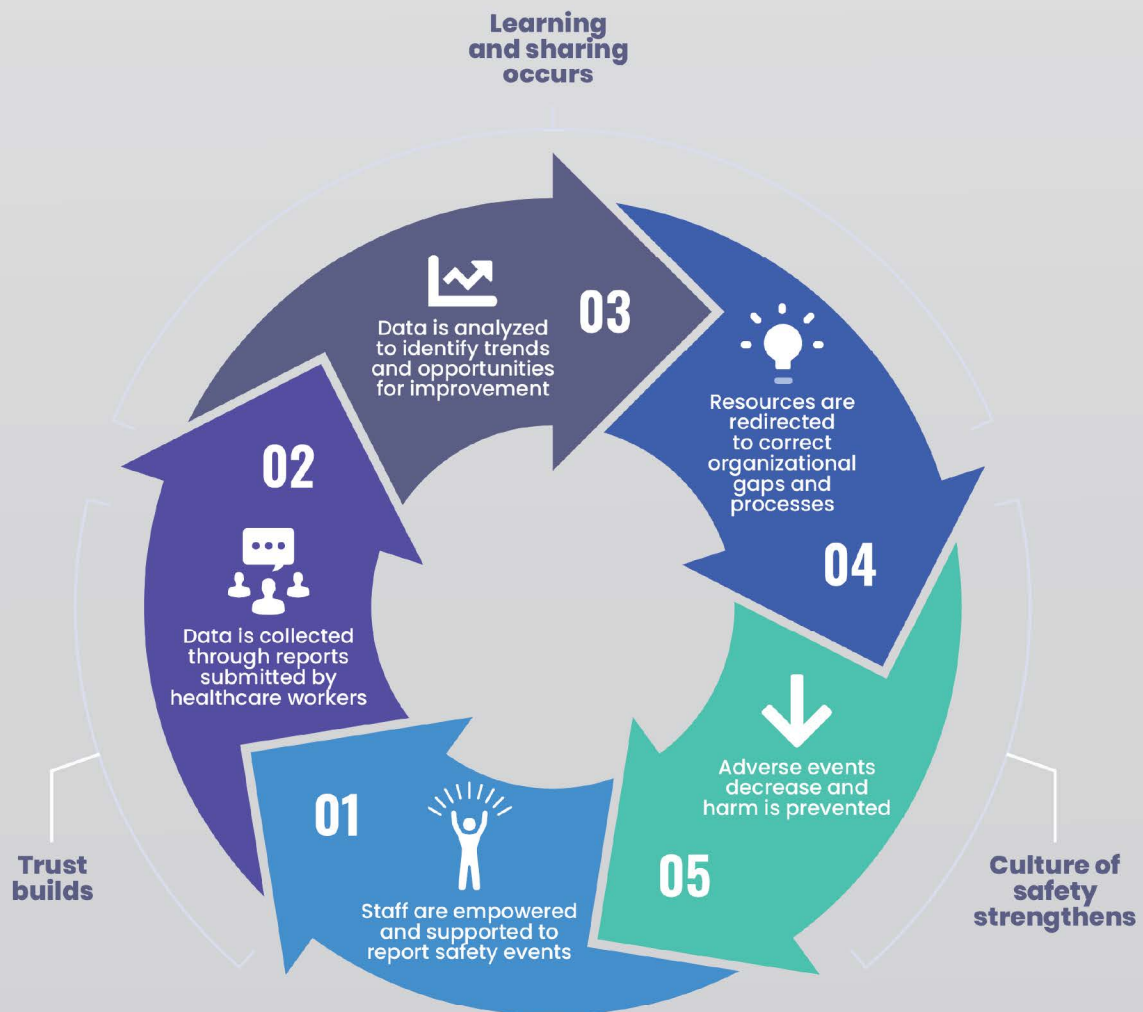




GAHAR MANUAL FOR REPORTABLE EVENTS MANAGEMENT



GAHAR MANUAL FOR
**REPORTABLE EVENTS
MANAGEMENT**

Edition 2025

Contents

Acknowledgments	5
Chapter (1) Raising Awareness.....	7
Introduction	9
Definitions.....	13
Safety Culture	15
Chapter (2) Dig for It.....	17
IHI trigger tool for measuring adverse events	19
List of reportable sentinel events.....	29
Chapter (3) Think Twice.....	39
Events Appropriate for RCA Review	41
Risk-Based Prioritization of Events, Hazards, and System Vulnerabilities	52
THE SAFETY ASSESSMENT CODE (SAC) MATRIX	55
Chapter (4) Reporting & intensive analysis	61
Reporting Framework.....	63
RCA Team Size and Team Membership	69
Root Cause Analysis for Sentinel Events in Hospitals.....	71
Chapter (5) Learn & Improve	87
Improvement Methodologies and Tools	89
Chapter (6) Enrich your Knowledge).....	101
Comprehensive Overview of Improvement Tools.....	103
References	117

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GAHAR Guidelines for Reportable Events Management

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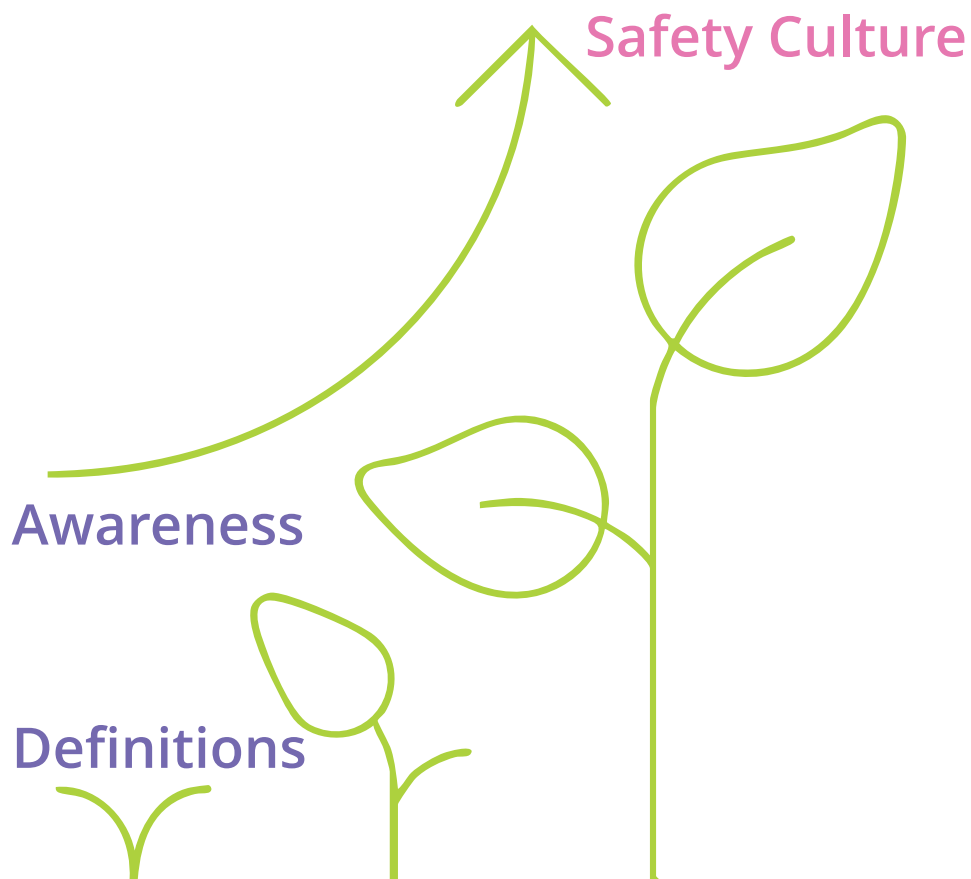
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CHAPTER (1)



RAISING AWARENESS



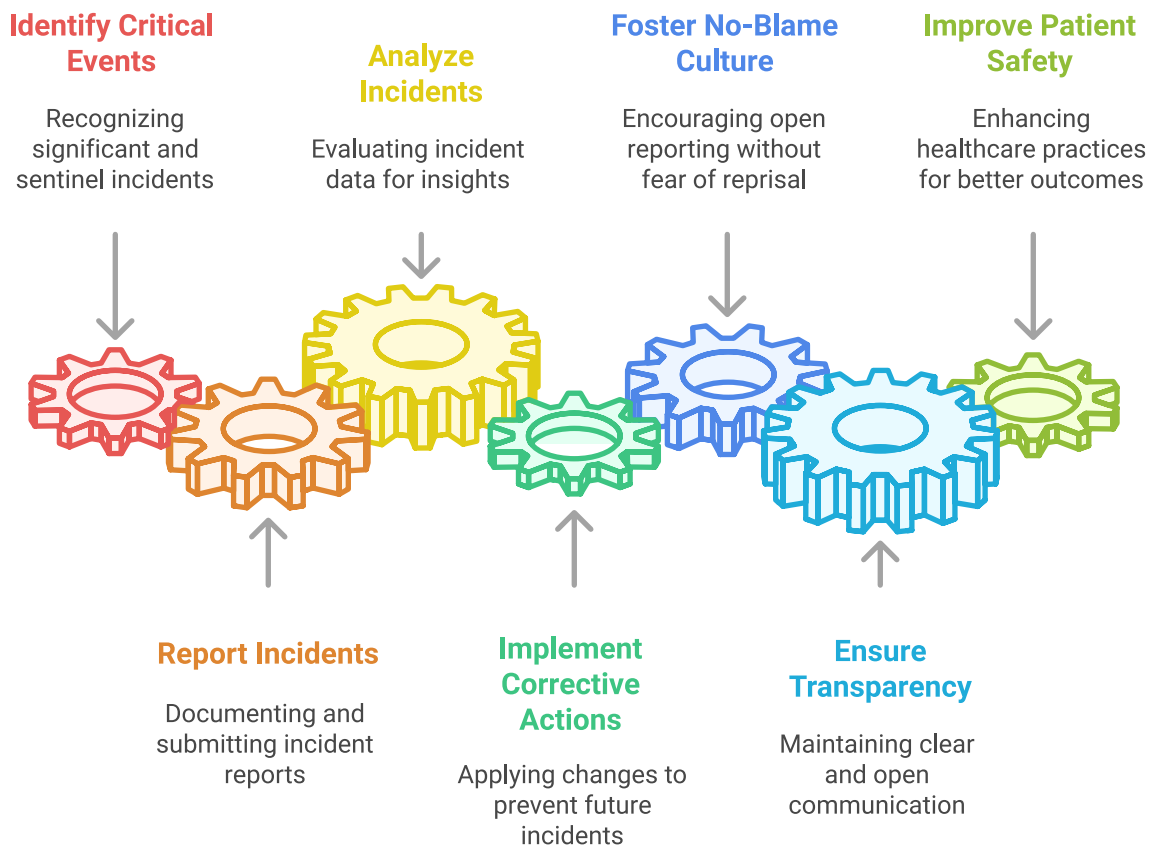
Introduction

In healthcare settings, the reporting of critical events is pivotal for safeguarding patients and advancing the overall quality of care. Such events—including significant and sentinel incidents—function as key indicators for monitoring system performance and identifying areas requiring urgent attention and corrective action. Significant events encompass a broad spectrum of occurrences with the potential to compromise patient safety, whereas sentinel events refer specifically to incidents resulting in severe harm or patient mortality.

Across all versions of its standards, GAHAR has consistently prioritized continuous quality improvement by promoting the systematic reporting, analysis, and management of incidents particularly significant and sentinel events. This approach is based on an organizational commitment to fostering a “no-blame culture” and ensuring full transparency, with the ultimate goal of cultivating a robust culture of safety within healthcare institutions.

Furthermore, effective management of reportable events enables organizations to transform adverse occurrences into opportunities for systemic learning and improvement. By utilizing data derived from these incidents, healthcare providers can design targeted interventions, refine clinical protocols, and implement staff training programs that reinforce safe practices. In an era where patient safety has emerged as a central concern, the prioritization of incident reporting and management extends beyond regulatory compliance; it represents an ethical obligation capable of driving transformative enhancements in healthcare delivery and outcomes.

Healthcare Incident Reporting and Management



Managing Reportable Events

In this handbook, GAHAR illuminates the pathway to patient safety by outlining comprehensive and clearly defined steps for the systematic identification, analysis, and management of reportable events. This proactive framework not only strengthens the quality of patient care but also fosters trust and confidence among patients and their families, reflecting an unwavering commitment to transparency, accountability, and excellence in healthcare delivery.

Understanding Reportable Events

Reportable events are defined as incidents that require formal documentation and notification to relevant authorities or stakeholders due to their potential impact. These may include accidents, breaches of safety protocols, regulatory noncompliance, or other occurrences with significant implications for patient welfare and organizational integrity.

Steps for Managing Reportable Events:

1. Identification

The first step in managing reportable events is to identify potential incidents. This can be achieved through regular monitoring, employee training, and establishing clear reporting channels. Encourage staff to report any unusual occurrences promptly.

2. Documentation

Once an event is identified, it is crucial to document all relevant details. This includes the date, time, location, individuals involved, and a description of the incident. Accurate documentation is essential for analysis and reporting.

3. Assessment

Assess the severity and impact of the event. Determine whether it meets the criteria for reporting based on organizational policies and regulatory requirements. This assessment will guide the subsequent steps in the management process.

4. Reporting

If the event is deemed reportable, follow the established procedures for reporting. This may involve notifying internal stakeholders, regulatory bodies, or other relevant parties. Ensure that reports are submitted within the required timeframes to avoid penalties.

5. Investigation

Conduct a thorough investigation to understand the root cause of the event. This may involve interviews, data analysis, and reviewing existing policies and procedures. The goal is to identify areas for improvement and prevent recurrence.

6. Corrective Actions

Based on the findings from the investigation, implement corrective actions to address any identified issues. This may include revising policies, providing additional training, or enhancing safety measures.

7. Communication

Maintain open lines of communication with all stakeholders throughout the process. Provide updates on the status of the event, the investigation, and any corrective actions taken. Transparency is key to maintaining trust and accountability.

8. Review and Learn

After managing the event, conduct a review to evaluate the effectiveness of the response. Identify lessons learned and incorporate them into future training and policies. Continuous improvement is essential for effective event management.



Conclusion

Managing reportable events is a critical aspect of organizational risk management. By following the outlined steps and fostering a culture of transparency and accountability, organizations can effectively handle incidents, ensure compliance, and protect their reputation. Regular training and updates to policies will further enhance the ability to manage reportable events successfully.

Effective Management of Reportable Events



Definitions

GAHAR: General Authority for Healthcare Accreditation and Regulation.

Event\ Incident: Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards.

Adverse event: An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.

Preventable adverse event: An adverse event caused by an error or other type of systems or equipment failure.

Near-miss\ Close call: Serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. Also called potential adverse event or near accident.

Sentinel Events: An unexpected occurrence involving death or serious physical or psychological injury to a patient or patients, not arising from the natural course of the patient's illness, such as:

- Unexpected mortality or major permanent loss of function not related to the natural course of the patient' illness or underlying condition
- Wrong patient, wrong site, wrong procedure events
- Patient suicide, attempted suicide or violence leading to death or permanent loss of function
- Unintended retention of a foreign object events in a patient after surgery or invasive procedure
- Wrong delivery of radiotherapy
- Any peri-partum maternal death
- Any perinatal death unrelated to a congenital condition in an infant having a birth weight greater than 2,500 grams

Latent error\ Latent failure: A defect in the design, organization, training or maintenance in a system that leads to operator errors and whose effects are typically delayed. Many other terms have been used: adverse outcomes, mishaps, untoward or unanticipated events, etc.

Adverse drug event: A medication-related adverse event. Hazard: Any threat to safety, e.g. unsafe practices, conduct, equipment, labels, names.

Adverse drug reaction (ADR): A response to a medication which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.

Medication reconciliation: A formal process that has been demonstrated to improve the continuity of medicines management.

Risk assessment: The identification, evaluation, and estimation of the levels of risks involved in a situation, their comparison against benchmarks or standards, and determination of an acceptable level of risk.

Root cause analysis (RCA): A process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not on individual performance.

Blameworthy events: Events that are the result of criminal acts, patient abuse, alcohol or substance abuse on the part of the provider, or acts defined by the organization as being intentionally or deliberately unsafe.

Corrective Action Plan (CAP): A step-by-step plan of action that is developed to achieve targeted outcomes for resolution of identified errors in an effort to, identify the most cost-effective actions that can be implemented to correct error causes, develop and implement a plan of action to improve processes or methods so that outcomes are more effective and efficient, achieve measurable improvement in the highest priority areas, eliminate repeated deficient practices.

Healthcare facility: Facilities that provide health care services. They include, but are not limited to hospitals, clinics, outpatient care centers, primary healthcare centers, and specialized care centers.

Healthcare facility's governing body: In healthcare, it represents the individual(s), group, or agency that has ultimate authority, responsibility, and accountability for the overall strategic direction, methods of operations (management and planning), establishment of policies, maintenance of safety and quality of care provided by the hospital.

Safety Culture

In healthcare organizations, where the primary mission is to preserve and restore life, cultivating a robust safety culture is indispensable. A safety culture reflects the collective organizational commitment to prioritizing the well-being of patients and staff through shared values, open communication, and proactive risk mitigation. It serves as the cornerstone for minimizing medical errors—one of the leading causes of preventable harm globally. Beyond improving patient outcomes, a strong safety culture enhances staff morale and operational performance by embedding safety as an institutional ethic that transcends individual responsibility.

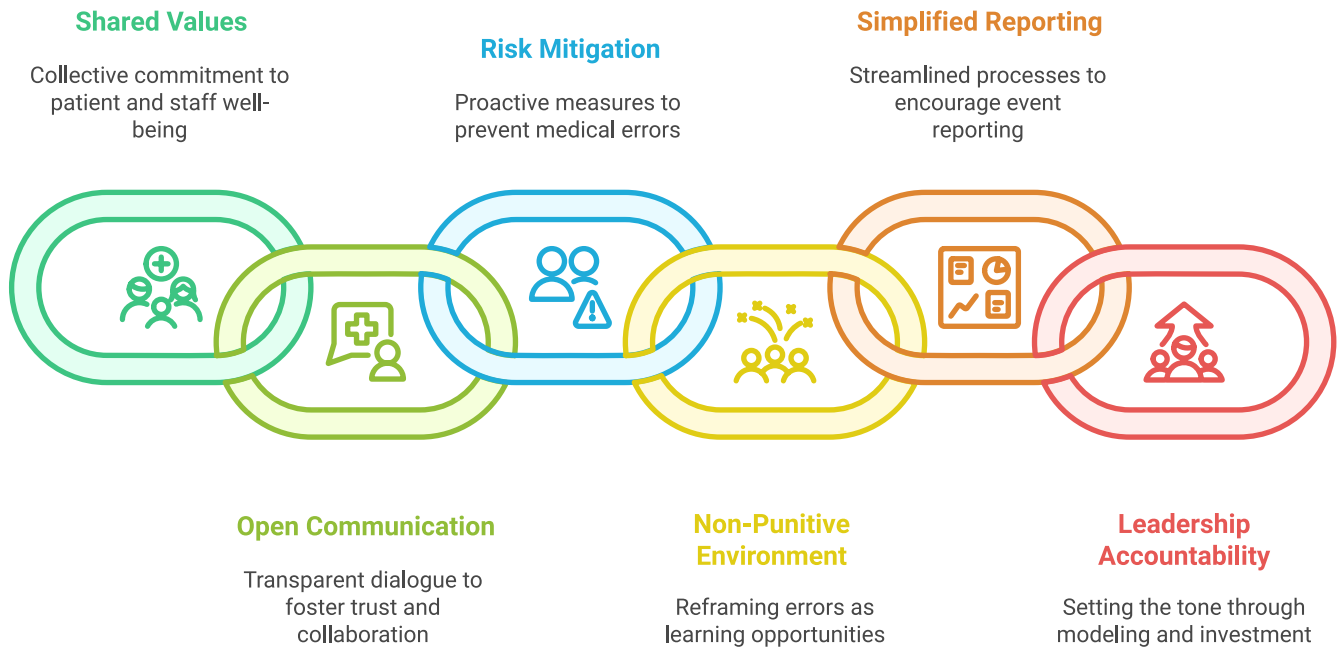
A critical component of such a culture is the systematic reporting of safety events with the potential to compromise care delivery. Yet, underreporting persists as a pervasive challenge, often driven by fear of blame, punitive repercussions, or skepticism regarding the utility of reporting. Addressing these barriers necessitates a comprehensive strategy: fostering a “non-punitive environment” that reframes errors as catalysts for organizational learning; simplifying reporting processes to minimize administrative burdens; and providing timely, meaningful feedback to underscore the value of staff contributions. Leadership is instrumental in this transformation, setting the tone by modeling accountability, investing in continuous professional development, and recognizing individuals and teams who actively advance safety initiatives.

When healthcare organizations empower employees to voice concerns without fear, they unlock critical insights that drive preventive strategies, transforming reactive practices into a culture of vigilance and trust. Ultimately, nurturing this environment not only mitigates risks but also reinforces the ethical mandate of healthcare: to do no harm while delivering compassionate, high-quality care.



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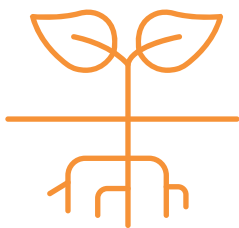
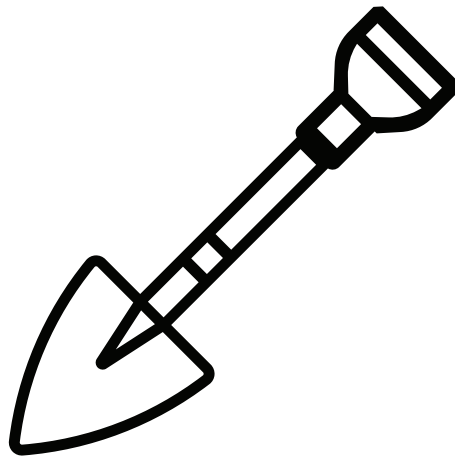
Foundations of Healthcare Safety



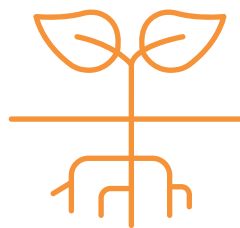
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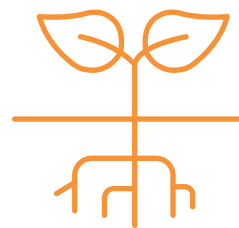
DIG FOR IT



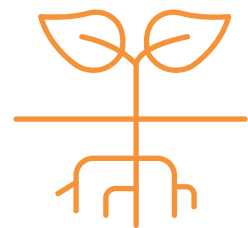
Trigger
tools



Near
miss



Significant
events



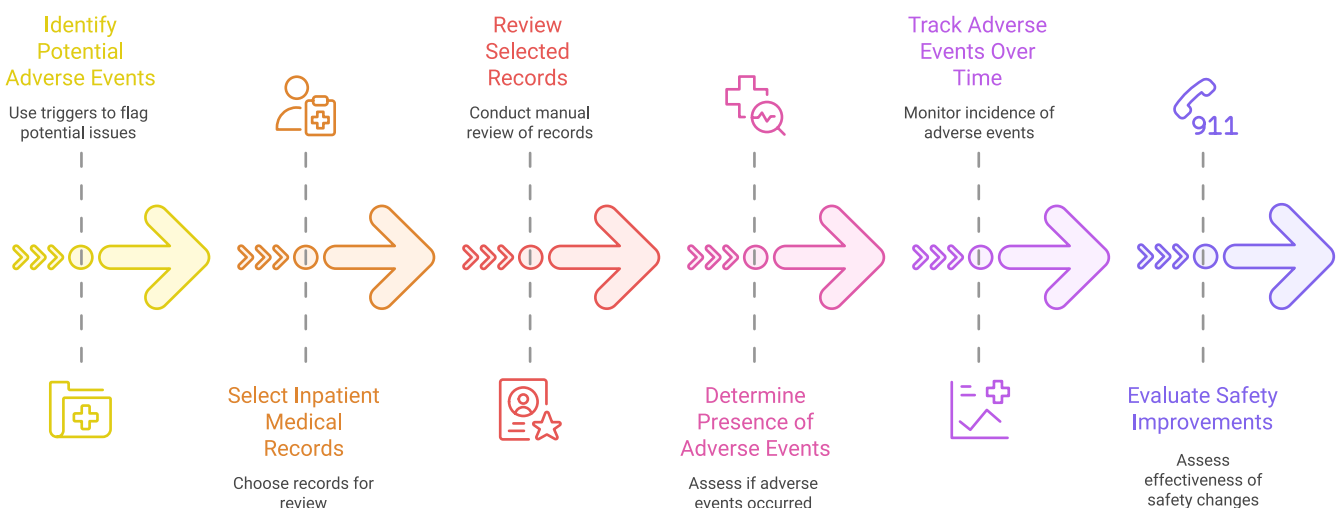
Sentinel
events

IHI trigger tool for measuring adverse events

The IHI Global Trigger Tool for Measuring Adverse Events offers a practical and reliable methodology for detecting adverse events (harm) and monitoring their incidence over time. Longitudinal tracking of adverse events provides valuable insight into whether implemented changes are effectively enhancing the safety of care delivery processes.

This methodology involves a retrospective analysis of a randomized sample of inpatient medical records, utilizing specific “triggers” or indicators as cues to identify potential adverse events. The process requires a manual review of closed inpatient records, those with finalized discharge summaries and coding. This section of the tool delineates the systematic approach for selecting and reviewing records and determining the presence of adverse events.

IHI Global Trigger Tool Process



Review Team

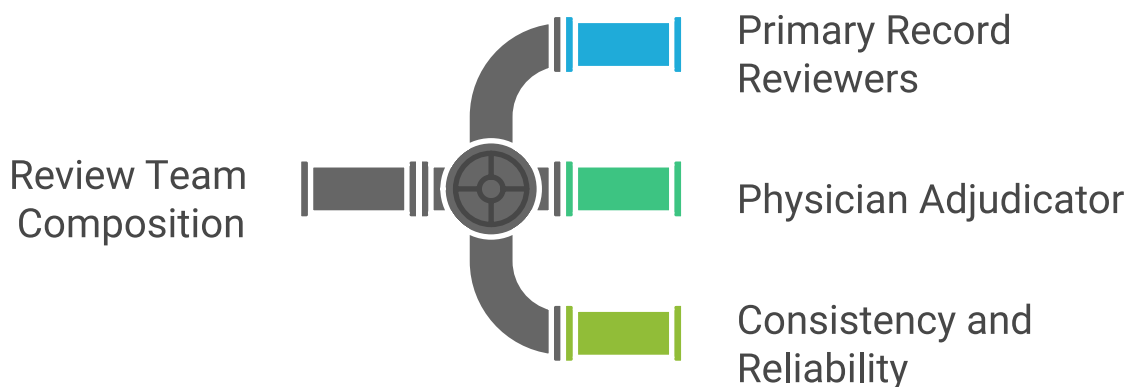
The review team should comprise, at a minimum, three members with complementary expertise:

Two primary record reviewers with clinical backgrounds and a thorough understanding of the hospital's medical records structure, as well as the typical patterns of care delivery within the institution. In practice, hospitals implementing the IHI Global Trigger Tool have often included nurses, pharmacists, and physicians on their review teams. While experienced nurses have demonstrated exceptional effectiveness in this role, alternative configurations of team members are also viable, as each professional contributes unique perspectives and expertise to the review process.

A physician reviewer who does not directly examine the medical records but serves as an adjudicator, validating the consensus of the two primary reviewers. This physician authenticates the identification of adverse events, assigns severity ratings, and addresses any clinical questions raised by the primary reviewers regarding specific cases.

For optimal consistency and reliability, the composition of the review team should remain stable over time whenever feasible. The team should convene at regular intervals to collectively review identified adverse events, aiming to detect and resolve discrepancies in event identification and severity grading between reviewers.

