### VA National Center for Patient Safety TM Root Cause Analysis (RCA)

Note: Also see Rules of Causation and Triggering and Triage Questions™

The goal of a Root Cause Analysis is to find out

- What happened
- Why did it happen
- What to do to prevent it from happening again.

**Root Cause Analysis** is a *tool* for identifying prevention strategies. It is a process that is part of the effort to build a *culture of safety* and move beyond the culture of blame.

In **Root Cause Analysis**, basic and contributing causes are discovered in a process similar to diagnosis of disease - with the goal always in mind of preventing recurrence.

#### **Root Cause Analysis is:**

- 1. Inter-disciplinary, involving experts from the frontline services
- 2. Involving of those who are the most familiar with the situation
- 3. Continually digging deeper by asking why, why, why at each level of cause and effect.
- 4. A process that identifies changes that need to be made to systems
- 5. A process that is as impartial as possible

#### To be thorough, a Root Cause Analysis must include:

- 1. Determination of human & other factors
- 2. Determination of related processes and systems
- 3. Analysis of underlying cause and effect systems through a series of *why* questions
- 4. Identification of risks & their potential contributions
- 5. Determination of potential improvement in processes or systems

### To be credible, a Root Cause Analysis must:

- 1. Include participation by the leadership of the organization & those most closely involved in the processes & systems
- 2. Be internally consistent
- 3. Include consideration of relevant literature

## VA National Center for Patient Safety Triage Questions TM Concept Definitions for Triggering Questions

Human Factors/Communication: Questions that help assess issues related to communication, flow of information, and availability of information as needed. These questions also reveal the importance of communication in use of equipment and application of policy and procedure, unintended barriers to communication, and the organization's culture with regard to sharing information.

**For example:** A patient without an identifying bracelet is administered medication based on the nurse's memory of the patient's identity. The hospital has a policy requiring that wrist bracelets be checked before every dose of medicine, but because the dose is overdue, the nurse delivers the medicine without confirming the patient's identity.

Human Factors/Training: Questions that help assess issues related to routine job training, special training, and continuing education; including the timing of that training. Training issues may concern application of approved procedures, correct use of equipment, or appropriate manipulation of protective barriers. These questions also focus attention on the interfaces between people, workspace, and equipment.

**For example:** A new group of physicians in residency training arrived this week to start a rotation at your facility. A lab error occurs when the wrong form is submitted with a blood vial.

Human Factors Fatigue/Scheduling: Questions that weigh the influence of stress and fatigue that may result from change, scheduling and staffing issues, sleep deprivation, or environmental distractions such as noise. These questions also evaluate relationships to training issues, equipment use, management concern and involvement.

**For example:** Renovation is taking place in adjoining space making it difficult for staff to converse and to hear patient call alarms.

**Environment/Equipment:** Questions to help evaluate factors related to use and location of equipment; fire protection and disaster drills; codes, specifications and regulations; the general suitability of the environment; and the possibility of recovery after an error has occurred. These questions show that what appears to be equipment failure may relate to human factors issues, policy and procedure questions and training needs.

**For example:** Housekeeping staff is thorough in their care of bedding material. While the patient is in physical therapy they flip a patient's air-filled anti-decubitis mattress inadvertently reversing the correct alignment of the air chambers.

Rules/Policies/Procedures: Questions that help assess the existence and ready

accessibility of directives including technical information for assessing risk, mechanisms for feedback on key processes, effective interventions developed after previous events, compliance with national policies, the usefulness of and incentives for compliance with codes, standards, and regulations. The qualifications of the facility and employees for the level of care provided; orientation and training for compliance with safety and security measures including handling of hazardous material and emergency preparedness; and the availability of information to all part time, temporary, or voluntary workers and students are also considered.

**For example:** A nurse hired for the day through the local registry is not familiar with your facility's policy against unlocking the door to the balcony in order to smoke while taking a break.

<u>Barriers:</u> Barriers protect people and property from adverse events. Questions assess barrier strength, fault tolerance, function and interaction/relationship to Rules/Policies/Procedures and Environment/Equipment.

**For example:** A negative pressure room for an infectious patient is a barrier to the spread of the disease. If the ventilation in the room stops working a critical barrier has been compromised.

#### The Five Rules of Causation\*

\*Adapted from David Marx.

The five rules of causation are designed to improve the RCA process by creating minimum standards for where an investigation and the results should be documented. The rules are created in response to the very real biases we all bring to the investigation process.

 Rule 1 - Causal Statements must clearly show the "cause and effect" relationship.

This is the simplest of the rules. When describing why an event has occurred, you should show the link between your root cause and the bad outcome, and each link should be clear to the RCA Team and others. Focus on showing the link from your root cause to the undesirable patient outcome you are investigating. Even a statement like "resident was fatigued" is deficient without your description of how and why this led to a slip or mistake. The bottom line: the reader needs to understand your logic in linking your causes to the outcome.

