake at the end of his second shift resulting in a medication overdose. The overdose was caught and reversed, and the patient recovered completely.

Correct: Working a double shift resulted in nurse fatigue, which led to programming an IV pump incorrectly, resulting in a medication overdose.

Incorrect: The nurse was fatigued. (No cause and effect, just a statement of fact that takes us nowhere.)

Rule 2 – Negative or derogatory words (e.g., poorly, careless, wrong) do not belong in causal statements.

Scenario:

Do we always read the instructions/user manuals that come with our home appliances? Or, do we often assume we'll know how to use them since we're smart people and have lots of hands-on experience with similar appliances, and besides the instructions are just too hard to tackle? Our sense of instructions being "too hard" or not worth our time is related to our limited attention span and the constant burden on our active memory. If we add production pressure (many tasks and limited time) to the sense of "too hard" it's no wonder we skip instructions sometimes!

In this scenario, an experienced staff member decided not to read the instructions for insertion and use of a new nasogastric tube after glancing at them; they were too hard to read and understand.

Correct: Instructions for insertion and use of a new nasogastric tube were in 8-point font and did not include photos or step-by-step diagrams, so staff did not review the instructions, and the tube was misplaced.

Incorrect: The nasogastric tube instructions were poorly written. (This negative statement doesn't tell us what could be fixed to make the instructions more useful.)

Rule 3 – Each human error or mistake must have a preceding system level cause.

Scenario:

If you can make a mistake today, I can make the same one tomorrow unless we figure out what the system level vulnerability is and fix it (e.g., inadequate lighting for a precise task). In this scenario phlebotomists are required to draw blood samples at night. And, lights are kept low at night to help patients sleep after their exhausting day. Enabling patients to sleep at night is highly valued and emphasized. One night, under low light conditions a phlebotomist unintentionally misidentifies a patient and the samples are mislabeled at the bedside.

Correct: Low nighttime bedside lighting substantially reduced visibility, increasing the likelihood of mislabeled lab specimens.

Incorrect: The phlebotomist mislabeled the specimen. (We don't need to fix well-intended staff, we need to fix the lighting or light sources available to them.)

Rule 4 – Violations of policy/procedures are not root causes, they must have a preceding system level cause.

These statements are easiest to write if your team has identified informal norms, work-arounds, or short cuts that differ from policy requirements. Work-arounds are a cue or clue to us that something isn't working ideally. It is also useful to discover perceived positive (addition of something valued) or negative (loss of something valued) incentives that led to the situation in order to leverage them.

Scenario:

Sometimes patients knowingly or unknowingly bring in contraband (e.g., weapons, illicit drugs, etc.) with their belongings. Contraband checks may occur at the time of admission to mental health units in order to discover and safely remove such items, reducing risk to the individual patient and the entire unit (a positive incentive). These checks may be time consuming for staff and decrease the comfort level of newly admitted patients (two negative incentives). In this scenario, the evening shift receives three new admissions in a short period of time. In the interest of addressing higher priority issues, evening staff decide to defer contraband checks, and contraband enters the unit.

Correct: Time-consuming contraband checks were deferred for three newly admitted patients on the evening shift, therefore prohibited items entered the unit.

Incorrect: The evening shift did not do contraband checks. (Blaming the evening shift for not doing the checks won't fix anything. But, in the "correct" statement, we are pointed to figuring out a less time-consuming process for use on off-tours.)

Rule 5 – Failure to act is only causal when there was a pre-existing duty to act.

Task or role expectations must be clearly communicated and understood.

Scenario:

Patients scheduled for surgery and anesthesia are often required to be NPO (no food or liquids by mouth) for a number of hours before their operation. It is very important that staff and patients/family know about the surgical schedule and NPO restrictions beforehand.

Correct: The night shift was not notified of an update to the surgical schedule and NPO restrictions, so the patient received breakfast, resulting in a delay in surgery.

Incorrect: The night shift violated NPO status.

5. Marx, D. *Maintenance Error Causation.* Prepared under contract for FAA Headquarters Office of Aviation Medicine (AAM-240) Washington DC: June 9, 1999.

Section 3

What Action Can We Take to Prevent It From Happening Again?