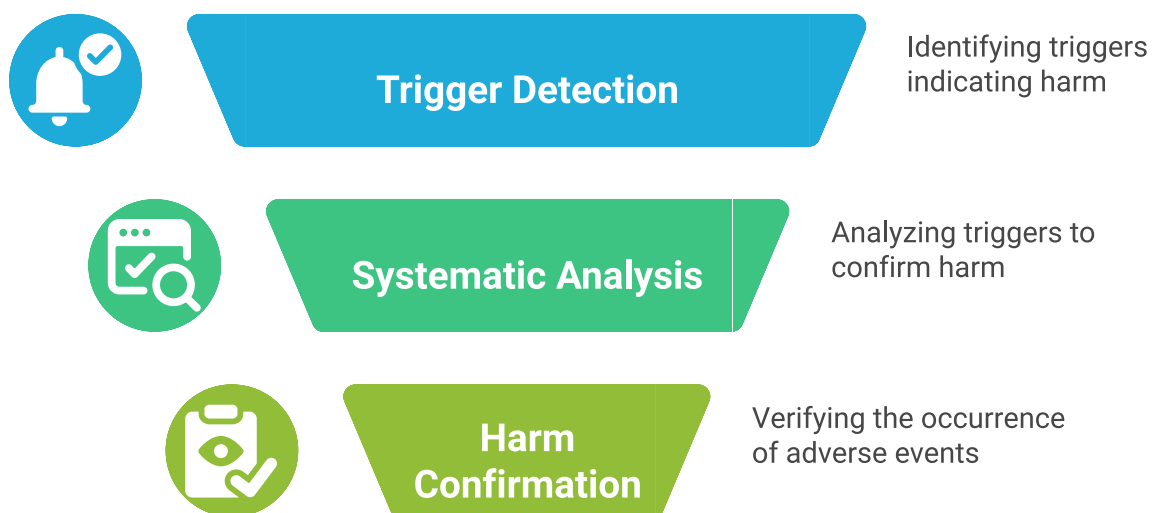
Unveiling the Review Team's Expertise



List of IHI trigger tool for measuring adverse events

The Institute for Healthcare Improvement (IHI) Trigger Tool is a valuable resource used by healthcare organizations to identify and measure adverse events in patient care. This document provides a comprehensive list of the triggers utilized in the IHI Trigger Tool, which helps in the systematic detection of potential harm to patients, thereby improving safety and quality in healthcare settings

Identifying Adverse Events in Healthcare



1. Emergency Department:

- Readmission to the ED within 48 Hours: Look for drug reactions, infections, or other reasons that events may have brought the patient back to the ED and then required admission.

Time in ED Greater than 6 Hours: Long ED stays in some cases can represent less than optimal care. Look for complications arising from the ED such as falls, hypotension, or procedure-related complications.

2. Blood Bank

- Any transfusion of packed red blood cells or whole blood should be investigated for causation, including excessive bleeding (surgical or anticoagulant-related), unintentional

trauma of a blood vessel.

- Transfusion of many units or beyond expected blood loss within the first 24 hours of surgery, including intra-operatively and post-operatively, will likely be related to a peri-operative adverse event.
- Patients receiving anticoagulants who require transfusion of fresh frozen plasma and platelets have likely experienced an adverse event related to the use of anticoagulants.

3. Lab

a) Decrease in Hemoglobin or Hematocrit of 25% or Greater

Any decrease of 25 percent or greater in hemoglobin (Hg) grams or hematocrit (Hct) should be investigated, especially when occurring in a relatively short period of time such as 72 hours or less.

- Bleeding events are commonly identified by this trigger and may be related to use of anticoagulants or aspirin or a surgical misadventure.
- The decrease in Hg or Hct in itself is not an adverse event unless related to some medical treatment. A decrease associated with a disease process is not an adverse event.

b) Coagulation profile

- Partial Thromboplastin Time (PTT) Greater than 100 Seconds
- Elevated PTT measurements occur when patients are on heparin. Look for evidence of bleeding to determine if an adverse event has occurred.
- Elevated PTT in itself is not an adverse event, there must be manifestation such as
- bleeding, drop in Hg or Hct, or bruising.
- International Normalized Ratio (INR) Greater than 6, Look for evidence of bleeding to determine if an adverse event has occurred. An elevated INR in itself is not an adverse event.
- Platelet Count Less than 50,000 Look for adverse events related to bleeding such
- as strokes, hematomas, and hemorrhage requiring blood transfusions. Look for information about why the platelet count decreased to see if it was as a result of a medication. Usually, a platelet transfusion is an indication that the patient has a low platelet count. Events related to transfusions or bleeding may indicate that an adverse event may have occurred.

c) Chemistry

i) Glucose Less than 50 mg/dl

- Review for symptoms such as lethargy and shakiness documented in nursing notes,

and the administration of glucose, orange juice, or other intervention. If symptoms are present, look for associated use of insulin or oral hypoglycemics. If the patient is not symptomatic, there is no adverse event.

ii) Rising BUN or Serum Creatinine Two Times (2x) over Baseline

- Review laboratory records for rising levels of either BUN or serum creatinine. If a change of two times greater than baseline levels is found, review medication administration records for medications known to cause renal toxicity.

Review physician progress notes and the history and physical for other causes of renal failure, such as pre-existing renal disease or diabetes, that could have put the patient at greater risk for renal failure; this would not be an adverse event, but rather the progression of disease.

d) Clostridium difficile Positive Stool

A positive C. difficile assay is an adverse event if a history of antibiotic use is present.

4. General Patient Safety

- Rapid Response Team Activation (Code, Cardiac or Pulmonary Arrest)
- Cardiac or pulmonary arrest intra-operatively or in the post anesthesia care unit should always be considered an adverse event. In the first 24 hours post-operatively, it is also very likely to be an adverse event.
- Patient Fall: A fall in a care setting represents a failure of care and may be the result of medications, equipment failure, or failure of adequate staffing.

Any fall in the care setting that causes injury, regardless of cause, is an adverse event; a fall without injury is not an adverse event. Falls resulting in injury and admission to the hospital should be reviewed for causation. A fall that is the result of medical treatment (such as from medications) should be considered an adverse event, even if the fall occurred outside the hospital.

- Pressure Ulcers: Pressure or decubitus ulcers are adverse events. Chronic decubiti are adverse events if they occurred during a hospitalization. If the ulcers occurred in the outpatient setting, consider the etiology (over-sedation, etc.) to assess if an adverse event occurred.
- Readmission within 30 Days: Any readmission, particularly within 30 days of discharge, could be an adverse event. An adverse event may not manifest itself until after the patient has been discharged from the hospital, especially if the length of stay is minimal. Examples of adverse events may include surgical site infection, deep vein thrombosis, or pulmonary embolism.
- In-Hospital Stroke: Evaluate the cause of the stroke to determine whether it is

associated with a procedure (e.g., surgical procedure, conversion of atrial fibrillation) or anticoagulation. When procedures or treatments have likely contributed to a stroke, this is an adverse event.

- **Transfer to Higher Level of Care:** Transfers to a higher level of care within the institution, to another institution, or to your institution from another must be reviewed. All transfers are likely to be the result of an adverse event and a patient's clinical condition may have deteriorated secondary to an adverse event. Look for the reasons for the transfer. For example, in the case of admission to intensive care following respiratory arrest and intubation, if the respiratory arrest was a natural progression of an exacerbation of chronic obstructive pulmonary disease (COPD), then it would not be an adverse event; if it was caused by a pulmonary embolism that developed post-operatively or resulted from over-sedation of a patient with COPD, it would be an adverse event. A higher level of care may include telemetry, intermediate care, or a step-down unit if the patient is transferred from a general medical or surgical nursing unit.
- **Development of a deep vein thrombosis (DVT) or pulmonary embolism (PE)** during a hospital stay in most cases will be an adverse event. Rare exceptions may be those related to disease processes such as cancer or clotting disorders. However, in most patients this is harm related to medical care, even if all appropriate preventive measures appear to have been taken.

If the hospitalization occurs due to a DVT or embolism, look for causation prior to admission that could be attributed to medical care such as a prior surgical procedure.

- **Restraint Use:** Whenever restraints are used, review the documented reasons and evaluate the possible relationship between the use of restraints and confusion from drugs, etc., which would indicate an adverse event.
- **Any Procedure Complication:** watch for complications noted in coding, the discharge summary, or other progress notes.

5. Acute Dialysis

A new need for dialysis may be the course of a disease process or the result of an adverse event. Examples of adverse events might be drug-induced renal failure or reaction to the administration of a dye for radiological procedures (investigate the cause of the new dialysis)

6. Medications:

- **Vitamin K Administration:** If Vitamin K was used as a response to a prolonged INR, review the record for evidence of bleeding. An adverse event has likely occurred if there are laboratory reports indicating a drop in hematocrit or guaiac-positive stools. Check

the progress notes for evidence of excessive bruising, gastrointestinal (GI) bleeding, hemorrhagic stroke, or large hematomas as examples of adverse events.

- **Diphenhydramine (Benadryl) Administration:** Diphenhydramine is frequently used for allergic reactions to drugs but can also be ordered as a sleep aid, a pre-op/pre-procedure medication, or for seasonal allergies. If the drug has been administered, review the record to determine if it was ordered for symptoms of an allergic reaction to a drug or blood transfusion administered either during the hospitalization or prior to admission, these are adverse event.
- **Romazicon (Flumazenil) Administration:** Romazicon reverses the effect of benzodiazepine drugs. Determine why the drug was used. Examples of adverse events are severe hypotension or marked, prolonged sedation.
- **Naloxone (Narcan) Administration:** Naloxone is a powerful narcotic antagonist. Usage likely represents an adverse event except in cases of drug abuse or self-inflicted overdose.
- **Anti-Emetic Administration:** Nausea and vomiting commonly are the result of drug administrations both in surgical and non-surgical settings. Anti-emetics are commonly administered. Nausea and vomiting that interferes with feeding, post-operative recovery, or delayed discharge suggests an adverse event. One or two episodes treated successfully with anti-emetics would suggest no adverse event. Reviewer judgment is needed to determine whether harm occurred.
- **Over-Sedation/Hypotension:** Review the physician progress, nursing, or multidisciplinary notes for evidence of over sedation and lethargy. Review vital signs records or graphics for episodes of hypotension related to the administration of a sedative, analgesic, or muscle relaxant. Intentional overdose is not considered an adverse event.
- **Abrupt Medication Stop:** Although the discontinuation of medications is a common finding in the record, abruptly stopping medications is a trigger requiring further investigation for cause. A sudden change in patient condition requiring adjustment of medications is often related to an adverse event. "Abrupt" is best described as an unexpected stop or deviation from typical ordering practice; for example, discontinuation of an intravenous antibiotic for switch to oral is not unexpected.
- **Terbutaline Use:** Use of terbutaline could result in an unnecessary intervention of a cesarean section that is created by the administration of a medication. Look for complicating factors. Use of terbutaline in pre-term labor is not a positive trigger.
- **Administration of Oxytocic Agents (such as oxytocin, methylergonovine, and 15-methyl-prostaglandin in the post-partum period):** Agents used to control post-partum hemorrhage, defined as blood loss greater than 500 ml for a vaginal delivery and

greater than 1,000 ml for a cesarean delivery. If standard administration of oxytocin occurs post-delivery, evaluate for administration amounts greater than 20 units in the immediate post-partum period.

7. Inpatients Events:

- **Pneumonia Onset:** Any pneumonia diagnosed in the ICU needs to be looked at carefully. If the evidence suggests the pneumonia started prior to admission to the hospital, there is no adverse event; but if the review suggests initiation in the hospital, it is an adverse event. In general, any infection starting in not only the intensive care unit but in any hospital, unit will be considered nosocomial. Readmissions either to the hospital or the intensive care unit could represent a nosocomial infection from a previous hospitalization.
- **In-Unit Procedure:** Any procedure occurring on a patient in the intensive care unit requires investigation. Look at all the bedside procedures and other procedures done while the patient was in the ICU. Complications will commonly not be on the dictated procedure note, but may be evident by the care required, which might indicate an event has occurred.
- **Intubation/Reintubation:** Anesthesia, sedatives, or pain medications can result in respiratory depression requiring the use of BiPap or reintubation post-operatively, which would be an adverse event.
- **Perinatal Module Triggers:** Only maternal records will be selected for review when using the IHI Global Trigger Tool; thus, only triggers related to documentation in the maternal record are included. Adverse events to neonates are not measured with this tool.
- **3rd- or 4th-Degree Lacerations:** By definition a 3rd- or 4th-degree laceration is an adverse event. Also look for additional events to the mother or child associated with the laceration as part of a cascade so appropriate severity can be assessed.

8. Operations:

- **Instrumented Delivery:** Instruments may cause injury to the mother, including bruising, trauma, and perineal lacerations.
- **Estimated Blood Loss Greater than 500 ml for Vaginal Delivery, or Greater than 1,000 ml for Cesarean Delivery:** The accepted limit for “normal” blood loss after vaginal delivery is 500 ml, and a blood loss of 1,000 ml is considered within normal limits after cesarean birth.
- **Return to Surgery:** A return to the operating room can either be planned or unplanned, and both can be a result of an adverse event. An example of an adverse event would be a patient who had internal bleeding following the first surgery and required a second

surgery to explore for the cause and to stop the bleeding. Even if the second surgery is exploratory but reveals no defect, this should be considered an adverse event.

- **Change in Procedure:** When the procedure indicated on the post-operative notes is different from the procedure planned in the pre-operative notes or documented in the surgical consent, a reviewer should look for details as to why the change occurred. An unexpected change in procedure due to complications or device or equipment failure should be considered an adverse event, particularly if length of stay increases or obvious injury has occurred.
- **Admission to Intensive Care Post-Operatively:** Admission to an intensive care unit can be either a normal post-operative journey or it may be unexpected. The unexpected admissions frequently are related to operative adverse events. For example, admission to intensive care following aortic aneurysm repair may be expected, but admission following knee replacement would be unusual. The reviewer needs to determine why intensive care admission occurred.
- **Intubation or Reintubation or Use of BiPap in Post Anesthesia Care Unit (PACU):** Anesthesia, sedatives, or pain medications can result in respiratory depression requiring the use of BiPap or reintubation post-operatively, which would be an adverse event.
- **X-Ray Intra-Operatively or in Post Anesthesia Care Unit:** Imaging of any kind that is not routine for the procedure requires investigation. An x-ray taken due to suspicion of retained items or incorrect instrument or sponge count would be a positive trigger. The identification of a retained item necessitating an additional procedure is an adverse event. If the retained item is identified and removed without any additional evidence of harm or re-operation to the patient, this is not considered an adverse event.
- **Intra- or Post-Operative Death:** All deaths that occur intra-operatively should be considered adverse events unless death is clearly expected and the surgery was of a heroic nature. Post-operative deaths will require review of the record for specifics, but in general all post-op deaths will be adverse events.
- **Mechanical Ventilation Greater than 24 Hours Post-Operatively:** Short-term mechanical ventilation post-operatively for cardiac, major thoracic, and certain abdominal procedures is planned. If the patient requires mechanical ventilation beyond 24 hours, an intra-operative or post-operative adverse event should be considered. Patients with pre-existing pulmonary or muscular disease may experience more difficulty in quickly weaning from a ventilator post-operatively, but this should not automatically exclude the possibility of an adverse event. Reviewers must use clinical judgment to determine whether the intra-operative and post-operative care was event free or part of the disease process.
- **Intra-Operative Administration of Epinephrine, Norepinephrine, Naloxone, or**

Romazicon: These medications are not routinely administered intra-operatively. Review anesthesia and operative notes to determine the reason for administration. Hypotension caused by bleeding or over-sedation are examples of adverse events that might be treated with these medications.

- Injury, Repair, or Removal of Organ During Operative Procedure: Review operative notes and post-operative notes for evidence that the procedure included repair or removal of any organ. The removal or repair must be part of the planned procedure or this is an adverse event and likely the result of surgical misadventure such as an accidental injury.
- Occurrence of Any Operative Complication: This refers to any of a number of complications, including but not limited to PE, DVT, decubiti, MI, renal failure, etc.
- Post-Operative Increase in Troponin Levels Greater than 1.5 Nanogram/ml: A post-operative increase in troponin levels may indicate a cardiac event. Reviewers will need to use clinical judgment as to whether a cardiac event has occurred.

9. Healthcare-Associated Infections:

Any infection occurring after admission to the hospital is likely an adverse event, especially those related to procedures or devices. Infections that cause admission to the hospital should be reviewed to determine whether they are related to medical care (e.g., prior procedure, urinary catheter at home or in long-term care) versus naturally occurring disease (e.g., community-acquired pneumonia).

List of reportable sentinel events

1. VTE (Venous thromboembolism):

Definition:

It is a Serious Adverse Event, including deep vein thrombosis (DVT) and pulmonary embolism (PE). VTE is considered a serious medical event due to its potentially life-threatening complications if not treated promptly.

Inclusion Criteria:

- Patients diagnosed with venous thromboembolism (VTE), including: DVT & PE.
- Age group: Adults aged 18 years and older.
- Occurrence of VTE as a serious adverse event:
 - ◆ During hospitalization.
 - ◆ Following surgical procedures or prolonged immobilization.
 - ◆ Associated with medication use (e.g., hormonal therapy, chemotherapy).
- Confirmed diagnosis by imaging (e.g., Doppler ultrasound, CT pulmonary angiography).
- Patients who experienced VTE within a specified time frame, for example, within 30 days of hospitalization or surgical procedure.

Exclusion Criteria:

- Patients with superficial vein thrombosis only, without deep vein involvement.
- Pediatric patients (under 18 years of age).
- Patients with a previous history of chronic VTE, unless this is a new, acute episode.
- Cases without confirmed imaging or laboratory diagnosis of VTE.
- Patients with incomplete or missing data relevant to the VTE event.

2. Medication error leading to death, permanent, or severe temporary harm:

Definition:

This event is intended to capture all medication error cases resulting in death, permanent harm, or severe temporary harm, such as errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong preparation, or wrong route of administration.

Inclusion:

- Medication errors include, but are not limited to, death, permanent or severe temporary harm associated with:

- Administration of the wrong dose, including over or under-dosing.
- Administration of a medication to a patient with a known allergy to the drug or one of its components, the failure to check/review the patient's allergies before administration, or the failure to record/retrieve a patient's allergy information before administration.
- Drug interactions or contraindications with known potential risk.
- Failure to administer prescribed medications, e.g., missed doses or missed medication.
- Wrong route of administration.

Exclusion:

- Medication errors related to unknown allergies.

3. Any (stage 3, 4 or unstageable) healthcare facility- acquired pressure injury (ulcer):

Definition:

This event is intended to capture any stage 3, 4, or unstageable pressure injury acquired after patient admission.

Inclusion:

- All stage 3, 4, or unstageable pressure injury cases acquired after patients' admission.
- This includes the following stages:
 - Stage 3 Pressure Injury: Full-thickness skin loss (reaching the fat layer).
 - Stage 4 Pressure Injury: Full-thickness skin and tissue loss (reaching muscles and bones).
 - Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss.

Exclusion:

- Progression from stage 2 to stage 3, if stage 2 was recognized upon admission.

4. Patient death, permanent harm, or severe temporary harm as a result of patient fall:

Definition:

This event is intended to capture patient death, permanent harm, or severe temporary harm associated with patient falls while being cared for within a healthcare facility.

Inclusion:

- Patients admitted within a healthcare facility, including day surgery and emergency department.
- Cases due to the failure of performing patient fall's risk assessment/identification.
- Failure to monitor/manage patients identified as "at fall risk."

Exclusion: None.

5. Death, permanent, or severe temporary harm associated with the use of incorrectly positioned orogastric or nasogastric tube event description:

Definition:

- This event is intended to capture all instances of death, permanent harm, or severe temporary associated with the use of a misplaced nasogastric or orogastric tube.
- All cases where a nasogastric or orogastric tube is accidentally inserted into the pleura or respiratory tract and not detected before starting a feed, flush, or medication administration.

Exclusion: None.

6. Administration of incompatible ABO, Non-ABO of blood/ blood products, or transplantation of incompatible organs:

Definition:

This event is intended to capture cases involving the unintentional administration of incompatible ABO, non-ABO of blood/blood products, or transplantation of incompatible organs.

Inclusion:

All cases involving the administration of incompatible blood/blood products or organs.

Exclusion: None.

7. Transfusing/transplantation of contaminated blood, blood products, organ or tissue:

Definition:

This event is intended to capture all cases of disease transmission associated with the infusion of contaminated blood, blood products, organs, or tissues.

Inclusion:

All cases of transfusing/transplantation of contaminated blood, blood products, organs, or tissues.

Exclusion: None.

8. Surgery/invasive procedures performed at the wrong site, on the wrong patient, or the wrong procedure:

Definition:

This event is intended to capture all surgical/invasive procedures performed on the wrong

patients, wrong site, or wrong procedure regardless of whether death, permanent harm, or severe, temporary harm has occurred or not.

Inclusion:

Any surgical/invasive procedure performed on the wrong patient, wrong site, or wrong procedure.

Exclusion: None.

9. Unintended retention of a foreign object in a patient after surgical/invasive procedure:

Definition:

This event is intended to capture all cases involving the unintended retention of a foreign object in a patient after surgery or other invasive procedure regardless of whether death, permanent harm, or severe, temporary harm occurred or not.

Inclusion:

- All cases involving the unintended retention of a foreign object in a patient, regardless of whether the retained object was discovered within a healthcare facility during hospitalization, post-procedure or post-discharge.
- Any item is subject to a formal counting/checking process at the start of a surgical/invasive procedure and before completing the procedure, such as swabs, needles, instruments, and guidewires.

Exclusion:

Any object left for medical reasons in a patient, e.g., sutures, stents, implants, and medical devices.

10. Maternal death, permanent harm, or severe, temporary harm

Definition:

This event is intended to capture death, permanent harm, or severe, temporary harm cases of women while pregnant or within 42 days of the termination of pregnancy.

Inclusion:

Any cause related to or aggravated by the pregnancy or its management.

Exclusion:

Cases that were not related to the birth process or due to pre-existing conditions.

11. Unanticipated death of a “term” infant:

Definition:

This event is intended to capture all unanticipated death cases of a “term” infant during the birth process.

Inclusion:

- All cases include the unanticipated death of a “term” infant during the birth process.
- All term pregnancies, according to the definition of the International Classification of Diseases delivered between 37 weeks 0 days and 41 weeks 6 days.

Exclusion:

- The death of a “term” infant was related to congenital abnormalities.
- Pregnancies resulting in fetal demise before 37 weeks of gestation.
- Terminations of pregnancy for life-limiting fetal anomalies, or inductions of labor for previable premature rupture of membranes.

12. Death or serious disability associated with failure to manage/identify neonatal hyperbilirubinemia.

Definition:

This event is intended to capture all cases when death or serious disability is associated with neonatal hyperbilirubinemia.

Inclusion:

All death or disability cases (e.g., Kernicterus) resulted from failure to identify/re-assess or manage neonatal hyperbilirubinemia.

Exclusion: None.

13. Discharge of an infant to the wrong family.

Definition:

This event is intended to capture all cases where an infant was discharged to the wrong parent/legal guardian regardless of whether death, permanent harm, or severe, temporary harm occurred or not.

Inclusion:

All incidents where an infant is discharged to the wrong parent/legal guardian

Exclusion: None.

14. Discharge of a Minor or Incapacitated Patient to an unauthorized person.

Definition:

This event is intended to capture all cases where a minor or incapacitated patient was

discharged to an unauthorized parent/legal guardian regardless of whether death, permanent harm, or severe, temporary harm has occurred or not.

Inclusion:

All incidents due to failure to discharge to the correct family, parents, or legal guardian.

Exclusion: None.

15. Abduction of any individual within a healthcare facility

Definition:

This event is intended to capture all instances when an individual of any age are abducted from a healthcare facility regardless of whether death, permanent harm or severe and temporary harm occurred or not.

Inclusion:

Abduction cases for any patients, whether under care or receiving care of any age group and health conditions (i.e., regardless of a patient's health condition) or any individual within a healthcare facility's premises/campus.

Exclusion:

Areas outside of the premises/campus of a healthcare facility.

16. Suicide, attempted suicide, or self-harm that results in severe, temporary harm, permanent harm, or death while being cared for in a healthcare setting:

Definition:

This event is intended to capture all cases of suicide, attempted suicide, or self-harm while being under care in any healthcare facility.

Inclusion:

- Any patient identified as “at risk of suicide” and/or discharged from a healthcare facility without proper assessment/family education.
- Failure to assess and/or identify a patients’ risk of suicide.
- Failure to manage/monitor patients “at risk of suicide” during an inpatient stay, or failure to educate a patient’s family about the suicidal risk upon discharge.

Exclusion: None.

17. Rape leading to death, permanent harm, or severe, temporary harm of a patient, staff member, licensed independent practitioner, visitor, or vendor while on-site at the healthcare facility:

Definition:

This event is intended to capture all cases of rape of a patient, staff member, licensed independent practitioner, visitor, or vendor within a healthcare facility that led to death, permanent harm, or severe, temporary harm or homicide cases.

Inclusion:

All rape cases encountered within the premises/campus of a healthcare facility

Exclusion: None.

18. Assault leading to death, permanent harm, or severe, temporary harm, or homicide of a patient, staff member, licensed independent practitioner, visitor, or vendor while on-site at the healthcare facility:

Definition:

This event is intended to capture all assault and homicide cases for patients, staff members, visitors, or vendors within the premises/campus of a healthcare facility that led to death, permanent harm, or severe temporary harm or homicide cases.

Inclusion:

All assault and homicide cases within the premises/campus of a healthcare facility.

Exclusion: None.

19. Patient death, permanent, or severe temporary harm associated with intravascular air embolism:

Definition:

This event is intended to capture all cases where patient death, permanent harm, or severe temporary harm was associated with air embolism.

Inclusion:

- High-risk procedures, including but not limited to procedures involving the head and neck, vaginal delivery and cesarean section, spinal instrumentation procedures, and liver transplantation.
- Low-risk procedures, including those related to the placement of infusion lines in a vascular space.

Exclusion: None.

20. Unauthorized departure of the patient (absconded) while on care from the healthcare facility that resulted in death, permanent harm, or severe temporary harm:

Definition:

This event is intended to capture all death, permanent harm, or severe temporary harm cases associated with a patient leaving a healthcare facility without the knowledge/authorization of the healthcare facility staff.

Inclusion:

All patients who leave a healthcare facility (including emergency care) while being cared for without the healthcare facility staff's knowledge/authorization.

Exclusion: None.

21.Unexpected death, permanent or severe temporary harm associated with transport/transfer of patients:

Definition:

This event is intended to capture all death, permanent, or severe temporary harm associated with the transport or transfer of patients.

Inclusion:

All cases of transport or transfer inside or outside the healthcare facility premises, where protocols were not followed.

Exclusion: None.

22.Delivery of radiotherapy to the wrong body region or dose exceeds more than 25% of the total planned radiotherapy dose.

Definition:

This event is intended to capture all cases where radiotherapy dose was delivered to the wrong body region or when the dose exceeds more than 25% of the total planned dose.

Inclusion:

This event includes radioisotope therapy and radiation producing machines when doses are delivered incorrectly.

Exclusion: None.

23.Accidental burn of second degree and above during patient care:

Definition:

This event is intended to capture all cases of second-degree burns or above that occur during patient care.

Inclusion:

- Inpatient and ambulatory care accidental burn due to, but not limited to, heat, electrical discharge, friction, chemicals, and radiation.

- The following classification of burns based on the American Burn Association:
 1. Second Degree (Partial Thickness): Skin may be red, blistered, swollen. Very painful.
 2. Third Degree (Full Thickness): Whitish, charred, or translucent, with no pinprick sensation in a burned area.

Exclusion: None.

24. Transmission of disease as a result of using contaminated instruments or equipment provided by the healthcare facility.

Definition:

This event is intended to capture all cases of disease transmission after using contaminated devices, instruments, or equipment regardless of the source of contamination.

Inclusion:

- All cases of disease/infection transmission.
- Inpatients and Ambulatory care services.

Exclusion: None.

25. Patient death, permanent harm, or severe temporary harm associated with wrong administration/connection of medical gas:

Definition:

This event is intended to capture all death, permanent harm, or severe temporary harm cases associated with the administration/connection of the wrong medical gas.

Inclusion:

Incidents where systems designated to deliver medical gas to a patient contain no gas or the wrong gas.

Exclusion: None.

26. Patient death, permanent, or severe temporary harm as a result of medical device breakdown or failure when in use:

Definition:

This event is intended to capture all cases of death, permanent or severe temporary harm as a result of medical devices failure within healthcare facilities.