 Rule 2 - Negative descriptors (e.g., poorly, inadequate) are not used in causal statement

As humans, we try to make each job we have as easy as possible. Unfortunately, this human tendency works it way into the documentation process. We may shorten our findings by saying "maintenance manual was poorly written" when we really have a much more detailed explanation in our mind. To force clear cause and effect descriptions (and avoid inflammatory statements), we recommend against the use of any negative descriptor that is merely the placeholder for a more accurate, clear description. Even words like "carelessness" and "complacency" are bad choices because they are broad, negative judgments that do little to describe the actual conditions or behaviors that led to the mishap.

Rule 3 - Each human error must have a preceding cause.

Most of our mishaps involve at least one human error. Unfortunately, the discovery that a human has erred does little to aid the prevention process. You must investigate to determine WHY the human error occurred. It can be a system-induced error (e.g., step not included in medical procedure) or an at-risk behavior (doing task by memory, instead of a checklist). For every human error in your causal chain, you must have a corresponding cause. It is the cause of the error, not the error itself, which leads us to productive prevention strategies.

#### • Rule 4 - Each procedural deviation must have a preceding cause.

Procedural violations are like errors in that they are not directly manageable. Instead, it is the cause of the procedural violation that we can manage. If a clinician is violating a procedure because it is the local norm, we will have to address the incentives that created the norm. If a technician is missing steps in a procedure because he is not aware of the formal checklist, work on education.

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

We can all find ways in which our investigated mishap would not have occurred - but this is not the purpose of causal investigation. Instead, we need to find out why this mishap occurred in our system as it is designed today. A doctor's failure to prescribe a medication can only be causal if he was required to prescribe the medication in the first place. The duty to perform may arise from standards and guidelines for practice; or other duties to provide patient care.

### VA National Center for Patient Safety Triage Questions <sup>TM</sup> Starting Point

<u>Concept definitions and examples</u> are used to determine Contributing Factors: This is a set of computer screens that will help you use the questions in a systematic way and lead your team to root causes for this case.

#### First:

Was this event thought to be the result of: a criminal act; a purposefully unsafe act related to alcohol or substance abuse (impaired provider/staff), or events involving alleged or suspected patient abuse of any kind (i.e., those situations which are outside the scope of the patient safety program)?

- If yes, go to the Director, request that the RCA process be stopped, and administrative process started.
- If no, continue with the RCA Triage Questions listed below

#### Second:

- 1. Were issues related to patient assessment a factor in this situation?
  - If yes, go to the <u>Human Factors/Communication</u> (beige sheet) questions.
- 2. Were issues related to staff training or staff competency a factor in this event?
  - If yes, go to the <u>Human Factors/Training</u> (pink sheet) questions.
- 3. Was equipment involved in this event in any way?
  - If yes, go to the Environmental/Equipment (green sheet) questions.
- 4. Was the work environment a factor in this event?
  - If yes, go to the <a href="mailto:Environmental/Equipment">Environmental/Equipment</a> (green sheet) questions.
- 5. Was the lack of information (or misinterpretation of information) a factor in this event?
  - If yes, go to the <u>Human Factors/Communication</u> (beige sheet) questions.

- 6. Was communication a factor in this event?
  - If yes, go to the <u>Human Factors/Communication</u> (beige sheet) questions.
- 7. Were appropriate rules/policies/procedures -- or the lack thereof -- a factor in this event?
  - If yes, go to the Rules/Policies/Procedure (purple sheet) questions.
- 8. Was the failure of a barrier -- designed to protect the patient, staff, equipment or environment -- a factor in this event?
  - If yes, go to the <u>Barriers</u> (blue sheet) questions.
- 9. Were personnel or personal issues a factor in this event?
  - If yes, go to the <u>Human Factors</u> (beige, pink, and yellow sheets) questions.

#### Third:

Remember, doing an RCA is an iterative process. So, as you learn more about the big picture for this event, feel free to come back and use the triage questions to get a clearer idea of what happened, and how to prevent it from happening again.

### VA National Center for Patient Safety Triage Questions <sup>™</sup> Barriers

In this section, address all questions.

