

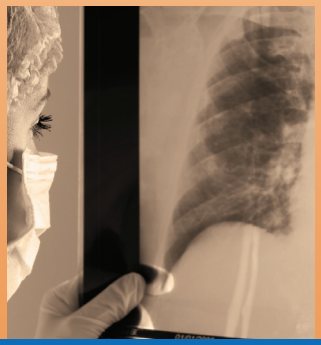

Conducting Root Cause Analysis

A Resource Guide for Health Care Providers

Including sections on:

- **Failure Mode and Effect Analysis**
- **Communicating With Patients Following an Adverse Event**

GREATER NEW YORK HOSPITAL ASSOCIATION
GNYHA

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Contents

Preface

Conducting Root Cause Analysis: A Resource Guide for Health Care Providers, a publication of the Greater New York Hospital Association (GNYHA), is intended to assist hospitals and other health care organizations in performing effective and meaningful root cause analysis (RCA) and failure mode and effect analysis (FMEA) for quality improvement and regulatory purposes. The Resource Guide can be used as a tool to help train and educate staff responsible for those activities.

The Resource Guide was first published by GNYHA in 2003, under the title *Conducting Effective Root Cause Analysis and Failure Mode and Effect Analysis: A Resource Guide.* This new edition of the updated *Resource Guide* was supported by a generous grant from the New York State Department of Health under the Health Workforce Retraining Initiative.

GNYHA would like to acknowledge the contributions of Monica Santoro, RN, CPHRM, CPHQ, Senior Vice President and Senior Consultant, Marsh USA, Inc.

Founded in 1904, Greater New York Hospital Association (GNYHA), is a one-of-a-kind trade association comprising nearly 250 hospitals and continuing care facilities, both voluntary and public, in the metropolitan New York area and throughout the State, as well as in New Jersey, Connecticut, and Rhode Island. GNYHA defines its membership not by geography, but by the common mission to serve health care providers, support patients in their journey toward better health, sustain communities for a brighter future, promote cultural diversity in health care leadership, and strengthen partnerships that promote high-quality, more affordable health care. GNYHA accomplishes its mission through policy analysis and development, advocacy, communication, education, research, and business services.

Root Cause Analysis

OVERVIEW

Root cause analysis (RCA) is a comprehensive, system-based review process used to identify the basic factors—or root causes—that underlie variation in performance. Such variation in health care includes the occurrence or risk of occurrence of a medical error, adverse event, or "near-miss event," which is defined as an event that could have resulted in harm but was identified before reaching the patient, thus not affecting the patient. This resource guide uses the term ***adverse event*** to refer to any medical error, near-miss, or undesirable occurrence that resulted or could have resulted in patient harm. A root cause is the most fundamental reason a problem has occurred, and is very specific. The Department of Veterans Affairs (VA) National Center for Patient Safety defines a root cause as any contributing factor in the chain of events that, when acted upon by a solution, prevents the problem from recurring.[1]

Root cause analysis is typically conducted reactively—that is, in response to an adverse event. It can also be conducted proactively—that is, before an event has occurred—when combined with failure mode and effect analysis (FMEA), to identify potential causes and contributing factors to the "failure mode" under review. The product of the RCA process is an ***action/improvement plan*** that identifies the strategies an organization intends to implement to reduce the risk of similar events from occurring in the future and for measuring the effectiveness of those strategies. While developing the action/improvement plan, interim actions may be required to address the problem in the short term, to prevent a recurrence.

TYPES OF FAILURES IN COMPLEX SYSTEMS

Research tells us that adverse events in complex systems—like health care institutions—occur primarily through a chain of events. Those events are triggered by multiple contributing factors, including organizational factors, which play a critical role in influencing the behavior of the people involved.

Latent and Active Failures

Complex systems fail because of the combination of multiple failures at different points in the process, each one individually insufficient to cause an adverse event by itself. These failures are latent or dormant in the system. ***Latent failures*** in organizational processes may be hidden and become obvious only when they combine with other factors to breach the barriers or defenses that typically prevent adverse events from reaching the patient. ***Active failures***, by contrast, occur at the point of care and are associated with the "frontline operators" in a complex system.[2] The effects of active failures are felt almost immediately and can lead to an adverse event—for example, programming an infusion control device incorrectly (active failure) can lead to patient morbidity or mortality (adverse event).

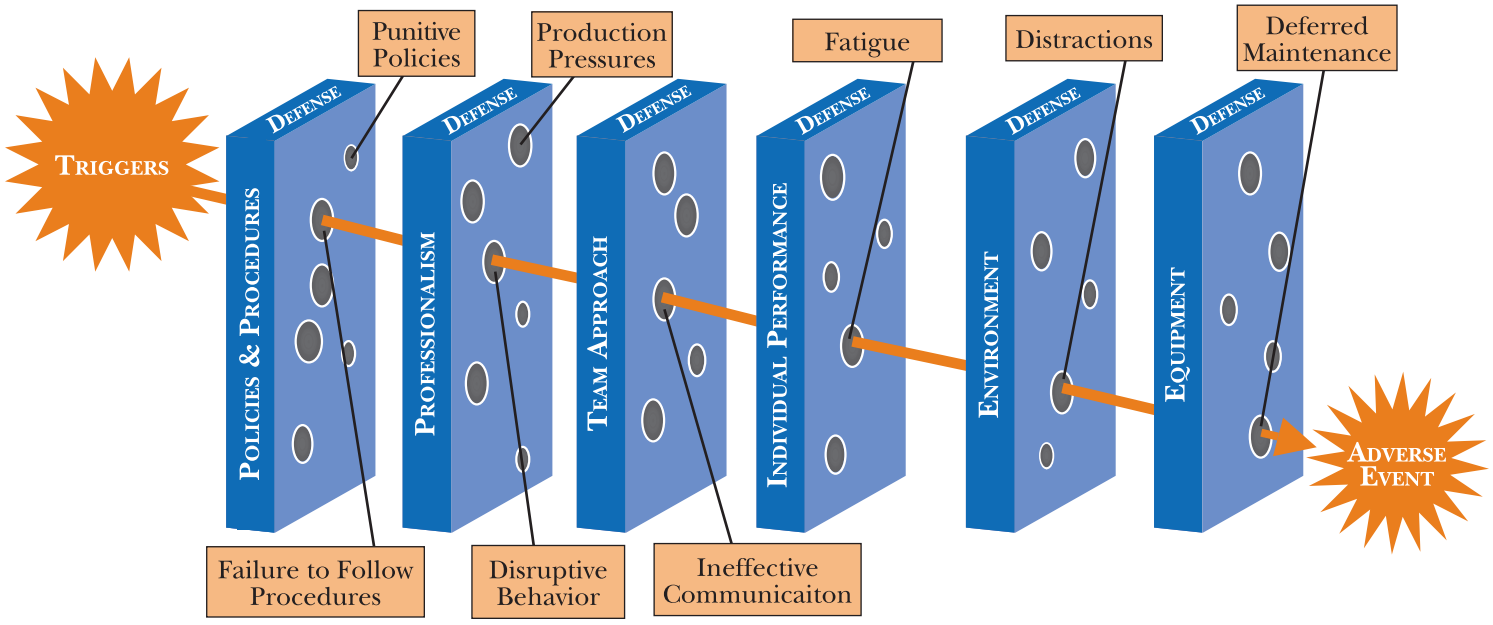
Exhibit 1 demonstrates how latent failures contribute to errors in complex systems. The latent failures are represented by the "holes in the Swiss cheese" and are typically associated with organizational processes and systems. Latent failures leading to the incorrect programming of an infusion control device, for example, might include the use of different concentrations of the same medication, or failure to carry out "double-checks" as required by policy because of staffing and time pressures.

The benefit of identifying latent failures when conducting a root cause analysis of a specific adverse event is that it uncovers failures in organizational processes that create conditions that can predispose an organization to a variety of errors.[3] For example, when the incorrect use of a defibrillator during a cardiac arrest—an active failure—leads to an adverse event, it is valuable to try to identify the associated latent failure(s). Latent failures in that adverse event might be lack of standardization of equipment—for example, different defibrillators are used on different patient care units throughout the organization—and/or lack of routine training to orient staff to the use of emergency equipment and to the roles of each team member in responding to an emergency. Both of these latent failures can lead to misuse of equipment and result in an adverse event.

Factors associated with an increased risk of failures, either active or latent, that can lead to health care errors include:[4]

- ineffective communication among members of the health care team;
- multiple individuals involved in the care of the patient—that is, multiple "hand-offs" of care;
- barriers to communicating with patients and/or coworkers;
- time and production pressures;
- inexperienced caregivers, including those in the teaching setting;
- high acuity of patient illness or injury;
- high volume and/or unpredictable patient/work flow;
- the need for rapid care management decisions;
- a health care environment that is prone to distractions resulting from interruptions, noise, and so on;
- many and varied interactions with diagnostic and/or treatment technology—that is, lack of standardization; and

Exhibit 1: Complex Systems and Latent Failure



Source: Adapted from James Reason. *Human Error.* Cambridge UK; Cambridge University Press; 1990 p 208.

- the use of diagnostic or therapeutic interventions that have a narrow margin of safety, including the use of high-alert drugs.

Human Error

It is helpful when conducting a root cause analysis and formulating the action/improvement plan to consider the different causes of errors that underlie variation in human performance—that is, why do humans err? The contributing causes and the actions/improvements to remedy those causes may be different if the error was due to an unintended "slip"—that is, a skill-based error, as opposed to a rule– or knowledge–based error, or procedural violation.[5]

Skill-based Errors. Skill-based errors can be characterized as slips or lapses. These unconscious "glitches" can occur because of a break in routine while attention is diverted. With a skill-based error, the correct plan was intended but there was an error in execution. For example, the clinician intended to administer Humalin N™ (an intermediate-acting insulin) but inadvertently administered Humalog™ (a rapid-acting insulin) as a result of their close proximity on the medication cart, sound-alike names, and look-alike vials.

Rule- and Knowledge-based Errors. Unlike skill-based errors, rule- and knowledge-based errors involve failures in planning and can be characterized as "mistakes." These failures can be associated with a misinterpretation of the situation leading to the application of a wrong rule, or with a knowledge deficit. Administering a rapid-acting insulin 30 minutes before meal time instead of just prior to meal time, because the clinician mistakenly applied the "rule" for intermediate-acting insulin, is one example of a rule-based error. Ordering the wrong dose or type of insulin because of a knowledge deficit related to the onset, peak, and duration of different types of insulin is an example of a knowledge-based error.

"Rather than being the main instigators of an accident, operators tend to be the inheritors of the system defects . . . Their part is that of adding the final garnish to a lethal brew whose ingredients have already been long in the cooking."

—James Reason, *Human Error*, page 173

Using the Incident Decision Tree

The Incident Decision Tree was developed with the intent to support managers in determining a fair and consistent or "just" course of action when evaluating staff members' involvement in an adverse occurrence.

The majority of health care errors occur as a result of the interaction of several process failures that are beyond the control of the individual involved. The Incident Decision Tree provides managers with a standardized approach to evaluating individual accountability within the context of systems and organizational issues that may have contributed to the event.

Question One – Deliberate Harm Test

Was the action and outcome as intended?

This question involves situations where the individual action was intentional and it was intended to cause harm. This is a very rare situation.

Question Two – Incapacity Test

Did illness or substance abuse contribute to the occurrence?

These situations need to be addressed immediately and evaluated on a case-by-case basis in conjunction with human resources. This question can be referred to as the "incapacity test."

Question Three – Foresight Test

Was there a knowing violation of a procedure?

This question addresses violations of policies and procedures. The majority of patient safety incidents will fall into this category. This is a challenging issue to address and managers are encouraged to conduct a careful evaluation of the facts. Some questions to ask and issues to consider include the following:

- Was there a procedure in place?
- Were there conflicting procedures?
- Was the individual trained in the procedure?
- Was the procedure routinely violated and/or not regularly followed?
- Was the procedure workable?
  - » Problematic procedures frequently result in "work arounds" that can result in variation in carrying out the procedure
- Did the individual intend to ignore the procedure?

In situations where there was a violation of a well-established procedure considerations should include:

- the information available at the time;
- the speed at which a decision had to be reached; and
- the individual's awareness of the risk being created.

The more control an individual had over the situation the more likely it is that the risk was unacceptable.

Conversely, culpability diminishes in emergency situations where the individual was under extreme pressure and had little time to consider the consequences.

continued on opposite page

Confirmation bias. Confirmation bias is a knowledge-based error involving the tendency to focus on evidence that supports a working hypothesis, such as a diagnosis, rather than looking for evidence that refutes the clinician's original impression or provides greater support to an alternative diagnosis. Confirmation bias is also referred to as cognitive fixation or lock-up. For example, a patient presents to the emergency department with abdominal pain and a history of kidney stones. The physical exam is inconclusive and the patient is treated for a presumptive diagnosis of kidney stones despite subsequent laboratory evidence that does not support that diagnosis.[6]

Procedural Violations. Procedural violations are deviations from established policies and procedures that are designed to promote patient safety. For example, failure to conduct a preoperative time out, as required by The Joint Commission's Universal Protocol, is a procedural violation. Such deviations can be the result of many factors including but not limited to: inadequate training, knowledge deficit, and time and resource constraints. Time and resource constraints can prompt staff to routinely compromise formal policy and procedures—that is to engage in "work arounds"—wherein staff work around a problem rather than resolve it because of barriers to following the procedure as formally prescribed. As discussed further in the section on action/improvement plans, it is important to consider the preceding cause(s) associated with the violations.

"JUST CULTURE"

It is also important, when reviewing events, to apply the principles of a "just culture"—that is, a culture that seeks to balance the need to learn from mistakes with the need to hold staff accountable. It is well recognized that in order to learn how to prevent errors, health care professionals need to create an environment in which staff are comfortable reporting errors and near-misses without the threat of blame and retribution. The

Using the Incident Decision Tree *continued*

Peer Review – Substitution Test

To pass the substitution test, consider: Would three individuals with similar experience and in a similar situation and environment act in the same manner as the person being evaluated?

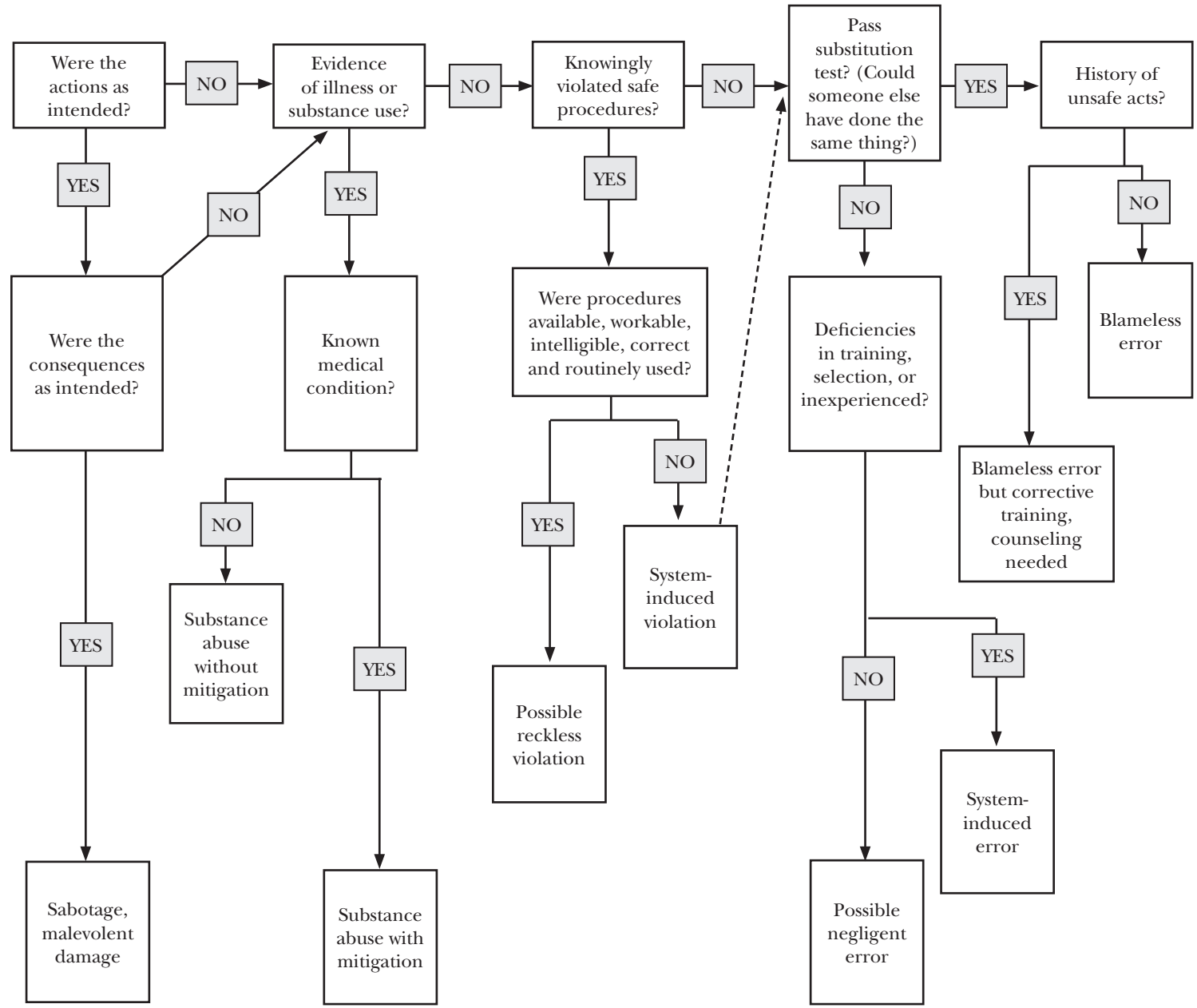
- If the answer is "Yes": The problem is not the individual, but more likely the environment that would lead most individuals to that action.
- If the answer is "No": If similarly experienced individuals would *not* have acted in a similar manner, it's more likely that the individual being evaluated is more culpable/accountable and in need of action – whether it is counseling or removal or another action.