Inclusion:

All medical devices.

Exclusion: None.

27. Fire, flame, or unanticipated smoke, or flashes occurring within a healthcare facility:

Definition:

This event is intended to capture all fire, flame, unanticipated smoke, or flashes that occur within a healthcare facility regardless of whether death, permanent harm, or severe temporary harm occurred or not.

Inclusion:

All fire, flame, unanticipated smoke, or flashes that occur within a healthcare facility.

Exclusion: None.

28. The unexpected collapse of any building within a healthcare facility:

Definition:

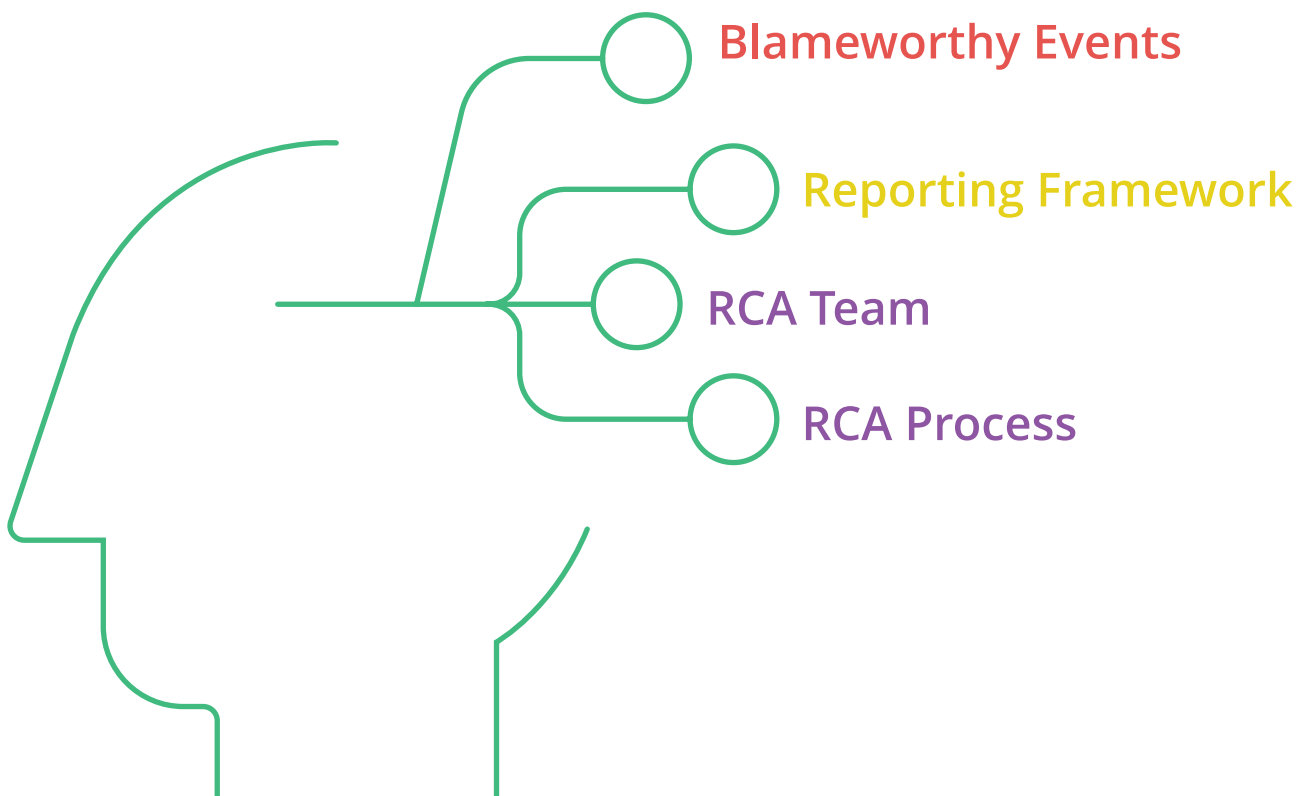
- This event is intended to capture all cases of unexpected building or construction collapse within the premises/campus of a healthcare facility regardless of whether death, permanent or severe temporary harm occurred or not.
- All buildings within the premises/campus of a healthcare facility, including structures under renovation or construction.

Exclusion: None.

CHAPTER (3)



THINK TWICE



Events Appropriate for RCA Review Versus Blameworthy Events

Establishing trust both within the organization and among the broader community is pivotal to fostering a culture of safety. Reports of hazards, vulnerabilities, and adverse events serve as the essential drivers of the patient safety improvement process. An organization cannot address problems that remain undisclosed; however, fear of negative repercussions—whether for individuals, their colleagues, or the institution—often acts as a significant barrier to reporting. Therefore, it is imperative to cultivate trust among staff by developing clear policies based on transparent rationales and ensuring these are effectively communicated to all stakeholders, including patients and the community. When an organization publicly commits to concrete actions for advancing patient safety, it reinforces its accountability to the community it serves.

Once an environment that encourages reporting and supports a no-blame culture has been established, it becomes equally important to delineate and address blameworthy events. Each organization must clearly define which behaviors and actions are considered blameworthy and subject to administrative or human resource interventions.

When a Root Cause Analysis (RCA) team identifies, or suspects, that an incident may be blameworthy, the team should promptly escalate the matter to the convening authority for appropriate handling in accordance with organizational policy.

Establishing Trust and Addressing Blameworthy Events



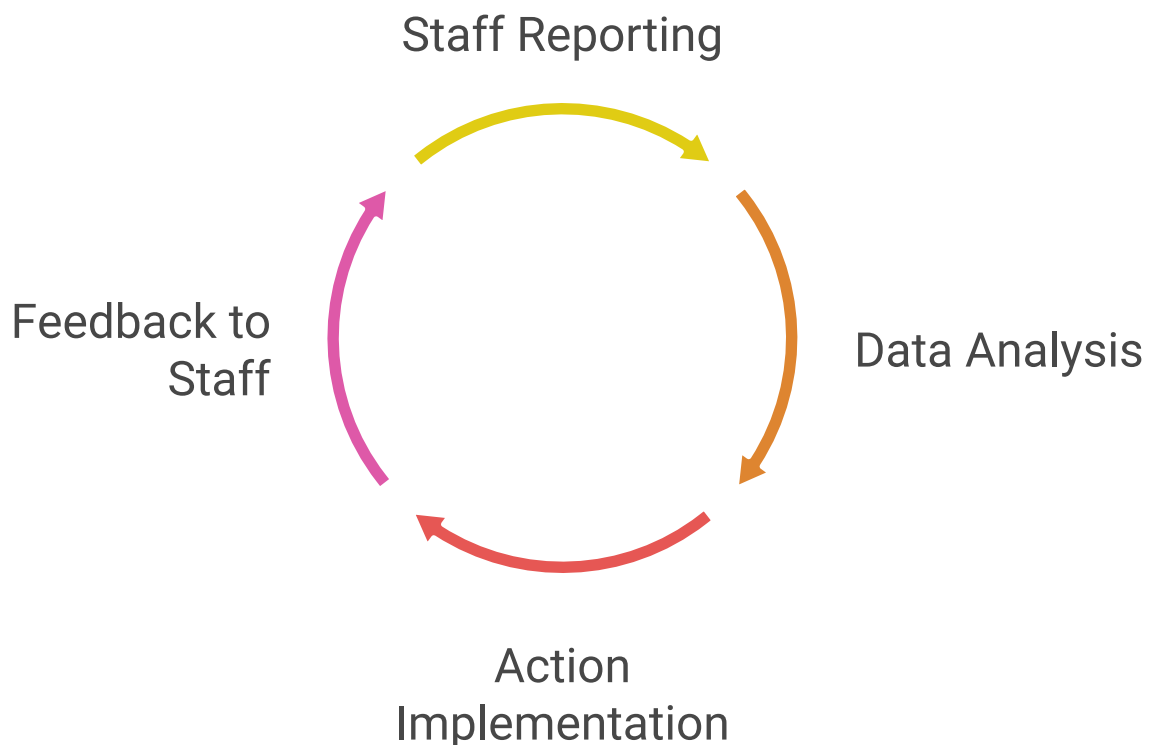
Referral of an event to the convening authority does not mean that the opportunity to learn from it has been lost or that no action will ultimately be taken. Referral just means that the primary responsibility to fully look into the event and formulate and implement corrective actions is assumed by a different organizational entity that will not only look for systems-based solutions, as should be the case with any safety investigation, but may also take actions that are directed at a specific individual. Doing so preserves the integrity of a safety system that has committed to using safety activities for system improvement, not for individual punitive action.

Safety System Improvement Cycle



For a risk-based prioritization system to function effectively, it must rely on consistent reporting of adverse events, near misses, hazards, and system vulnerabilities by staff. A lack of such reports undermines the organization's ability to accurately assess the likelihood of future events or hazards. Addressing this challenge requires a multifaceted approach: educating staff on the importance of reporting, simplifying reporting processes to reduce barriers, demonstrating visible organizational action in response to reported issues, and providing timely feedback to reporters. When staff recognize that their contributions lead to tangible safety improvements, they are more likely to engage in reporting. Importantly, even reports that do not culminate in a formal Root Cause Analysis (RCA) remain invaluable for identifying trends and informing proactive measures to enhance patient safety.

Cycle of Risk-Based Prioritization



This document seeks to clarify the distinction between events that necessitate a Root Cause Analysis (RCA) and those deemed blameworthy. Recognizing this differentiation is essential for organizations striving to strengthen their processes and cultivate a culture of learning rather than blame. By appropriately delineating the circumstances that warrant an RCA, organizations can improve their capacity to prevent the recurrence of adverse events and foster a more proactive, solutions-oriented approach to patient safety and quality improvement.

How should organizations respond to adverse events?



RCA Events

Focus on prevention and improvement



Blameworthy Events

Focus on accountability and justice

Events Appropriate for RCA Review

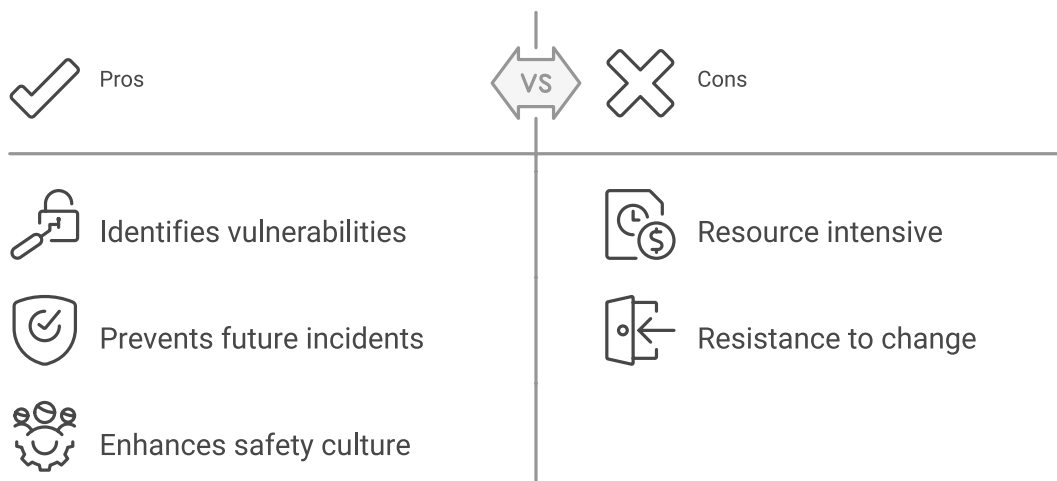
1. System Failures: Events that result from systemic issues, such as process breakdowns or equipment malfunctions, should be reviewed through RCA. These failures often indicate underlying problems that need to be addressed to prevent recurrence.

System failures are often symptoms of deeper issues.



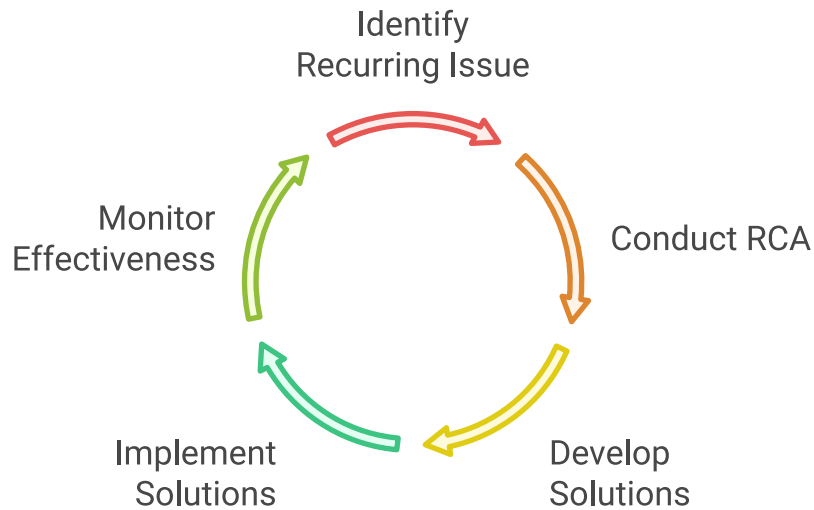
2. Near Misses: Incidents that nearly resulted in harm but did not cause actual damage or injury are prime candidates for RCA. Analyzing these events can help organizations identify vulnerabilities and implement preventive measures.

RCA for near misses



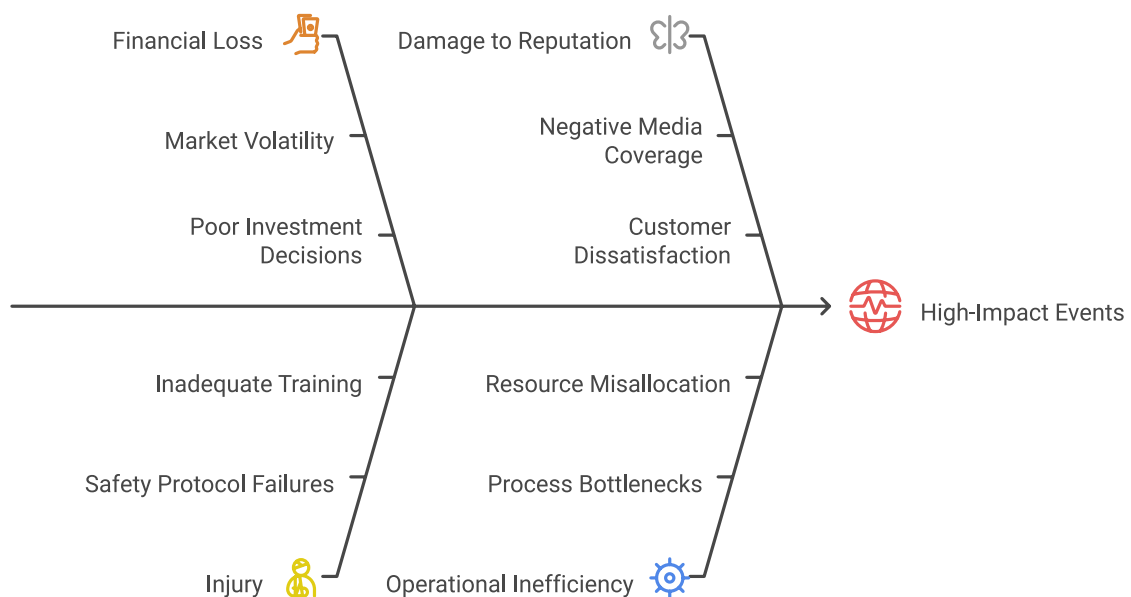
3. **Recurring Issues:** If a specific problem occurs multiple times, it is essential to conduct an RCA to uncover the root causes. This approach helps in developing long-term solutions rather than temporary fixes.

Cycle of Root Cause Analysis for Recurring Issues



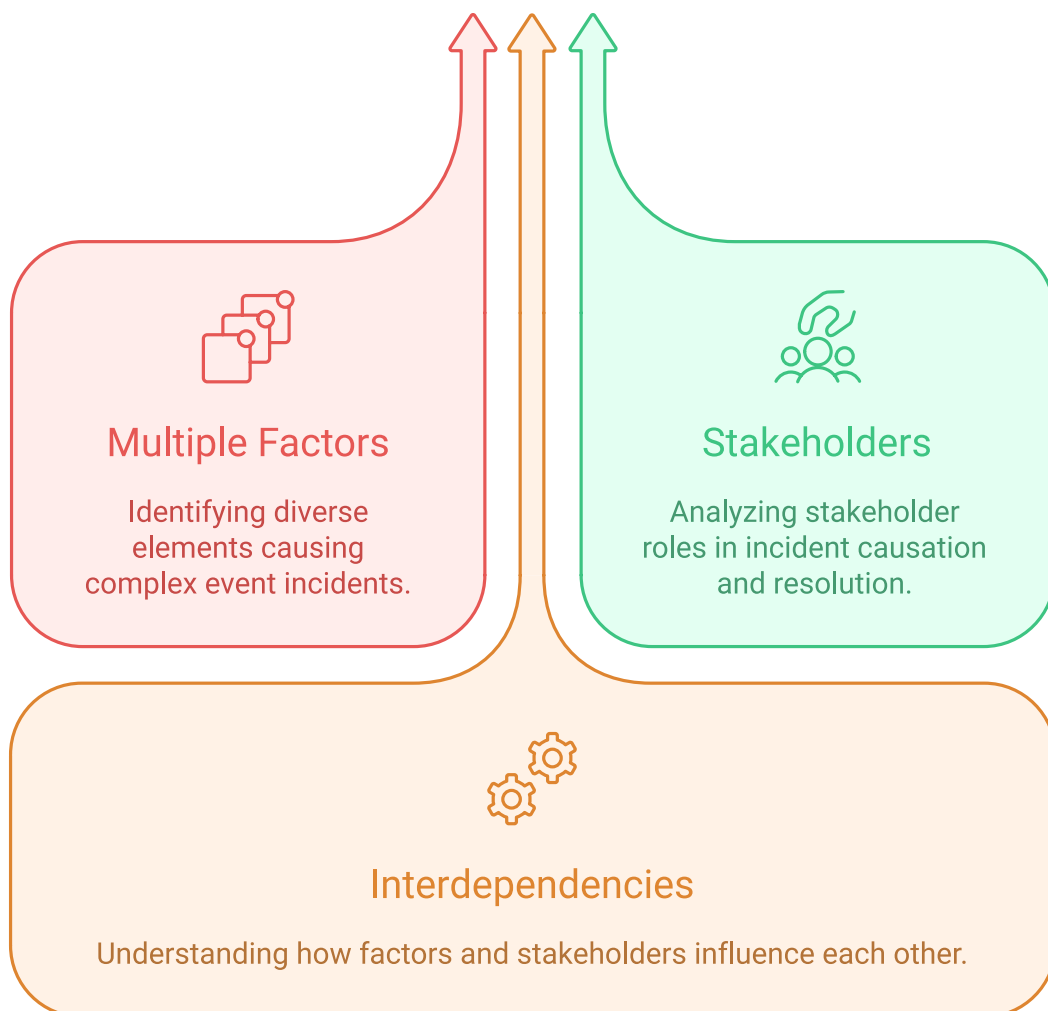
4. **High-Impact Events:** Any event that has significant consequences, such as financial loss, injury, or damage to reputation, should be subjected to RCA. The insights gained can lead to substantial improvements in safety and operational efficiency.

Analyzing High-Impact Events for Improvement



5. **Complex Events:** Situations involving multiple factors or stakeholders that contribute to an incident are suitable for RCA. These analyses can reveal interdependencies and help streamline processes.

Unraveling Complex Events



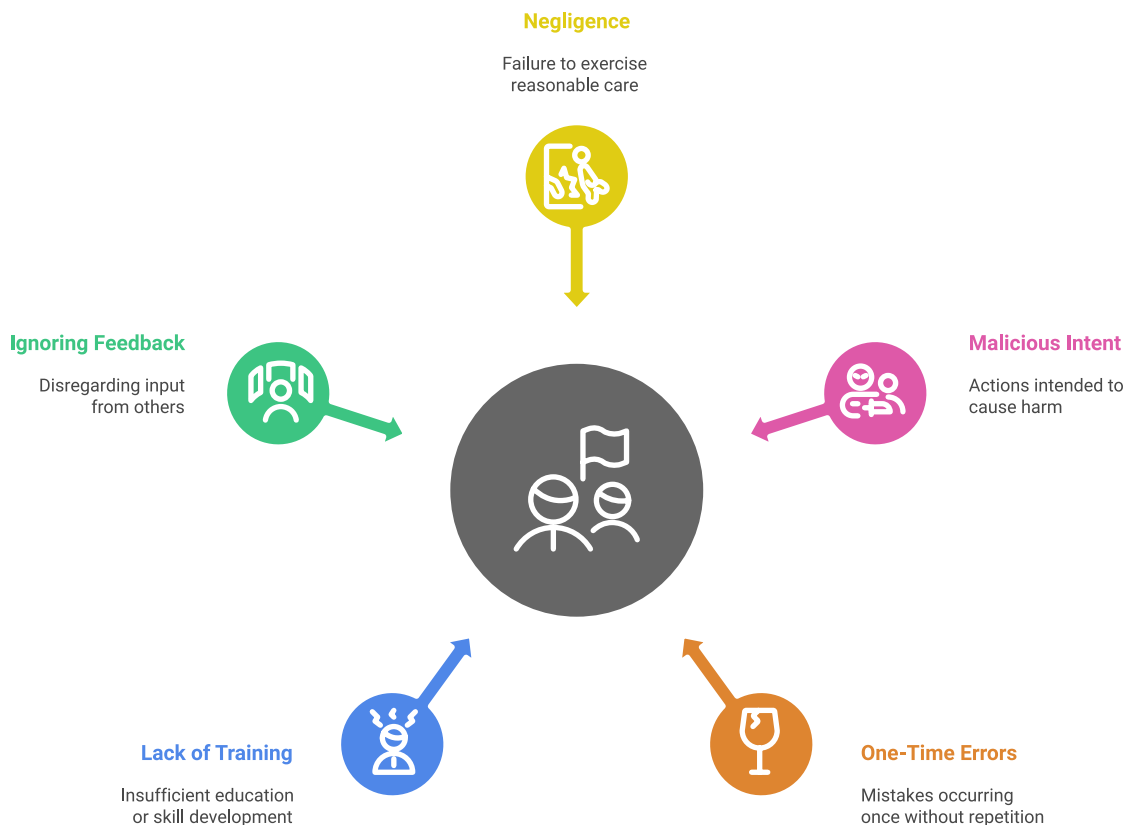
Events for RCA Review



Blameworthy Events

It is important to clearly define blameworthy events in each facility, such as negligence, malicious intent, one-time errors, lack of training and ignoring feedback>

Factors Leading to Blameworthy Events

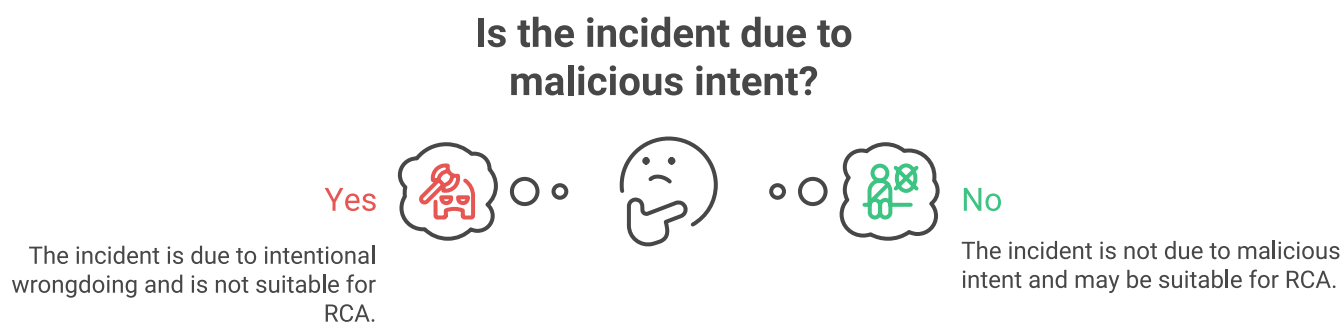


1. **Negligence:** Events resulting from an individual's failure to follow established protocols or guidelines due to carelessness or disregard for safety should be viewed as blameworthy. These situations often require disciplinary action rather than RCA.

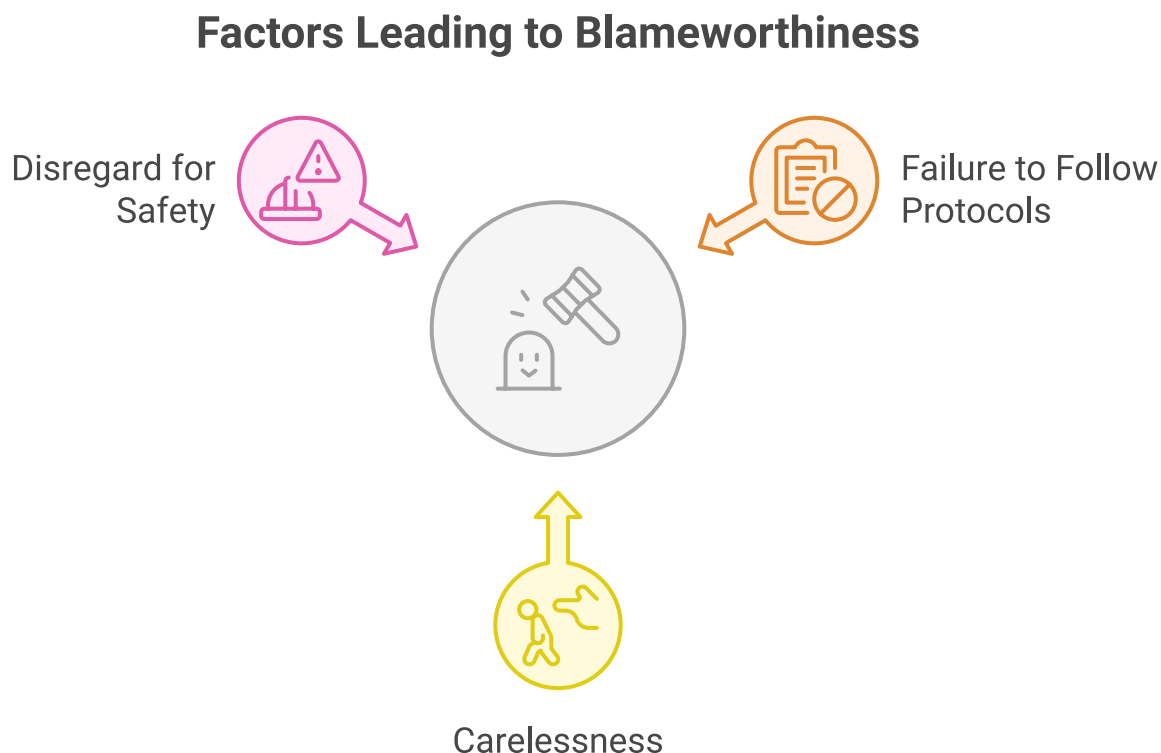
Is the incident due to malicious intent?



2. **Malicious Intent:** Any incident caused by intentional wrongdoing or sabotage falls into the blameworthy category. These events are not suitable for RCA as they do not stem from systemic issues.

