

Checklist Flip Chart

for Root Cause Analysis Teams

Instructions

Definitions

Initial Checklist Questions

Communication

Knowledge / Skills / Competence

Work Environment / Scheduling

Patient Factors

Equipment

Policies / Procedures / Guidelines

Safety Mechanisms

Rules of Causation

Actions and Outcome Measures

3rd Edition



NSW  HEALTH

Acknowledgment

This flip chart is designed to support improved practice in both the clinical and non-clinical work environments and help participants perform systematic root cause analysis to find the real causes of problems.

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Instructions

The following process is the recommended framework for conducting a **Root Cause Analysis** (RCA) investigation. Please note however that the process may vary depending on the complexity of the case.

Meeting 1

1. Make a simple flow diagram of the activities that surrounded and led to the event. Limit the diagram to five or six boxes and include only the key events that are crucial to understanding what happened.

Use the **initial checklist questions** at the blue tab to lead you to the appropriate sets of questions.

2. Having considered these questions, and asking 'how, what and why' at each point of the flow diagram, an intermediate flow diagram can be developed. This will assist in identifying what you know, what you don't know and what you need to find out.

Instructions

3. Use the how, what and why questions to determine the information to be collected through speaking with people, gathering relevant documents and looking at the literature when applicable.

Meeting 2: Part 1

1. Once all the information has been gathered, the team can construct the final flow diagram, a detailed chronology of what happened.
2. At each point in the flow diagram, the team should ask 'so what' or 'what is the relevance' of each box in the incident chain.
3. The team should identify whether barriers at each step might stop the problem from occurring again.
4. The cause and effect diagram can then be constructed. This will assist in formulating the causal links and error chains leading to the contributing factors or root causes.

Instructions

Meeting 2: Part 2

1. First, the team must outline what is the real problem to be eliminated, what happened that directly led to the event and what the team is trying to prevent.
2. The team should brainstorm the most significant issues outlined in the final flow diagram and use these for the cause and effect diagram.
3. Continue to ask 'why' or 'caused by' at each box on the tree until there are no more answers. These are the contributing factors or root causes.

Meeting 3

Development of causation statements, actions and recommendations and key outcome measures – see light purple tab **actions and outcomes** of flip chart.

Instructions

Remember: Before commencing an RCA, the team must initially ascertain if the event is outside the RCA scope, ie it appears to be the result of:

- a criminal act
- a purposefully unsafe act
- an act related to substance abuse by provider or staff or
- an event involving suspected patient abuse of any kind.

If the event is thought to be related to any of the above, it should not be reviewed using this method but referred to the executive to be handled using the existing performance management structures in your organisation.

Definitions

Communication

These are questions that help assess issues related to communication and the flow and availability of information. These questions also reveal the importance of communication in the use of equipment, the application of policies and procedures, the identification of unintended barriers to communication, and insight into the organisation's culture with regard to sharing information.

For example: A patient scheduled for elective joint replacement surgery is reviewed in the pre-admission clinic two weeks prior to the booked admission. On the day of surgery, the anaesthetist notes a significantly raised white cell count that was not documented in the medical record. The operation is cancelled and rescheduled following treatment of an infection.

Definitions

Knowledge/Skills/Competence

These are 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 safety mechanisms. These questions also focus attention on the interfaces between people, workspace and equipment.

For example: A new group of resident medical officers (RMO's) arrived this week to start a rotation at your facility. A laboratory error occurs when the wrong form is submitted with a blood vial.

Work Environment/Scheduling

These are questions that weigh the influence of stress and fatigue that may result from change, scheduling and staffing issues, sleep deprivation and the general suitability of the environment or the presence of environmental distractions such as noise. These questions also evaluate relationships to training issues, equipment use, management concern and involvement.

Definitions

For example: A resident, having completed a double shift the previous day, in completing the ward discharge summaries at a busy, noisy workstation, prescribes the wrong medications on one discharge summary. This is recognised in pharmacy when the medications are being dispensed.

Patient Factors

These questions help identify the salient clinical events or condition of the patient at the time of the incident (eg active bleeding, labile pulse and blood pressure) and other patient factors that may have affected the process of care, ie patient very distressed or unable to understand instructions.

For example: A patient scheduled for semi-urgent insertion of a pacemaker for a potentially life-threatening arrhythmia, becomes excessively agitated upon entering the catheter lab.

The procedure is unable to be performed under a local anaesthetic and a general is administered. The patient reacts to the anaesthetic and requires intubation and transfer to the general intensive care unit.