It is important to consider the acts in the context of what was known at the time to try to minimize the hindsight bias associated with retrospective review.

This test serves to highlight deficiencies in training, experience or supervision that may have contributed to the incident and helps to assess whether the individual was properly equipped to deal with the situation.

Source: Meadows, et al. *The Incident Decision Tree: Guidelines for Action Following Patient Safety Incidents. Advances in Patient Safety: Vol. 4.* http://www.ahrq.gov/downloads/pub/advances/vol4/Meadows.pdf

Exhibit 2: Decision Tree for Determining Culpability of Unsafe Acts



Source: Adapted from James Reason (1997). *Managing the Risks of Organizational Accidents.*

importance of promoting a culture of safety—which is characterized in large part by a "just culture"—cannot be overemphasized. In evaluating adverse events within the framework of a culture of safety, considerations such as substance abuse and willful violations of safety procedures are balanced against deficiencies in training and system-induced violations.[7]

An algorithm to assist in determining the appropriate course of action to take following an adverse event appears in **Exhibit 2**. David Marx has also developed an algorithm that is available at **www.justculture.org.** The "Just Culture" algorithm helps evaluate events by classifying three types of behavior: human error such as inadvertent actions or slips; at risk-behaviors where the risk was not recognized or was believed to be justified; and reckless behaviors which rarely occur and involve a conscious choice to disregard a known risk. The Agency for Healthcare Research and Quality (AHRQ) explains, "A just culture recognizes that competent professionals make mistakes and acknowledges that even competent professionals will develop unhealthy norms (shortcuts, 'routine rule violations'), but has zero tolerance for reckless behavior."[8]

FEATURES OF ROOT CAUSE ANALYSIS

The root cause analysis focuses on the ***processes*** and ***systems*** involved in the adverse event under review, rather than on the individuals involved in that event, and, as described above, focuses on latent failures in organizational processes to determine the underlying causes of the active failure or error. It then progresses from identifying ***special causes*** in clinical processes to identifying ***common causes*** in organizational processes.[9]

Root cause analysis also identifies changes that could be made in systems and processes—either through redesign or development of new systems or processes—that would improve the reliability of the process in achieving the intended results and reduce the risk of adverse events from occurring in the future.[10]

Implementation Cue:

The Incident Decision Tree should be used as a guide, and cannot substitute for the judgment of management as to the most appropriate course of action to take following careful review of the circumstances of a particular event.

Finally, root cause analysis typically identifies several root causes for any given adverse event.

DESIGNATING A TEAM

Root cause analysis is a team-based process. Successful and effective root cause analysis cannot be done by a single individual.

The RCA team must include:

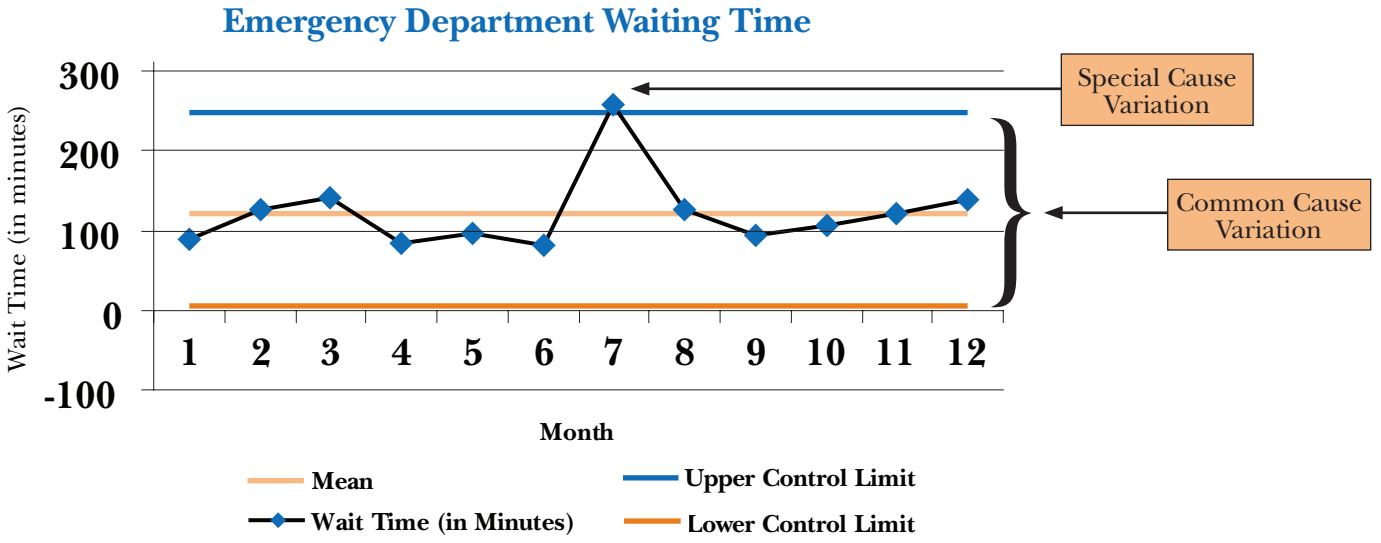
- frontline staff who are directly involved in the processes under review, including post-graduate trainees, as applicable;
- clinicians who have expertise in the subject matter under review;
- other representatives from the departments involved in the adverse event and associated processes under review; and
- others who are well-versed in the RCA process.

The team may also include those individuals who were directly involved in the particular incident under review. This decision is up to the individual organization.

In addition, consider having representatives from other departments—such as Radiology, Pharmacy, Information Technology, and Biomedical Engineering—participate on the team. These professionals often have unique and fresh ways of looking at how processes are designed and the impact of equipment and technology on human performance. Broader representation also helps expose more staff to the RCA process and helps to promote the organization's commitment to safety.

Organizational leaders who are empowered to make decisions and effect change must also be included on the team. The participation of leadership in the RCA process demonstrates

Exhibit 3: Control Chart



Source: Greater New York Hospital Association, Lorraine Ryan and Monica Santoro, 2009.

Using Control Charts to Identify Special and Common Cause Variation

Variation is inherent in every process. Adverse events involve unexpected variation in a process. "Special cause" and "common cause" variation are terms used in statistical process control to describe the type of variation that is occurring. A degree of common cause variation is inherent in every process and is a consequence of the way the process is designed. In order to reduce common cause variation and improve the level of performance and/or reliability, the process must be redesigned. An example of common cause variation is the waiting time in an emergency department. There will always be a degree of variation from the average (mean) waiting time.

Special cause variation is an atypical variation that arises from unusual circumstances or events that result in marked variation. Special cause variation is not inherently present in the systems and processes we work with every day, although special cause variation can be a common occurrence that must be addressed. Special cause variation results from factors that are not part of the system as designed. ***Control charts*** are helpful in determining the stability of a process and to identify the degree of common cause and special cause variation (see **Exhibit 3**). In **Exhibit 3**, special cause variation would result if there was a significant deviation from the mean (average) waiting time because of a large number of sick calls or an unusually high patient volume in the emergency department. Special cause variation in a process is frequently the result of common causes in the larger system of which the process is a part. Root cause analysis provides an opportunity to reduce the risk of special cause variation. In Exhibit 3, the degree of special cause variation, as evidenced by the increased waiting time, may not have occurred had there been systems in place to promote effective communication and planning to address variable patient flow and resources. However, keep in mind that eliminating the special cause variation will address only that specific cause for variation. The RCA team should also identify the factors that contribute to common cause variation as a result of the way the process was originally designed.

Source: *Root Cause Analysis in Healthcare Tools and Techniques Second Edition* (Oakbrook Terrace, Illinois: The Joint Commission on Accreditation of Healthcare Organizations, 2003) pp 6-8.

that patient safety is an organizational priority.

Team Member Roles

Each root cause analysis requires individual staff members to participate in the review and analysis of the case and to serve in specific roles on the RCA team. These roles are highlighted below; however, each organization may structure the team differently according to its own needs and available resources.

Team Leader: The team leader should have expertise related to the clinical and/or operational systems under review and should be familiar with the RCA process. Depending on the resources available at a given organization, the team leader may also serve as the facilitator.

Facilitator: This person must be knowledgeable in the RCA process, have expertise in applying the tools used to conduct a root cause analysis, and be skilled in moving the team forward.[11] The facilitator should *not* be a "stakeholder" in the processes being reviewed—in other words, the facilitator must be an objective party to the process.

Scribe: The scribe documents the results of the team's analysis and action/improvement plan.

Designated Subject Matter Experts: These individuals review the medical record, present those aspects of the case under review that pertain to their area(s) of responsibility, and conduct the literature search.

Implementation Cue:

It is essential to include frontline staff in the root cause analysis process. If it is difficult to take frontline staff away from their assigned duties, *go to them*. Find out what they think is the root cause or causes of the event and get their input on how to prevent a recurrence. Ask the frontline staff how they actually carry out the process to identify variations from the way the process should ideally be carried out.

STEPS IN THE ROOT CAUSE ANALYSIS

The root cause analysis itself begins with a team meeting. At the first meeting, the facilitator or a designated team member should:

- explain the objectives and process of a root cause analysis;
- emphasize confidentiality;
- make it clear that the focus is on opportunities for

improvement and not assigning blame;

- explain that the focus is on the process involved, not the people involved;
- advise the team of the time frame for completing any necessary peer review, submission of literature review, action/improvement plans; and
- schedule future meetings.

The RCA team will continue to meet until the analysis is finalized.

Determine What Occurred

At the first meeting, designated team members should present an objective summary of the known facts of the event, including, at a minimum:

- information about the patient; and
- information about the event under review—what happened, at what point in the care process the event occurred, when it occurred, where it occurred, who was involved (by job function or title, not *individual names*), and how it was discovered. A graphic representation of the sequence of events demonstrated on a time line is recommended.

Following this review, the team should formulate a "problem statement"—a concise description of the adverse event. In many cases this will be obvious (for example, misadministration of medication). In other cases, it may not be so obvious and the team may need to decide on the problem statement based on the review of the case as outlined by the team leader or facilitator (for example, a delay in diagnosis).

Depending on the nature of the event, applicable policies, procedures, staffing schedules, and so forth, related to the adverse event should be reviewed. It may be useful to draft a flow chart of the process(es) that were involved in the adverse event.

Implementation Cue:

Prior to the initial RCA meeting, identify the individuals who will fulfill the team member roles. This will help facilitate discussion and save time at the meeting. Avoid names and use descriptive titles of staff involved in the event to explain who did what, when, how, and why in all documentation.

Implementation Cue:

When you are conducting a root cause analysis, don't get distracted by other quality issues that were not a contributing or "root" cause of the event under review. Refer those quality issues to the appropriate department, standing committee, or ad hoc committee for follow-up. In considering whether a factor is a root cause, ask the following question: Had this *not* occurred, would the chain of events have been altered and the occurrence have been prevented from reaching the patient?

Flow Chart. A flow chart is a graphic representation of a process. (See **Exhibit 4.** Rectangles represent a step in the process and diamonds represent decision points.) It can be used to help the RCA team understand all the steps in the process as well as high-risk points in the process. The flow chart can illustrate the path a process should have taken as defined in the institution's procedure, as well as the actual path a process took in the particular adverse event under review.

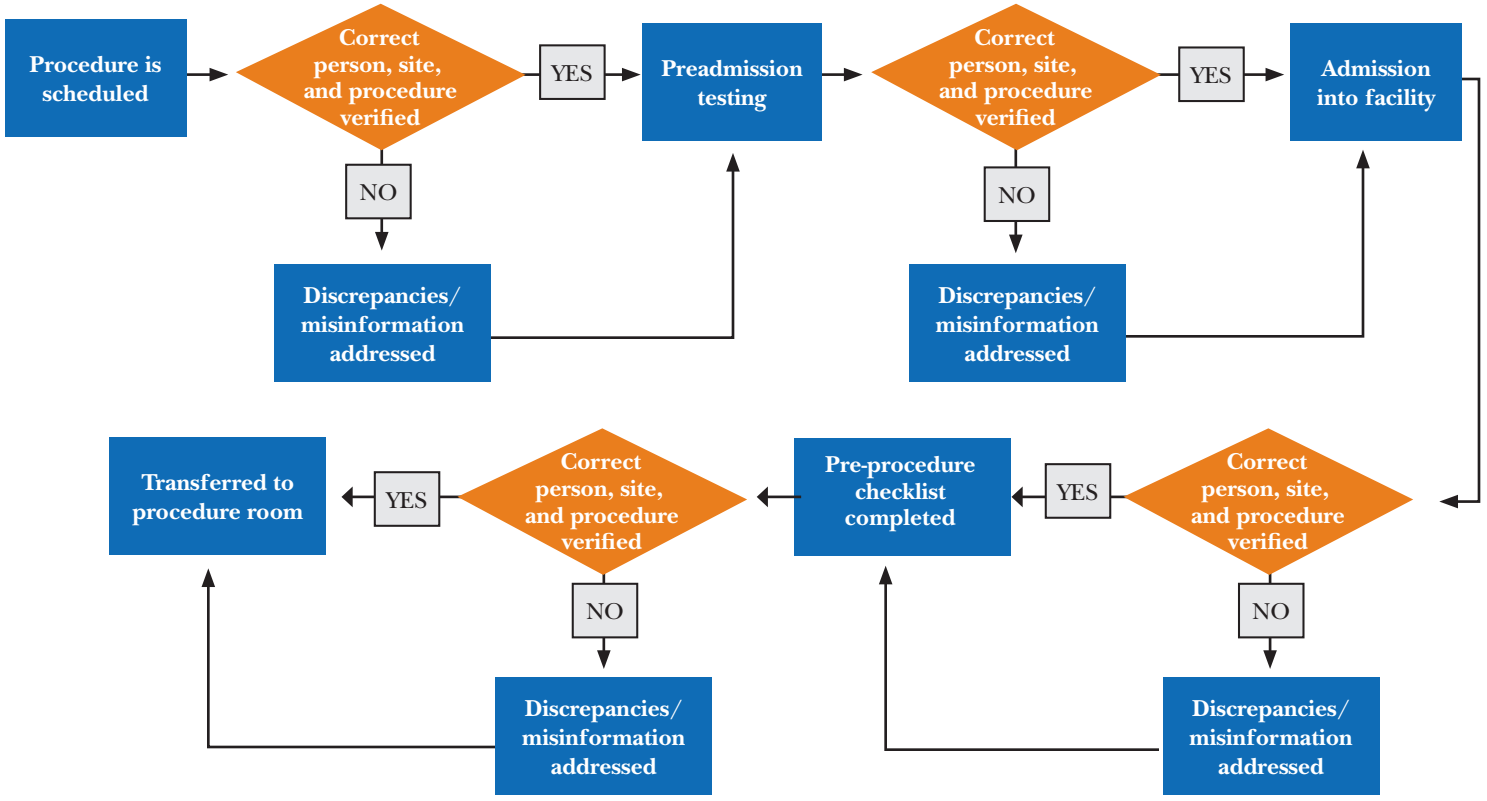
Determine Why the Adverse Event Occurred

Using specific tools that are described below—such as brainstorming, cause-and-effect diagrams, The Joint Commission Root Cause Analysis Matrix, and the literature review, the RCA team determines why the adverse event occurred by identifying both its proximate (or immediate) causes and its underlying (or "root") causes and contributing factors.