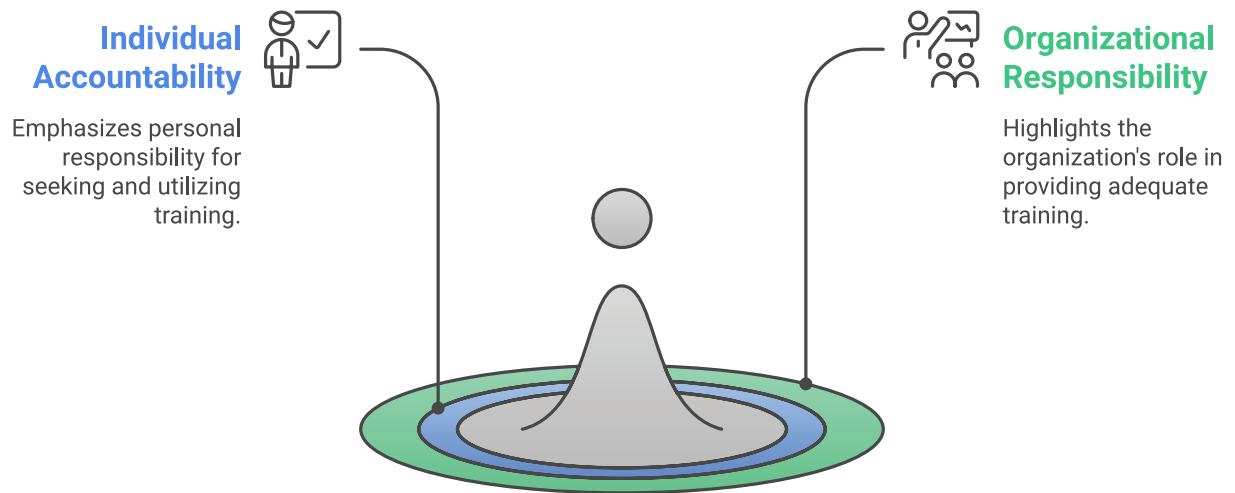


3. **One-Time Errors:** Isolated mistakes that do not indicate a pattern or systemic problem may be considered blameworthy. While learning from these events is important, they do not typically require an RCA.

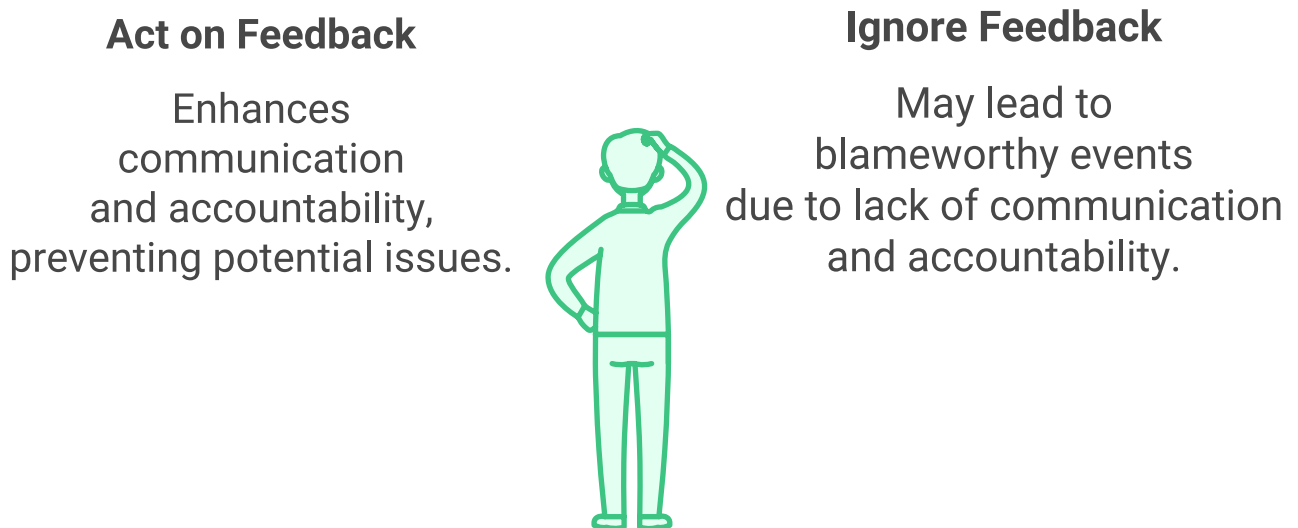


4. **Lack of Training:** If an event occurs due to an individual's failure to seek or receive necessary training, it may be seen as blameworthy. Organizations should ensure proper training is provided, but individual accountability is also essential.

Training and Accountability



5. **Ignoring Feedback:** Events that arise from an individual's refusal to act on feedback or warnings from colleagues can be categorized as blameworthy. These situations highlight the importance of communication and accountability.



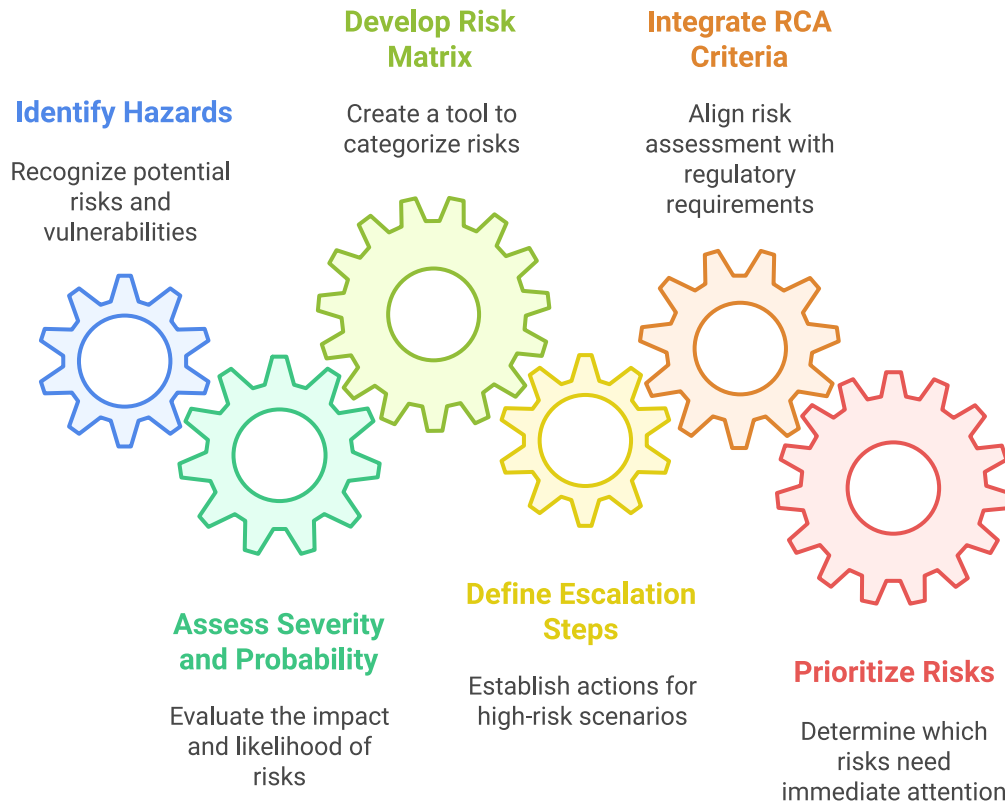
Risk-Based Prioritization of Events, Hazards, and System Vulnerabilities

Given that the resources required to identify, analyze, and mitigate hazards are inherently limited, it is imperative for organizations to adopt a risk-based prioritization framework. Such a system enables credible and efficient determination of which hazards demand immediate attention. Unlike harm-based approaches—which remain the most widely utilized and prioritize events only after patient harm has occurred, a risk-based prioritization system emphasizes proactive identification and management of hazards and vulnerabilities before they result in adverse outcomes. By addressing potential risks preemptively, organizations can effectively reduce the likelihood of harm and strengthen overall patient safety.

Risk-based selection criteria should incorporate both the outcome severity or consequence and its probability of occurrence.

An effective approach to implementing risk-based prioritization is the development of a risk matrix with clearly defined and consensus-based criteria for severity (or consequence) and likelihood of occurrence. This matrix should also include predefined escalation steps to be activated when organizationally established thresholds are met. By integrating definitions of severity or consequence that align with events or outcomes requiring Root Cause Analysis (RCA) as mandated by accrediting bodies, the matrix facilitates both regulatory compliance and the operationalization of the process. Furthermore, the origin of information, whether from safety reports or other sources—is secondary, provided that sufficient data is available to support prioritization through a structured, explicit risk-based tool.

Risk-Based Prioritization Process



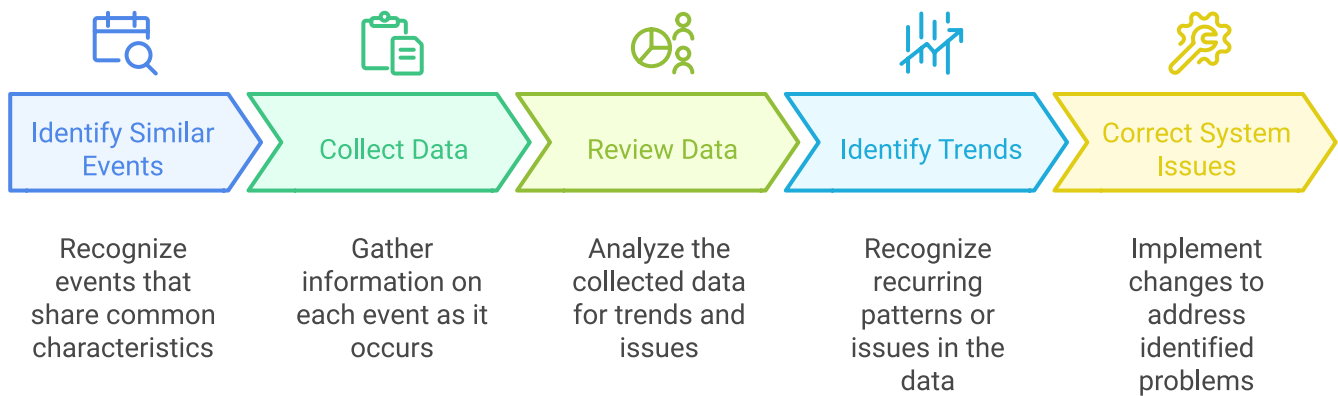
The actual implementation of the prioritization system should be performed by an individual and not a committee; an explicit, well-devised prioritization system should not require group deliberation. Also, the efficiency of the process is enhanced and needless inertia is eliminated when prioritization for hazards does not have to wait for a group to be convened and to deliberate.

Close calls (also called near misses or good catches) should also be prioritized using the risk matrix by asking what a plausible severity or consequence for the event, hazard, or vulnerability is, coupled with the likelihood or probability of the event/hazard scenario occurring. This plausible outcome is then used as the severity or consequence when applying the risk matrix to determine the appropriate response (RCA or other actions). Some may believe that since there was no patient injury, close calls do not need to be reported or investigated. However, close calls occur 10 to 300 times more frequently than the actual harm events they are the precursors of and provide an organization the opportunity to identify and correct system vulnerabilities before injury or death occurs.

Aggregated Review:

It is a process of analyzing similar events to look for common causes. For example, close call events in high frequency event categories that would typically require root cause analysis (e.g., falls, medication adverse events) are collected and reviewed as a group on a quarterly or semi-annual basis. Data and information on each event is collected as it occurs by front line staff who complete forms developed for this purpose. The review team looks for trends or recurring issues in the data or information associated with the events to identify system issues needing correction.

Aggregated Review Process

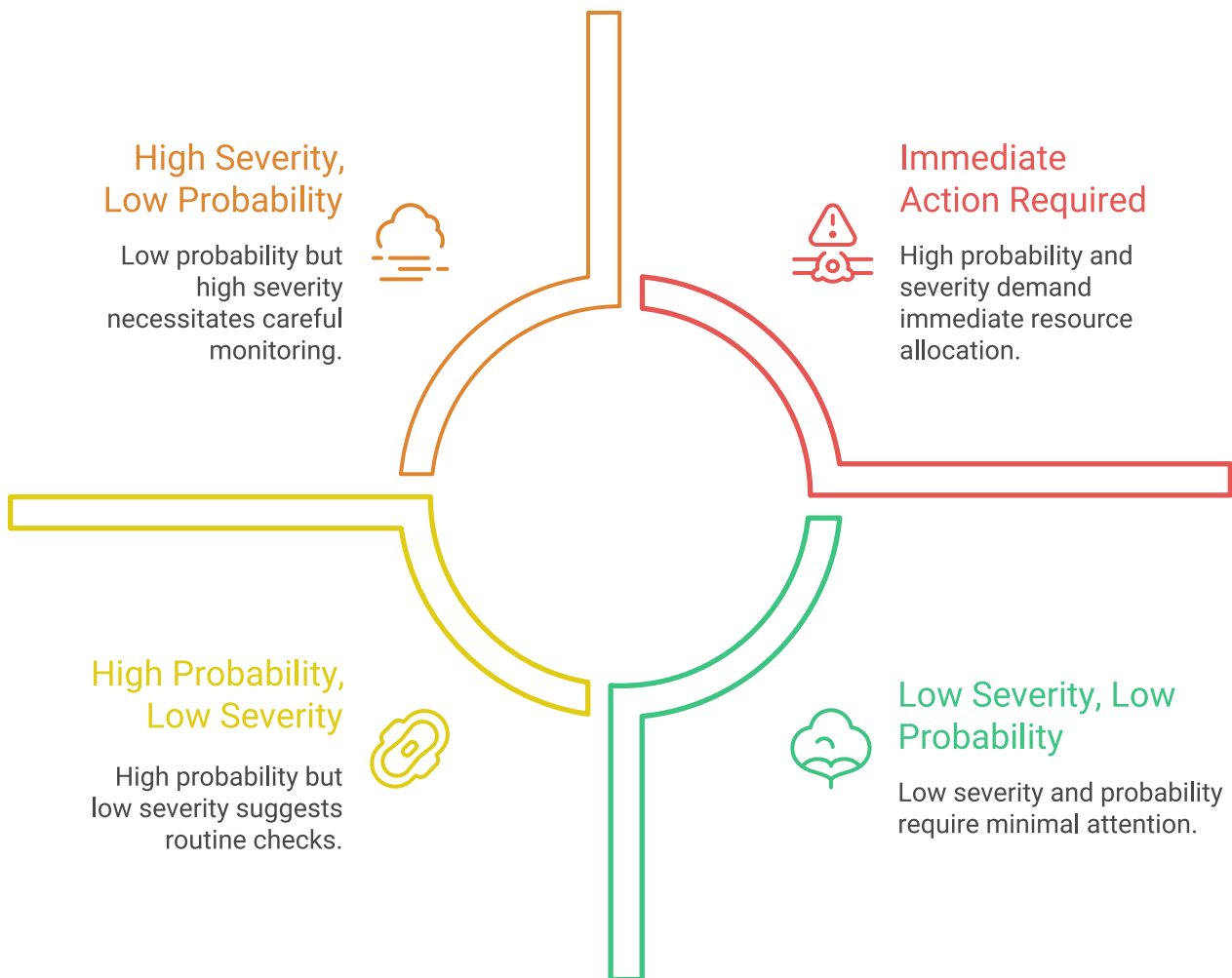


Finally, the prevention of harm is the goal of these efforts. The organization should not be distracted from taking immediate actions to minimize risk of harm while it is engaged in the more formal RCA process.

THE SAFETY ASSESSMENT CODE (SAC) MATRIX

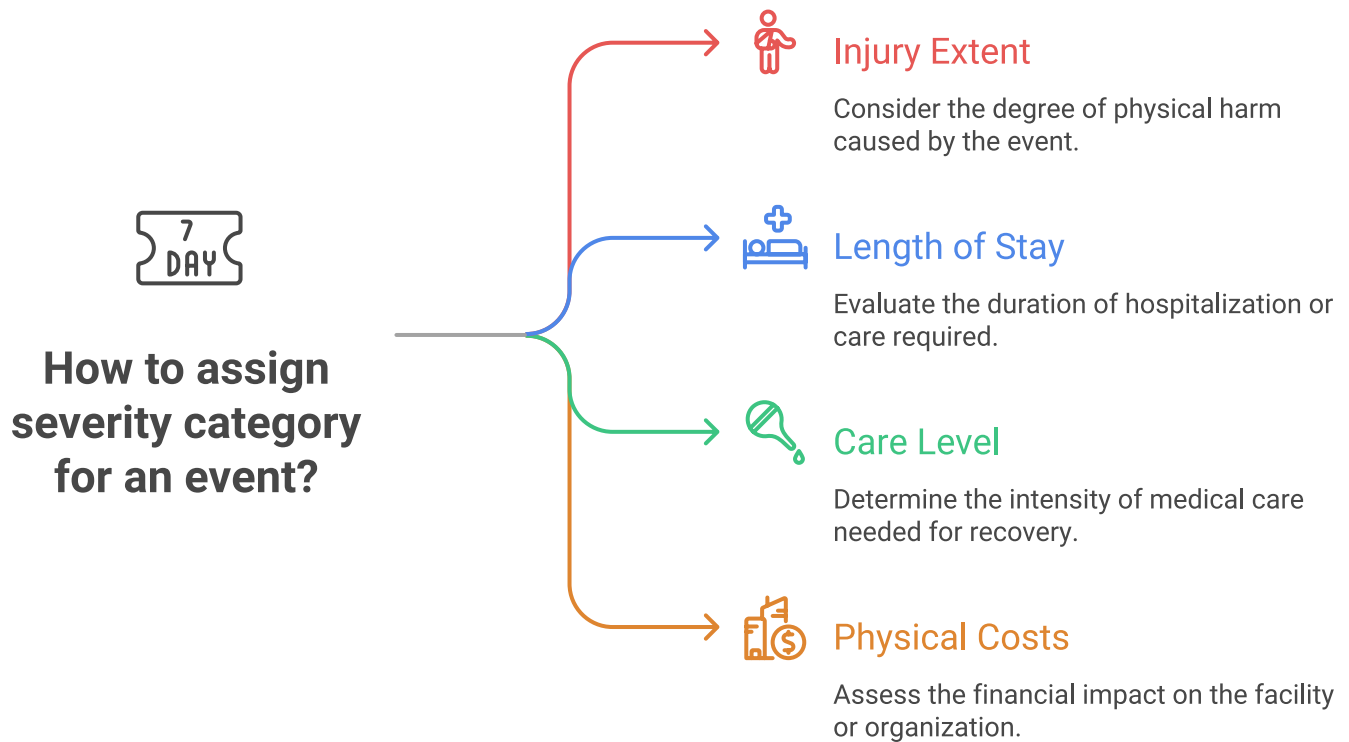
The Safety Assessment Code (SAC) Matrix exemplifies a risk-based prioritization methodology designed to systematically rank hazards, vulnerabilities, and events. This approach enables organizations to consistently and transparently allocate resources by determining which risks should be investigated and mitigated first. The matrix incorporates predefined “Severity Categories” and “Probability Categories” that are utilized to calculate SAC scores for both adverse events and near misses, as outlined below:

Safety Assessment Code (SAC) Matrix



1. SEVERITY CATEGORIES:

- a. Key factors for the severity categories are extent of injury, length of stay, level of care required for remedy, and actual or estimated physical plan costs. These four categories apply to actual adverse events and potential events (close calls). For actual adverse events, assign severity based on the patient's actual condition.



- b. If the event is a close call, assign severity based on a reasonable "worst case" systems level scenario, e.g. if you entered a patient's room before they were able to complete a lethal suicide attempt, the event is catastrophic, because the reasonable "worst case" is suicide.

Catastrophic	Major
Patients with actual or potential: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission). This includes outcomes that are a direct result of injuries sustained in a fall; or associated with an unauthorized departure from an around-the-clock treatment setting; or the result of an assault or other crime. Any of the adverse events defined by the GAHAR as reviewable "Sentinel Events" should also be considered in this category. Visitors: A death; or hospitalization of three or more visitors Staff: A death or hospitalization of three or more staff*	Patients with actual or potential: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e., acts of commission or omission) or any of the following: a. Disfigurement b. Surgical intervention required c. Increased length of stay for three or more patients d. Increased level of care for three or more patients Visitors: Hospitalization of one or two visitors Staff: Hospitalization of one or two staff or three or more staff experiencing lost time or restricted duty injuries or illnesses Equipment or facility: Damage equal to or more than \$100,000**
Moderate	Minor
Patients with Actual or Potential: Increased length of stay or increased level of care for one or two patients Visitors: Evaluation and treatment for one or two visitors (less than hospitalization) Staff: Medical expenses, lost time or restricted duty injuries or illness for one or two staff Equipment or facility: Damage more than \$10,000, but less than \$100,000**	Patients with Actual or Potential: No injury, nor increased length of stay nor increased level of care Visitors: Evaluated and no treatment required or refused treatment Staff: First aid treatment only with no lost time, nor restricted duty injuries nor illnesses Equipment or facility: Damage less than \$10,000 or loss of any utility without adverse patient outcome (e.g., power, natural gas, electricity, water, communications, transport, heat and/or air conditioning)

*Title 29 Code of Federal Regulations (CFR) 1960.70 and 1904.8 requires each Federal agency to notify the Occupational Safety and Health Administration (OSHA) within 8 hours of a work-related incident that results in the death of an employee or the in-patient hospitalization of three or more employees. Volunteers are considered to be non-compensated employees.

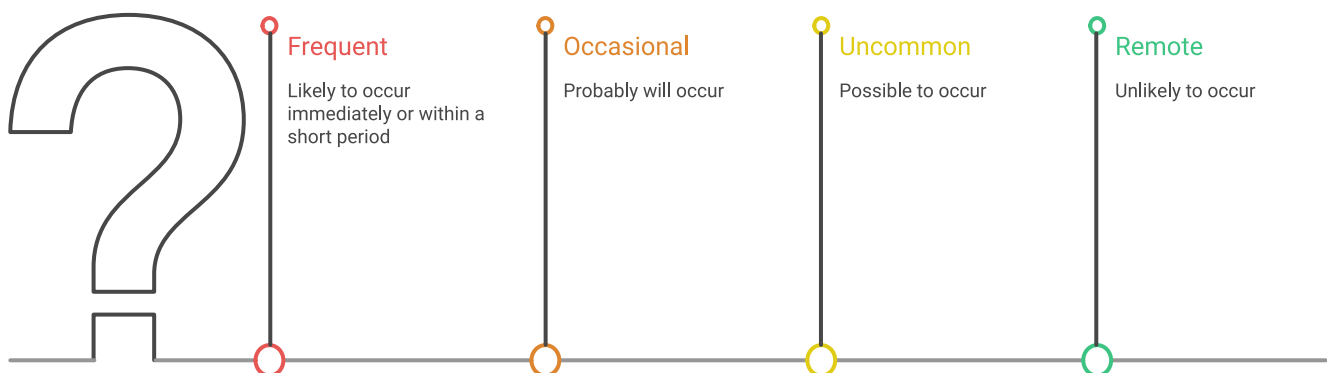
**The Safe Medical Devices Act of 1990 requires reporting of all incidents in which a medical device may have caused or contributed to the death, serious injury, or serious illness of a patient or another individual.

*The effectiveness of the facilities disaster plan must be critiqued following each implementation to meet GAHAR Environment of Care Standards.

2. PROBABILITY CATEGORIES:

- a) Like the severity categories, the probability categories apply to actual adverse events and close calls.
- b) In order to assign a probability rating for an adverse event or close call, it is ideal to know how often it occurs at your facility. Sometimes the data will be easily available because they are routinely tracked (e.g., falls with injury, Adverse Drug Events ADEs, etc.). In other times, the probability of events that are not routinely tracked, you'll have to ask for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess:
 1. Frequent: Likely to occur immediately or within a short period (may happen several times in 1 year).
 2. Occasional: Probably will occur (may happen several times in 1 to 2 years).
 3. Uncommon: Possible to occur (may happen sometime in 2 to 5 years).
 4. Remote: Unlikely to occur (may happen sometime in 5 to 30 years).

How to assign probability rating for adverse events?

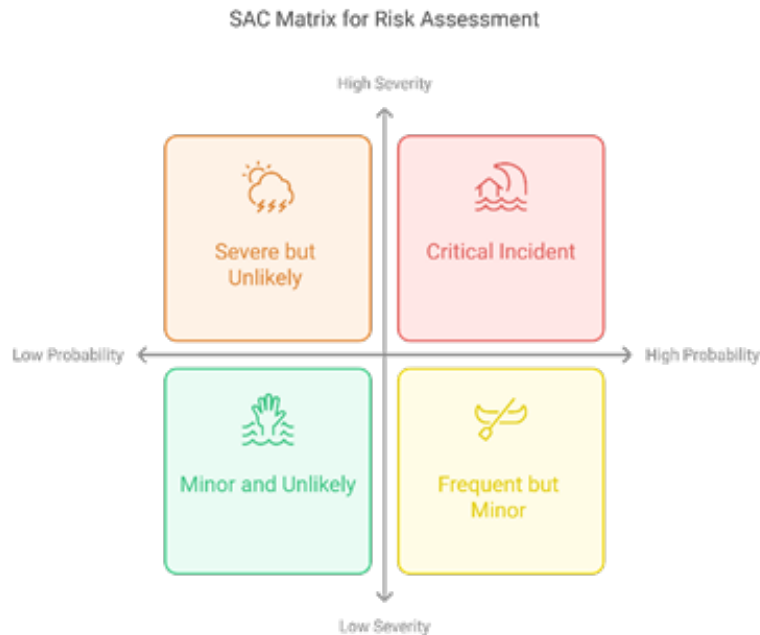


3. How the Safety Assessment Codes (SAC) Matrix Looks

Probability & Severity	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	3	2	1	1
Remote	3	2	1	1

4. How the SAC Matrix Works:

When a severity category is paired with a probability category for either an actual event or close call, a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk) results. These ranks, or SACs, can then be used for doing comparative analysis and for deciding who needs to be notified about the event.



5. Reporting:

- a. All known reporters of events, regardless of SAC score (one, two, or three), must receive appropriate and timely feedback.
- b. The patient safety manager, or designee, must refer adverse events or close calls related solely to staff, visitors, or equipment and/or facility damage to relevant facility experts or services on a timely basis, for assessment and resolution of those situations.

CHAPTER (4)



REPORTING & INTENSIVE ANALYSIS



Reporting Framework

All incidents are reportable and considered as learning and improving opportunities. However, significant\ near miss events require intensive analysis and investigations to perform an action plan within a known timeframe. On the other hand, all sentinel events are communicated to GAHAR.

Who can report?

All caregivers and workers in healthcare facilities are legible to report incidents, including paramedical staff and ancillary or contracted services. Continuous training should be implemented to all workers.

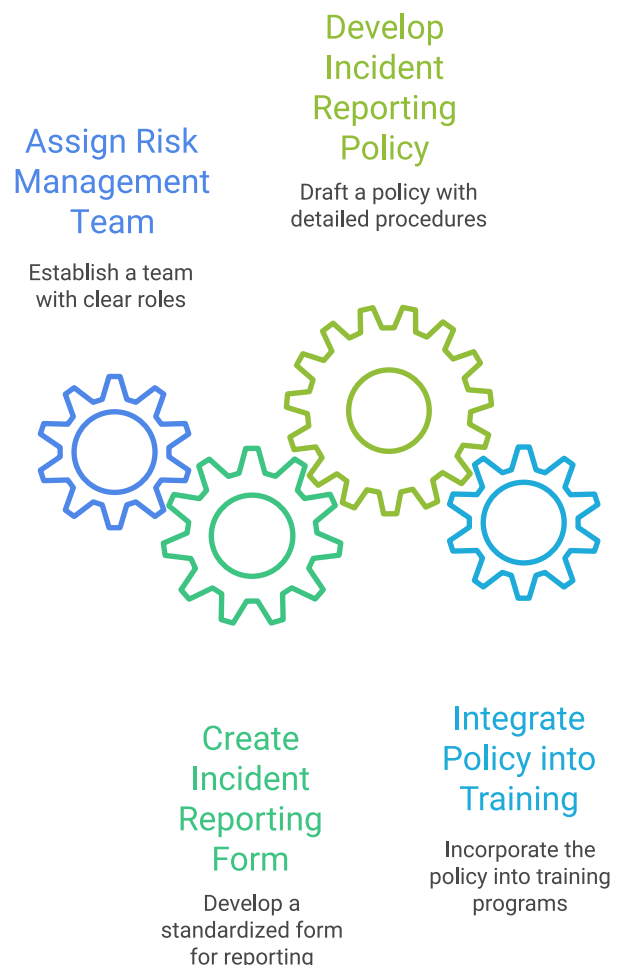
How to report incidents?

A) Internal reporting:

Each healthcare facility is responsible for creating a system for incident reporting within the facility. This should include at least the following steps:

1. Assigning risk management team with clear job description. Risk management team members should be qualified and well trained on categorization of events with a standardized scale, analysis and management of events, spotting the opportunities to improve performance by initiating and applying Root Cause Analysis and Action plan.
2. Creating the internal incident reporting form.
3. Creating an incident reporting policy with detailed clear procedures.
4. Imbedding this policy in the continuous training program within the healthcare facility.