Definitions

Equipment

These are questions to help evaluate factors related to use and location of equipment, fire protection, disaster drills, codes, specifications and regulations. 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: An infusion pump delivering pain relief continuously alarms. The nurse keeps silencing the alarm – it is not until the patient is writhing in pain that a malfunction in the equipment is identified.

Definitions

Policies/Procedures/Guidelines

These are 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 locum doctor, hired for the night through an agency is not familiar with your facility's policy and discharges a child with asthma at 2am. The child is readmitted at 5am in extremis requiring transfer to a paediatric intensive care unit.

Definitions

Safety Mechanisms

These questions assess safety mechanisms (barriers) that have been implemented to strengthen and ensure reliability and function of the organisation in relation to supervision, policies, procedures and guidelines, the environment and equipment.

For example: The policy states that two technicians should cross-match blood. A technician is called in after hours for an urgent cross-match and the incorrect blood is sent to the ward for the patient.

Initial Checklist

Starting point

1. Were there issues related to patient assessment in this event?

If *yes*, go to the **communication** questions.

2. Were issues related to staff training or staff competency a factor in this event?

If *yes*, go to the **knowledge/skills/competence** questions.

3. Was equipment (or the use or lack of use of equipment) involved in this event in any way?

If *yes*, go to the **environment/equipment** and **knowledge/skills/competence** questions.

4. Was a lack of information or misinterpretation of information a factor in this event?

If *yes*, go to the **communication** questions.

Initial Checklist

5. Was communication a factor in this event?

If *yes*, go to the **communication** questions.

6. Were appropriate policies/procedures or guidelines – or lack thereof – a factor in this event?

If *yes*, go to the **policies/procedures and guidelines** questions.

7. Was the failure of a safety mechanism or a barrier, designed to protect the patient, staff, equipment, or environment a factor in this event?

If *yes*, go to the **safety mechanism** questions.

8. Were specific patient issues a factor in this event?

If *yes*, go to the **patient factors** questions.

Return to these questions often

Communication

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?
3. Did existing documentation provide a clear picture of the work-up, the treatment plan and the patient's response to treatment?
(These could include: assessments, consultations, orders, treatment team notes, progress notes, medication charts, x-ray reports, laboratory reports etc.)
4. Was communication between management /supervisors and front line staff adequate?
(Was it: accurate, complete, using standard vocabulary and not jargon, and unambiguous?)
If *no*, describe how management/supervisors and front line communications are not adequate.

Communication

5. Was communication between team members adequate?
If *no*, describe how communications between team members were deficient and identify where it could be improved.
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 **policies, procedures and guidelines** questions.
7. Was the correct technical information adequately communicated to the people who needed it 24 hours a day?
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: 'read back', confirmation messages, debriefs etc?)

Communication

9. Was the communication of potential risk factors provided to the people who needed to know?
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 *yes*, consider **environment and equipment** 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?

Communication

- 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 organisational boundaries occur?

Knowledge/Skills/Competence

1. Was there a program to identify what is actually needed for training of staff?
2. Was training provided prior to the start of the work process?
3. Were the results of training monitored over time?

4. Was the training adequate?

(If not, consider the following factors: supervisory responsibility, procedure omission, flawed training, flawed guidelines, policy, or procedure)

If *yes*, go to the **policies, procedures and guidelines** questions.

5. Were training programs for staff designed up-front with the intent of helping staff perform their tasks without errors?

Knowledge/Skills/Competence

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 (ie human factors engineering)?

If *no*, see the **policies, procedures and guidelines** questions.

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

If *no*, see the **safety mechanism** questions.

8. If equipment was involved, did it work smoothly in the context of: staff needs and experience, existing procedures, requirements, workload and physical space and location?

If *no*, see the **equipment** questions.

Work Environment / Scheduling

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 (ie safety audit) of the area?
If *no*, consider reviewing the **rules/policies and procedures** questions and the **barrier** questions.
3. Were the work environment stress levels (either physical or psychological) appropriate, eg temperature, space, noise, intra-facility transfers, construction projects?
4. Had appropriate safety evaluations and disaster drills been conducted?
5. Did the work area/environment meet current codes, specifications, and regulations?
6. Were the levels of vibration, noise, or other environmental conditions appropriate?

Work Environment / Scheduling

7. If applicable, were environmental stressors properly anticipated?

If stressors were anticipated, see the Human factors **knowledge/skills/competence** questions.