Brainstorming. Everyone has an opinion. Brainstorming allows for the spontaneous contribution of ideas from all members of the group. Rules for brainstorming include the following:

- Team members should be able to call out ideas freely—ideas generate ideas.

Exhibit 4: Universal Protocol – Pre-procedure Verification Process



- There is no bad idea. Ideas should not be censored, edited, or discussed at this point.
- Team members should not criticize ideas.
- Brainstorming should focus on the processes involved, not the people involved.
- If team members get sidetracked from the particular event under review, the facilitator should intervene and bring the team's focus back to the event under review.
- Set a time limit for brainstorming; however, there should be enough time for every member to make a contribution.

Hindsight Bias. During the brainstorming process, keep "hindsight bias" in mind—that is, knowing the outcome of an event influences how we assess past events. Things that were not seen at the time the event occurred may seem obvious in retrospect. Hindsight bias:

- misleads the individuals reviewing the adverse event so that they simplify the causes, highlighting a single element and overlooking multiple contributing factors; and
- makes it easy to blame an individual or arrive at a simple solution, but difficult to determine the underlying cause(s) of the adverse event.

Cause-and-Effect Diagrams. Also known as Ishikawa, or fishbone, diagrams (see **Exhibits 5 and 6**), cause-and-effect diagrams:

- present a clear picture of the many contributing factors that result in a defined outcome;
- determine general categories for the proximate and underlying causes of an event;
- are designed to identify, categorize (although any cause may be attributable to more than one category), and display large numbers of possible causes for each

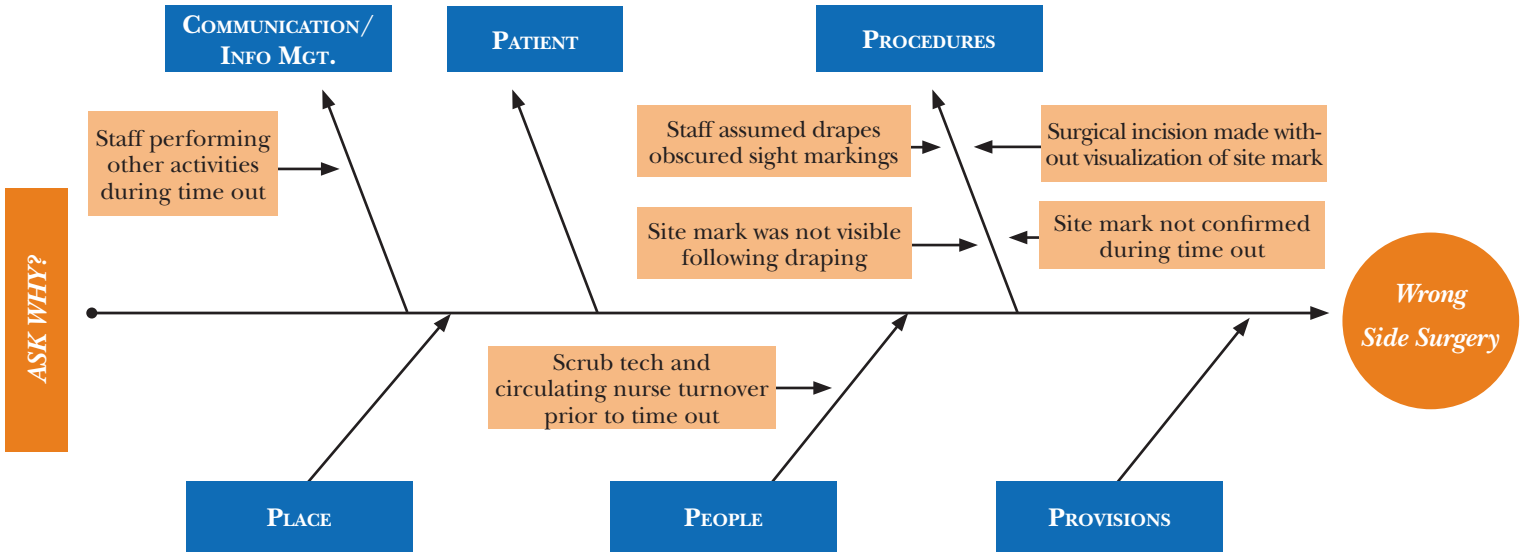
Implementation Cue:

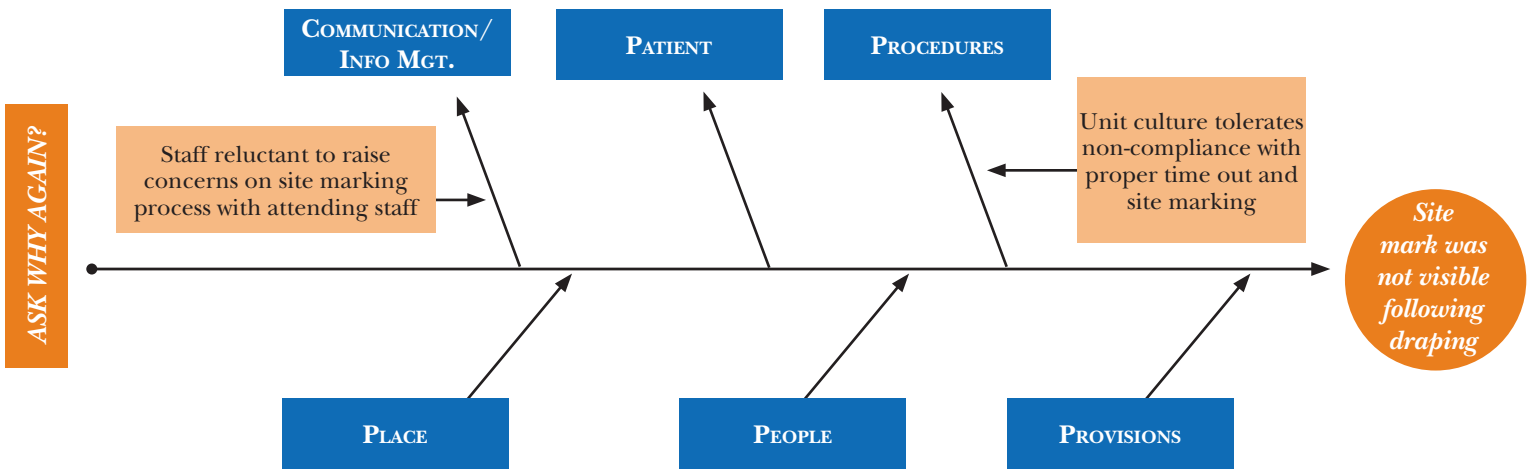
Prepare target goals for the meeting indicating which team member is responsible for each goal and distribute the goals to the team. This communicates clearly what needs to be accomplished at the meeting.

Implementation Cue:

Use a flip chart to write down and capture ideas as they are called out during the root cause analysis team meeting. Ideas generate ideas, so it is important for the team members to be able to visualize the potential issues identified as they consider other contributing factors.

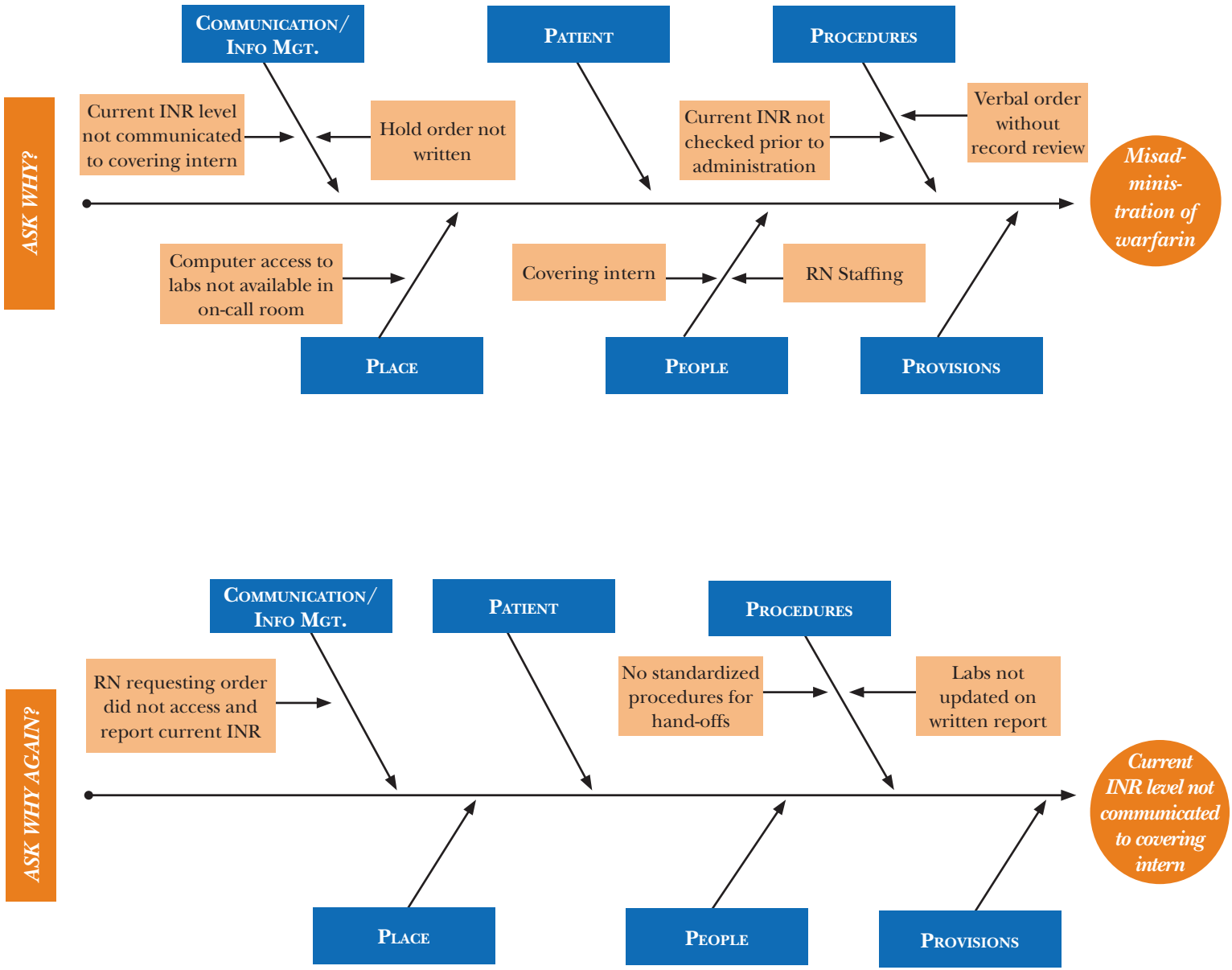
Exhibit 5:
Sample Cause-and-Effect Diagram





Source: Greater New York Hospital Association, Lorraine Ryan and Monica Santoro, 2009.

Exhibit 6:
Cause-and-Effect Diagram



Source: Greater New York Hospital Association, Lorraine Ryan and Monica Santoro, 2009.

outcome; and

- illustrate the process of repeatedly asking "why?" as often as necessary.

When using cause-and-effect diagrams during the RCA process, consider any issues related but not linked to the following:

- **Communication and information management**
  - » Availability of pertinent clinical information
  - » Verbal communication among health care team members, including hand-offs
  - » Communication using the chain-of-command
  - » Issues related to organizational culture, such as intimidating and disruptive behaviors by members of the health care team
  - » Communication across the continuum of care
  - » Communication with the patient/family
  - » The use of prohibited abbreviations
  - » The use of verbal orders
  - » Access to drug reference information
  - » Screen appearance, prompts, and so forth if computer prescriber order entry (CPOE) was involved
- **People involved**
  - » Staffing levels
  - » Fatigue and scheduling
  - » Orientation and training
  - » Credentialing/competency
  - » Supervision of staff
- **Policies and procedures involved**
  - » What policies and procedures were in effect?
  - » Were the policies and procedures followed as written?
  - » Do existing policies and procedures need to be updated to reflect current practice?

Implementation Cue:

Once the team has identified an issue—for example, misadministration of a high alert medication—drill down deeper to the root cause by asking "why" using a cause-and-effect diagram. Once the team has identified a new process issue—for example, lab value not reported to the responsible clinician—apply the same process of drilling down to the identified contributing causes and ask "why" again.

- » Are there barriers that can be incorporated into the policies and procedures that would minimize the risk of patient harm?

- **Provisions involved**
  - » Adequacy of technological support
  - » When ***equipment*** is involved:
    - » Was the necessary equipment available?
    - » Was preventive maintenance performed as scheduled?
    - » Was the equipment being used for its intended purpose?
    - » Were staff trained in the proper use of the equipment?
    - » Were alarms being used as indicated?
    - » Were alarms audible?
    - » Were alarms set at the appropriate parameters?
    - » Were alarms, displays, and controls identifiable and operating properly?
    - » Is there a design or interface issue that inhibits safe use?
  - » When ***medications, I.V. solutions, and other provisions*** are involved:
    - » Consider storage and access, labeling, dispensing, frequency of use, similar names of other products, design of packaging, number of available concentrations.
- **Patient(s) involved**
  - » Past medical and surgical history
  - » Co-morbidities
  - » Compliance with medical regimen
  - » Language or other communication barriers
  - » Cultural, religious, and other individual beliefs.
- **Place involved**
  - » Location of the event
  - » Physical layout (including adequacy of space)
  - » Environmental conditions (noise, heat, lighting)
  - » Visibility
  - » Safety features
  - » Adherence to life safety code requirements
  - » Emergency preparedness response.

Five Rules of Causation. After the team has identified possible root or contributing causes, apply the following rules of error causation as you describe the root causes of the adverse event.[12] **Exhibit 7** describes the five rules of causation and provides examples. Using the principles described in the five rules of causation as you identify root causes will facilitate formulating action/improvement plans and provide clear documentation when describing identified root causes in your RCA documentation.

Pareto Charts—All Causes Are Not Created Equal. A Pareto chart is a vertical bar graph that is used to compare causes or problems according to their relative frequency in order to identify the "vital few" causes that account for the majority of the effect (see **Exhibit 8**). Pareto charts are based on the "Pareto principle," which holds that whenever a number of individual factors contribute to some overall effect, relatively few of those factors account for the bulk of the effect. In fact, the Pareto principle is frequently referred to as the "80-20" rule: 80% of the effect/outcome is a result of 20% of the causes/factors/problems.