Internal Incident Reporting Process



5. Statistical analysis should be performed monthly and discussed thoroughly in the committee of quality & performance improvement & risk management. Upon which, radical decisions should be taken by leaders to reduce harm and increase safety to patients & healthcare workers.

B) External reporting: Reporting to GAHAR:

All sentinel events are communicated to GAHAR within two days of the event or becoming aware of the event. All events that meet the definition must have a root cause analysis in order to have a clear understanding of contributing factors behind the system gaps. The analysis and action must be completed within 45 days of the event or becoming aware of the event.

Reporting to GAHAR will be through "GAHAR Events Reporting Form". All items are to be completely & clearly fulfilled within the form. A complete form should be sent to GAHAR within two days of the event via e-mail: Sentinel.Event@gahar.gov.eg

The notification should be supported by the following via e-mail or if not possible through a hard copy during predefined time frame (45 day).

- A copy of the medical record including all tests and radiological images performed.
- Statements from the concerned professionals involved/in charge of the patient.
- A copy of the full internal investigation report conducted in the facility including the root cause analysis, related policies, action plans for improvement/prevention of recurrence, training conducted, and any actions taken against involved staff should be sent to GAHAR within 45 days of the event according to attached forms.

Facilities should also be prepared for unannounced visits from the GAHAR, which can be triggered not only by the sentinel events reported but also by calls from affected patients or concerned healthcare staff from the affected facility.

GAHAR reserves the right to take actions against a facility or healthcare provider in cases such as:

- Fail to report about sentinel event to GAHAR within 2 days of the event or knowing about the event.
- The facility fails to implement corrective actions.
- The incident indicates a gross misconduct.

Sentinel Event Reporting Process to GAHAR



نموذج الإبلاغ عن الأحداث الجسيمة/متكررة الحدوث إلى الهيئة العامة للاعتماد والرقابة الصحية

GAHAR Reporting Form for Sentinel \ Repeated Events

أولاً: بيانات المنشأة و القائم بالإبلاغ:

اسم المنشأة		محافظة		
العنوان		مدير المنشأة		
اسم القائم بالإبلاغ ثلاثياً		المسمى الوظيفي	رقم الموبايل	
تاريخ وقوع الحدث		تاريخ الإبلاغ إلى الهيئة العامة للاعتماد و الرقابة الصحية		
ساعة وقوع الحدث		 ☐ صباحاً ☐ مساءً		

ثانياً: بيانات المتضرر من الحدث:

اسم المتضرر رباعياً		صفة المتضرر	
تاريخ الميلاد		الجنسية	
الرقم القومي		رقم الموبايل	
* بيانات تُملأ في حالة أن المتضرر من الحدث مريض بالمنشأة:			
رقم الملف الطبي		هل تم إبلاغ المريض	نعم لا
القسم الطبي الذي وقع به الحدث		الطبيب المسئول عن الحالة	
التشخيص			
تاريخ دخول المنشأة		تاريخ الخروج من المنشأة	

ثالثاً: تفاصيل الحدث: استخدم المساحة أدناه لوصف تفاصيل الحدث مع مراعاة الترتيب الزمني للأحداث:

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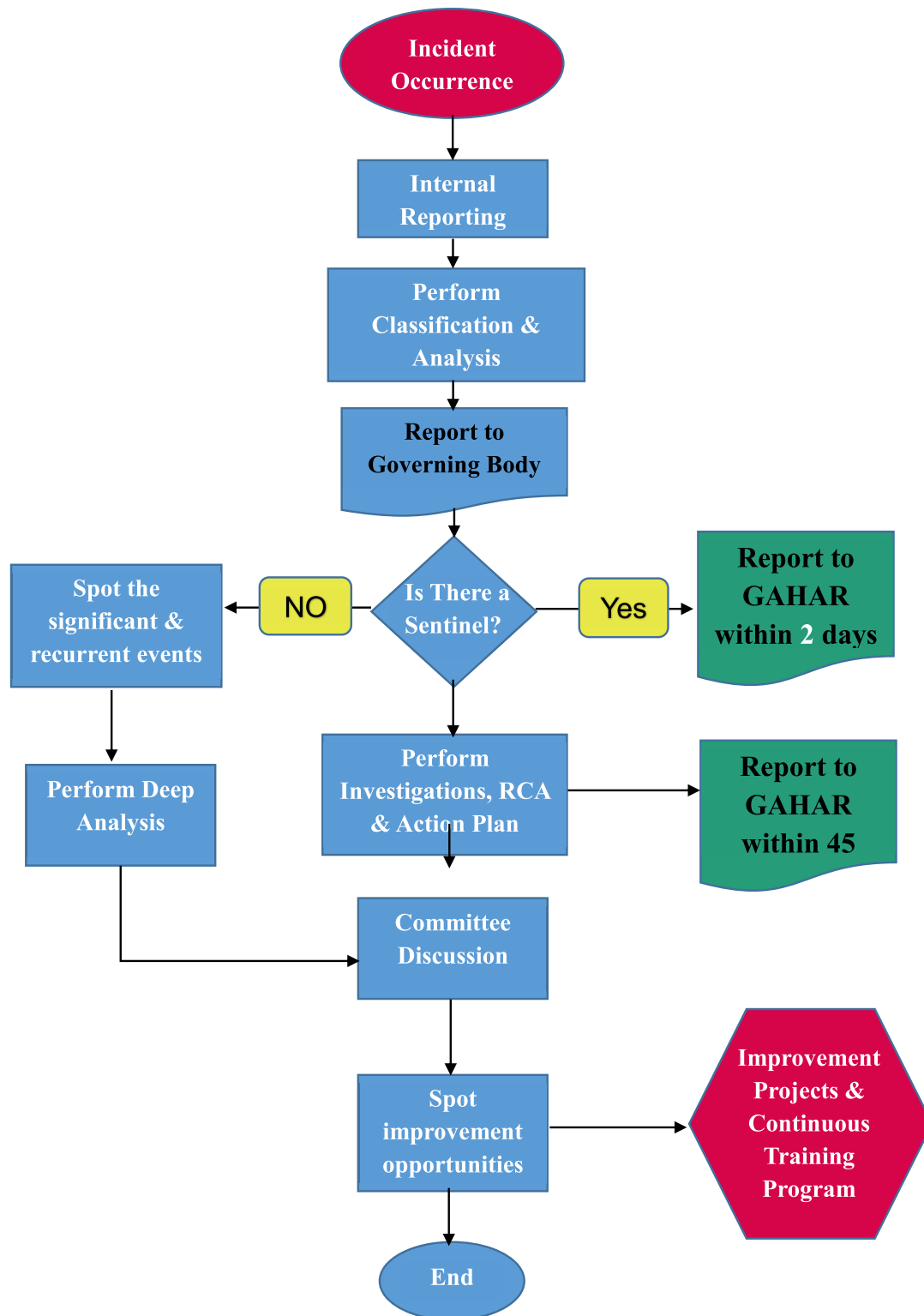
رابعاً: تفاصيل الحدث:

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*ملحوظة: يتم إرسال تحليل السبب الجذري و خطة الإجراءات التصحيحية في موعد أقصاه 45 يوم من تاريخ وقوع الحدث.

اعتماد مدير المنشأة:

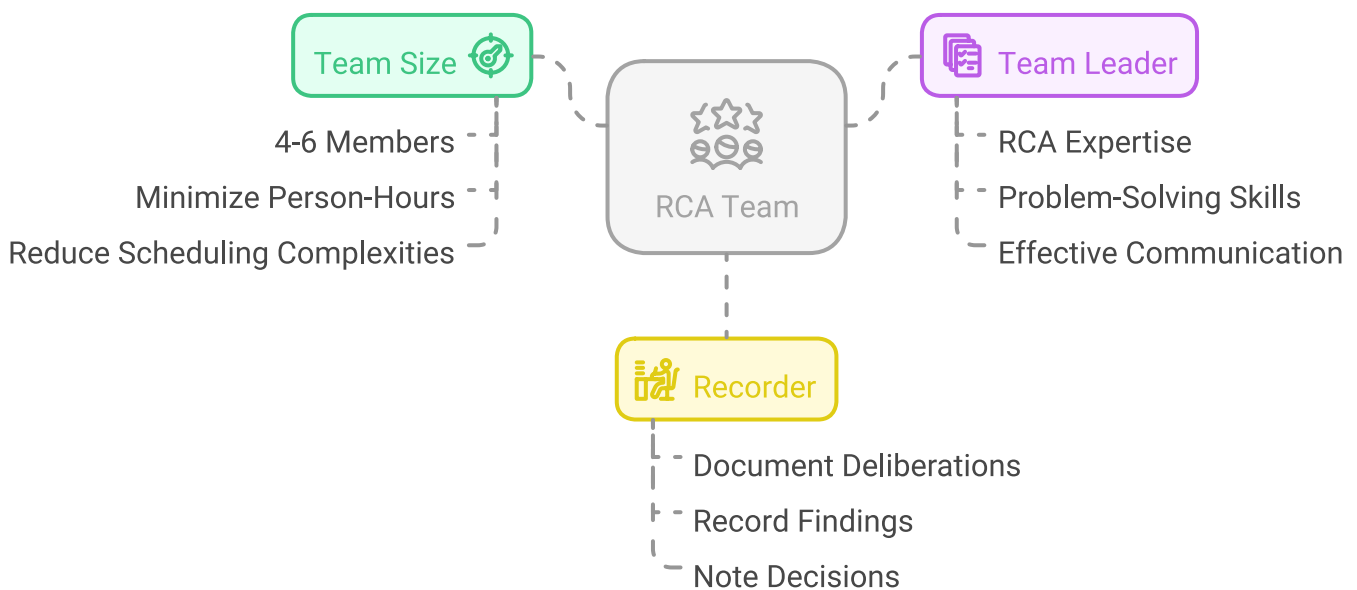
Incident Reporting Framework



RCA Team Size and Team Membership

For the purposes of this document, the term team refers to the individuals responsible for guiding the Root Cause Analysis (RCA) process from initiation to completion. It is recommended that RCA review teams be limited to 4 to 6 members. This size strikes an optimal balance by minimizing the total person-hours required, reducing scheduling complexities, and maintaining the agility necessary for an effective RCA process. One team member should be designated as the team leader, tasked with ensuring adherence to the RCA methodology and timely completion of the review. The leader should possess expertise in RCA techniques, strong problem-solving skills, and the ability to communicate effectively. Additionally, a recorder should be appointed to document the team's deliberations, findings, and decisions throughout the process.

RCA Team Structure and Roles



Team Membership* and Involvement:

NOTE: An individual may serve in multiple capacities	Team Member	Interview
Subject matter expert(s) on the event or close call process being evaluated	Yes	Yes, if not in the team
Individual(s) not familiar with (naïve to) the event or close call process	Yes	No
Leader who is well versed in the RCA process	Yes	No
Staff directly involved in the event	No	Yes
Front line staff working in the area/process	Yes	Yes
Patient involved in the event	No	Yes**
Family of patient involved in the event	No	Yes**
Patient representative	Yes	Yes

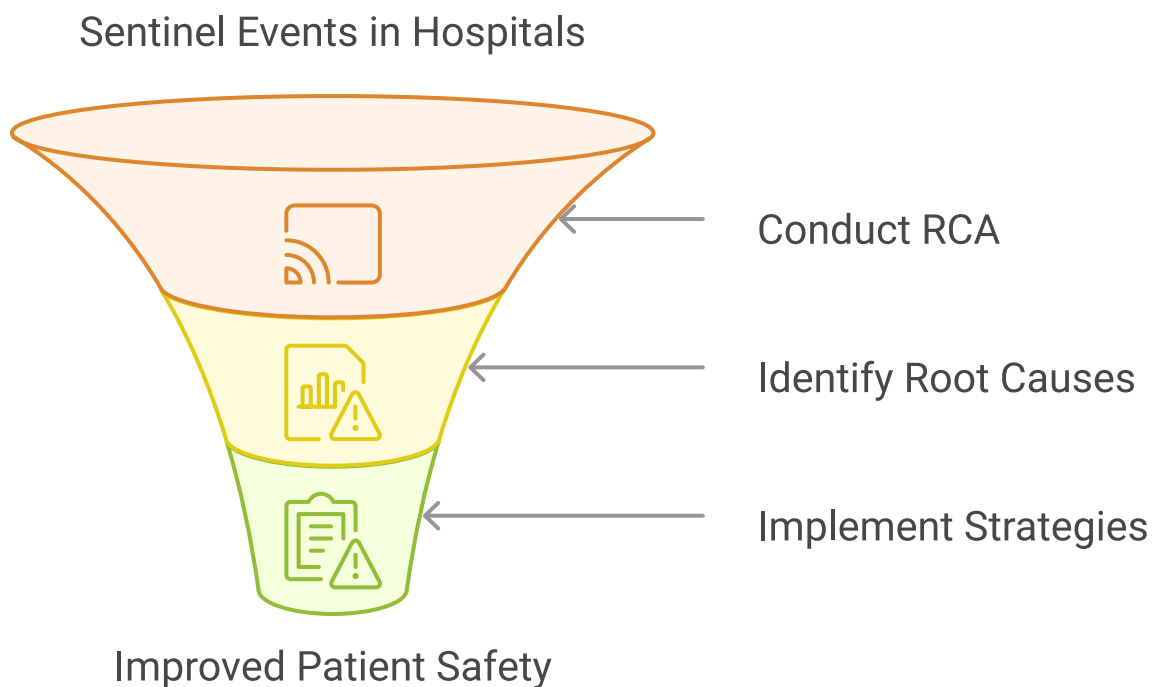
* Strongly consider including facility engineering, biomedical engineering, information technology, or pharmacy staff on an RCA team, as individuals in these disciplines tend to think in terms of systems and often have system-based mindsets. Including medical residents on a team when they are available is also suggested.

** This might not be needed for some close calls or events that are far removed from the bedside.

Root Cause Analysis for Sentinel Events in Hospitals

- ▶ This document explores the critical process of Root Cause Analysis (RCA) in the context of sentinel and significant events occurring in hospitals.
- ▶ The aim of this document is to provide a comprehensive understanding of RCA, its importance in improving patient safety, and the steps involved in conducting an effective analysis. By identifying the underlying causes of sentinel and significant events, healthcare organizations can implement strategies to prevent future occurrences and enhance overall patient care.

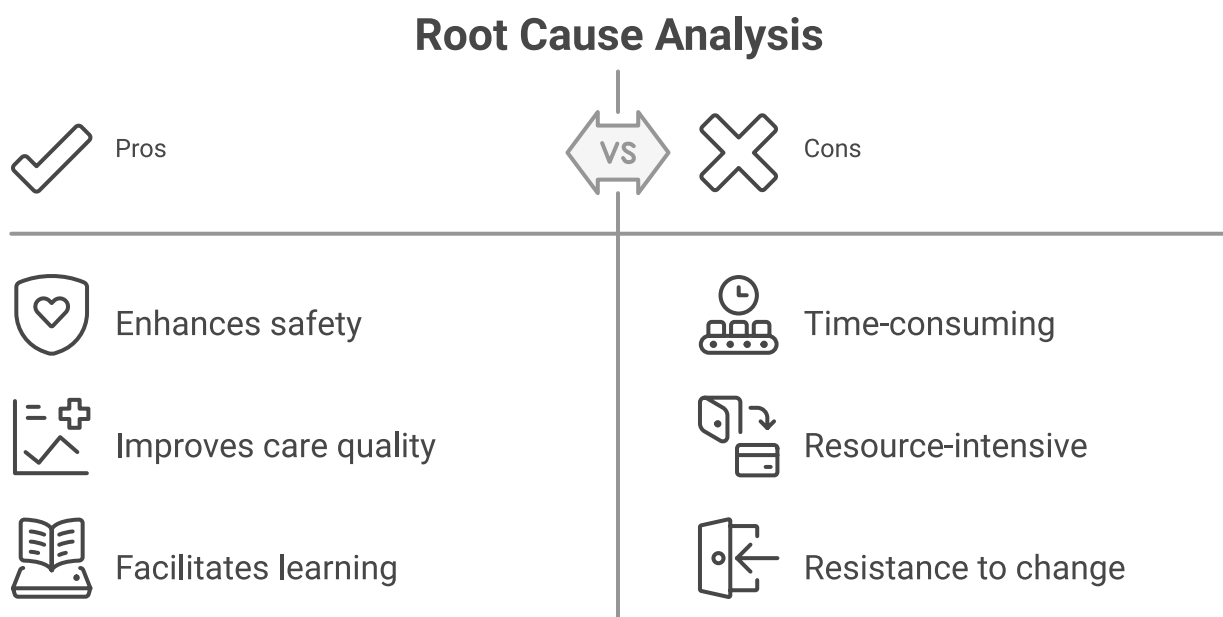
Enhancing Patient Safety through RCA



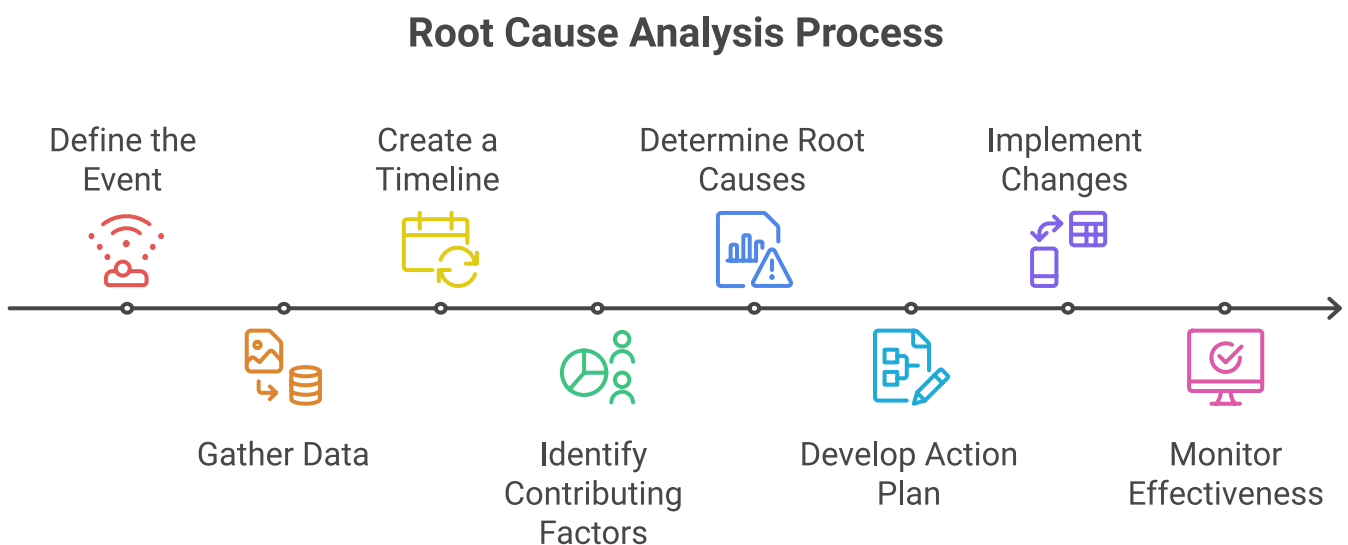
Importance of Root Cause Analysis:

Root Cause Analysis is a systematic approach used to identify the fundamental reasons behind sentinel events. The importance of RCA lies in its ability to:

- Enhance Patient Safety culture: By uncovering the root causes, hospitals can implement preventive measures to avoid similar incidents in the future.
- Improve Quality of Care: RCA fosters a culture of continuous improvement, leading to better healthcare practices and outcomes.
- Facilitate Learning: RCA encourages a non-punitive environment where healthcare professionals can learn from mistakes without fear of retribution.

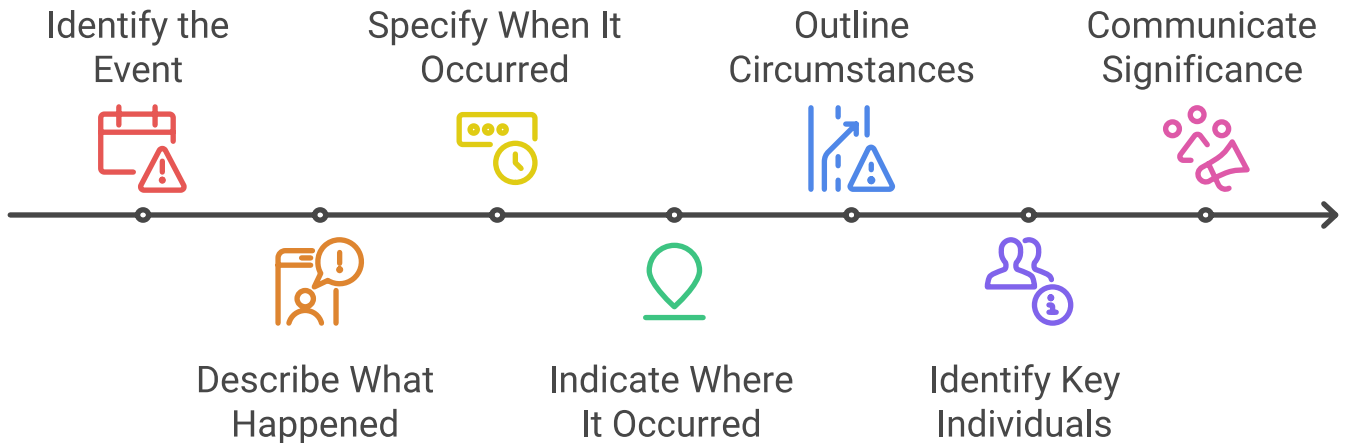


Steps in Conducting Root Cause Analysis:



- 1. Define the Event:** Clearly describe the sentinel event, including what happened, when, and where it occurred.

Sentinel Event Definition Process

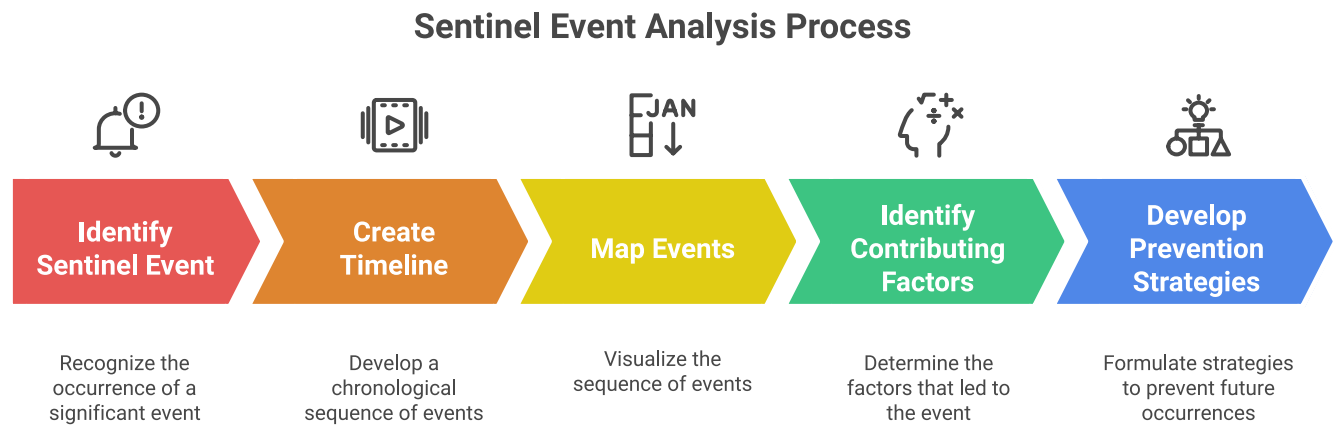


- 2. Gather Data:** Collect relevant information, including medical records, witness statements, and any other documentation related to the event.

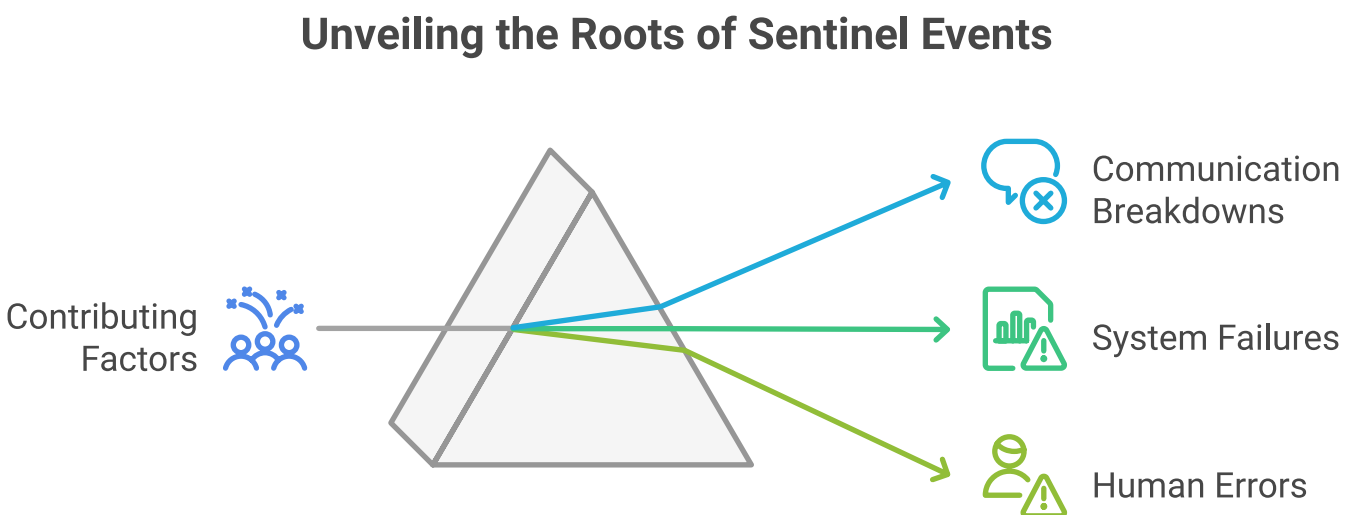
Data Gathering Process for Sentinel Event Analysis



- 3. Create a Timeline:** Develop a chronological timeline of events leading up to the sentinel event to identify contributing factors.

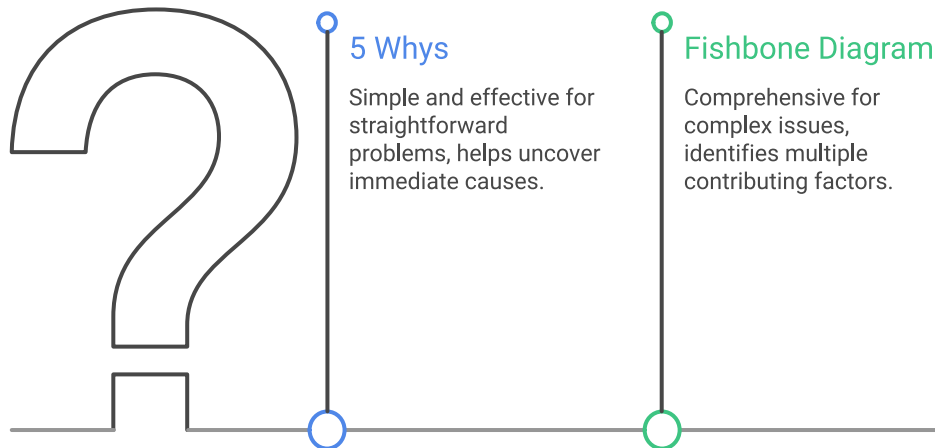


- 4. Identify Contributing Factors:** Analyze the data to identify factors that may have contributed to the event, such as communication breakdowns, system failures, or human errors.



5. **Determine Root Causes:** Use techniques such as the "5 Whys" or Fishbone Diagram to drill down to the underlying causes of the event.

Which technique should be used to determine root causes?