- 1. What barriers and controls were involved in this adverse event or close call?
- 2. Were these barriers designed to protect patients, staff, equipment, or environment?
- 3. Was patient risk considered when designing these barriers and controls?
- 4. Were these barriers and controls in place before the event happened?
- 5. Had these barriers and controls been evaluated for reliability?
- 6. Were there other barriers and controls for work processes?
- 7. Was the concept of "fault tolerance" applied in system design?
- 8. Were the relevant barriers and controls maintained and checked on a routine basis by designated staff?
  - o If no, go to the <u>Rules/Policy/Procedures</u> questions.
- 9. Would the adverse event have been prevented if the existing barriers and controls had functioned correctly?
- 10. Were the system or processes tested before they were implemented?
- 11. Did the audits/reviews related to barriers include evaluation of plans, designs, installation, maintenance, and process changes?
  - o If yes, go to the <u>Rules/Policy/Procedures</u> questions.
- 12. Did management have a method for identifying what the results of the system changes would be before implementation?
  - o If yes, go to the <u>Rules/Policy/Procedures</u> questions

### VA National Center for Patient Safety Triage Questions <sup>™</sup> Human Factors: Communication

In this section, address all questions.

- 1. Was the patient correctly identified?
- 2. Was information from various patient assessments shared and used by members of the treatment team on a timely basis?

If "No" -- This could be a Root Cause/Contributing Factor.

- 3. Did existing documentation provide a clear picture of the work-up, the treatment plan and the patient's response to treatment?
  Including:
  - o assessments
  - o consultations
  - o orders
  - o treatment team notes
  - o progress notes
  - o medication administration record
  - o x-ray
  - o lab reports
  - o -- etc. --

If "No" -- This could be a Root Cause/Contributing Factor.

4. Was communication between management/supervisors and front line staff adequate?

#### Was it:

- o accurate
- o complete
- o using standard vocabulary and no jargon
- o unambiguous

If "No" -- Describe how management/supervisors and front line communications are not adequate.

5. Was communication between front line team members adequate?

If "No" -- Describe how communications between team members were not adequate.

6. Were policies and procedures communicated adequately?

If "No" -- Describe how policies and procedures were not communicated adequately. If this is an issue, see the <u>Rules/Policies/Procedures</u> questions.

7. Was the correct technical information adequately communicated 24 hours a day to the people who needed it?

If "No" -- Describe how communication about technical information is not adequate.

- 8. Were there methods for monitoring adequacy of staff communication? Were there methods for:
  - o "read back"
  - o confirmation messages
  - o debriefs
  - o --etc.--

If "No" -- This could be a Root Cause/Contributing Factor.

9. Was the communication of potential risk factors free from obstacles?

If "No" -- This could be a Root Cause/Contributing Factor.

10. Was there manufacturer's recall/alert/bulletin on file for equipment, medication, or transfusion related elements at the time of the event or close call? Were relevant staff members aware of the recall/alert/bulletin?

If this is an issue, consider <u>Environment and Equipment</u> questions.

- 11. If relevant, were the patient and their family/significant others actively included in the assessment and treatment planning?
- 12. Did management establish adequate methods to provide information to employees who needed it in a manner that was easy to access/use, and timely?

If "No" -- This could be a Root Cause/Contributing Factor.

13.

Did the overall culture of the facility encourage or welcome observations, suggestions, or "early warnings" from staff about risky situations and risk reduction?

(Also, has this happened before and was anything done to prevent it from happening again?)

14. Did adequate communication across organizational boundaries occur?

# VA National Center for Patient Safety Triage Questions <sup>™</sup> Environment and Equipment

In this section, address all questions.

#### **Environment**

- 1. Was the work area/environment designed to support the function it was being used for?
- 2. Had there been an environmental risk assessment (i.e., safety audit) of the area?
  - o If no, consider reviewing the <u>Rules/Policy/Procedures</u> and <u>Barriers</u> questions.
- 3. Were the work environment stress levels (either physical or psychological) appropriate (e.g. Temperature, space, noise, intra-facility transfers, construction projects.)?
  - o If yes, go to the <u>Human Factors/Scheduling/Fatigue</u> questions.
- 4. Had appropriate safety evaluations and disaster drills been conducted?
- 5. Did the work area/environment meet current codes, specifications, and regulations?

#### Equipment (If training was an issue go to Human Factors/Training.)

- 6. Was equipment designed to properly accomplish it's intended purpose?
- 7. Did the equipment involved meet current codes, specifications, and regulations?
- 8. Was there a documented safety review performed on the equipment involved?
  - o If relevant, were recommendations for service/recall/maintenance, etc., completed in a timely manner?
- 9. Was there a maintenance program in place to maintain the equipment involved?
  - o If no, go to Rules/Policy/Procedures.