Thus, a Pareto chart shows which causes are the most frequent and can have the greatest impact. A Pareto chart can be helpful when the team has identified many underlying issues contributing to a specific effect and needs to set priorities for further analysis and action planning. Use of a Pareto chart

Exhibit 7: Five Rules of Causation Summary

Rule	Incorrect	Correct
1. **Root cause statements must clearly show the cause-and-effect relationship.** When describing why an event has occurred, you should show the link between the root cause and the adverse event or outcome. Each link should be clear to the RCA team and others.	The scrub tech prepped and draped the wrong extremity.	As a result of poor communication among team members and the team starting the procedure without visualizing the site mark during the final time out, the procedure was performed on the wrong extremity.
2. **Negative descriptions should not be used in root cause statements.** Avoid negative terms such as "improper," "careless," and "inadequate." These broad, negative judgments do little to describe the actual conditions or behaviors that led to the adverse event.	The staff was careless during the final time out.	Staff was frequently distracted during the time out process with other activities in preparation for the procedure and did not focus on the process and verify the correct extremity.
3. **Each human error must have a cause.** Identify underlying causes for why the human error occurred—for example, doing a task by memory instead of relying on a checklist. For every human error in the causal chain, there should be a corresponding cause. It is identifying the cause of the error, not the error itself, that leads to the development of an effective action/improvement plan.	The team failed to recognize that the wrong side was draped.	As a result of time pressures, turnover of the team just prior to the time out, a tolerance for not allowing correct site marking procedures, and the lack of active team engagement in the time out process, the team verbally confirmed the correct extremity but the procedure was performed on the incorrect extremity.
4. **Each procedural deviation must have a cause.** Identify the cause(s) of procedural violations. If a staff member violates a procedure because it is the "local norm," the issues that created that norm will need to be addressed in the corrective action/improvement plan.	The staff failed to follow the procedure for time out and site marking.	Due to a unit culture that tolerates non-compliance with proper time out and site marking, the staff was not concerned when the site mark was not visible during the final time out.
5. **Failure to act is causal only when there is a pre-existing duty to act.**	In this example, all members of the operative team had a duty to participate in the time out and resolve discrepancies before starting the procedure.	

Source: Department of Veterans Affairs National Center for Patient Safety, Available at **www.va.gov/ncps/CogAids/RCA/index.html.**

does, however, require that you have some data about the factors that contributed to a particular effect.

The Joint Commission Root Cause Analysis Matrix. The Joint Commission Root Cause Analysis Matrix (**Exhibit 9**) provides a checklist of the minimum scope of review for specific types of adverse events. The matrix is a useful tool to ensure that you have conducted a thorough inquiry into the specific areas required.

After brainstorming, the team should review The Joint Commission Root Cause Analysis Matrix to ensure that all areas listed have been addressed. The matrix is updated periodically. The most current version is available at: **www.jointcommission.org/NR/rdonlyres/3CB064AC-2CEB-4CBF-85B8-CFC9E7837323/0/se_root_cause_analysis_matrix.pdf.**

Literature Review. The literature review can be very helpful in identifying best practices and developing the action/improvement plan, which is discussed in more detail below. It is also helpful to the analysis in terms of determining why the adverse event occurred and successful strategies to prevent a recurrence. Prior to or at the first RCA meeting, the literature review/search should be assigned to a clinical member (or members) of the RCA team. If team members are having difficulty identifying the relevant literature, they should seek the assistance of the medical librarian at their facility. The results of the literature review should be summarized with citations in the documentation of your RCA findings.

Refer to The Joint Commission *Sentinel Event Alerts* for pertinent information relative to the case under review. All *Sentinel Event Alerts* are available at **www.jointcommission.org/SentinelEvents/SentinelEventAlert**.

Implementation Cue:

Distribute the five rules of causation to the team as you begin drilling down into underlying causes. Effective use of the five rules of causation can help jump-start the RCA team in developing an action/improvement plan.

The ultimate goal of the root cause analysis is to prevent adverse events from recurring. The hallmark of effective analysis of adverse events is that it leads to system changes that inherently make it easier for those working in health care to deliver safe and appropriate care, as opposed to constant emphasis on more education or closer oversight—both second-hand markers for blame.[13]

THE ACTION/IMPROVEMENT PLAN

While interim or short-term strategies may be implemented until the root cause analysis is finalized, the product of the RCA process is an action/improvement plan, which:

- identifies strategies an organization intends to implement to reduce the risk of adverse events from recurring; and
- identifies how the effectiveness of those strategies will be measured.

The individuals most closely involved in the processes being targeted for redesign should be included when developing the action/improvement plan. These individuals may or may not have been part of the original RCA team.

The action/improvement plan may involve referring an issue for further evaluation and action to another standing committee or, depending on the complexity of the issue, establishing an *ad hoc* committee to review and act on the particular issue.

Exhibit 8: Sample Pareto Chart on Contributing Factors Identified in Hospital-Acquired Pressure Ulcers

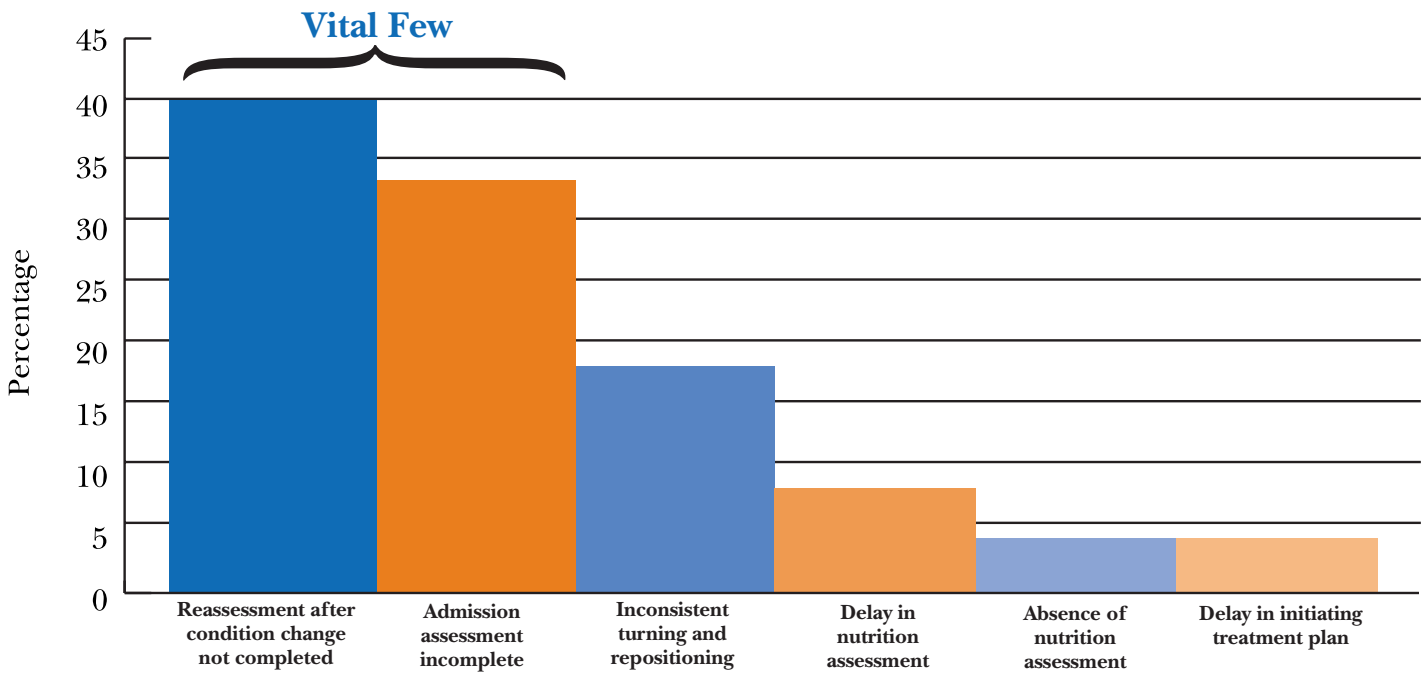


Exhibit 9: Root Cause Analysis Matrix

Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events – October 2005

Detailed inquiry into those areas is expected when conducting a root cause analysis for the specified type of sentinel event. Inquiry into areas not checked (or listed) should be conducted as appropriate to the specific event under review.

	Suicide (24 Hour Care)	Medication Error	Procedural Complication	Wrong Site Surgery	Treatment Delay	Restraint Death	Elopement Death	Assault/Rape/ Homicide	Transfusion Death	Patient Abduction	Unanticipated Death of Full Term Infant	Unintended Retention of Foreign Body	Fall Related
Behavioral assessment process (1)	X					X	X	X					
Physical assessment process (2)	X	X	X	X	X	X	X				X		X
Patient identification process		X		X					X				
Patient observation procedures	X				X	X	X	X	X		X		X
Care planning process	X		X			X	X				X		X
Continuum of care	X	X			X	X							X
Staffing levels	X	X	X	X	X	X	X	X	X	X		X	X
Orientation and training of staff	X	X	X	X	X	X	X	X	X	X	X	X	X
Competency assessment and credentialing	X	X	X	X	X	X	X	X	X	X	X	X	X
Supervision of staff (3)	X	X	X		X	X			X			X	
Communication with patient/family	X	X		X	X	X	X		X	X			X
Communication among staff members	X	X	X	X	X	X	X	X	X	X	X	X	X
Availability of information	X	X	X	X	X	X			X		X		X
Adequacy of technical support		X	X		X								
Equipment maintenance/management		X	X		X	X					X		X
Physical environment (4)	X	X	X	X		X	X	X	X	X			X
Security systems and processes	X						X	X		X			
Medication management (5)		X	X		X				X		X		X

(1) Includes the process for assessing patient's risk to self (and to others, in cases of assault, rape, or homicide where a patient is the assailant).
(2) Includes search for contraband.
(3) Includes supervision of physicians-in-training.
(4) Includes furnishings; hardware (e.g., bars, hooks, rods); lighting; distractions.
(5) Includes selection and procurement; storage; ordering and transcribing; preparing and dispensing; administration; and monitoring.

The improvement plan should include actions that:

- address the root cause/contributing factor;
- are specific;
- are based on consultation with staff directly involved in the process; and
- are tested or simulated prior to full implementation when feasible.[14]

As the team develops the action/improvement plan and implements process and system changes:

1. Consider the features of safe systems.
   - Reduce reliance on memory.
   - Standardize procedures, displays, and layouts.
   - Use checklists and protocols.
   - Promote effective team work and communication.
   - Consider implementation of specific communication strategies (see **Exhibit 10**).
2. Strive to design safer systems that reduce the likelihood of human error.
   - Start with the premise that anything can and will go wrong.
   - Make the safest thing to do the easiest thing to do.
   - Build in redundancy as necessary—keeping in mind that additional steps can raise the risk of error.
   - Simplify and standardize procedures.
   - Improve information access.
3. Ensure rigidly enforced training and competence assessment processes.
4. Make it difficult for humans to err.
   - Simplify tasks to avoid the need for work-arounds.
   - Minimize reliance on short-term memory.

Barrier Analysis

Barrier analysis is the study of safeguards that can prevent or mitigate an unwanted event. During the RCA process, brainstorm for barriers that failed to work optimally or did not exist. Identify barriers that may:

- remove or reduce hazards, such as decreasing the number of concentrations of a medication or removing floor stock;
- enforce compliance with procedures, such as making sure that prescriptions for children are not being filled without a current documented weight; and
- control hazards, such as having back-up equipment or rescue medications readily available.

- Incorporate protective constraints or barriers such as forcing functions—for example, intravenous adaptors that do not fit into feeding-tube adaptors.

As the action/improvement plan is developed, also consider the hierarchy of actions/improvements—and their potential to lead to effective and sustainable changes (see **Exhibit 11**).[15]

Implementing the Action/Improvement Plan

Once the action/improvement plan is developed, keep the following steps in mind when implementing it:

- Assign oversight of the implementation and monitoring the effectiveness of each part of the action plan to a specific individual.
- Always proceed carefully when implementing changes and *pilot-test* changes prior to widespread implementation.
  - » Pilot-test within a small group to evaluate effectiveness and identify any unintended consequences of the redesigned or new process.
  - » Demonstrated success in the pilot will promote widespread adoption and will accelerate change.

Exhibit 10: Examples of Strategies to Promote Effective Communication and Teamwork

Strategy	Description
SBAR	**SBAR – *S*ituation, *B*ackground, *A*ssessment, *R*ecommendation** A structured format for communicating information that requires immediate attention concerning a patient's condition. SBAR can also be used to structure and standardize communication during hand-offs. **Situation – What is going on with the patient?** *Example: I am calling about Mrs. Smith. She is short of breath.* **Background – What is the patient's clinical background?** *Example: The patient is a 75 year old one day post op abdominal surgery. She has no significant medical history. Her vital signs are…* **Assessment- What the caller thinks the problem is.** *Example: Breath sounds are decreased on the right and the patient is reporting pain. I think she may have a pneumothorax.* **Recommendation – What the recommendation is.** *Example: I think the patient needs to be assessed now.*
Brief	Short planning session to discuss team roles; establish expectations; communicate the plan of care and agree upon goals; and discuss resource needs.
Debrief	Informal information exchange to discuss team performance and opportunities for improvement following a non-routine procedure/intervention.
Cross-monitoring	Providing a safety net by monitoring the actions of other team members; "watching each other's back."

Source: Agency for Healthcare Research and Quality. TeamSTEPPS™ Strategies and Tools to Enhance Performance and Patient Safety Pocket Guide. AHRQ Pub. No. 06-0020-2. Revised March 2008.

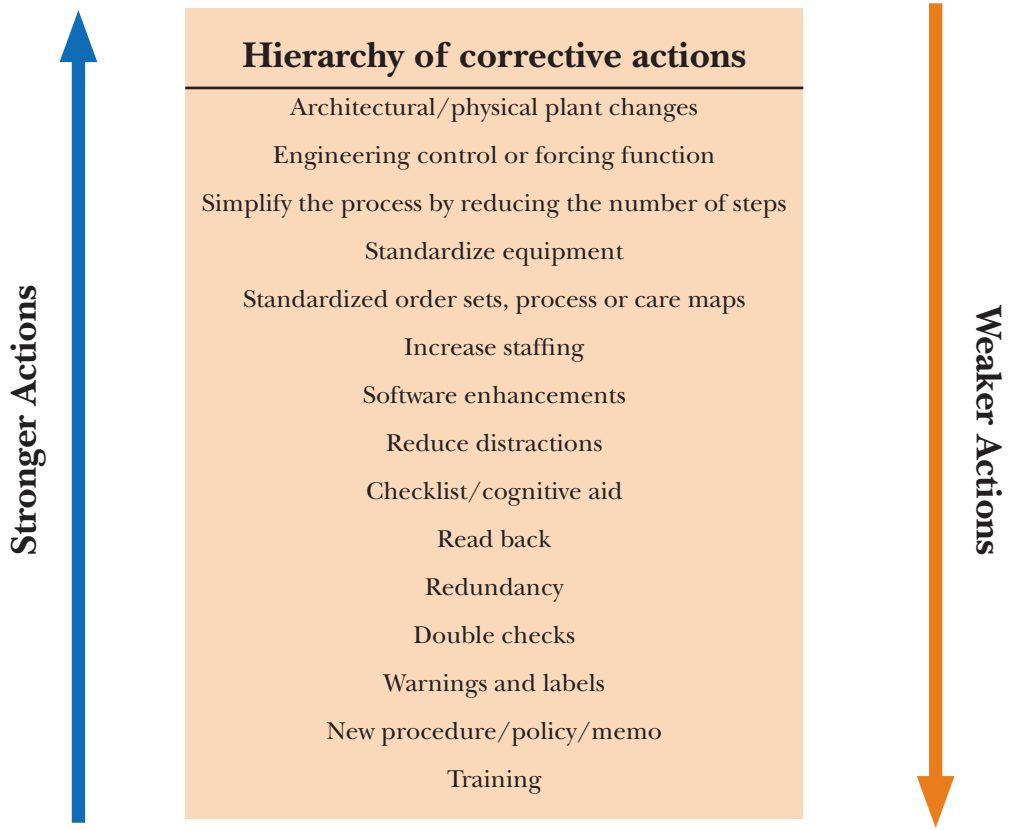
- Apply the principles of the "Plan, Do, Study, Act" (PDSA) performance improvement model, or a similar model (see **Exhibit 12**).
- Follow up regularly until there is documented evidence—obtained by collecting data—that an effective action/improvement plan has been implemented.
- Report the results of implementation and monitoring to the Quality Improvement Committee at your institution and ultimately to the governing board on an ongoing basis as needed. (Note: Different health care organizations refer to this committee variously as the Quality Assurance Committee or Performance Improvement Committee, and other similar names.)