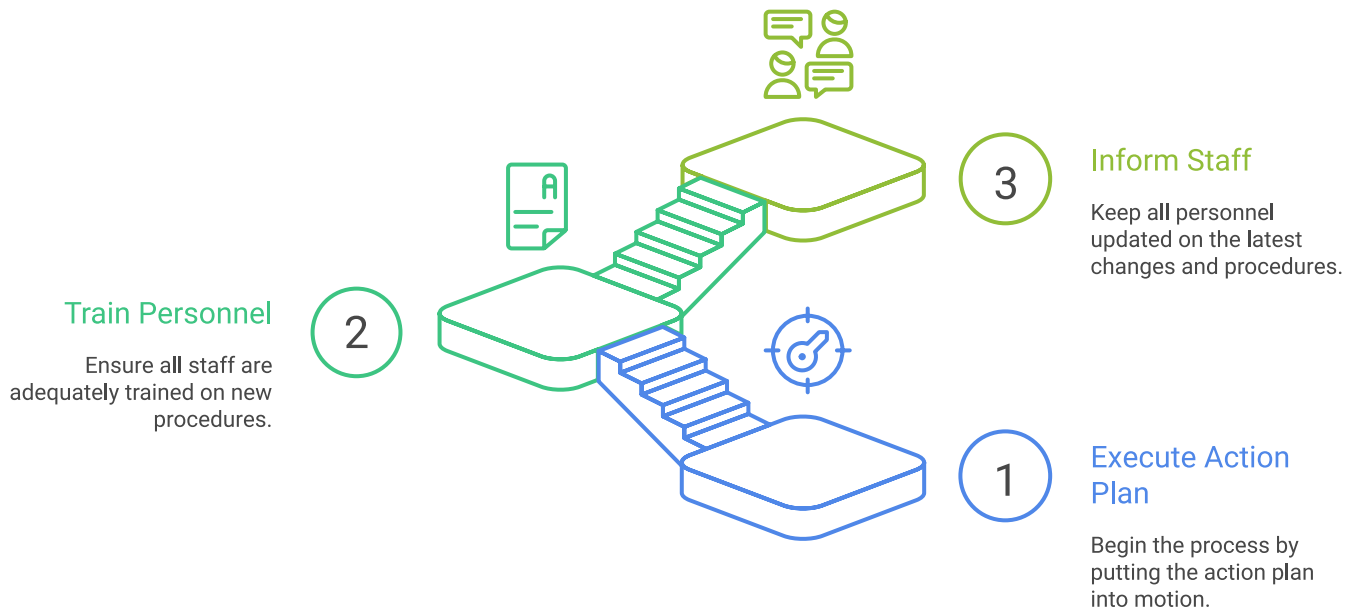
6. **Develop Action Plan:** Create a plan that outlines specific actions to address the identified root causes and prevent recurrence.

Cycle of Preventive Action



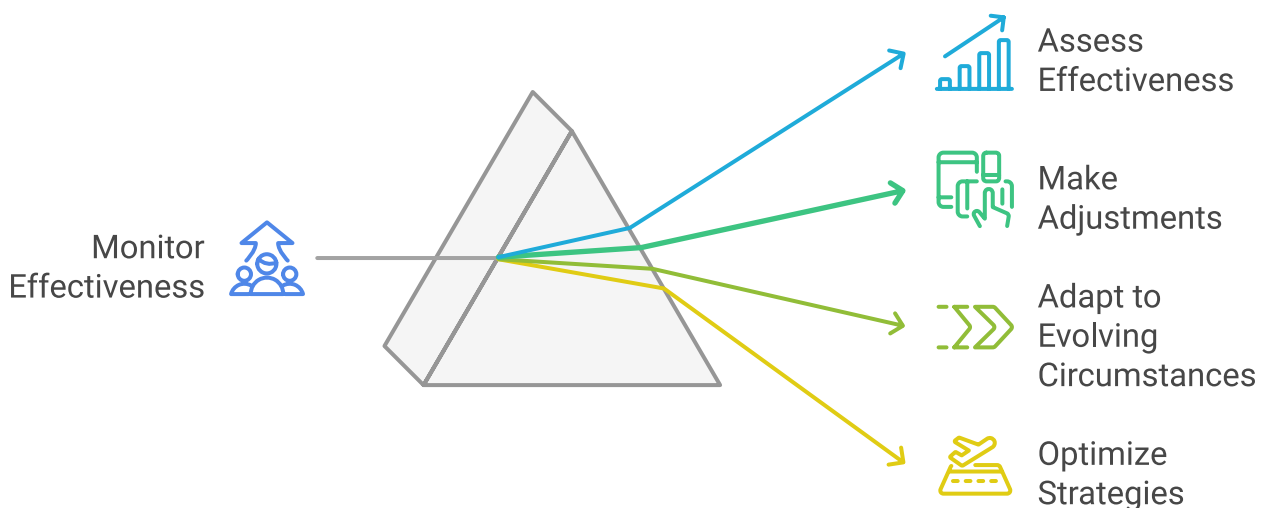
- 7. Implement Changes:** Put the action plan into practice, ensuring that all staff are trained and aware of the new procedures.

Implementing Changes Effectively



- 8. Monitor Effectiveness:** Continuously monitor the implemented changes to assess their effectiveness and make adjustments as necessary.

Unveiling the Dimensions of Monitoring Effectiveness





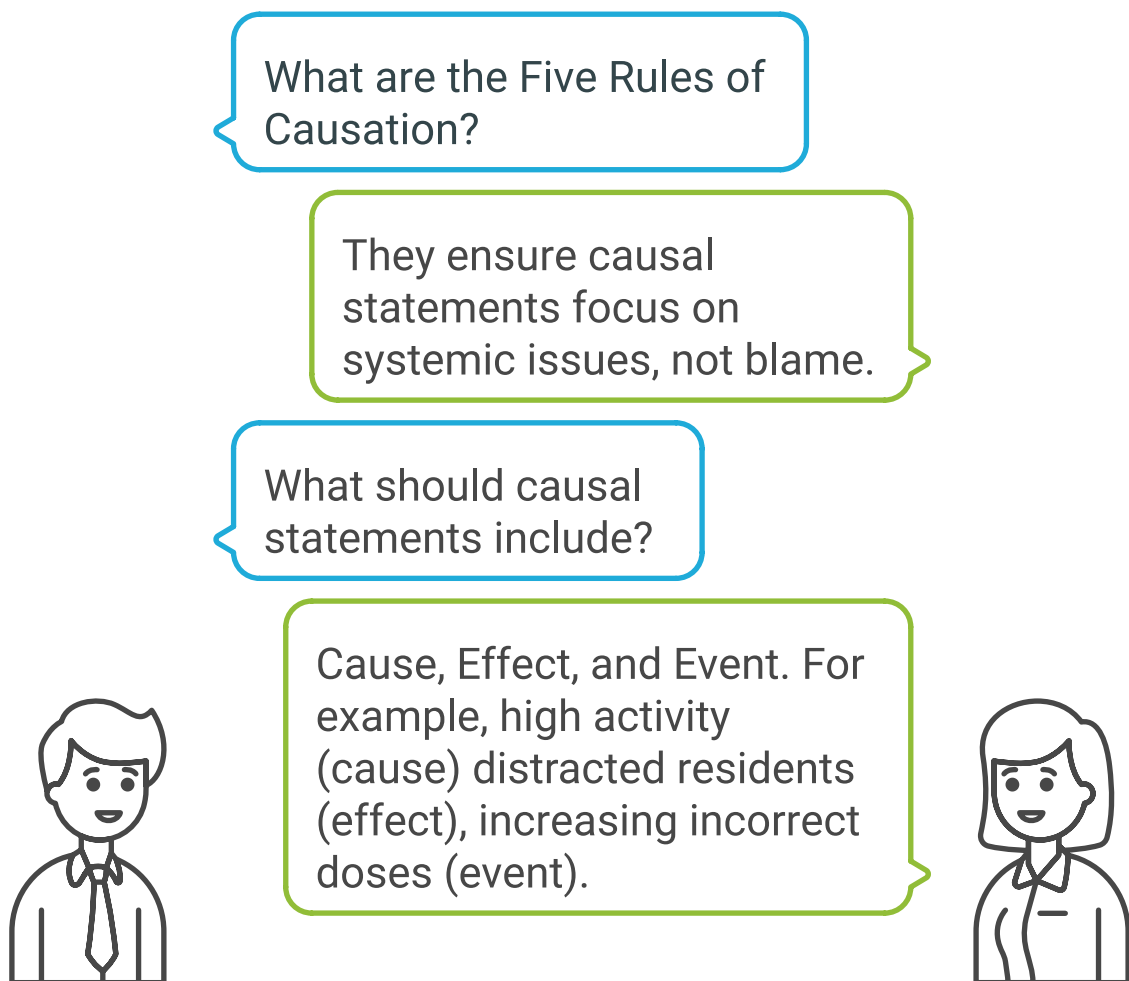
Root Cause Analysis is an essential tool for hospitals to address sentinel events and improve patient safety. By systematically identifying and addressing the underlying causes of these incidents, healthcare organizations can foster a culture of safety and quality care. Implementing RCA not only helps prevent future sentinel events but also enhances the overall healthcare experience for patients and providers alike.

THE FIVE RULES OF CAUSATION:

Once the RCA team has identified system vulnerabilities, these findings must be documented in alignment with the Five Rules of Causation. Adhering to these rules ensures that causal statements remain focused on addressing systemic issues rather than attributing blame to individuals. Utilizing the recommended format enhances the likelihood that proposed corrective actions will gain organizational support and be effectively implemented.

Causal statements should clearly articulate three components: (1) the **Cause**, (2) the **Effect**, and (3) the **Event**. For example: *A high volume of activity and noise in the emergency department (cause) resulted in the residents being distracted while entering medication orders (effect), thereby increasing the likelihood of ordering an incorrect dose (event).*

The Five Rules of Causation



Rule 1. Clearly show the “cause and effect” relationship:

INCORRECT: A resident was fatigued.

CORRECT: Residents are scheduled 80 hours per week, which led to increased levels of fatigue, increasing the likelihood that dosing instructions would be misread.

Rule 2. Use specific and accurate descriptors for what occurred, rather than negative and vague words: Avoid negative descriptors such as: Poor; Inadequate; Wrong; Bad; Failed; Careless.

INCORRECT: The manual is poorly written.

CORRECT: The pumps user manual had 8-point font and no illustrations; as a result, nursing staff rarely used it, increasing the likelihood that the pump would be programmed incorrectly.

Rule 3. Human errors must have a preceding cause:

INCORRECT: The resident selected the wrong dose, which led to the patient being overdosed.

CORRECT: Drugs in the Computerized Physician Order Entry (CPOE) system are presented to the user without sufficient space between the different doses on the screen, increasing the likelihood that the wrong dose could be selected, which led to the patient being overdosed.

Rule 4. Violations of procedure are not root causes, but must have a preceding cause:

INCORRECT: The techs did not follow the procedure for CT scans, which led to the patient receiving an air bolus from an empty syringe, resulting in a fatal air embolism.

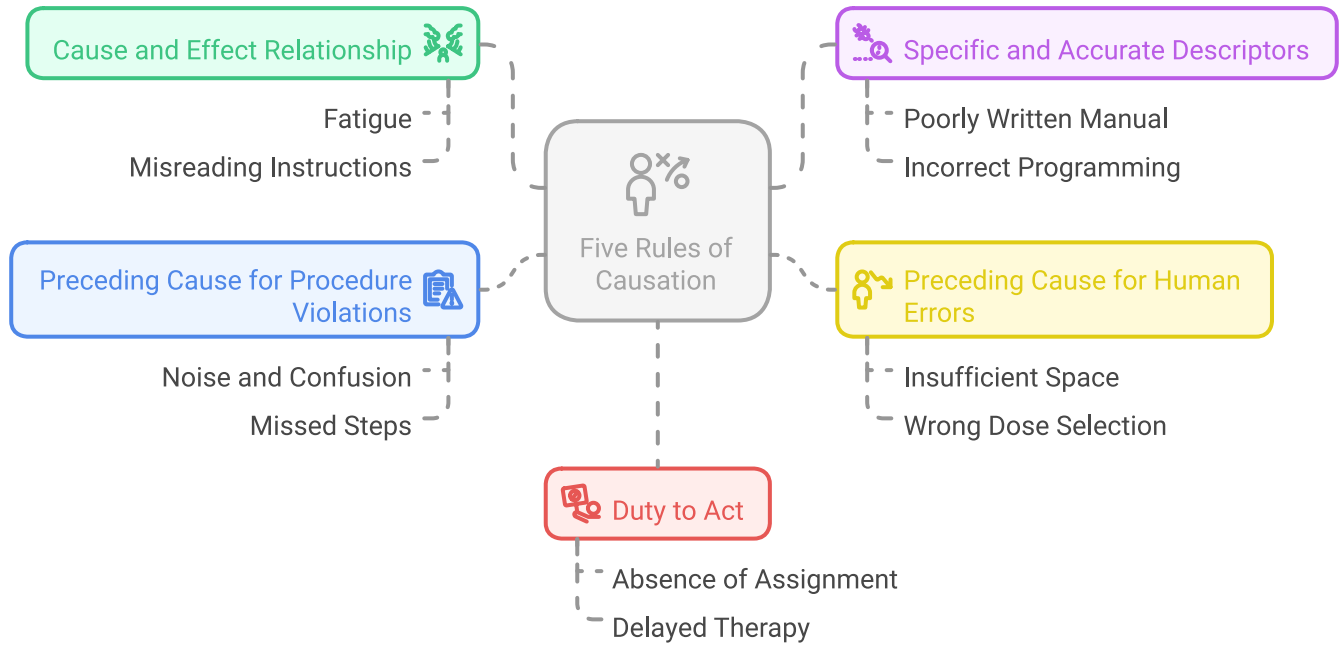
CORRECT: Noise and confusion in the preparation area, coupled with production pressures, increased the likelihood that steps in the CT scan protocol would be missed, resulting in the injection of an air embolism from using an empty syringe.

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

INCORRECT: The nurse did not check for STAT orders every half hour, which led to a delay in the start of anticoagulation therapy, increasing the likelihood of a blood clot.

CORRECT: The absence of an assignment for designated nurse to check orders at specified times increased the likelihood that STAT orders would be missed or delayed, which led to a delay in therapy.

Five Rules of Causation in RCA

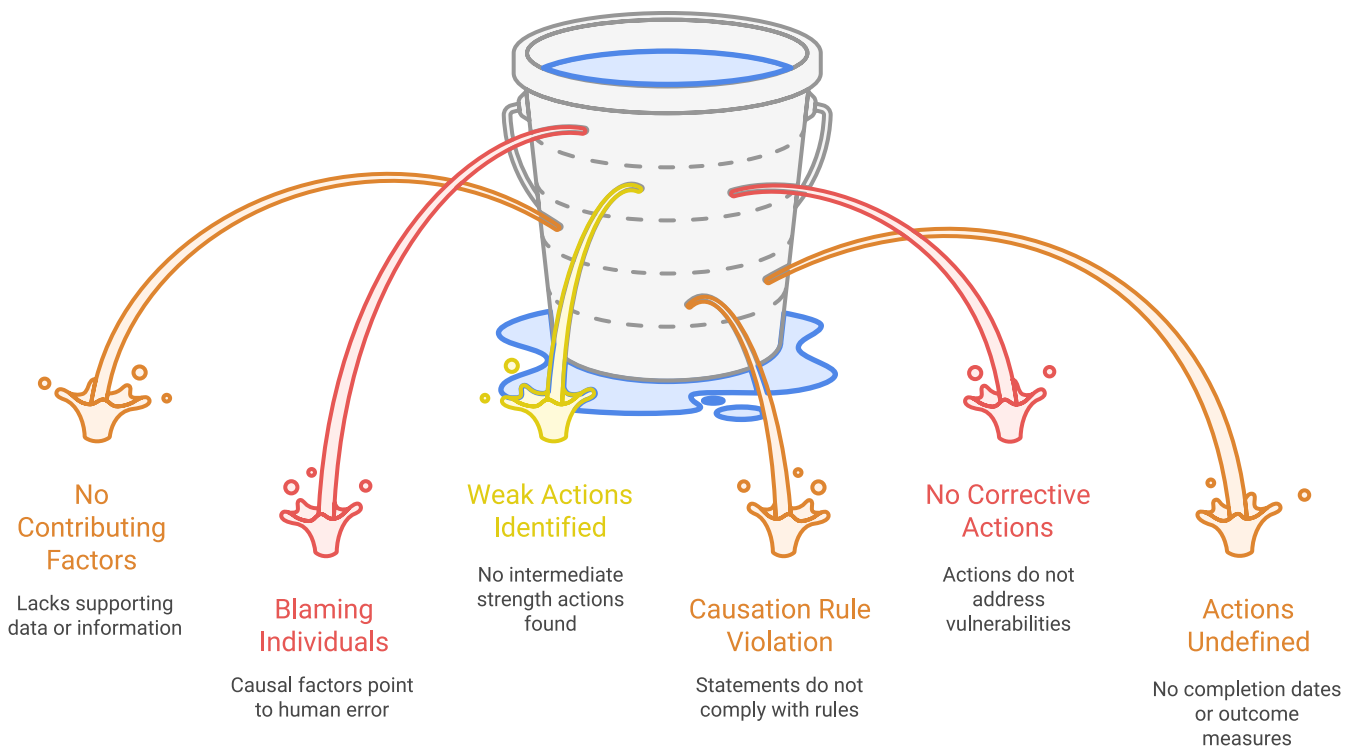


Warning Signs of Ineffective RCA:

If any one or more of the following factors are true, then your specific RCA review needs to be re-examined and revised because it is failing:

- There are no contributing factors identified, or the contributing factors lack supporting data or information.
- One or more individuals are identified as causing the event; causal factors point to human error or blame.
- No stronger or intermediate strength actions are identified.
- Causal statements do not comply with the Five Rules of Causation.
- No corrective actions are identified, or the corrective actions do not appear to address the system vulnerabilities identified by the contributing factors.
- Actions do not have completion dates or meaningful process and outcome measures.
- The event review took longer than 45 days to complete.
- There is little confidence that implementing and sustaining corrective action will significantly reduce the risk of future occurrences of similar events.

Ineffective Root Cause Analysis



Root cause analysis format					
Incident Description					
1	Date of Incident:				
2	Time of Incident:				
3	Location of incident				
4	Describe the full Incident details:				
Immediate Impact and action					
1	What was the immediate effect of the incident?				
2	What immediate action was taken?				

3	What processes or departments were impacted?	
Team formulation (consider process owner and patient advocate)		
1	Team leader	
2	Team facilitator	
3	Team members	
4		
5		
6		
7		
8		
Data Collection		
1	Identify process details	
	Actual Process flowchart	

	Ideal process flowchart	
2	Gather necessary data	
	Documents to be reviewed	Medical files – lists – registers – logs – policies – plans – programs – clinical pathways – protocols – clinical practice guidelines- staff qualifications - others
	interviews	Process owners – leaders – patients – persons responsible for the incident- others
	observations	Identify who and what to observe
Problem statement: Clearly define the problem		

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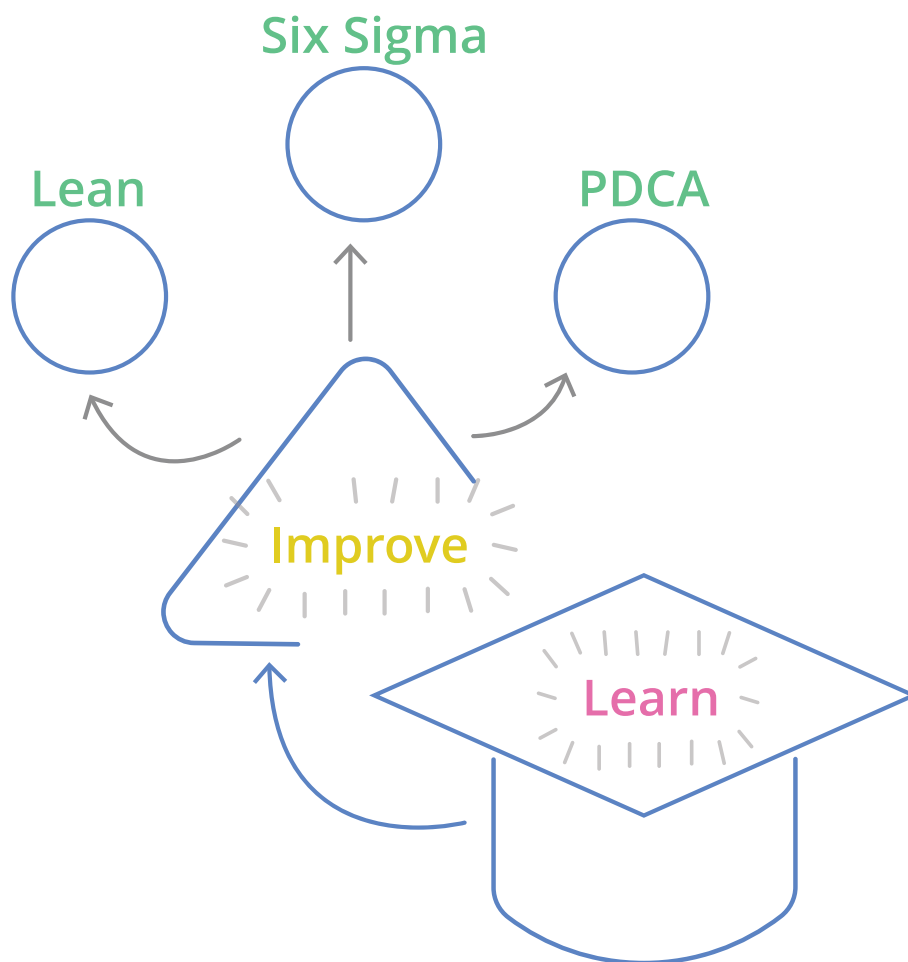
Corrective actions					
	Root cause	Solution	Responsible person	Time frame	Measure of success

Lessons Learned	
	What lessons can be learned from this incident?
	How can similar incidents be prevented in the future?

CHAPTER (5)



LEARN & IMPROVE



Improvement Methodologies and Tools



After completing the RCA process, the facility may need to implement improvement process. This chapter outlines the key phases of improvement, highlighting the tools used to support each stage effectively. Healthcare facilities aiming to enhance their processes rely on systematic improvement methodologies and specialized tools at each phase of implementation.

Among the most effective methodologies employed are Lean, Six Sigma, and the PDCA (Plan-Do-Check-Act) cycle. Each of these approaches brings unique strengths that can be tailored to meet the specific needs of healthcare facilities.

1. Lean Methodology

Overview: Lean methodology is a systematic approach focused on eliminating waste, enhancing value, and optimizing workflows. Originally developed by Toyota, Lean principles have been adapted across various industries, including healthcare. The primary goal of Lean is to maximize value for patients by identifying and removing non-value-adding activities.

Core Principles of Lean is based on five core principles:

- Define Value: Identify what the patient perceives as valuable in healthcare services.
- Map the Value Stream: Analyze the steps involved in delivering care to highlight activities that add value versus those that create waste.
- Create Flow: Ensure that processes run smoothly without interruptions or delays.
- Establish Pull: Implement a system

Achieving Lean Healthcare

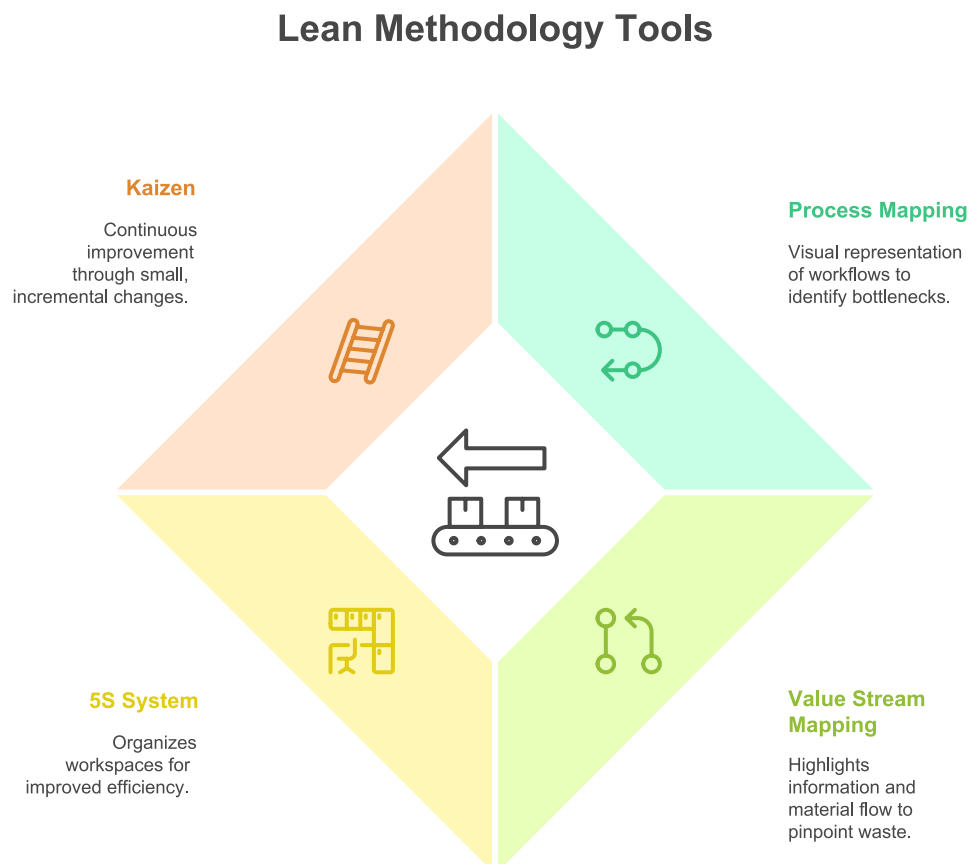


where services are provided based on patient demand rather than predetermined schedules.

- Pursue Perfection: Continuously refine processes to move closer to optimal efficiency and effectiveness.

Tools Used in Lean: Common tools employed in Lean methodology include:

- Process Mapping: Provides a visual representation of workflows to identify bottlenecks.
- Value Stream Mapping: Highlights the flow of information and materials, pinpointing areas of waste.
- 5S System (Sort, Set in order, Shine, Standardize, Sustain): Organizes workspaces to improve efficiency.
- Kaizen: Emphasizes continuous improvement through small, incremental changes.



Application in Healthcare: Lean can reduce patient wait times, optimize the use of medical supplies, and improve coordination among departments. For example, Lean can streamline admissions processes, reduce paperwork, and facilitate better communication among healthcare professionals.

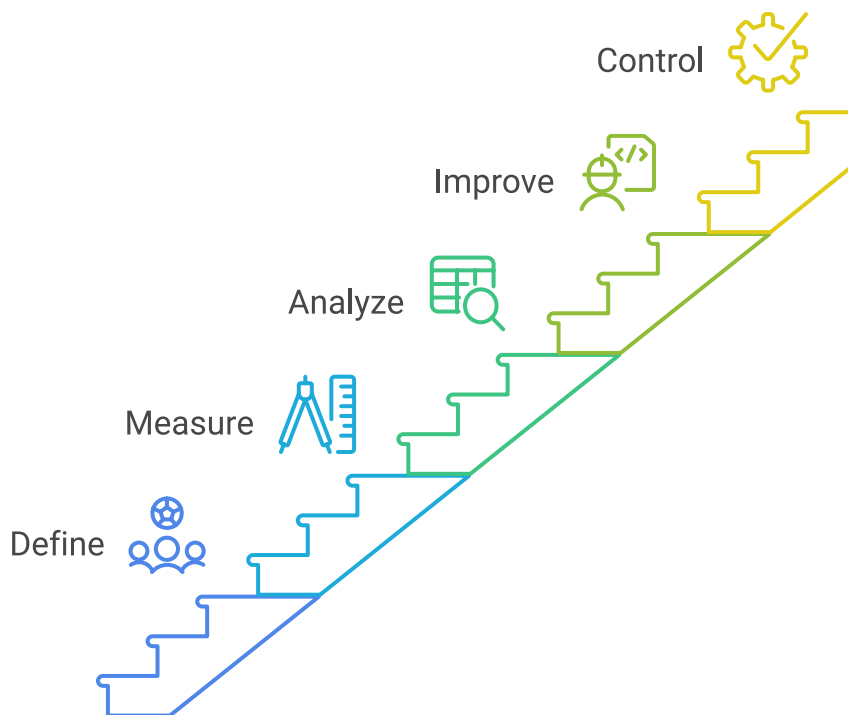
2. Six Sigma Methodology

Overview: Six Sigma is a data-driven approach aimed at improving process quality by identifying and removing the causes of defects and minimizing variability. It follows the DMAIC (Define, Measure, Analyze, Improve, Control) framework to structure improvement projects systematically.