If stressors were not anticipated, why weren't they anticipated?

8. Did personnel have adequate sleep?

9. Did scheduling allow personnel adequate sleep?

10. Was fatigue properly anticipated?

11. Was the environment free of distractions?

12. Were there sufficient staff on hand for the workload at the time (ie workload is too high, too low, or wrong mix of staff)?

If yes, see the Human factors **knowledge/skills/competence** questions.

13. Was the level of automation appropriate (ie neither too much nor not enough)?

Patient Factors

1. Was the patient's condition, either complexity or seriousness, a factor in this case?
2. Did personal issues – personality, language, external support or social and family circumstances contribute to this event?
3. Were there known risks associated with the treatment being provided to the patient?
4. Was there a medical, personal or emotional history that may have contributed to this event?
5. Was there a good staff/patient working relationship?
6. Were the patient/visitors helpful and cooperative?
7. Was the management plan appropriate for the condition.



Equipment

If training was an issue go to the knowledge/skills/competence questions.

1. Was equipment designed to properly accomplish its intended purpose?
2. Did the equipment involved meet current codes, specifications, and regulations?
3. Was there a documented safety review performed on the equipment involved?

If relevant, were recommendations for service/recall/maintenance, etc completed in a timely manner?

4. Was there a maintenance program in place to maintain the equipment involved?
If *no*, go to **policies, procedures and guidelines.**
5. If there was a maintenance program, did the most recent previous inspections indicate that the equipment was working properly?
6. If previous inspections pointed to equipment problems, what corrective actions were implemented and were they effective?

Equipment

7. Were adequate time and resources allowed for physical plant and equipment upgrades, if problems were identified?
8. Was there adequate equipment to perform the work processes?
9. Were emergency provisions and back-up systems available in case of equipment failure?
10. Had this type of equipment worked correctly and been used appropriately in the past?
11. Was the equipment designed such that usage mistakes would be unlikely to happen?
12. Was the design specification adhered to?
If *yes*, go to the **knowledge/skills/competence** questions.
13. Was the equipment produced to specifications and operated in a manner that the design was intended to satisfy?

Equipment

14. Were personnel trained appropriately to operate the equipment involved in the adverse event/ close call?
If *no*, see the **knowledge/skills/competence** questions.
15. Did the design of the equipment enable detection of problems and make them obvious to the operator in a timely manner?
16. Was the equipment designed so that corrective actions could be accomplished in a manner that minimised/eliminated any undesirable outcome?
17. Were equipment displays and controls working properly and interpreted correctly?
18. Was the medical equipment or device intended to be reused (eg not a Single Use Device)?

Policies, Procedures and Guidelines

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. Were the staff involved in the adverse event or close call properly qualified and trained to perform their functions?

Policies, Procedures and Guidelines

7. Had all staff involved been 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 state policies, standards, and regulations?
10. Were relevant policies/procedures clear, understandable and readily available to all staff?
If *no*, go to the **communication** 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 prevented their use by the staff?
13. If policies and procedures were not used, what positive and negative incentives were absent?

Safety Mechanisms

1. What safety mechanisms (barriers) and controls were involved in this adverse event or close call?
2. Were these safety mechanisms designed to protect patients, staff, equipment or environment?
3. Was patient risk considered when designing these safety mechanisms and controls?
4. Were these safety mechanisms and controls in place before the event happened?
5. Had these safety mechanisms and controls been evaluated for reliability?
6. Were there other safety mechanisms and controls for work processes?
7. Was the concept of 'fault tolerance' applied in system design?
8. Were the relevant safety mechanisms and controls maintained and checked on a routine basis by designated staff?

If *no*, go to the **policy, procedures and guidelines** questions.

Safety Mechanisms

9. Would the adverse event have been prevented if the existing safety mechanisms and controls had functioned correctly?
10. Were the system or processes tested before they were implemented?
11. Did the audits/reviews related to safety mechanisms include evaluation of plans, designs, installation, maintenance and process changes?
If *yes*, go to the **policy, procedures and guidelines** questions.
12. Did management have a method for identifying what the results of the system changes would be before implementation?
If *yes*, go to the **policy, procedures and guidelines** questions.
13. Was support or supervision a factor in this case?
14. Did the staff involved feel they could discuss the case freely prior to the incident?

Rules of Causation

Contributing factor and root cause statements must clearly address why something occurred, with a focus on process and system vulnerabilities, not individuals.