Measuring the Effectiveness of the Action/ Improvement Plan

The measures of effectiveness should:

- measure the impact of the risk reduction strategy;
- have defined time frames;
- have a defined sampling strategy with numerators for audits;
- have realistic thresholds (expressed as percents) for compliance; and
- demonstrate follow-up for non-compliance.[16]

Exhibit 11: Hierarchy of Corrective Actions Taken in Response to an Adverse Event



Source: Department of Veterans Affairs National Center for Patient Safety, Available at **www.va.gov/ncps/CogAids/RCA/index.html**.

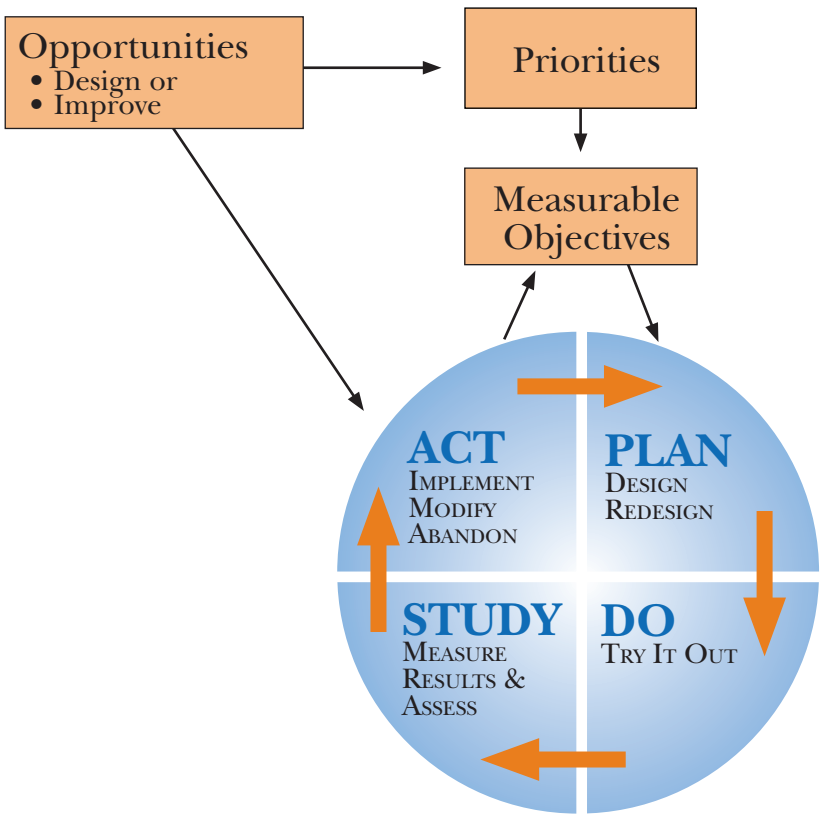
Exhibit 13 illustrates a sample worksheet you can use to develop your action/improvement plan.

THE JOINT COMMISSION REQUIREMENTS

The Joint Commission's leadership standards require the organization to conduct a thorough and credible root cause analysis as detailed in the Sentinel Event chapter. For a root cause analysis to be acceptable to The Joint Commission, it must:[17]

- Focus primarily on systems and processes, not individual performance.
- Progress from special causes in clinical processes to common causes in organizational processes.
- Repeatedly dig deeper by asking "why?" and, when answered, ask "why?" again.
- Identify changes that could be made in systems and processes (either through redesign or development of new systems or processes) that would reduce the risk of

Exhibit 12: The PDSA Approach to Performance Improvement Includes Identifying Design or Redesign Opportunities, Setting Priorities for Improvemtent, and Implementing the Improvement Project



Source: *Root Cause Analysis in Healthcare Tools and Techniques Third Edition* (Oakbrook Terrace, Illinois: The Joint Commission on Accreditation of Healthcare Organizations, 2003) p 118.

Exhibit 13: Sample RCA Action/Improvement Plan Worksheet

The corrective action plan below is an example involving a case of surgery on the wrong side due to the site mark being positioned so that it was not visible following draping.

Issue	Action/Improvement	Responsible Party/Title	Timetable for Implementation	Measure of Effectiveness
Universal Protocol (UP): Variation in location of site mark and non-compliance with policy that site mark must be visible after draping.	Scrub tech and surgeon to state at time out that they see the site mark. This statement is required prior to the drape being removed from the instrument tray. Documentation that mark was visualized during the time out is required on the UP check list. Re-education through interdisciplinary mandatory training with explicit requirements for positioning of site marking and time out.	Director of Perioperative Services		Audit 20% of all records for compliance with documentation requirements. Direct observation of 5% of cases (no less than 30) per month. These audits will be done on an ongoing basis. When compliance is at 100%, the direct observation will be done quarterly. An audit tool will be used that includes all elements of the UP. Compliance with all elements is required.
Staff performing other activities during time out.	Reinforce procedure where all other activities are suspended and team members are focused on the active confirmation of the correct patient, procedure, site, and other critical elements.	Director of Perioperative Services		Direct observation of 5% of cases (no less than 30) per month involving all surgical services. These audits will be done on an ongoing basis. When compliance is at 100%, the direct observation will be done quarterly. An audit tool will be used that includes all elements of the UP. Compliance with all elements is required.

Source: Greater New York Hospital Association, Lorraine Ryan and Monica Santoro, 2009.

such events from occurring in the future.
- Be thorough and credible.

To be ***thorough*** according to The Joint Commission, the root cause analysis must include:

- a determination of the human and other factors most directly associated with the event, and the processes and systems related to its occurrence;
- an analysis of the underlying systems through a series of "why" questions to determine where redesign might reduce risk;
- inquiry into all areas appropriate to the specific type of event as outlined in The Joint Commission's "Minimum Scope of Review of Root Cause Analysis" (accessible at **www.jointcommission.org**);
- identification of risk points and their potential contributions to this type of event; and
- a determination of potential improvement in processes and systems that would tend to decrease the likelihood of such events occurring in the future, or a determination, after analysis, that no such improvement opportunities exist.

To be ***credible*** according to The Joint Commission, the root cause analysis must:

- include participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review;
- be internally consistent—that is, not contradict or leave obvious questions unanswered;
- provide an explanation for all findings of "not applicable"; and
- include consideration of any relevant literature.

For the ***action plan*** to be acceptable to The Joint Commission, it must:

- identify changes that can be implemented to reduce risk or formulate a rationale for not undertaking such changes;
- identify, in situations where improvement actions are planned, who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.

DOCUMENTATION AND CONFIDENTIALITY

The Joint Commission has a prescribed framework for documenting the RCA process in response to a sentinel event. In addition, in New York State, there is a New York Patient Occurrence Reporting and Tracking System (NYPORTS) Framework for Root Cause Analysis. See **Appendices 1 and 2** for the sample frameworks.

Confidentiality

The documents developed as part of the Root Cause Analysis should be protected by the confidentiality provisions covering information that is reviewed as part of the quality assurance/quality improvement processes, contained in the Public Health and Education Laws of New York State, the New Jersey Administrative Code, and similar laws in other states. The following steps maximize the protection of RCA documents from discovery:

- All RCA meetings should be conducted under the framework of the organization's quality improvement plan.
- All RCA-related documents should be clearly labeled as "confidential quality improvement" documents, and the relevant state statute should be referenced.
- RCA documents should only be used for quality im-

provement purposes and not for any other purpose or sent to any other party for another purpose.

SUMMARY

The following is a summary of the steps that need to be undertaken when conducting a root cause analysis.

1. Organize a team.
2. Define what happened (the event) and why. Identify the process(es) related to the event under review and the proximate causes (the most apparent or immediate reasons) for the adverse event.
3. Design and implement any necessary "quick fix" interim changes to protect the safety of other patients/staff.
4. Identify the root causes of the adverse event (the most fundamental reason(s) for the process failure).
5. Develop the corrective action/improvement plan.
    - Identify potential risk-reduction strategies.
    - Formulate and evaluate proposed improvement actions.
    - Identify measures of success.
6. Implement the action/improvement plan.
7. Measure the effectiveness of the action plan implemented and fine-tune improvement strategies.
8. Communicate the results.

CONCLUSION

Root cause analysis can be an invaluable and powerful performance improvement tool and will enhance your patient safety efforts when used effectively. Teams that apply a consistent framework for conducting the analysis such as that described in this resource guide are more likely to implement improvement strategies that are sustainable over time. The RCA process is a time-consuming, resource-intensive process and must have the full support of the leadership of the organization in order to succeed.

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3. Lucian Leape, MD, "Error in Medicine," *JAMA* 272, no. 23 (December 21, 1994) p 1854.

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5. Reason, *Human Error* pp 53-60.

6. Patrice Spath, *Error Reduction in Health Care* (San Francisco: Jossey-Bass Publishers, 2000) pp 104-105.

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15. Ibid.

16. "NYPORTS Root Cause Analysis Evaluation Protocol," *NYPORTS Annual Report 2002–2004*, Appendix D.

17. *The Joint Commission Sentinel Event Policy and Procedures* (updated July 2007). Available at **www.jointcommission.org/NR/rdonlyres/F84F9DC6-A5DA-490F-A91F-A9FCE26347C4/0/SE_chapter_july07.pdf**.

Failure Mode and Effect Analysis

OVERVIEW

Failure mode and effect analysis (FMEA), a method historically used by engineers to design highly reliable and safe processes in complex industries, is used today by health care professionals to design safer health care systems and processes by identifying the source of potential problems before they occur. A proactive risk-assessment technique, failure mode and effect analysis differs from root cause analysis, which is typically done reactively, after a problem has been encountered (see **Exhibit 14**). Failure mode and effect analysis is a systematic approach that relies on structured, methodical analysis to determine the ways that a process can fail, why it might fail, and how it can be made safer. Failure mode and effect analysis in the health care industry involves identifying potential failure mode(s) at each step in the process, assessing the frequency and severity of the failure(s), and redesigning the process to minimize the risk of failure(s) from occurring; failure mode and effect analysis strives to stop the failure before it reaches the patient, or at a minimum to mitigate the effects of any failure that may reach the patient.

Failure mode and effect analysis is best utilized on high-risk processes with the goal of redesigning the process to reduce the risks of failure. High-risk processes are typically complex, tightly coupled (that is, they involve steps that occur in such rapid sequence that it is difficult or impossible to intervene between steps), heavily dependent on human intervention, and often vary in how the process is carried out, for example the administration of blood products and anticoagulants. Failure mode and effect analysis is also useful when introducing new products or services to the organization.

Exhibit 14: Comparison of RCA and FMEA

RCA	FMEA
Reactive and done in response to an adverse event	Typically proactive and done prior to a process or systems failure.
Focuses on a specific event.	Focuses on the entire process or a sub-process.
Affected by hindsight bias.	Unbiased.
May arouse fear, anxiety, and resistance from those involved in the event under review.	A more open process than root cause analysis because error has not yet occurred.
Repeatedly asks, "Why?" to determine the root cause of an adverse event.	Repeatedly asks, "What if...?" to determine what could possibly go wrong or fail in the process or a step in the process.

Source: Greater New York Hospital Association, Lorraine Ryan and Monica Santoro, 2009.

CONDUCTING FAILURE MODE AND EFFECT ANALYSIS

There is no prescribed way to conduct a failure mode and effect analysis, although published frameworks are available. One way to approach failure mode and effect analysis is described below.[1]

1. **Select a process.** Process selection can be based on your own data related to high-risk processes (for example, quality indicators, risk management data, morbidity and mortality data, comparative quality data) or on high-risk processes identified in the literature (for example, The Joint Commission *Sentinel Event Alerts*, New York Patient Occurrence Reporting and Tracking System (NYPORTS) data, The Institute for Safe Medication Practices [ISMP] Alerts). Avoid selecting an overly broad process—consider using Pareto analysis (see page 17) to identify which sub-processes contribute to the most failures in order to narrow your selection.

2. **Designate a team.** The team members should include:

   - frontline staff members involved directly in the processes under review (subject matter experts);
   - other individuals with knowledge of the process who are critical to the implementation of anticipated process changes;
   - a leader with decision-making authority;
   - a team leader or "champion" of improving the process under review; and
   - a facilitator, someone who can be objective and who is not a "stakeholder" in the process being reviewed.

3. **Create flow charts.** Create one flow chart of the process as it is *intended to be performed* and a second chart of the process as it is *routinely performed*. When preparing a flow chart of the process under review, identify all the sub-

Failure Mode and Effect Analysis—Definition of Terms

Failure Mode: What could go wrong or "fail" at a given step in a process; steps in the process where there may be undesirable variation.

Effect: The result of the failure mode.

Frequency: An estimate of the likelihood of the failure occurring.

Severity: An estimate of the potential degree of harm the failure would have on the patient.

Detectability: An estimate of the probability of the failure being detected before it reaches the patient.

Criticality Index or Risk Priority Number (RPN):

1. A means of prioritizing failure modes for further analysis and action.
2. The product of the frequency of the failure (F) multiplied by severity of the failure (S) multiplied by probability of detection (D), or F x S x D = RPN.

processes. Select a part of the process or sub-process on which to focus. Number each step in the process under review and use a combination of numbers and/or letters to label sub-processes (see **Exhibit 15**.)

4. **Look for variation or "failure modes" in the process.** At each step, determine any variation between the intended process as designed and the process as typically carried out, and identify such variations as potential failure modes.

5. **Look further.** At each step in the process, brainstorm for possible ways the system could fail and list those failures as possible "failure modes."

6. **Prioritize failure modes for further analysis.** Prioritize which failures should be analyzed further for identification of root causes and implementation of risk-reduction strategies. One approach to prioritizing failures is to calculate the criticality index, or risk priority number (RPN), and then to assign priority to those failure modes with a high RPN or criticality index. For each failure mode, the RPN is calculated by estimating the frequency and the severity of the failure, and the likelihood that the failure will be detected before it reaches the patient. (See definitions of terms on page 32.) Such estimates can be obtained through the use of numeric rankings. Examples of rank-

Exhibit 15: Pressure Ulcer FMEA Sample Flow Chart

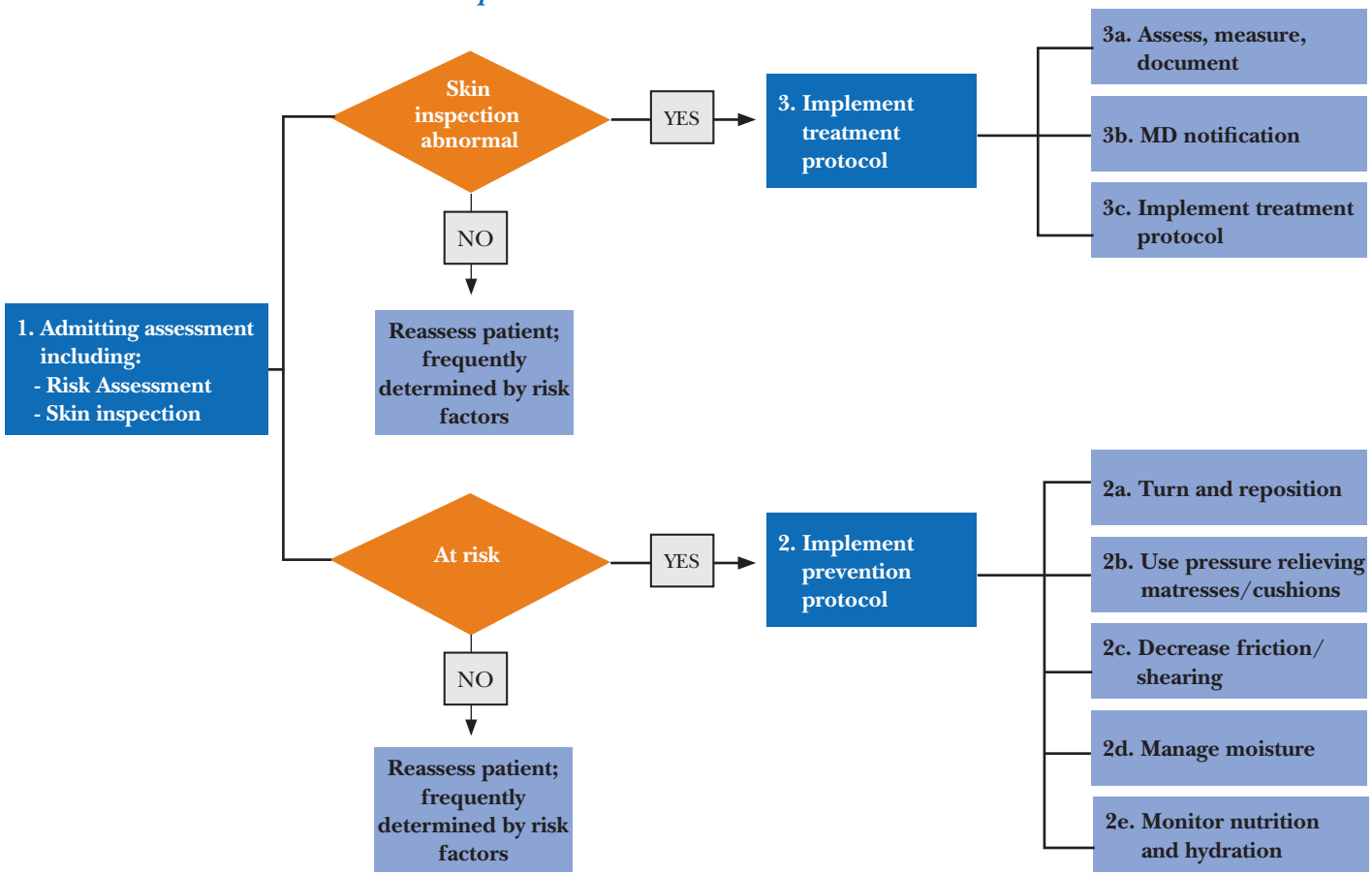

Exhibit 15 (continued): Draft FMEA Example Pressure Ulcer Prevention[1,2]

For purposes of illustration, we have selected two steps in the process as an example of how FMEA can be conducted. When actually completing an FMEA, *all* steps in the process or sub process under review must be considered. Frequency and likelihood of detection of a particular failure mode will vary from facility to facility. When these data are not available, estimates (as determined by the team) may be used as a substitute.