The DMAIC Framework:

- Define: Clearly outline the problem, objectives, and project scope.
- Measure: Collect data to establish baseline performance and identify key metrics.
- Analyze: Use statistical tools to determine the root causes of inefficiencies.
- Improve: Develop and test solutions that address the identified causes.
- Control: Implement controls to sustain the improvements and prevent regression.

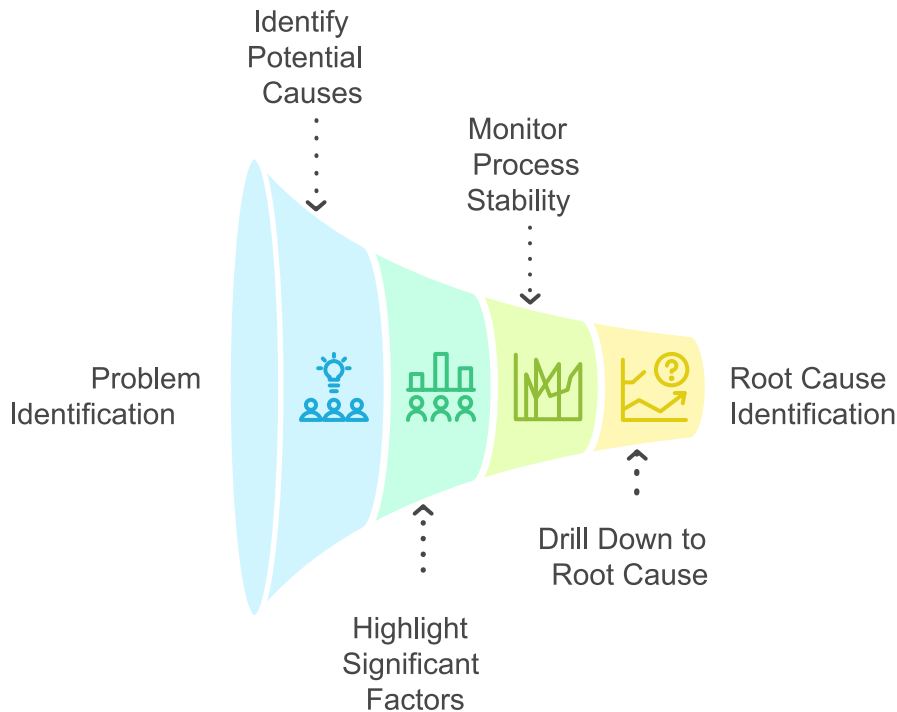
Achieving Process Improvement with DMAIC



Tools Used in Six Sigma projects include:

- Fishbone Diagram (Ishikawa): Helps identify potential causes of a problem.
- Pareto Chart: Highlights the most significant factors contributing to an issue.
- Control Chart: Monitors process stability over time.
- 5 Whys Analysis: Drills down to the root cause by repeatedly asking "Why?"

Six Sigma Problem-Solving Process



Application in Healthcare: Six Sigma helps healthcare organizations reduce errors in clinical and administrative processes, such as medication administration, patient discharge procedures, and surgical preparation. By minimizing defects and standardizing procedures, healthcare facilities can enhance patient safety and operational reliability.

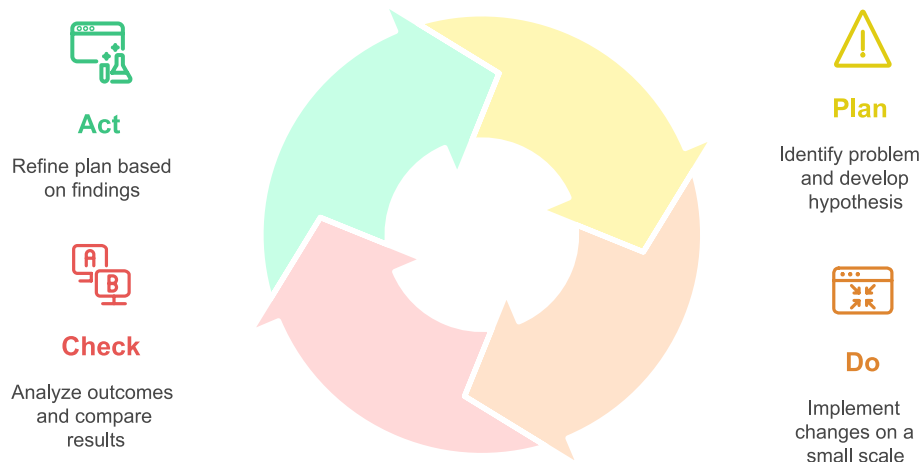
3. PDCA Cycle

Overview: The PDCA cycle, also known as the Deming cycle, is a four-step iterative process that supports continuous improvement. This methodology focuses on testing small changes to assess their impact before full-scale implementation.

The Four Phases of PDCA:

- Plan: Identify a problem and develop a hypothesis for solving it. This step involves gathering data, defining objectives, and outlining a course of action.
- Do: Implement the planned changes on a small scale. This phase allows for controlled testing to minimize risks.
- Check: Analyze the outcomes of the test phase by collecting data and comparing results against expectations. This step helps determine if the changes led to improvements.
- Act: Refine the plan based on findings from the check phase. Successful changes can be implemented more broadly, while unsuccessful ones can be modified and re-tested.

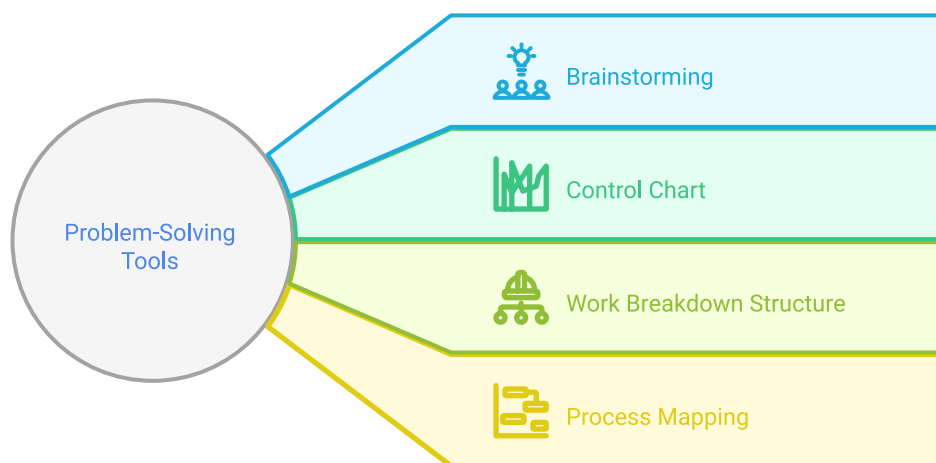
PDCA Cycle for Continuous Improvement



Tools Used in PDCA: The PDCA cycle leverages tools such as:

- Brainstorming: it helps teams collaborate and suggest a range of solutions to operational or patient care issues
- Control Chart: Used to monitor changes over time and ensure consistency.
- Work Breakdown Structure (WBS): Helps break down tasks into manageable components for better oversight during the “Do” phase.
- Process Mapping: Utilized to visualize and analyze processes during the planning phase.

Visualizing Problem-Solving Tools



Application in Healthcare: PDCA is particularly effective for iterative improvements such as optimizing patient flow, testing new clinical protocols, and revising patient intake

procedures. Its adaptability allows healthcare teams to test changes, learn from results, and implement solutions that enhance both patient outcomes and operational efficiency.

Integrated Tips and Tools for Each Phase of FOCUS PDCA

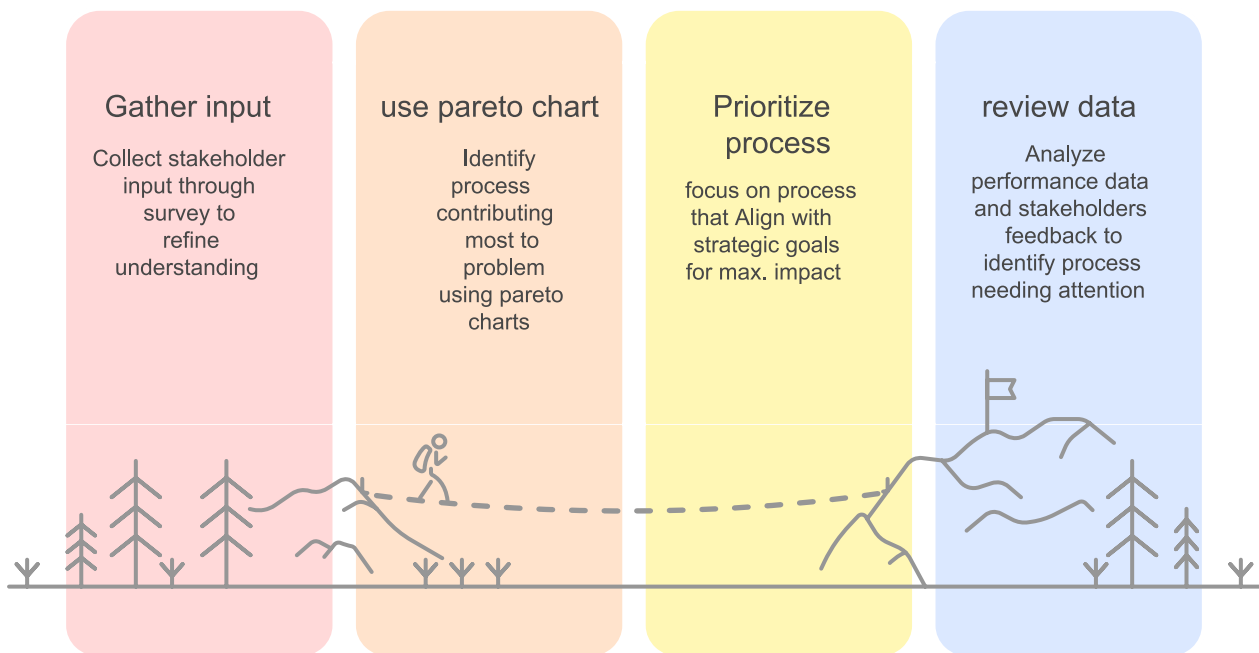
FOCUS Phase

Find a Process to Improve

Tips: Start by reviewing performance data and feedback from stakeholders to identify which processes need attention. Prioritize processes that align with strategic goals for maximum impact.

Tools: Use Pareto Charts to identify processes contributing most to problems and surveys to gather stakeholder input.

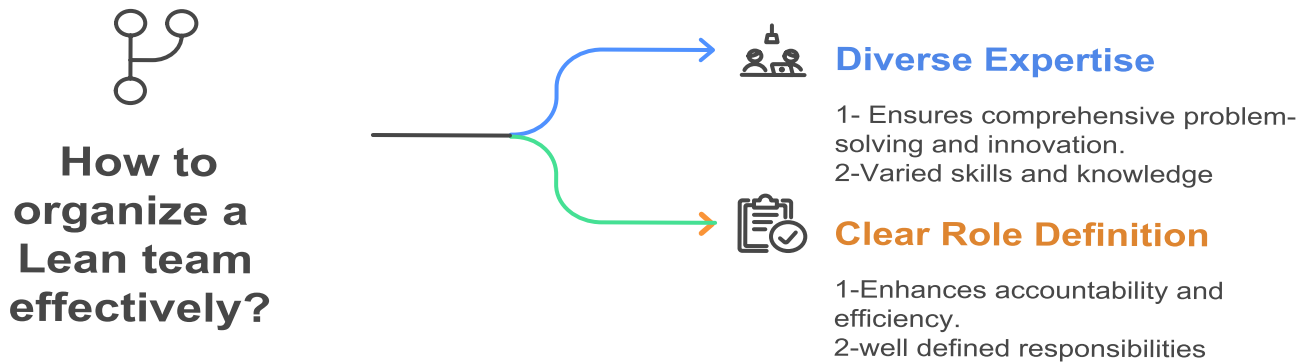
Process Improvement Journey



Organize a Team

Tips: Choose a team with diverse expertise that includes individuals who interact directly with the process. Clearly define roles to ensure accountability.

Tools: Utilize a RACI Matrix to outline team roles and a Team Charter to clarify the team's purpose, scope, and objectives.



Clarify Current Knowledge

Tips: Use visual tools to map the current process and gather comprehensive data from multiple sources to understand how the process functions.

Tools: Employ flowcharts and process maps for visual representation and data collection forms to standardize how data is gathered. Stakeholder analysis tools help understand various perspectives.

Understanding Causes of Variation

Tips: Conduct a root cause analysis and involve frontline staff to gain valuable insights into why deviations occur.

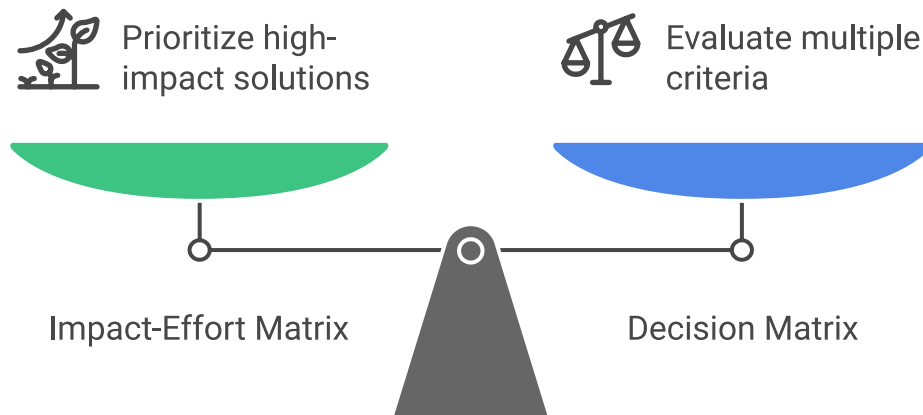
Tools: Use the 5 Whys and Fishbone Diagrams for in-depth root cause analysis. Visualize trends with histograms and control charts to identify patterns and variances.



Select an Improvement Plan

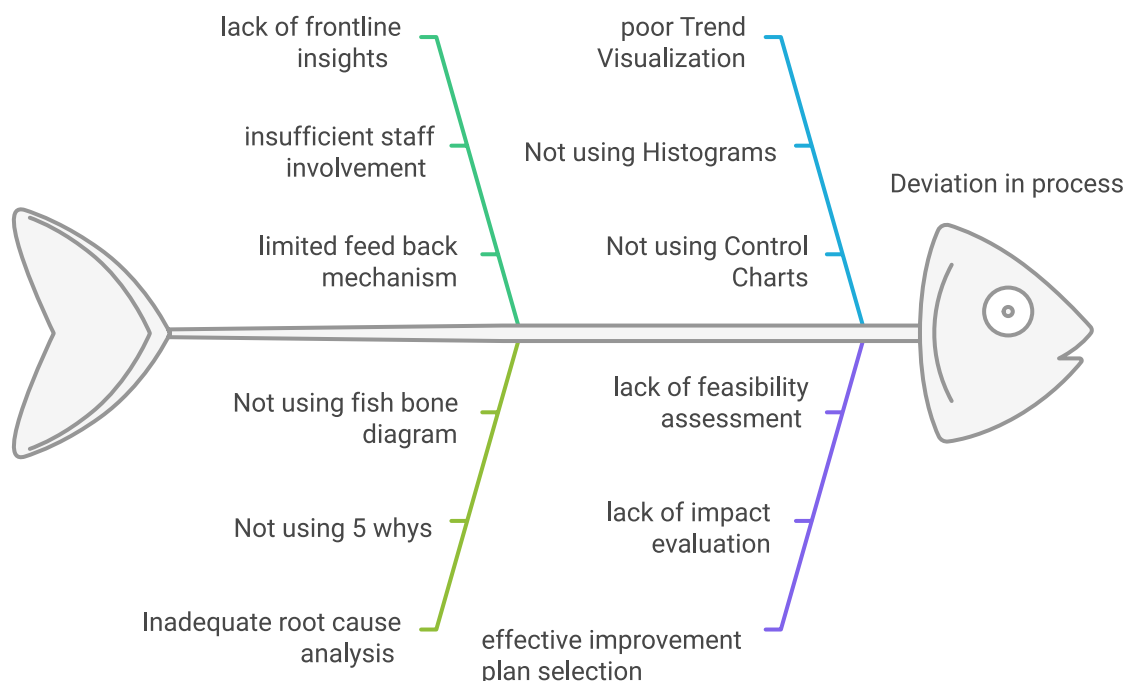
Tips: Evaluate potential solutions based on impact and feasibility, involving the team in brainstorming sessions to maximize idea generation.

Compare tools for effective solution prioritization.



Tools: Use an Impact-Effort Matrix and Decision Matrix to prioritize solutions. Hold structured brainstorming sessions for input.

Root Cause Analysis for a process

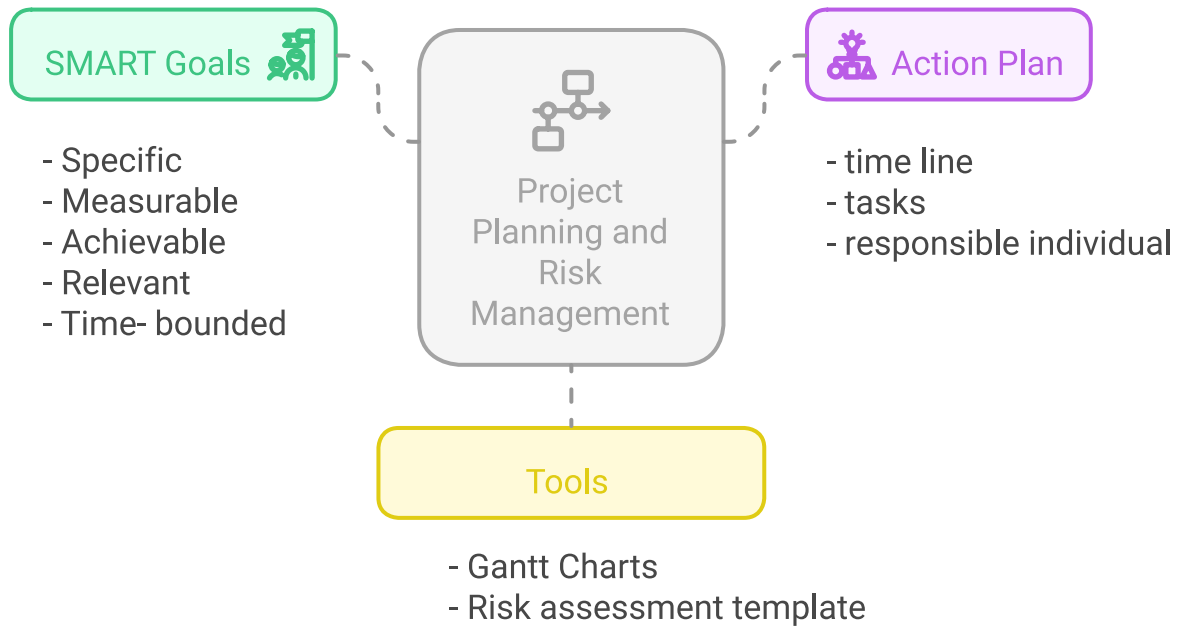


PDCA Cycle

Plan

Tips: Define objectives using the SMART framework and create a detailed action plan, including timelines, tasks, and responsible individuals.

Tools: Gantt Charts can help plan timelines, while Risk Assessment Templates can be used to identify and mitigate potential risks. Set SMART goals to ensure clear and measurable objectives.

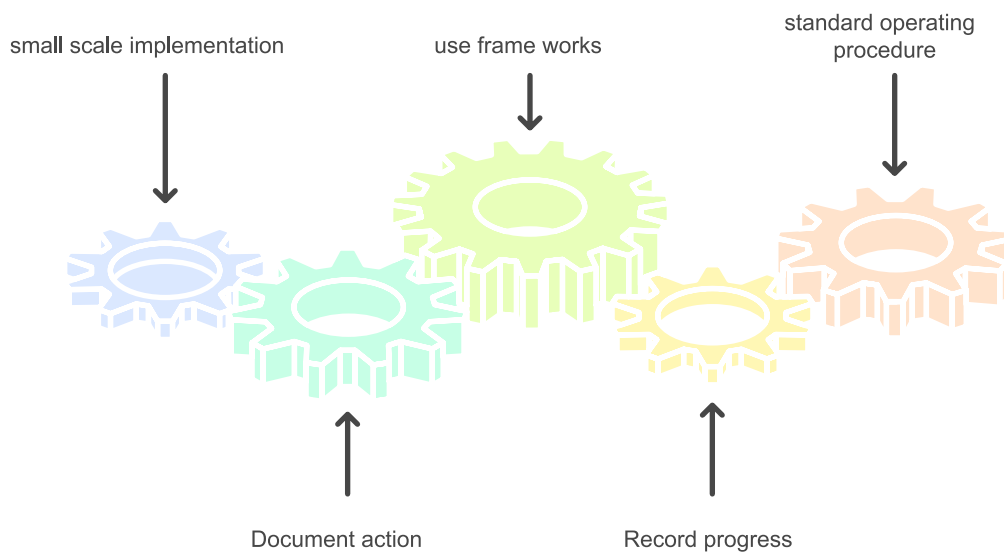


Do

Tips: Implement the plan on a small scale to test effectiveness and minimize risk. Document all actions and unexpected occurrences.

Tools: Use a Pilot Testing Framework to guide implementation and observation checklists to record progress. Document the process with Standard Operating Procedures (SOPs).

Steps to effective plan implementation

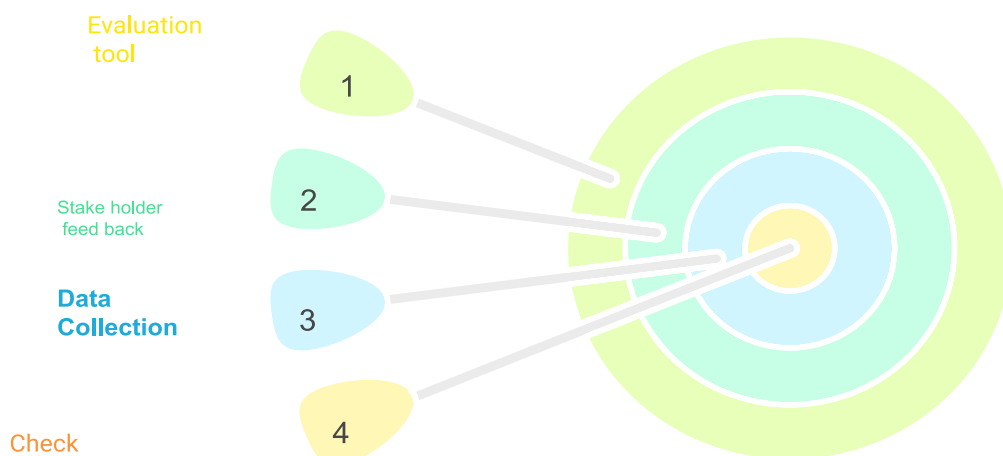


Check

Tips: Collect data to assess the outcomes of the test phase and compare results to planned objectives. Gather feedback from stakeholders to refine understanding.

Tools: Use performance dashboards and comparison charts to evaluate results, and collect qualitative feedback using surveys and feedback forms.

project evaluation process

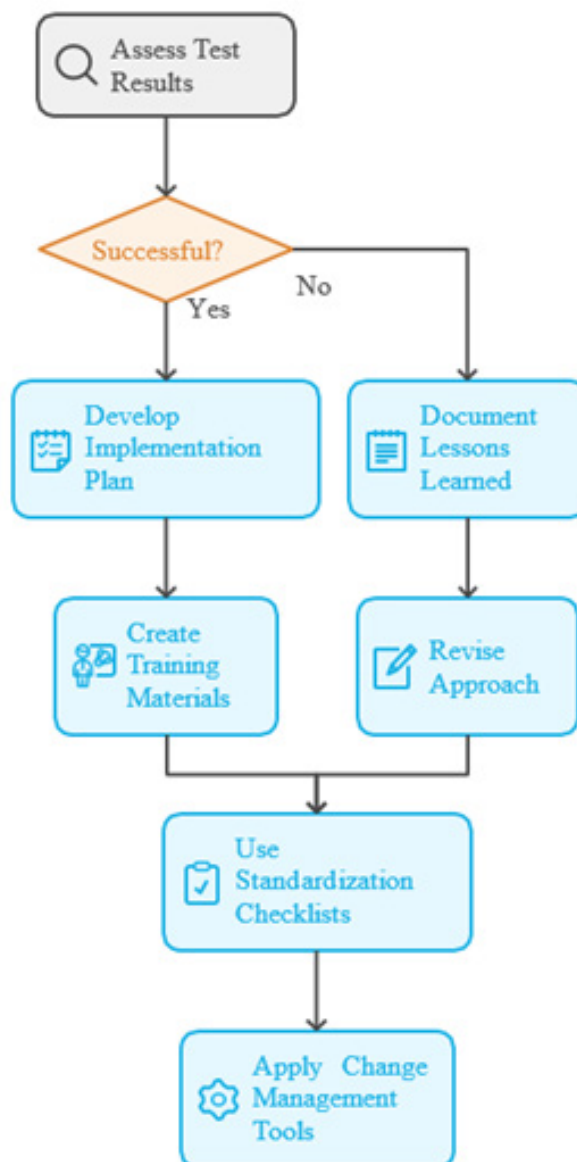


Act

Tips: If the test is successful, develop a plan for full implementation and create training materials for staff. If it falls short, use lessons learned to revise the approach and repeat the cycle.

Tools: Utilize standardization checklists to ensure consistent implementation and lessons learned templates to document insights. Apply change management tools like ADKAR or Kotter's 8-Step Model to manage the transition.

By integrating these tips and tools, organizations can systematically navigate each phase of the FOCUS PDCA cycle, ensuring thorough preparation, effective testing, accurate assessment, and sustainable implementation.



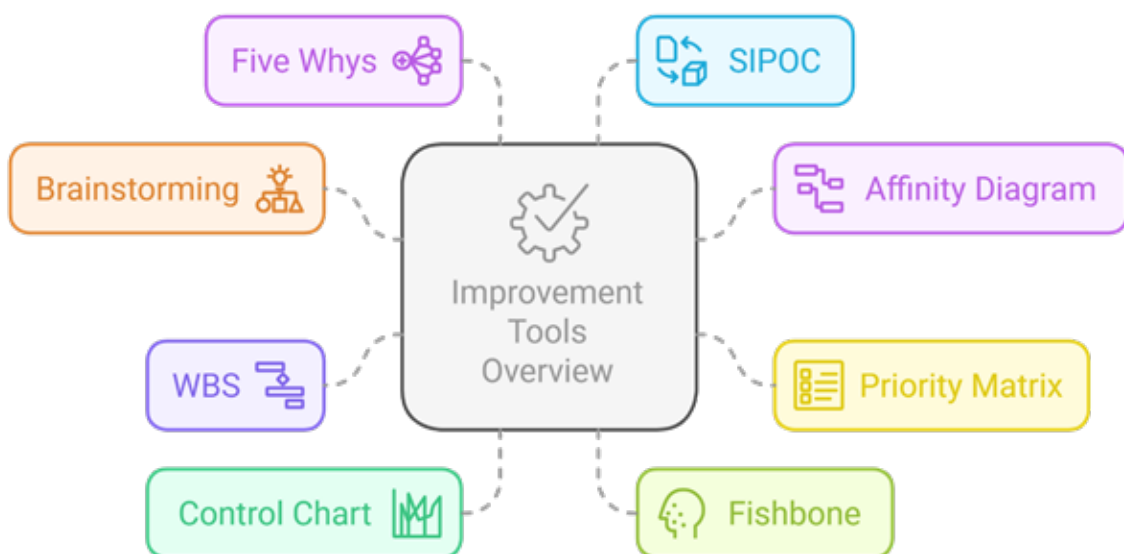


Effective use of improvement methodologies and tools ensures that healthcare facilities can address inefficiencies, improve patient care, and enhance operational efficiency. By strategically applying these tools in each phase of the improvement process, healthcare organizations can create a sustainable model for ongoing progress and high-quality care.

CHAPTER (6)



ENRICH YOUR KNOWLEDGE



Comprehensive Overview of Improvement Tools

Brainstorming

What: Brainstorming is a collaborative tool used to generate a wide range of ideas and solutions in a creative and non-judgmental setting. It encourages participants to share thoughts freely, fostering an environment where innovation can thrive.