The following **five rules of causation** assist in developing contributing factor and root cause statements.

Rule 1. Causal statements must clearly show the 'cause and effect' relationship.

If you eliminate or control this contributing factor/ root cause, will you prevent or minimise future events?

The statement should show the link between your root cause and the adverse outcome. Each link should be clear to the Root Cause Analysis Team and others.

Examples:

Incorrect – A resident was fatigued.

Correct – The level of the resident's fatigue increased the likelihood that he/she misread the instructions, which led to incorrect tube insertion.

Rules of Causation

Rule 2. Use specific and accurate descriptors for what occurred, rather than negative and vague words.

Negative descriptions should not be used.

Avoid words such as poorly, inadequately, haphazardly, carelessness and complacency. These are bad choices because they are broad, negative judgments that do little to describe the actual conditions or behaviours that led to the mishap.

Examples

Incorrect – Poorly trained nurse.

Correct – The level of the nurse's training increased the likelihood that he/she misunderstood the IV pump controls, which led to missing steps in the programming of the dose and rate.

Rule 3. Identify the preceding cause(s) not the human error.

Many adverse events involve a set of events and errors; for every human error in your causal chain, you must have a corresponding cause. Much like Rule 1, the links need to be clear and obvious to the readers of the RCA. It is the cause of the error, not the error itself, which leads to productive prevention.

Rules of Causation

Examples

Incorrect – The registrar did not review the discharge summary.

Correct – The level of staffing caused the registrar to rush and take shortcuts resulting in the patient being discharged with the wrong discharge summary.

Rule 4. Identify the preceding cause(s) of procedure violations.

Procedural violations are not directly manageable. Instead, it is the cause of the procedural violation that can be managed. The goal is to identify the positive and negative incentives that created the informal norm or accepted way of doing things.

Examples

Incorrect – The pharmacy technician did not follow the correct dispensing procedure.

Correct – Due to staffing shortages, routine checking by two persons was bypassed resulting in the incorrect dispensing of medications.

Rules of Causation

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

The duty to act may arise from standards and guidelines for practice or other duties to provide patient care. The failure to act is judged on the duty to act at the time the error occurred.

Example: A doctor's failure to prescribe a cardiac medication after a myocardial infarction can only be causal if he was required (as per agreed guideline for all practitioners) to prescribe the medication in the first place.

Actions and Outcome Measures

Actions

Actions are developed to **prevent or minimise future adverse events or close calls**. Actions come from the Root Cause Analysis Team asking:

1. How can we decrease the chance of the event or close call from occurring?
2. How can we decrease the injury if the event occurs?
3. If we're considering changing procedures or rules, ask – What happened that day?
What should have happened ideally?
What usually happens?
4. How can involved devices, software, work processes, or work space be redesigned using a human factors approach? How can we 'put knowledge in the world' instead of relying on memory and vigilance?

Actions should look at eliminating, controlling or accepting conditions.

Actions and Outcome Measures

Strong

(Eliminate) These are strong actions that may include to remove, fix or replace a piece of equipment or put a measure in place so as the problem will not occur (simplify a process and remove unnecessary steps).

Medium

(Control) These are intermediate actions that may include putting up a warning notice, advising people at orientation, development of a checklist or cognitive aid, enhanced documentation/communication, software enhancements etc.

Weak

(Accept) These are the weakest actions – acknowledge that there is an associated risk and accept it.

The successful implementation of actions will be increased if they are **specific** and **clear** (ie a ‘cold’ reader should be able to understand what to do next).

Example: Instead of ‘provide training’ use something like: *develop and implement a training module on medical emergency procedures for all emergency staff by dd/mm/yy.*

Actions and Outcome Measures

Outcome measures

Outcome measures are designed to show whether or not the actions have actually prevented or minimised additional adverse events or close calls.

Outcome measures work best at demonstrating change over time if they are as **specific** and **quantifiable** as possible. Use **numerators, denominators, thresholds** and **timeframes** whenever possible.

Outcome measures should target what you want to address – if you have a 100% target for your measure, the vulnerability should be eliminated.

There is also a need to measure the effectiveness of your actions, not just completion of the action.

Set realistic thresholds – don't be unrealistic.

Example: Instead of 'decreased injuries' use something like 'monthly monitoring of patient and staff injuries related to each episode of seclusion and restraint'. Numerator = number of patient injuries and number of staff injuries. Denominator = total number of seclusion and restraint episodes etc.