Step in Process	Possible Failure Modes	Frequency (F)	Effect(s) of Failure	Severity (S)	Likelihood of Detection (D)	Criticality Index or RPN *F x S x D*	Cause(s) of Failure	Risk-Reduction Strategies
1. Admitting assessment	Failure/ delay in conducting	3	Failure/delay in identifying patient at risk or patient with wound and delay in implementing treatment/ prevention	7	5	105	1. Time pressures 2. Knowledge deficit 3. Reliance on memory	1. Include a pressure ulcer assessment prompt on admission 2. Use standardized tool that can be easily completed (short phrases/check boxes) 3. Provide feedback to staff on unit performance
	Incomplete risk assessment	7	Failure to identify patient at risk and failure to implement prevention strategies	7	7	343	1. Knowledge deficit 2. Skills deficit 3. Time pressures	1. Hospital-wide education 2. Formal competency assessment including direct observation
	Incomplete skin inspection	9	Failure to identify wound; delay in treatment and prevention	7	7	441	1. Knowledge deficit 2. Skills deficit 3. Time pressures	1. Hospital-wide education 2. Formal competency assessment including direct observation
2a. Turning and repositioning	Inconsistent implementation	8	Patient develops hospital-acquired pressure ulcer	8	7	448	1. Knowledge deficit 2. Failure to communicate plan 3. Staffing	1. Hospital-wide education 2. Use audible reminders to turn/reposition patients every few hours 3. Place turn-clock posters in each at risk patient's room 4. Use visual cues (e.g., stickers on chart and door to identify patients at risk

[1] Griffin, Bevette, Cooper, Hoa, Horack, Cassandra, Klyber, Melissa, Schimmelpfenning. *Institute for Healthcare Improvement's 5 Million Lives Campaign, Best-practice Protocols: Reducing Harm from Pressure Ulcers.* Nursing Management. September 2007.

[2] 5 Million Lives Campaign. Getting Started Kit: Prevent Pressure Ulcers How-to Guide, Cambridge, MA: Institute for Healthcare Improvement; 2008. (Available at **www.ihi.org.**)

ing scales are outlined on page 36. Be sure to address any failure mode that is associated with a high severity ranking (for example death or permanent harm) regardless of frequency or detectability (which may be low because the failure mode occurs infrequently or because there is a strong likelihood that the failure will be detected before it reaches the patient).[2]

7. **Identify the causes of failure modes.** For those failure modes determined to be a priority based on the criticality index, identify the causes of failure at each step and develop risk-reduction strategies. Causes of failure modes can be identified through brainstorming, use of a cause-and-effect diagram(s), and through a literature search.

8. **Process redesign.** The next step is to begin redesigning the process as needed. As you redesign, consider the features of safe systems:

    - Reduce reliance on memory by using, for example, checklists, visual aids, reminders, and other strategies.
    - Incorporate redundancy.
    - Standardize.
    - Simplify tasks.
    - Incorporate the use of constraints or forcing functions.
    - Reduce hand-offs.
    - Ensure rigidly enforced training and competency assessment.
    - Improve information access.

Review the literature for failure modes identified in specific processes and recommended risk-reduction strategies.

9. **Implementation and Testing:** Implement the redesigned process. Begin by testing changes to processes prior to widespread implementation to identify any unintended consequences of the redesigned process. Success during the testing phase may help to promote widespread adoption of the redesigned process.

10. **Measure the Effectiveness:** Evaluate the redesigned process by defining specific process and outcomes/measures related to its performance. For example, process measures for a failure mode and effect analysis on The Joint Commission's Universal Protocol could include: auditing a sample of medical records for documentation of surgical site verification; observing staff during the time out process; reviewing near miss and variance reports related to the Universal Protocol. Another approach to measuring the effectiveness of your redesigned process is to re-evaluate the frequency, severity, and detectability rankings after completing the failure mode and effect analysis. The estimated frequency of the failure should decrease and the likelihood of detection should be greater, thus reducing the risk of harm to the patient.

11. **Sustaining Improvements:** Implement a strategy for maintaining the effectiveness of the redesigned process over time—including, for example, periodic observation, record reviews, and ongoing training programs.

    The Joint Commission, the National Patient Safety Foundation (NPSF), the National Quality Forum (NQF), the Institute for Safe Medication Practices (ISMP), and the Agency for Healthcare Research and Quality (AHRQ) are all helpful resources.

    The Institute for Healthcare Improvement (IHI) Web site also contains a self-help tool for completing a failure mode and effect analysis as well as sample failure mode and effect analyses completed by other organizations, **www.ihi.org/ihi/workspace/tools/fmea/CreateTool.aspx**.

FMEA Scales

The frequency and detectability rankings for any given failure mode are often subjective and should be based on group consensus if data are not available. Once a ranking scale is defined by the group, it should be applied consistently and the parameters should be documented.

The group should decide in advance on a ranking scale. Three examples, in order of increasing complexity, follow. Facilities can adapt the ranking scales according to their needs and the nature of the process under review.

FMEA Ranking Scale: Example One

For each failure mode, estimate the frequency, severity, and likelihood of detection before it reaches the patient as *low, moderate, or high.*

FMEA Ranking Scale: Example Two[3]

For each failure mode, apply a *numeric ranking.*

- Rank the possibility or frequency of the failure: 1 = remote possibility; 5 = possibility; 10 = almost certain.
- Rank the estimated severity of the overall failure: 1 = will not cause patient harm; 5 = may affect patient adversely; 10 = injury or death will occur.
- Rank the estimated likelihood that the failure will be detected before it reaches the patient. 1 = will always be detected; 5 = might be detected; 10 = detection not possible.

FMEA Ranking Scale: Example Three[4]

Estimate the frequency of the failure (F).

- Remote possibility: 1 in 10,000, no known occurrence = 1.
- Low probability: 1 in 5,000, possible but no known data = 2, 3, or 4.
- Moderate probability: 1 in 200, documented but infrequent = 5 or 6.
- High probability: 1 in 100, documented and frequent = 7; or 1 in 50 = 8.
- Very high probability: 1 in 20 = 9; or 1 in 10 = 10.

Estimate the severity of the failure (S).

- Minor impact on patient: no injury, or no increased length of stay, or no increased level of care = 1.
- Moderate impact on patient: increased length of stay or increased level of care for one or two patients = 4.
- Major impact on patient: permanent lessening of bodily functioning, disfigurement, surgical intervention required, increased length of stay or level of care for three or more patients = 7.
- Catastrophic impact on patient: death or major permanent loss of function, hemolytic transfusion reaction, surgery/procedure on wrong body part, infant abduction, or infant discharge to the wrong family = 10.

Estimate the detectability or likelihood of the failure being detected. (D)

- Very high: system will always detect error = 1.
- High: likelihood of detection 7 out of 10 = 2 or 3.
- Moderate: likelihood of detection 4 or 5 out of 10 = 4, 5, or 6.
- Low: likelihood of detection 1 or 2 out of 10 = 7 or 8.
- Remote: detection not possible at any point in the system = 9.

HEALTHCARE FAILURE MODE AND EFFECT ANALYSIS™: AN ALTERNATIVE APPROACH TO FMEA

The Department of Veterans Affairs (VA) National Center for Patient Safety has developed another approach to proactive risk assessment and process redesign called Healthcare Failure Mode and Effect Analysis (HFMEA)™, which is being used throughout the VA Health Care System. HFMEA™ is a five-step prospective risk-assessment tool that can be used to proactively evaluate any health care process or system. Similar to the FMEA process, HFMEA™ uses an interdisciplinary team approach as well as process flow diagramming to identify and assess potential vulnerabilities of the process under review. HFMEA™ also uses a "Hazard Scoring Matrix" in conjunction with an HFMEA™ "Decision Tree" to determine whether the failure mode warrants further action based on its frequency, severity, and detectability. In determining how critical a failure mode is, the Decision Tree requires the team to determine whether:

- a given failure mode is a single-point weakness—that is, it is so critical that its failure will result in an adverse event;
- there is an effective control measure that reduces the likelihood of the event occurring;
- the hazard is so obvious that a control measure is not warranted (detectability).

An HFMEA™ Worksheet is used to record the team's assessment, proposed actions, and outcome measures. Detailed information on how to perform an HFMEA™ is available on the Web site of the National Center for Patient Safety at **www.patientsafety.gov/HFMEA_JQI.html.**

THE JOINT COMMISSION REQUIREMENTS

The Joint Commission Leadership Standards require accredited health care organizations to have an organization-wide integrated patient safety program. As part of that program health care organizations are required to select one high-risk process and conduct proactive risk assessment, such as failure mode and effect analysis, at least once every 18 months. The suggested components of the proactive risk assessment are as follows:

- Describe the chosen process (for example, through the use of a flowchart).
- Identify ways in which the process could breakdown or fail to perform its desired function, which are often referred to as "failure modes."
- Identify the possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.
- Prioritize the potential process breakdowns or failures.
- Determine why the prioritized breakdowns or failures could occur, which may involve performing a hypothetical root cause analysis.
- Redesign the process and/or underlying systems to minimize the risk of the effects on patients.
- Test and implement the redesigned process.
- Monitor the effectiveness of the redesigned process.[5]

DOCUMENTATION AND CONFIDENTIALITY

There is no prescribed Joint Commission format for documenting the FMEA process. The Joint Commission will look for evidence that a health care facility's patient safety program includes a proactive process for identifying and mitigating risk in an established process and that the required specific

components of the proactive process have been met. The Joint Commission will want to see what was actually changed as a result of identifying and reducing the risk in the established process and what the measures of effectiveness demonstrate.

Protecting FMEA Documents from Discoverability—Preserving Confidentiality

As with the documents created as part of the RCA process, the documents developed as part of the FMEA process should be protected by the confidentiality provisions covering information that is reviewed as part of the quality assurance/quality improvement processes, contained in the Public Health and Education Laws of New York State, or the New Jersey Administrative Code, and similar laws in other states. The following steps should be taken to maximize the protection of FMEA documents from discovery:

- Conduct all FMEA meetings under the framework of the organization's quality improvement plan.
- All FMEA-related documents should be labeled as "confidential quality improvement" documents and the relevant state statue should be referenced.
- FMEA documents should only be used for quality improvement purposes and not for any other purpose.

CONCLUSION

Proactive risk assessment to improve the reliability and safety of complex processes is an important component of an organization-wide patient safety program. The Joint Commission requires that organizations select a high-risk process and conduct a proactive risk assessment at least every 18 months. Failure mode and effect analysis is a useful tool to meet this requirement. The proactive nature of failure mode and effect analysis makes it possible to engage staff in the principles of patient safety as part of an unbiased team, not influenced by factors that may preclude open discussion. By acknowledging the high-risk, error prone nature of health care and collaborating as a team to seek effective solutions to potential failures, the organization can demonstrate its commitment to a culture of safety, and to improving the reliability of high-risk processes.[6]

References

1. *Root Cause Analysis in Health Care: Tools and Techniques Second Edition.* pp 153-154 (Oakbrook Terrace, Illinois: JCAHO, 2003).

2. *Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction.* p 87 (Oakbrook Terrace, Illinois: JCAHO, 2002).

3. *Root Cause Analysis in Health Care: Tools and Techniques Second Edition.* p 105 (Oakbrook Terrace, Illinois: JCAHO, 2003).

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6. Pizzi, Laura T., Neil I. Goldfarb, and David B. Nash. "Chapter 40. Promoting a Culture of Safety." *Making Healthcare Safer: A Critical Analysis of Patient Safety Practices. Agency for Healthcare Research and Quality*, 2001. pp 447-57.

This section is adapted from Health Care News In-Depth *(February 5, 2007), published by GNYHA.*

Communicating with Patients Following an Adverse Event

The past decade has seen a growing trend and greater demand for more transparency in health care. Part of this trend is reflected by the practice of health care providers making full disclosure to patients and/or their families following the occurrence of a medical error or adverse event. Institutional disclosure policies have become more prevalent since the release of the 1999 Institute of Medicine report, *To Err Is Human*, and the 2001 Joint Commission patient safety standards requiring the disclosure of certain "unanticipated outcomes of care."

This section addresses patients' expectations about adverse events or medical errors, approaches to communicating with patients and their families following such events—including recommendations from a communication skills training program sponsored by the Greater New York Hospital Association (GNYHA)—and ethical and regulatory standards related to disclosure.

OVERVIEW: DISCLOSURE PROGRAMS AND POLICIES

It is widely recognized that, following an adverse event or medical error in a health care facility, physicians and other involved health care practitioners should communicate openly with—or make "full disclosure" to—the patient and family who were affected. As such, and given the sensitivity of this type of communication, health care facilities have developed policies to guide their staff in making full disclosure. Although the primary goals of most policies are to enhance patient safety and fulfill an ethical responsibility to patients, an unexpected benefit experienced by some who have instituted "proactive" disclosure programs, which may include an offer of compensation, is a decrease in the number and cost of malpractice claims. Key to the success of these programs is the open, honest exchange of information that enables the early settlement of meritorious claims and the vigorous defense of non-meritorious claims.

The U.S. Department of Veterans Affairs as well as a number of hospital systems, insurers, and patient/provider coalitions are among the entities that endorse full disclosure and early offers. The University of Michigan Health System, for example, has a proactive disclosure and compensation program that is built on the principles of quick and fair compensation when "unreasonable medical care causes patient injuries," vigorous defense of reasonable care, honesty with patients, and learning from past mistakes. Those at Michigan responsible for the program say that over the years they have seen a reduction in the cost of malpractice claims, as well as in litigation expenses, as a direct result of this approach. Stanford University Medical Center's disclosure program, known as *Process for Early Assessment and Resolution of Loss* ("PEARL"), requires full disclosure for all outcomes that cause distress to patients. Patients who experience preventable, unanticipated outcomes are provided a full apology, offer of compensation, and an explanation of the "lessons learned."[1]

On the Federal level, former Senators Hillary Rodham Clinton and Barack Obama in 2005 sponsored the National Medical Error Disclosure and Compensation Act, a national version of the "full disclosure and early offer" policy. The bill was designed

to enhance patient safety and to reduce, in part, medical malpractice litigation costs by encouraging early disclosure to patients and early offers of compensation. In return, the program would provide grant support and technical assistance to providers who disclose medical errors; providers would also receive legal protection for any statements of remorse made within the context of a pre-claim compromise negotiation. Although the bill did not move at the Federal legislative level, a number of states have used the legislation as a model for developing their own policies.