- 10. If there was a maintenance program, did the most recent previous inspections indicate that the equipment was working properly?
- 11. If previous inspections pointed to equipment problems, what corrective actions were implemented and were they effective?
- 12. Were adequate time and resources allowed for physical plant and equipment upgrades, if problems were identified?
- 13. Was there adequate equipment to perform the work processes?
- 14. Were emergency provisions and back-up systems available in case of equipment failure?
- 15. Had this type of equipment worked correctly and been used appropriately in the past?
- 16. Was the equipment designed such that usage mistakes would be unlikely to happen?
- 17. Was the design specification adhered to?
  - o If yes, go to the <u>Human Factors/Training</u> questions.
- 18. Was the equipment produced to specifications and operated in a manner that the design was intended to satisfy?
- 19. Were personnel trained appropriately, to operate the equipment involved in the adverse event/close call?
  - o If no, see the <u>Human Factors/Training</u> questions.
- 20. Did the design of the equipment enable detection of problems and make them obvious to the operator in a timely manner?
- 21. Was the equipment designed so that corrective actions could be accomplished in a manner that minimized/eliminated any undesirable outcome?
- 22. Were equipment displays and controls working properly and interpreted correctly?
- 23. Was the medical equipment or device intended to be reused (e.g. not a Single Use Device)?

## VA National Center for Patient Safety Triage Questions <sup>™</sup> Human Factors: Fatigue

- 1. Were the levels of vibration, noise, or other environmental conditions appropriate?
- 2. If applicable, were environmental stressors properly anticipated?
  - o If stressors were anticipated, see the <u>Human Factors/Training</u> questions.
  - o If stressors were not anticipated, why weren't they anticipated?
- 3. Did personnel have adequate sleep?
- 4. Did scheduling allow personnel adequate sleep
- 5. Was fatigue properly anticipated?
- 6. Was the environment free of distractions?
- 7. Was there sufficient staff on-hand for the workload at the time?
  - (i.e., Workload is too high, too low, or wrong mix of staff.)
    - o If yes, see the <u>Human Factors/Training</u> questions.
- 8. Was the level of automation appropriate?
  - (i.e., Neither too much nor not enough.)
    - o If yes, see the <u>Environment and Equipment</u> questions.

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# VA National Center for Patient Safety Triage Questions <sup>™</sup> Human Factors: Training

In this section, address all questions.

1. Was there a program to identify what is actually needed for training of staff?

If "No" -- This could be a Root Cause/Contributing Factor.

2. Was training provided prior to the start of the work process?

If "No" -- This could be a Root Cause/Contributing Factor.

3. Were the results of training monitored over time?

If "No" -- This could be a Root Cause/Contributing Factor.

- 4. Was the training adequate? If not, consider the following factors:
  - o supervisory responsibility
  - o procedure omission
  - o flawed training
  - o **flawed rules**, **policy**, **or procedure** *If yes, go to the <u>Rules/Policy/Procedure</u> questions.*
- 5. Were training programs for staff designed up-front with the intent of helping staff perform their tasks without errors?

If "No" -- This could be a Root Cause/Contributing Factor.

6. Had procedures and equipment been reviewed to ensure that there was a good match between people and the tasks they did; or people and the equipment they used (i.e., human factors engineering)?

If procedures were not followed as intended, see the Rules/Policy/Procedure questions.

7. Were all staff trained in the use of relevant barriers and controls?

If yes, see the <u>Barriers</u> questions.

- 8. If equipment was involved, did it work smoothly in the context of:
  - o staff needs and experience
  - o existing procedures, requirements, and workload
  - physical space and location
     If equipment was involved, see the <u>Environment and Equipment</u> questions.

### VA National Center for Patient Safety Triage Questions <sup>™</sup> Rules, Policies and Procedures

In this section, address all questions.

- 1. Was there an overall management plan for addressing risk and assigning responsibility for risk?
- 2. Did management have an audit or quality control system to inform them how key processes related to the adverse event are functioning?
- 3. Had a previous audit been done for a similar event, were the causes identified, and were effective interventions developed and implemented on a timely basis?
- 4. Would this problem have gone unidentified or uncorrected after an audit/review?
- 5. Was required care for the patient within the scope of the facility's mission, staff-expertise and availability, technical and support service resources?
- 6. Was the staff, involved in the adverse event or close call, properly qualified and trained to perform their functions?
- 7. Were all involved staff oriented to the job, facility, and unit policies regarding: safety, security, hazardous material management, emergency preparedness, life-safety-management, medical equipment, and utilities management?
- 8. Were there written up-to-date policies and procedures that addressed the work processes related to the adverse event or close call?
- 9. Were these policies/procedures consistent with relevant federal and VHA policies, standards, and regulations?
- 10. Were relevant policies/procedures clear, understandable, and readily available to all staff?
  - o If no, go to the <u>Human Factors/Communication</u> questions.
- 11. Were the relevant policies and procedures actually used on a day-to-day basis?
- 12. If the policies and procedures were not used, what got in the way of their usefulness to the staff?
- 13. If policies and procedures were not used, what positive and negative incentives were absent?