Developing and Choosing Actions

Purpose of Actions

- Now that you have figured out WHY the adverse event occurred it is time to examine/answer the question:
    - **How to prevent it from happening again?**
- The goal of action implementation is to **make patient care safer.**
- Actions are system "fixes":
    - Focus on the elements of the system that caused it to work improperly.
    - Actions **do NOT focus on people** but rather **how to get people to interact with the system more effectively.**

Steps to Developing Actions

1) **Map the actions to the root causes**
    a) Identify actions that focus on those root cause categories from the questions that were answered or identified as potential issues for the system. Note: There may be need for more than one action to address one root cause category.
        i. Rules (Policies and Procedures)
        ii. Safeguards (Barriers and Controls)
        iii. Environment
        iv. Equipment
        v. Information Technology
        vi. Fatigue and Scheduling
        vii. Training
        viii. Communication
2) **Brainstorm and identify ways to enhance, enforce, redesign or homogenize the process for everyone**
    a) Is there something missing? Working improperly? Are there distractions in the environment? Miscommunicated information? Is the process out of order or easy to do incorrectly or misunderstand?
    b) What is influencing staff to rely on personal or clinical judgment instead of the policy? Are there things in place to manage unexpected or busy circumstances?
    c) What tools and resources will the user need to fulfill the action correctly?
3) **Write the actions** as **SPECIFIC, CONCRETE and CLEAR** as possible:
    a) The actions may be shared throughout VHA –Other facilities may have the same issue and they will want to know **HOW, specifically, the action will be carried out**.
    b) The most well thought out action/intention is not helpful if it is not written or communicated well and in detail. Things to include: who, what, where, when, why, and how.

    Example: A facility has an issue with contraband on the unit and they develop a process to control for contraband.

i) Who will be doing it? Nursing staff.
ii) What will they be doing? Implement a room safety check.
iii) Where will it be done? In the patient's room (bedding, bathroom, closets, etc.).
iv) When will this occur? Beginning and end of every shift.
v) Why are they doing this? Prevent patient harm resulting from contraband.
vi) How is it going to be accomplished? Staff will wear gloves and manually search the bed and use a metal detector wand around the perimeter of the room.

4) **Identify and consult the person responsible** (process owner) for completing the action

a) Have them read and evaluate feasibility of the action. Ask them about what has been tried in the past and whether it made things better or worse. Ask them for their best suggestions/ideas for making care safer. Finally, ask them how they would know if things got safer (this piece of information will help you design outcome measures).

5) **Pilot test or simulate prior to system-wide implementation**

a) Can these tools/actions be accurately used in the "real world setting":

i) Will people have time to do this?
ii) Will people have the information needed to do this?
iii) Will there be support for people to fulfill this action?
iv) Do people clearly understand what they need to do and how?
v) Will something help people remember and enforce this action?
vi) Is this of value to the patient, staff and organization?
vii) Will the patient, staff or process be penalized by the action in any way?
viii) Will people be provided with feedback about whether or not the action was done correctly?

Action Strength

- Action strengths are based on the principles of human factors where the most effective actions accommodate or control for the limitations of human behavior and how people interact with systems, tools, tasks and the environment through the use of design and standardization.
- **Stronger actions**:
    - The **best at removing the dependence on the human** to "get it right" (they are physical and permanent, rather than procedural and temporary).
    - Questions to ask in evaluating if the action is stronger in preventing the event/cause:
        - Does the action force the person to get it right?
        - Does it eliminate the chance to choose the wrong option?
        - Is it designed for the environment or system to operate without additional issues/concerns for the person taking the action?
        - Can this be replicated successfully under any circumstance or by a different person?
        - Does it require minimal supervision or measurement of compliance?
        - Does it involve standardized forcing functions to remove human error and variation through technology and/or design?

      Example of a stronger action statement (a forcing function): *All passwords must be at least eight characters long and contain a combination of upper and lowercase letters, numbers and symbols. The login system will not accept passwords without these features.*

- **Intermediate actions**
    - **Reduce the reliance on the human** to get it right, but do not fully control for human error.
    - Questions to ask in evaluating if the action is intermediate in preventing the event/cause:
        - Does the action help the person to remember the process?
        - Does it improve upon the information needed to do the process?
        - Does it serve as a guide tool used during the process?
        - Does this action reduce variation of the outcome (most people do it successfully)?
        - Does this action account for human limitations: time, workload, tasks?

      Example of an intermediate action statement (a checklist): *A checklist located next to the computer shows the steps and requirements necessary to login to the system, including password requirements.*
- **Weaker actions**
    - **Support/clarify the process, but rely solely on the human.** These actions do not necessarily prevent the event/cause from occurring.
    - Questions to ask in evaluating if the action is weaker:
        - Is this action focused on informing the person?
        - Is this action establishing rules that do not already exist?
        - Does this action prompt, warn or alert a person (capture their attention)?
        - Does this action examine if the process could be improved/made better?
        - Is the outcome of the action left up to personal interpretation?