In addition to The Joint Commission's patient safety standards, several states—including New York, New Jersey, and Pennsylvania—require disclosure to patients and, in some cases, their families in the event of an unanticipated outcome or complication of treatment. Finally, professional codes of ethical responsibility for physicians and other practitioners require honest communication and disclosure of medical errors, and advise that, as stated in the American Medical Association's Code of Medical Ethics, "Concern regarding legal liability . . . should not affect the physician's honesty with a patient."

WHAT PATIENTS WANT

Patients involved in an adverse event or medical error want an explanation of what occurred and why. They want to understand the effect of the event on their health and their future and how the problem will be corrected—and they want assurances that they will not be held financially responsible for the costs associated with any resulting care and treatment. Patients typically want someone to take responsibility for what has occurred and want to know that the institution is doing something to prevent similar events from occurring in the future. Most, if not all, patients also want an apology.

The Power of an Apology

Research has shown that an apology is one of the responses a patient and family often expect after they have experienced an adverse event or medical error. A "full" apology has been defined as "an acknowledgment of responsibility for an offense coupled with an expression of remorse."[2] Research has also demonstrated that the type of an apology can be just as important as the act of apologizing itself with regard to settling legal disputes.[3] When liability is clear, an apology of only sympathy ("I am sorry this happened to you"), also known as a "partial apology" and one that does not indicate the provider is accepting any responsibility for what has occurred, may negatively affect the injured party's perception of the physician or institution and can decrease the likelihood of resolving the matter without litigation. A "full" apology—an apology accompanied by responsibility ("I am sorry we did this to you")—on the other hand, in which the practitioner or someone on behalf of the institution accepts responsibility for having caused the event, has been assessed as more effective and meaningful to the patient involved and has more often led to rebuilding trust between the physician/facility and the patient. It may also lead to a resolution of the matter without litigation. Additionally, a full apology and one that acknowledges the physician's and/or institution's responsibility often includes a fair offer of compensation.

To date, approximately 35 states have enacted "apology protection" statutes that protect apologies and other statements of remorse from admissibility in civil suits.

EFFECTIVE DISCLOSURE FOLLOWING AN ADVERSE EVENT

Effective disclosure following an adverse event can be facilitated by planning ahead, knowing what to disclose, knowing what to document, arranging for next steps, and knowing what to expect from patients and families.

Plan Ahead

- As soon as the institution is aware of an adverse event, begin to prepare for the disclosure conversation.
- Consult hospital policy on which staff and department(s) should be informed about the event and the planned discussion with patient and family.
- Make sure that the person who will be speaking to the patient/family has all the facts.
- Review the medical record in advance.
- Think about who should speak to the patient and who else should be present.
- Be mindful of cultural diversity and language barriers.
- Think about where to hold the conversation/meeting and keep in mind that this may be the first of several meetings.

What to Disclose

- Defend the actions of the staff and the institution when care was reasonable and appropriate.
- Accept responsibility or fault on behalf of the institution only if it is clear, after discussion with legal counsel.
- Explain clearly only the known facts.
- Be prepared to review the medical record with the patient.
- Use a layperson's language, not medical terms.
- Apologize and express sympathy, accepting responsibility as appropriate.
- Remember that the patient's reaction often depends on how the information is disclosed.
- Invite questions. Ask: "What questions do you have?" and be prepared to respond appropriately.
- Assure the patient that you will provide additional information as it becomes known.

Barriers to Effective Disclosure

While providers can be adept at communicating complex medical information to patients, communicating bad news or information about errors or adverse events for which a person may bear some responsibility is never easy. This difficulty is compounded by the strong emotions of those involved, which may hamper the objectivity of both the provider and the patient. Other barriers to disclosure include the culture of the organization, fear of litigation—disclosure can be mistakenly interpreted as an admission of liability if not done properly—and liability insurance company policies that, for the most part, providers have generally interpreted as discouraging of full disclosure and apology.

Documentation, Next Steps, What to Expect

- Factually document the conversation in the medical record.
- Let the patient and family know that future discussions will take place as necessary; provide contact information for follow-up.
- Explain the steps that have been or will be taken to prevent similar events from occurring.
- Be prepared for patient/family responses and strong emotions.
- Give patients ample time to express their feelings.

COMMUNICATION SKILLS

GNYHA has sponsored an ongoing communication skills training program for its members based on the premise that better communication leads to improved patient outcomes of care and ultimately improved patient satisfaction, which in some cases could result in reducing the costs associated with medical malpractice claims. The goals of the training are to help staff develop and improve effective communication skills necessary to accomplish effective disclosure; to prepare a core group or team of skilled staff who can assist others in preparing for such communications with patients and families; and to help create a more supportive environment in hospitals for physicians and other caregivers following an adverse event. Some of the key communication skills covered in GNYHA's training are:[4]

Listen Actively. Show you are listening through body language, eye contact, asking questions, reflecting what's been said, acknowledging feelings, and identifying and responding to patient and family needs.

Talk Openly. Provide the patient and family with basic information—that you know to be true—in understandable terms. Describe what additional questions need to be answered. Don't avoid describing the error. Providers need to show feelings they are experiencing as a result of the error and its impact on the patient. Apologize or express sympathy, and accept responsibility when appropriate.

Invite Participation. Include the patient and family in fact-finding.

Explore and Discuss Next Steps. Explain plans to provide more information to the patient and family and ask what they would like to see happen. Provide contact information for follow-up questions or meetings.

For more information, see the GNYHA Quality and Patient Safety Resource Center on GNYHA's Web site, **www.gnyha.org**.

References

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3. Jennifer K. Robbennolt, *Michigan Law Review*, Vol. 102, No. 3 (Dec. 2003), pp. 460-516 Published by: The Michigan Law Review Association, **http://www.jstor.org/stable/3595367**.

4. “Communicating About Medical Errors and Adverse Events: Introductory Training,” GNYHA-sponsored training, 2005. Accessible in the Resource Centers section of the GNYHA Web site (**www.gnyha.org**), under “Quality and Patient Safety.”

Appendix 1:
The Joint Commission: A Framework for a Root Cause Analysis & Action Plan in Response to a Sentinel Event

This template is provided as an aid in organizing the steps in a root cause analysis. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities and questions should be fully considered in your quest for "root cause" and risk-reduction.

As an aid to avoiding "loose ends," the three columns on the right are provided to be checked off for later reference:

- "Root cause?" should be answered "yes" or "no" for each finding. A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. If a particular finding that is relevant to the event is not a root cause, be sure that it is addressed later in the analysis with a "Why?" question. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan.
- "Ask Why?" should be checked off whenever it is reasonable to ask why the particular finding occurred—or didn't occur when it should have. In other words, use "ask why?" to drill down further. Each item checked in this column should be addressed later in the analysis with a "Why?" question. It is expected that any significant findings that are not identified as root causes themselves have "roots."
- "Take action?" should be checked for any finding that can reasonably be considered for a risk-reduction strategy. Each item checked in this column should be addressed later in the action plan. It will be helpful to write the number of the associated Action Item on page 3 in the "Take Action?" column for each of the findings that requires an action.

Level of Analysis		Questions	Findings	Root Cause?	Ask Why?	Take Action
What happened?	Sentinel Event	What are the details of the event? (Brief description)				
		When did the event occur? (Date, day of week, time)				
		What area/service was impacted?				
Why did it happen?	The process of activity in which the event occurred	What are the steps in the process, as designed? (A flow diagram may be helpful here)				
What were the most proximate factors? (Typically "special cause" variation)		What steps were involved in (contributed to) the event?				
	Human factors	What human factors were relevant to the outcome?				
	Equipment factors	How did the equipment performance affect the outcome?				
	Controllable environmental factors	What factors directly affected the outcome?				
	Uncontrollable external factors	Are they truly beyond the organization's control?				
	Other	Are there any other factors that have directly influenced this outcome?				
		What other areas or services are impacted?				

Level of Analysis		Questions	Findings	Root Cause?	Ask Why?	Take Action
Why did that happen? What systems and processes underlie those proximate factors? (Common cause variation here may lead to special cause variation in dependent processes.)	Human resource issues	To what degree are staff properly qualified and currently competent for their responsibilities?				
		How did actual staffing compare with ideal levels?				
		What are the plans for dealing with contingencies that would tend to reduce effective staffing levels?				
		To what degree is staff performance in the operant process(es) addressed?				
		How can orientation and in-service training be improved?				
	Information management issues	To what degree is all necessary information available when needed? Accurate? Complete? Unambiguous?				
		To what degree is communication among participants adequate?				
	Environmental management issues	To what degree was the physical environment appropriate for the processes being carried out?				
		What systems are in place to identify environmental risks?				
		What emergency and failure-mode responses have been planned and tested?				
	Leadership issues: *- Corporate culture*	To what degree is the culture conducive to risk identification and reduction?				
	- Encouragement of communication	What are the barriers to communication of potential risk factors?				
	- Clear communication of priorities	To what degree is the prevention of adverse outcomes communicated as a high priority? How?				
	Uncontrollable factors	What can be done to protect against the effects of these uncontrollable factors?				

Action Plan	Risk-Reduction Strategies	Measures of Effectiveness
For each of the findings identified in the analysis as needing an action, indicate the planned action expected, implementation date, and associated measure of effectiveness. OR. … If after consideration of such a finding, a decision is made not to implement an associated risk-reduction strategy, indicate the rationale for not taking action at this time. Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action. Consider whether pilot testing of a planned improvement should be conducted. Improvements to reduce risk should ultimately be implemented in all areas where applicable, not just where the event occurred. Identify where the improvements will be implemented.	Action Item #1:	
	Action Item #2:	
	Action Item #3:	
	Action Item #4:	
	Action Item #5:	
	Action Item #6:	
	Action Item #7:	
	Action Item #8:	
Cite any books or journal articles that were considered in developing this analysis and action plan:		

APPENDIX 2:
NYPORTS Framework for Root Cause Analysis

Event Description	Detailed Narrative Description/Chronology of Event
What happened? A **detailed description of the adverse event must include**: the date, day of the week, time, area/service involved, unit or department, who was involved by title, and **a detailed chronology of pertinent facts** that includes times. When **relevant**, include: • co-morbid conditions • height • weight • serial lab values • surgical procedures • changes in level of care • diagnostic testing results • vital signs • consults • medications • other clinical data • other non-clinical data	

Aspects for Analysis **Consider each statement/aspect for analysis, all disciplines and departments involved in the event. Check YES (or true), if applicable. If NO (or false), check NO and identify Root Cause # in last column. Then elaborate with corresponding root cause statement, risk-reduction strategies/corrective actions, and measures of effectiveness in next section.**	**Yes**	**No, is a Root Cause**	**See Root Cause #**
P. Policy or Process (system) in which event occurred			
1. The system in place related to the event is effective			
2. The system in place related to the event was carried out as intended			
3. An effective policy is in writing			
4. The policy was effectively communicated			
5. An effective procedure is in place			
6. The procedure was carried out as intended			
H. Human Resource Factors & Issues (include all involved disciplines/staff)			
1. Staff are properly qualified, credentialed, trained, and/or certified			
2. Staff are currently assessed as competent to carry out their responsibilities			
3. Staffing level plans were in place			
4. Staffing level plans were appropriate			
5. Staffing level plans were implemented			
6. Staff performance in relevant process(es) is evaluated			
7. Applicable orientation & in-service training in place were completed			
8. No human error contributed to the outcome			
9. No delay(s) or omission(s) contributed to the event			
E. Environment of Care/Equipment/Supplies			
1. The physical environment was appropriate for the processes/treatments being carried out			
2. A system is in place to identify environmental risk			
3. Emergency and failure mode responses have been planned and tested			
4. Preventative maintenance was carried out per policy on all involved equipment			
5. All involved equipment, supplies, and biologicals were available and utilized per manufacturer's specifications			
6. No controllable equipment factors contributed to the event			
7. No controllable environmental factors contributed to the event			
8. No controllable external factors (natural disasters, power outages, etc.) were a factor in this case			
9. An emergency preparedness plan is in place			
I. Information Management			
1. Necessary information was available			
2. Necessary information was accurate			
3. Necessary information was complete			
4. Necessary information was clear and unambiguous			
5. Communication among participants was effective			
6. No barriers to communication were identified			
L. Leadership: Corporate Culture			
1. Leadership is involved in the evaluation of adverse patient care occurrences			
2. Leadership is involved in the development and implementation of risk-reduction			
O. Other			
1. Other internal factors did not influence or contribute to this event			
2. Other areas of service did not contribute to this event			

Root Cause Analysis Section

Improvements to reduce risk should be implemented in all areas where applicable, not just where the event occurred. Identify where the improvements will be implemented including units, departments and/or facility-wide.

Root Cause #1	**Root Cause Statements** Must **clearly** show cause and effect relations (**use** "due to" or "in the absence of"). Identify the preceding cause(s) of the procedure violation(s). Remember that failure to act is only causal when there is a pre-existing duty to act.	
	Risk-Reduction Strategies (RRS)/Actions Should eliminate, greatly reduce, or control the root cause. Include systems and individual actions.	
	Title of Person Responsible Title of person responsible for the risk-reduction strategies/actions.	____Date: RRS will be implemented: mm/dd/year
	Measures of Effectiveness Must measure the impact of risk-reduction strategies and include defined timeframes, numerators for audit, realistic thresholds in percentages for performance/compliance, and follow-up for non-compliance. Title of person responsible.	

Literature Search

Can include books, articles, and Web sites. Include at least 3 sources that are pertinent to the event. List findings from literature search including *key quotes to support RCA findings* and risk-reduction strategies/actions.

Executive Summary

Root cause analysis review of occurrence is thorough and credible. Any external expert review findings are included. Relevant QA findings are summarized. Relevant staff qualifications and credentials, MD complication rate(s), number of procedures performed/year are included when applicable. Pertinent findings from literature search are cross-referenced. All elements are tied together to justify root causes, risk-reduction strategies, and measures of effectiveness.

List of RCA Participants by Title Only

Standard of Care Determination **Standard of care met? Did the quality of care and services meet generally accepted standards of practice?**	**Standard Care Met?** **If applicable, check both "No" responses.**
☐ Yes, no further action.	☐ No, attributable to systems.
☐ Yes, room for improvement.	☐ No, attributable to an individual practitioner (MD, resident, or PA).

Notified by the Facility	**Date Notified** **mm/dd/year**	**Title of Reporter**
☐ Office of Professional Medical Conduct		
MD, PA, Resident Name	License #	

Date RCA is complete and ready for review: _____ mm/dd/year

Agencies Notified by the Facility	**Date Notified** **mm/dd/year**	**Title of Reporter**
☐ Bureau Environmental Radiation Protection		
☐ Bureau of Narcotics		
☐ County Health Department		
☐ Department of Education		
☐ Food and Drug Administration		
☐ Office of Mental Health		
☐ Wadsworth Laboratories		
☐ Other		

Appendix 3:
NYPORTS Root Cause Analysis Evaluation Protocol

The facility is responsible for assuring that all RCA Protocol Criteria are met prior to initial submission. When the facility fills in the date RCA is complete and ready for review, it confirms the protocol criteria are met.

RCA Item #	Standard Criteria Required	Intent Met	Intent Not Met	NA	Comments Follow-Up	Date Intent Met
1.	**Short Form**					
1a.	Short form category code(s) accurately reflects occurrence described.					
1b.	Detail code (900 series code) accurately reflects occurrence described.					
2.	**RCA Narrative Description**					
2a.	A detailed description of the adverse event must include: the date, day of the week, time, area/service involved, unit or department.					
2b.	Identify who was involved by title and a detailed chronology of pertinent facts that includes times.					
2c.	When relevant include: co-morbid conditions, height, weight, serial lab values, surgical procedures, changes in level of care, diagnostic testing results, vital signs, consults, medications, other clinical data, and non-clinical data.					
2d.	Fully explain the event so that a reader unfamiliar with the occurrence understands what happened and why the event happened.					
3.	**Policy or Process in Which Event Occurred (P), Human Resource Factors & Issues (H), Environment of Care/Equipment/Supplies (E), Information Management & Communication Issues (I), Leadership: Corporate Culture (L), and Other (O)**					
3a.	Root cause statement(s) are consistent with the 5 rules of causation.					
3b.	Root cause statement(s) must clearly show cause and effect relationship (use "due to" or "in the absence of"). Identify the preceding cause, not the human error. Identify the preceding cause(s) of the procedure violation(s).					