When: This tool is most effective at the beginning of a project or when tackling a problem that requires fresh perspectives. It is particularly useful for team-based projects that benefit from diverse input and out-of-the-box thinking.

Why: Brainstorming helps teams explore multiple ideas and identify potential solutions that may not have been considered individually. By pooling the knowledge and creativity of the group, it uncovers new opportunities and approaches to complex challenges.

How:

Define the Objective: Clearly state the problem or topic for which ideas are being sought.

Gather a Team: Assemble a diverse group of individuals who can contribute different perspectives.

Set Ground Rules: Establish an open and supportive atmosphere where all ideas are welcomed without criticism.

Generate Ideas: Encourage participants to share their thoughts rapidly, recording each idea as it is presented.

Refine and Group: Once the session is complete, review and categorize the ideas to identify themes and viable options.

Outcome: Brainstorming sessions yield a wide array of ideas, promoting creativity and collaboration. This tool serves as a foundation for further analysis and decision-making, ensuring that innovative and comprehensive solutions are explored.



Affinity Diagram:

What: An Affinity Diagram is a visual tool used to organize a large number of ideas or data points into meaningful groups based on their natural relationships. It helps in synthesizing information and identifying patterns among disparate elements.

When: This tool is particularly useful during brainstorming sessions, project planning, or when analyzing complex issues where multiple viewpoints are present. It aids teams in collaboratively sorting ideas and reaching a consensus.

Why: Affinity Diagrams are essential for transforming chaotic information into structured insights. By grouping similar ideas together, teams can identify themes and prioritize action items, which facilitates effective decision-making and problem-solving.

How:

Collect Ideas: Gather all relevant ideas, observations, or data from team members through brainstorming or other means.

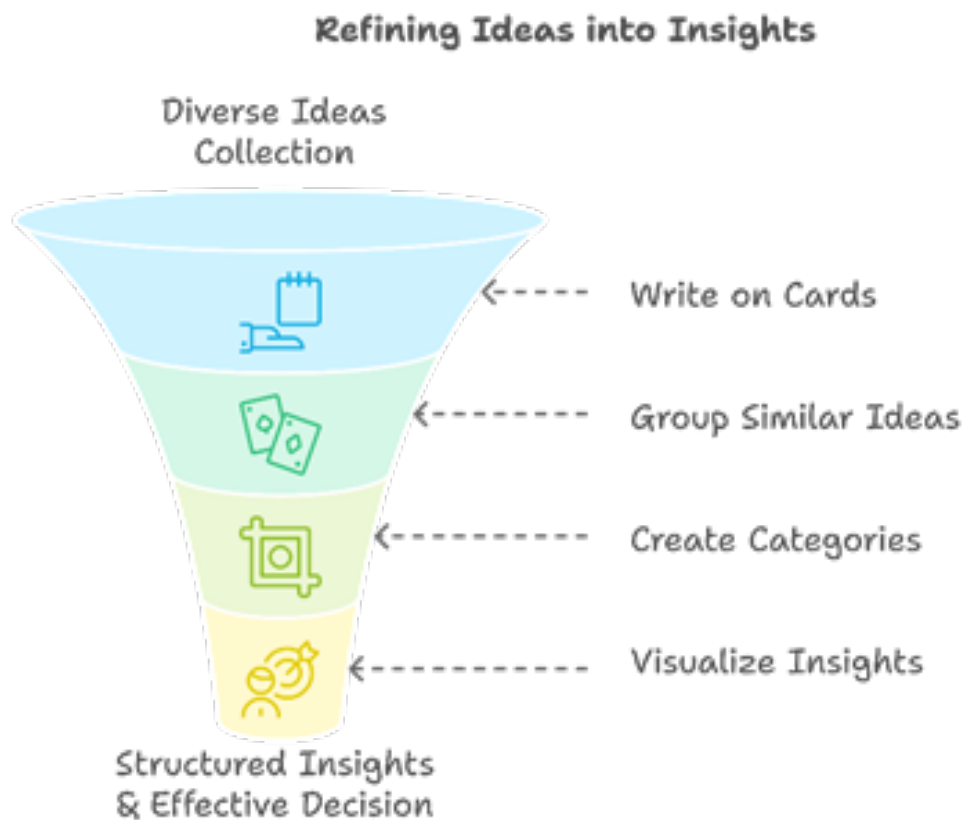
Write on Cards: Document each idea on individual sticky notes or cards to allow for easy movement and reorganization.

Group Similar Ideas: Collaboratively sort the cards into clusters based on similarities, discussing relationships and common themes.

Create Categories: Develop overarching category titles for each group that encapsulate the essence of the ideas contained within them.

Visual Representation: Arrange the grouped ideas and categories visually on a board or wall, providing a clear overview of the information.

Outcome: An Affinity Diagram offers a structured approach to organizing thoughts and ideas, making it easier for teams to see the big picture and identify actionable steps. By using this tool, organizations can enhance collaboration, streamline processes, and improve strategic planning.



Priority Matrix

What: A Priority Matrix is a strategic tool that visually categorizes tasks or improvement initiatives based on their impact and feasibility. It serves as an effective method for prioritizing projects, helping teams focus on actions that will yield the greatest benefits with the least amount of effort or resources.

When: This tool is particularly useful when multiple potential initiatives or tasks need to be assessed for their relative importance and practicality. It helps streamline decision-making by providing a clear visual representation of priorities, especially when resources are limited, and choices need to be made efficiently.

Why: The Priority Matrix aids teams in identifying which tasks should be tackled first to maximize results. It prevents wasted effort on low-impact or difficult-to-implement initiatives by ensuring that resources are directed towards actions that have the highest potential for positive outcomes. This structured approach supports better planning and resource allocation.

How:

List Initiatives: Start by compiling a list of all proposed projects or tasks that require assessment.

Determine Criteria: Establish key criteria for evaluation, such as potential impact on patient care and feasibility based on available resources.

Rate Each Initiative: Score each project according to the criteria, assessing their impact and feasibility on a scale (e.g., high, medium, low).

Plot on the Matrix: Place each initiative within a 2x2 grid with axes representing impact (low to high) and feasibility (low to high).

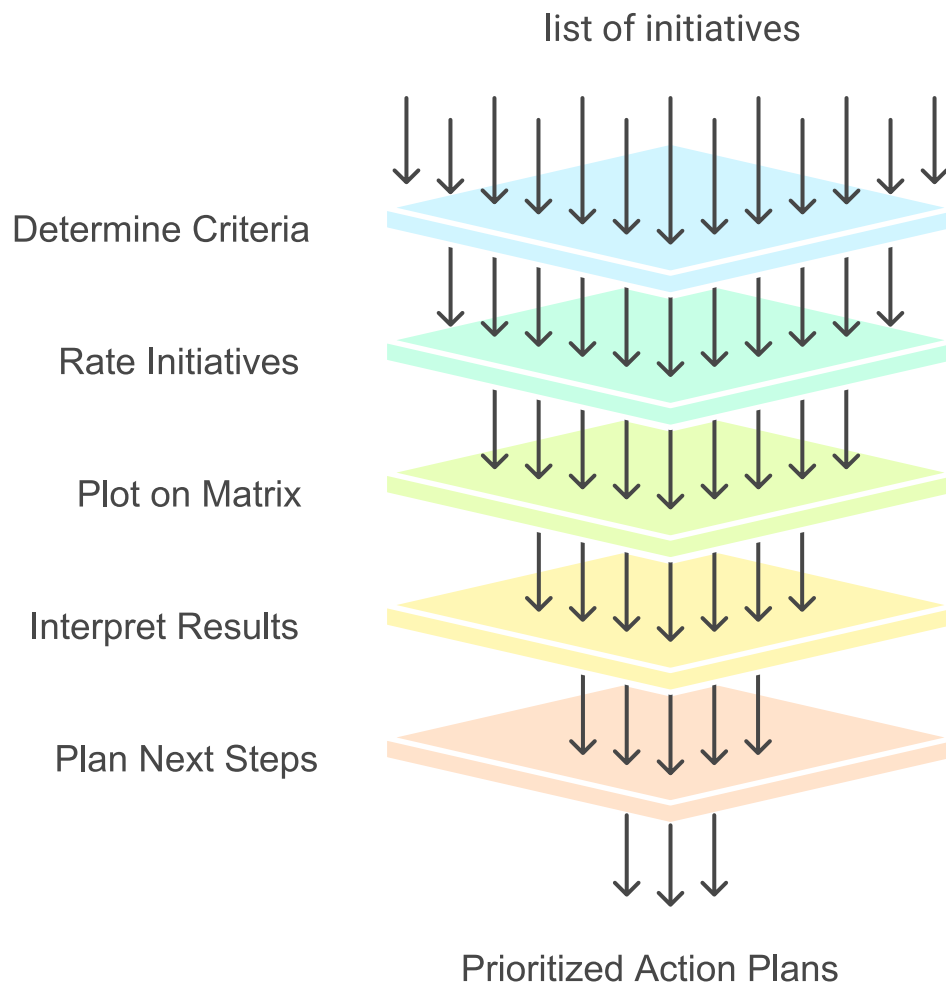
Interpret Results: Initiatives in the top-right quadrant (high impact/high feasibility) should be prioritized for immediate action. Projects in other quadrants can be reconsidered based on available resources and strategic goals.

Adjust and Discuss: Review the matrix as a team to ensure that placement reflects current priorities and organizational objectives.

Plan Next Steps: Use the matrix to guide action plans, focusing first on the highest-priority initiatives.

Outcome: The completed Priority Matrix provides a clear framework for decision-making, helping teams align their efforts with strategic goals and optimize resource use. This method facilitates a shared understanding of priorities and promotes more effective execution of improvement initiatives

Prioritizing Initiatives with priority Matrix



Work Breakdown Structure (WBS)

What: A Work Breakdown Structure (WBS) is a project management tool that breaks down a complex project into smaller, manageable components. It provides a hierarchical structure that outlines tasks and sub-tasks, making it easier for teams to understand, assign, and monitor work.

When: This tool is best used in the planning phase of a project to organize tasks and ensure that no critical steps are overlooked. It is particularly effective for large projects where clear delegation and progress tracking are essential.

Why: The WBS helps teams visualize the full scope of a project and promotes clarity in roles and responsibilities. By detailing tasks in a structured format, it facilitates resource allocation, timeline estimation, and better project control, leading to more efficient execution and reduced risk of oversight.

How:

Define the Project Goal: Start by clearly stating the main objective of the project at the top of the hierarchy.

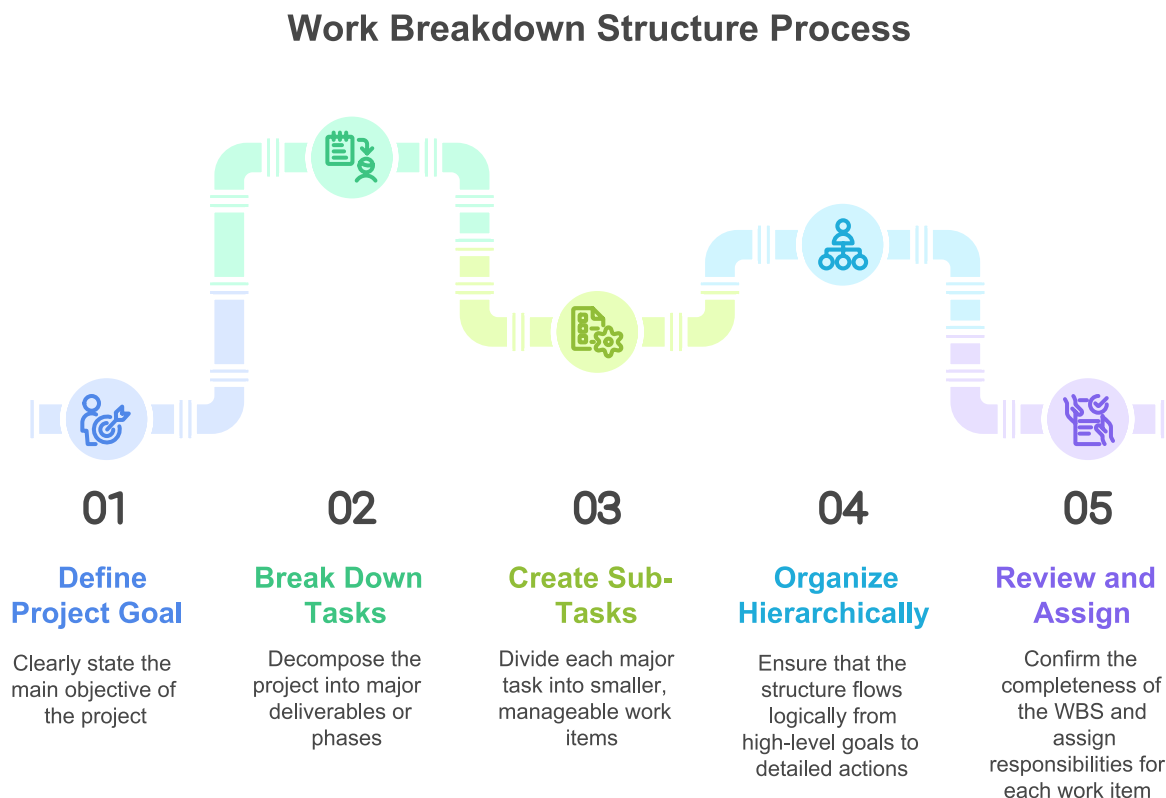
Break Down Tasks: Decompose the project into major deliverables or phases.

Create Sub-Tasks: Divide each major task into smaller, manageable work items until each can be assigned to a team member.

Organize Hierarchically: Ensure that the structure flows logically from high-level goals to detailed actions.

Review and Assign: Confirm the completeness of the WBS and assign responsibilities for each work item.

Outcome: A completed Work Breakdown Structure provides a clear, comprehensive outline of project activities and responsibilities. It enhances communication, improves task management, and ensures that all project components are aligned and achievable within the set timeline.



Control Chart

What: A Control Chart is a statistical tool used to monitor the stability and performance of a process over time. It visually represents data points in chronological order and includes control limits to indicate whether the process variations are within acceptable boundaries.

When: This tool is particularly useful when continuous process monitoring is needed to detect trends, shifts, or unexpected variations. It helps identify when a process is going out of control and requires intervention.

Why: Control Charts are essential for distinguishing between common cause variations (natural variations within the process) and special cause variations (unexpected changes due to external factors). This differentiation allows teams to take proactive measures before minor issues escalate into significant problems, ensuring consistent quality and reliability in operations.

How:

Collect Data: Gather relevant data points over a set period from the process you wish to monitor.

Plot the Data: Arrange the data sequentially on the chart with time on the x-axis and the process metric on the y-axis.

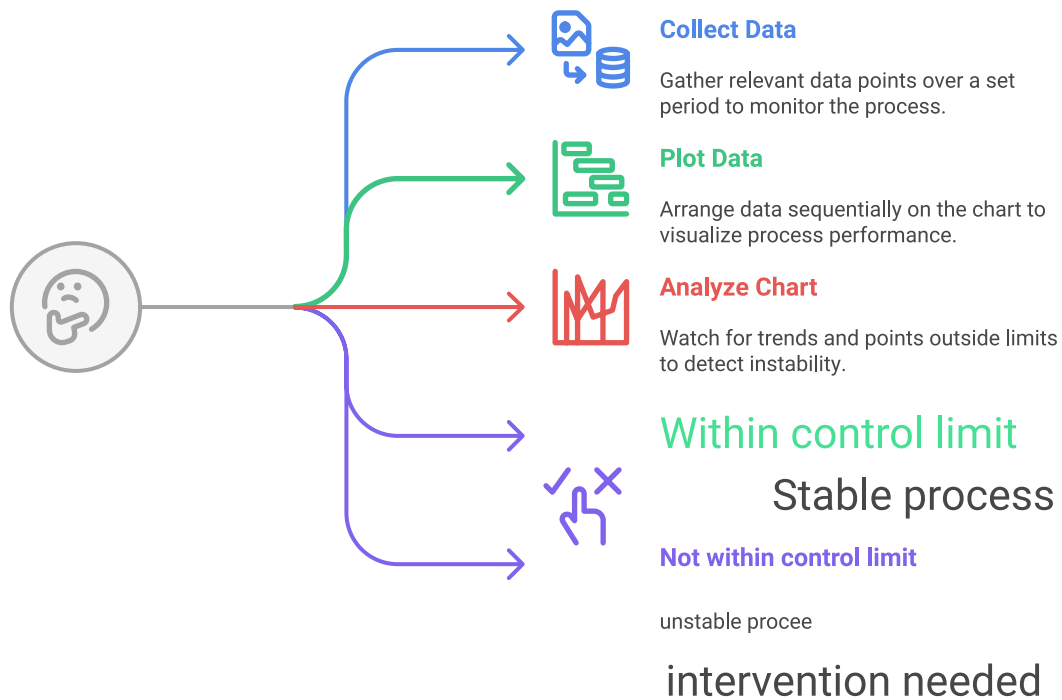
Calculate Control Limits: Determine the upper and lower control limits, typically set at ± 3 standard deviations from the process mean.

Analyze the Chart: Watch for trends, patterns, or points outside the control limits that indicate instability.

Take Action: Investigate and address any signs of special cause variation to bring the process back within control limits.

Outcome: A Control Chart provides real-time insights into process performance, helping teams maintain process consistency and take corrective action as needed. By using this tool, organizations can enhance quality control and foster continuous process improvement.

How to use a Control Chart effectively?



Fishbone Diagram (Ishikawa)

What: A Fishbone Diagram, also known as an Ishikawa or cause-and-effect diagram, is a visual tool used to identify and organize potential causes of a specific problem. Shaped like a fish's skeleton, it helps teams trace root causes by categorizing contributing factors into major branches.

When: This tool is best used during the analysis phase of an improvement project or when a team needs to understand the underlying causes of complex issues. It is particularly effective in brainstorming sessions and problem-solving workshops.

Why: The Fishbone Diagram aids in structuring discussions around potential causes of a problem, ensuring that teams consider a broad range of factors instead of jumping to conclusions. It encourages a thorough analysis and fosters collaborative thinking to identify the root cause of a problem.

How:

Define the Problem: Write a clear statement of the problem at the head of the "fish."

Identify Main Categories: Draw the main branches extending from the spine and label them (common categories include People, Methods, Equipment, Materials, Environment, and Processes).

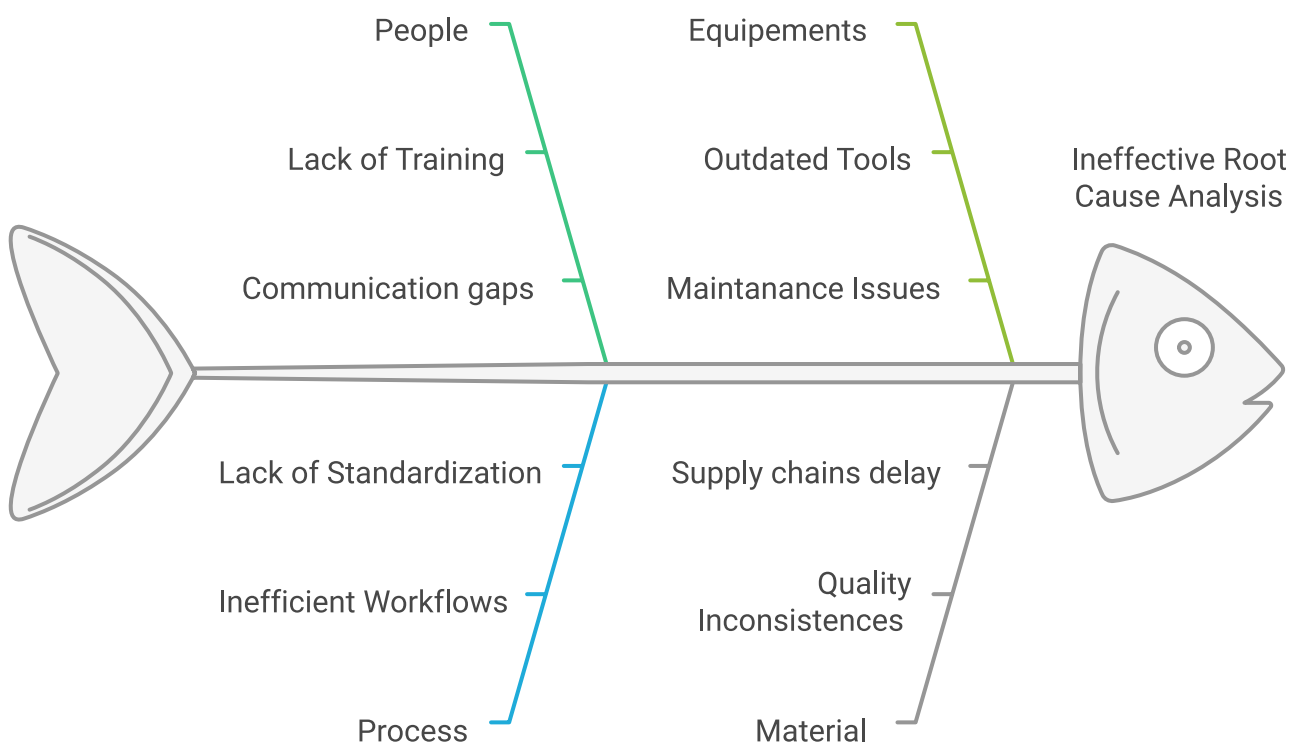
Brainstorm Causes: Collaboratively identify potential causes and add them as smaller branches under the relevant main categories.

Expand on Details: Break down each cause further by adding sub-branches to explore deeper levels of contributing factors.

Analyze: Review the completed diagram to identify which causes are most likely contributing to the issue.

Outcome: A completed Fishbone Diagram provides a structured overview of possible causes, helping teams pinpoint areas for further investigation and targeted intervention. This tool facilitates more effective root cause analysis and supports strategic planning for problem resolution.

Analyzing Root Causes with Fishbone Diagram



Five Whys Tool

What: The 5 Whys Tool is a simple, yet powerful technique used to explore the root cause of a problem by repeatedly asking the question “Why?” until the underlying issue is revealed. Typically, five iterations of asking “Why?” are sufficient to trace back to the root cause, but more or fewer may be needed depending on the complexity of the problem.

When: This tool is particularly effective when a quick, straightforward analysis is needed to identify the source of a problem. It is best applied during the early stages of an investigation or as part of a root cause analysis process.

Why: The 5 Whys Tool helps teams avoid superficial solutions by encouraging deeper exploration of issues. By identifying the real cause rather than just addressing symptoms, teams can implement more effective, long-lasting solutions.

How:

State the Problem: Clearly define the problem that needs investigation.

Ask “Why?”: Ask why the problem is occurring and document the response.

Repeat the Process: Use the answer from the previous step as the basis for the next “Why?” question.

Continue Asking: Repeat this process until the root cause is found, typically after five questions.

Verify the Root Cause: Ensure the final answer logically addresses the original problem and is actionable.

Outcome: The 5 Whys Tool provides a clear path to understanding the core issue behind a problem. This simple approach ensures that solutions are targeted and effective, preventing the recurrence of the issue and promoting continuous improvement.



SIPOC Diagram

What: A SIPOC diagram is a visual tool that outlines the key elements of a process, specifically focusing on Suppliers, Inputs, Process, Outputs, and Customers. It serves as a high-level summary that helps teams understand and analyze the essential components of any process. By categorizing these elements, teams can gain clarity on how each component interacts and contributes to the overall workflow.

When: The SIPOC diagram is best used during the initial stages of process improvement projects or when mapping out new processes. It is particularly effective in project planning sessions, process design, and process improvement initiatives, allowing teams to establish a common understanding of the process before diving into more detailed analysis.

Why: The SIPOC diagram aids in identifying all critical aspects of a process, ensuring that teams consider the entire workflow from beginning to end. It fosters collaboration and communication among stakeholders, allowing for a comprehensive view of how inputs are transformed into outputs. By visualizing these elements, teams can more easily identify areas for improvement and optimize performance.

Define the Process: Start by clearly defining the process to be analyzed, outlining its scope and objectives.

Identify Suppliers: List all suppliers that provide the necessary inputs for the process, including internal departments and external organizations.

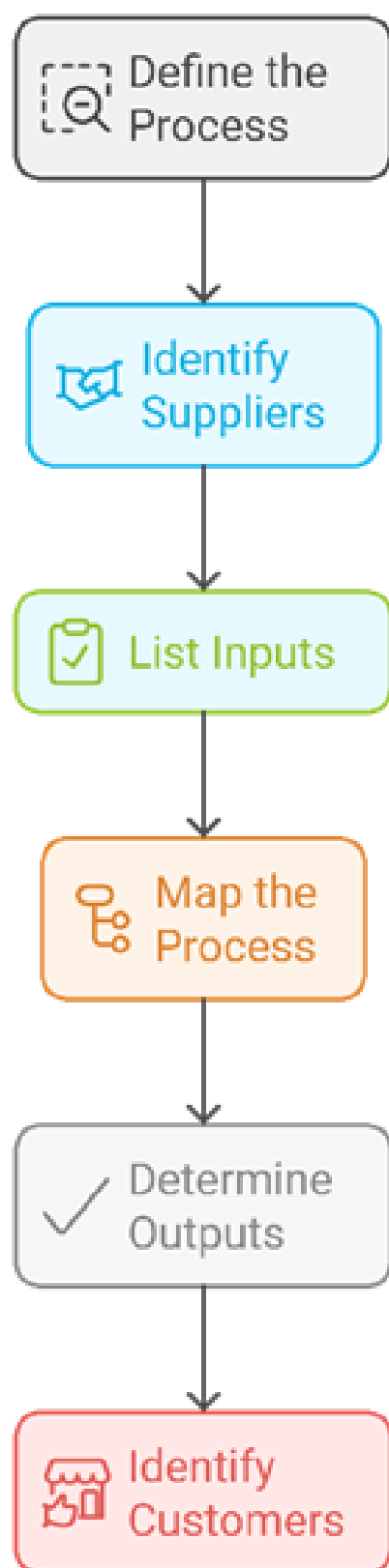
List Inputs: Identify the resources, materials, or information required to execute the process effectively.

Map the Process: Outline the main steps involved in the process, ensuring to capture the flow of activities.

Determine Outputs: Identify the outputs generated by the process, detailing the products or services delivered to customers.

Identify Customers: List the customers who receive or benefit from the outputs of the process, both internal and external.

Outcome: A completed SIPOC diagram provides a structured overview of the process, helping teams pinpoint areas for further investigation and targeted intervention. This tool enhances understanding of process dynamics, facilitates strategic planning, and supports effective decision-making for process improvement initiatives.



RACI Matrix:

What: A RACI Matrix is a responsibility assignment tool used to clarify roles and responsibilities within a team or project. It maps out four key roles: (Responsible, Accountable, Consulted, and Informed) to ensure everyone understands their specific involvement in each task or decision. The RACI Matrix provides a clear framework that reduces confusion and streamline collaboration by defining each person's level of participation.

When: The RACI Matrix is best used at the start of a project, during team onboarding, or when responsibilities need to be clarified. It is especially helpful in projects with multiple stakeholders, cross-functional teams, or complex tasks where role confusion could lead to delays or misunderstandings.

Why: The RACI Matrix enhances accountability, minimizes overlaps, and ensures that all team members know their roles in each part of the project. By assigning clear responsibilities, the tool promotes efficient communication, prevents task duplication, and helps teams work in sync towards shared objectives.

How to Create a RACI Matrix:

List Tasks or Activities: Identify all the tasks or activities within the project or process.

Define Roles: For each task, assign one or more team members to each RACI role:

Responsible (R): The person(s) who do the work to complete the task.

Accountable (A): The individual ultimately answerable for the task's completion.

Consulted (C): Those whose input is needed before the task is completed.

Informed (I): Those who need to be kept up-to-date on progress.

Review and Confirm: Ensure each team member understands their role, adjusting assignments as needed to prevent overlap or gaps.

Outcome: A completed RACI Matrix provides a clear, organized view of responsibilities within a project or process, enhancing collaboration and reducing ambiguity. By ensuring that every role is clearly defined, teams can operate more effectively, meeting deadlines and achieving project goals with fewer misunderstandings and conflicts. This tool supports efficient project management and promotes accountability, leading to smoother project execution.



Responsible



Accountable



Consulted



Informed

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