      Example of a Weaker Action statement (a policy): *All computer users must maintain strong, unique passwords for system accounts.*

Action Hierarchy

The following table breaks down some actions by strength category. For more information on other action categories please reference **the Primary Analysis Categorization (PAC) Glossary** Keyword Categories and Rules for Applying Them.

ACTION	PAC GLOSSARY
Stronger Actions	• Architectural/physical plant changes • New devices with usability testing before purchasing • Engineering control, interlock, forcing functions • Simplify the process and remove unnecessary steps • Standardize on equipment or process or care maps • Tangible involvement and action by leadership in support of patient safety
Intermediate Actions	• Redundancy/back-up systems • Increase in staffing/decrease in workload • Software enhancements/modifications • Eliminate/reduce distractions • Checklist/cognitive aid • Eliminate look- and sound-alikes • Enhanced documentation/communication
Weaker Actions	• Double checks • Warnings and labels • New procedure/memorandum/policy • Training • Additional study/analysis

Section 4

How Will We Know If the Action We Took Made a Difference?

Selecting Outcome Measures and Sustaining Improvement

Purpose of Outcome Measures

Measure the actions to see if they are making patient care safer by:

- Eliminating/reducing the occurrence of the adverse event or root cause(s).
- Measure what you expect to improve through the implementation of your actions.

The Basic Requirements

1. **Numerator.** What specific group/event/cause/outcome is being measured/monitored/changed for improvement?
2. **Denominator**. Out of what population/total group is the numerator being sampled?
3. **Threshold**. What is the realistic expected level of compliance (percent) / result of the numerator?
4. **Date/Timeframe**. How long it will be measured?

   Example: N = number of collected specimens with proper labeling
   D = Total number of specimens collected on the nursing unit
   Threshold = 98 percent of the specimens will have the proper labeling
   Date = the collection will be monitored for three months

Types of Outcome Measures

1) **Adverse Event Outcome** Measure. (This level of measurement is what teams should aim for; demonstration that the action reduced or prevented the adverse event from happening again.)

   a) Effectiveness Measure. Measures the improvement the action will have on eliminating the adverse event

   Example: Three months following staff training, the number of incidents of patient violence on the behavioral health unit resulting in injury to staff or patients will be reduced by 50 percent. The numerator will be the number of incidents of patient violence on the behavioral unit.

2) **Root Cause Outcome** Measure. (This is also a good target for teams; preventing the root cause situation from happening again.)

   a) Effectiveness Measure. Measures the impact the action will have on the root cause

   Example: Hourly rounds will show that 90 percent of patients, at high risk for falls will not ambulate independently for the next six months.

3) **Action/Process Outcome** Measure. (Process measures have minimal utility and teams should avoid them; these measures just bookkeep that an action was done, not its effect.)

   a) A statement about implementing the action or about measuring whether the action was completed

   b) Implementation Measure – Does not measure effectiveness of the action, only completion of the action

   Example: 95 percent of staff on the unit will have completed the training by June 2013. (This outcome measure just tells us that staff completed the training; we don't know if the training made care safer or not.)

Quantifiable Vs. Non-Quantifiable/ Non-Outcome

1) **Quantifiable**. Meets the basic requirements of a threshold, numerator and denominator

   Example: N= number of acute psychiatry admissions with notifications to mental health outpatient provider upon admission and prior to discharge

   D= total number of acute psychiatry admissions
   Threshold = 90 percent will have been notified
   Monitor for three months until July 2011

2) **Non-Quantifiable**

   a) No threshold, numerator and denominator – no counts/number/percentage of expected results

   Example: A quarterly random sample of acute psychiatry admissions will be revealed for notification of mental health outpatient providers upon admission and prior to discharge.

3) **Non-Outcome**

   a) Restatement of the original action, or mention of a new action

   Example: Staff will assess patients on their potential for aggressive behavior upon admission. (A new action offered in addition to the original action of notifying mental health outpatient providers about an acute inpatient admission.)

Conclusion

We hope that this information on the Root Cause Analysis process has been interesting and useful to you and your team. By applying Human Factors Engineering and High-Reliability Organization concepts we can design safer care. By keeping an open mind and asking thoughtful questions we can figure out why adverse events or close calls happen and how to prevent them from happening again.

Thank you and best wishes from your friends and colleagues at NCPS.