RCA Item #	Standard Criteria Required	Intent Met	Intent Not Met	NA	Comments Follow-Up	Date Intent Met
3c.	Risk-reduction strategies/actions should prevent or minimize future events or close calls.					
3d.	Risk-reduction strategies/actions should eliminate, greatly reduce or control the root cause. Include system(s) and individual action(s).					
3e.	Title of person responsible for the risk-reduction strategies/actions must be entered.					
3f.	Date risk-reduction strategies/actions will be implemented must be entered.					
3g.	Measure of effectiveness must measure the impact of risk-reduction strategies and include defined timeframes, numerators for audit, realistic thresholds in percentages for performance/compliance and follow-up for non-compliance. Must enter title of person responsible.					
3h.	Hospital policies, clinical practice guidelines, critical pathways or practice protocols related to event are followed as intended, developed, or revised after review of the occurrence.					
3i.	Review identifies all root causes likely to prevent recurrence of event.					
3j.	RCA and identified root causes do not leave any obvious unanswered questions.					
3k.	RCA is internally consistent and does not contradict itself.					
4.	**Literature Search**					
4a.	Can include books, articles, and Web sites. Include at least 3 sources that are pertinent to the event.					
4b.	List findings from literature search including key quotes to support RCA findings and risk-reduction strategies/actions.					
5.	**Leadership: Corporate Culture**					
5a.	Root cause statement(s) must clearly show cause and effect relationship (use "due to" or "in the absence of"). Identify the preceding cause, not the human error. Identify the preceding cause(s) of the procedure violation(s).					
5b.	Leadership is involved in the evaluation of adverse patient care occurrences. They participate in the RCA process and are identified by title.					

RCA Item #	Standard Criteria Required	Intent Met	Intent Not Met	NA	Comments Follow-Up	Date Intent Met
6	**Executive Summary of the Analysis**					
6a.	Root cause analysis review of occurrence is thorough and credible.					
6b.	Any external expert review findings are included.					
6c.	Relevant Q/A findings are summarized.					
6d.	Relevant staff qualifications and credentials, MD complication rate(s), number of procedures performed/year are included when applicable.					
6e.	Pertinent findings from literature search are cross-referenced.					
6f.	All elements are tied together to justify root causes, risk-reduction strategies, and measures of effectiveness.					
7.	**RCA Participants**					
7a.	Individuals in roles involved in the processes and systems under review participate in RCA and are identified by title only (i.e. RN, Pharmacist, Radiological Technician, LPN, Attending Surgeon, Resident, PCA, etc.).					
8.	**Standard of Care Determination**					
8a.	RCA findings support the facility's standard of care determination.					
8b.	Facility's determination of standard of care is consistent with current practice.					
8c.	If standard of care not met and is directly linked to an individual practitioner, the full name and license number or certification number must be entered.					
9	**Agencies Notified by Facility if Applicable**					
9a.	Bureau of Environmental Radiation Protection					
9b.	Bureau of Narcotics					
9c.	County Health Department					
9d.	Department of Education					
9e.	Food and Drug Administration					
9f.	Office of Mental Health					
9g.	Wadsworth Laboratories					
9h.	Other					

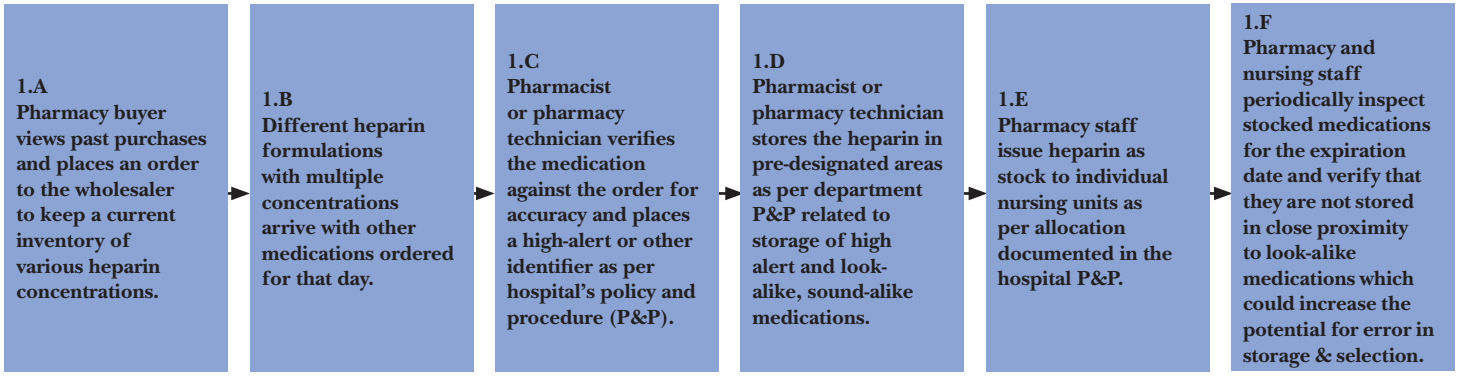
APPENDIX 4:
Sample FMEA – Medication Use Process for Initiating I.V. Heparin Infusion

I. Identify the steps in the process for initiating I.V. heparin by creating a flow chart. *An example of such a flow chart is outlined below.*

II. Create a detailed flow chart for each of the sub-processes identified. *Examples of sub-processes for the six steps identified for the I.V. heparin medication use process are listed below and on the subsequent pages.*

Process Step **Step 1: Selection, Procurement, & Storage**

Sub-process



III. Identify possible failure modes for each step in the sub-process. *In the example below, and on the subsequent pages, one or more steps in the selected sub-processes are identified and examples of possible failure modes are listed.*

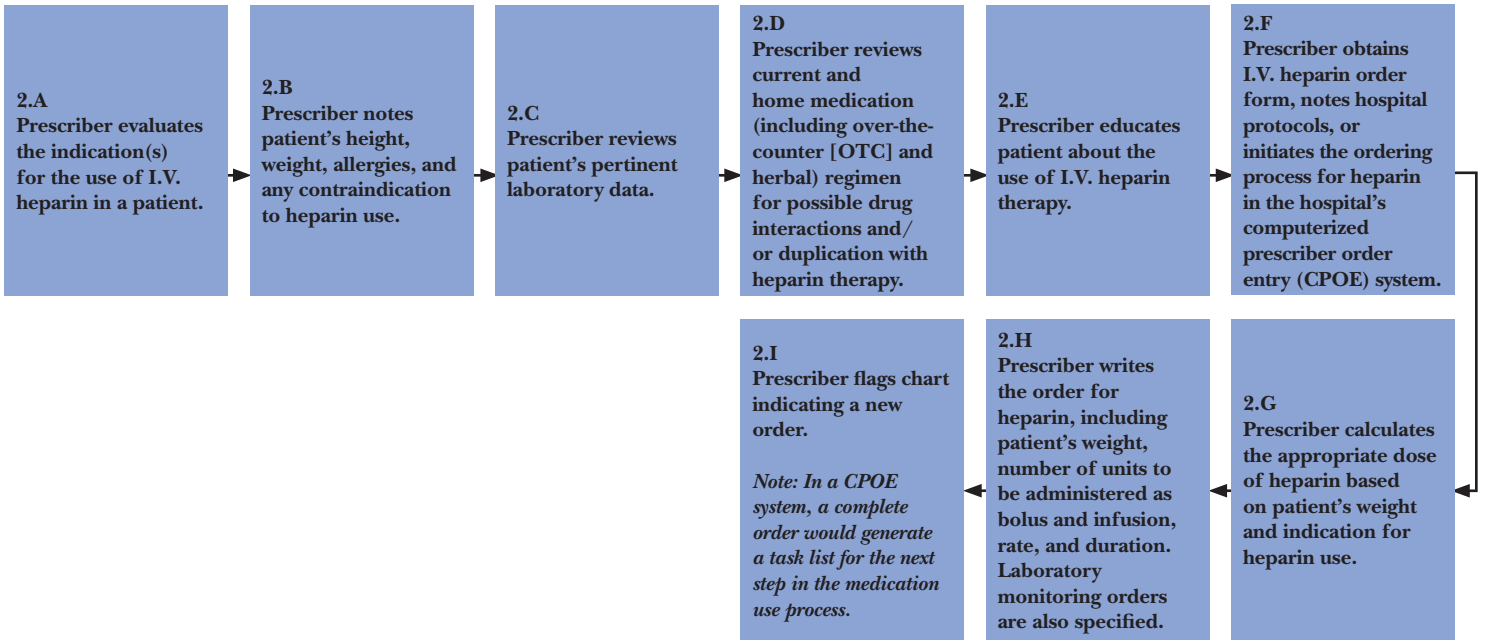
1.A Pharmacy buyer views past purchases and places an order to the wholesaler to keep a current inventory of various heparin concentrations.	**Failure Modes:** • Order inadvertently placed for a concentrated heparin product not previously stocked
1.C Pharmacist or pharmacy technician verifies the medication against the order for accuracy and places a high-alert or other identifier as per hospital's policy and procedure (P&P).	**Failure Modes:** • Failure to notice receipt of medication with different concentration • High alert sticker or other identifier omitted (failure to follow P&P)
1.D Pharmacist or pharmacy technician stores the heparin in pre-designated areas as per department P&P related to storage of high alert and look-alike, sound-alike medications.	**Failure Modes:** • Medication stored incorrectly adjacent to several other concentrations of the same product (creating look-alike confusion)
1.E Pharmacy staff issue heparin as stock to individual nursing units as per allocation documented in the hospital P&P.	**Failure Modes:** • Incorrect concentration of heparin provided as stock to the nursing unit • Incorrect concentration of heparin placed in automated dispensing cabinet (ADC) • Heparin placed in wrong location in ADC

Sample FMEA – Medication Use Process for Initiating I.V. Heparin Infusion *cont.*

I. Process Step

Step 2: Prescribing

II. Sub-process



III. Possible Failure Modes for Sub-process Step 2.H

2.H
Prescriber writes the order for heparin, including patient's weight, number of units to be administered as bolus and infusion, rate, and duration. Laboratory monitoring orders are also specified.

Failure Modes

- Wrong patient's chart
- Use of unapproved abbreviation "U" for Units
- Incorrect protocol chosen
- Addition/omission of zero
- Drug contraindicated – allergy or other reason
- Illegible signature/cannot identify prescriber
- Wrong medication, route, frequency ordered
- Illegible order
- Wrong dose calculated based on wrong weight
- Duplicate anticoagulant order
- Miscommunication of telephone/verbal order
- Incomplete order
- Order written, but chart not flagged

- Computerized Prescriber Order Entry (CPOE)
  - » Safety alerts in CPOE system bypassed
  - » Wrong dose selected from drop-down menu
  - » Heparin protocol in CPOE system bypassed; free-text option used
  - » Drug-drug interaction alert ignored
  - » Look-alike names on ordering screen leading to incorrect selection

Sample FMEA – Medication Use Process for Initiating I.V. Heparin Infusion *cont.*

I. Process Step: **Step 3: Transcription**

II. Sub-process

3.A
New order for heparin infusion noted in the chart or retrieved from electronic task list (for those with electronic medication administration record (eMAR).

→

3.B
Unit secretary sends written order to the pharmacy.

Note: This step may not apply in settings utilizing CPOE.

→

3.C
Nurse reviews and verifies order for accuracy and completeness, including the patient's weight and the calculated dose of heparin.

→

3.D
Nurse transcribes the order onto the Medication Administration Record (MAR).

Note: This step may not apply in settings utilizing eMAR.

III. Possible Failure Modes for Sub-process Steps 3.B, 3.C, 3.D

3.B
Unit secretary sends written order to the pharmacy.

→

Failure Modes

- **Order misplaced**
- **Order sent to the wrong unit**
- **Wrong patient identified on order (wrong addressograph)**
- **Order not transmitted to pharmacy due to availability in ADC**
- **Order sent without patient identification**
- **Delay in communicating the STAT order to pharmacy**

3.C
Nurse reviews and verifies order for accuracy and completeness, including the patient's weight and the calculated dose of heparin.

→

Failure Modes

- **Wrong drug transcribed during telephone order**
- **Failure to note incomplete/ incorrect order**
- **Incorrect pound to kilogram conversion**
- **Error in calculation**
- **Failure to communicate changes in the order to pharmacy**

3.D
Nurse transcribes the order onto the Medication Administration Record (MAR).

→

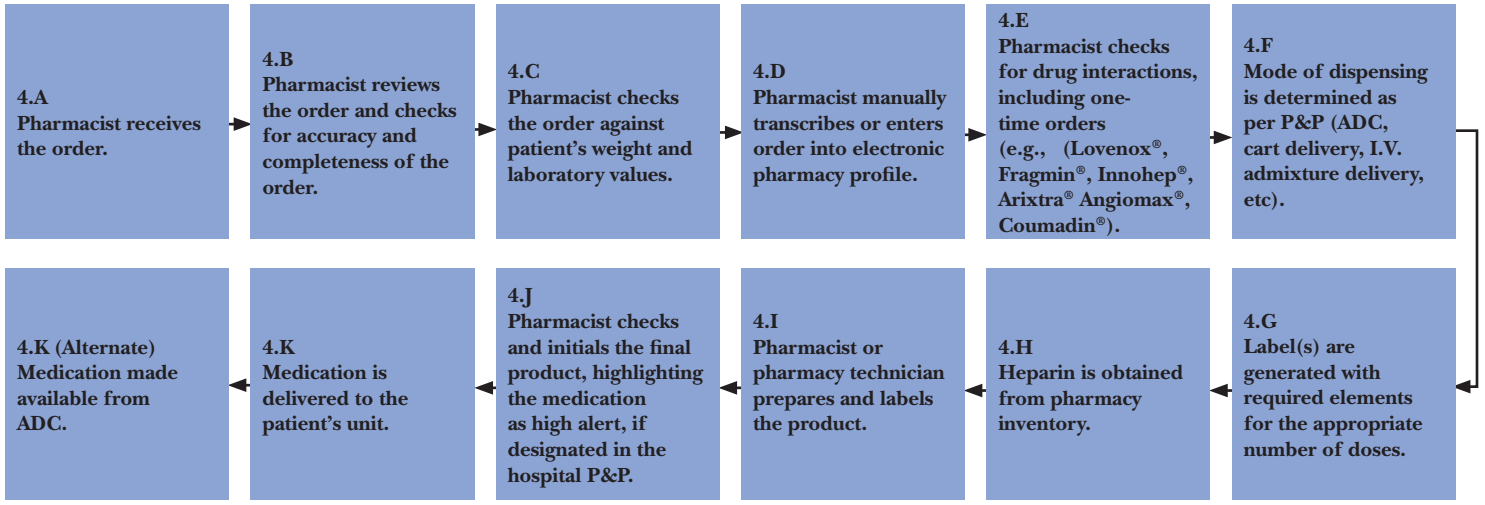
Failure Modes

- **Order transcribed onto wrong patient's MAR**
- **Illegible transcription**
- **Order is transcribed with wrong route, dose, medication, schedule, frequency**
- **Order not transcribed onto MAR**

Sample FMEA – Medication Use Process for Initiating I.V. Heparin Infusion *cont.*

I. Process Step: **Step 4: Dispensing**

II. Sub-processes



III. Possible Failure Modes for Sub-process Steps 4.D, 4.I, 4.K

4.D
Pharmacist manually transcribes or enters order into electronic pharmacy profile.

Failure Modes

- Allergy, dose range checks, drug-disease contraindication, laboratory, and duplicate therapy alerts bypassed
- No verification/ communication of the mode of dispensing (i.e., ADC, I.V. room, nursing unit stock leading to duplication or missing med.)
- Incorrect drug, concentration, unit of measure, calculation, route, frequency

4.I
Pharmacist or pharmacy technician prepares and labels the product.

Failure Modes

- Incorrect or expired product selected
- Drug not added to diluent; wrong diluent chosen
- Prepared in the wrong delivery device, i.e., oral syringe vs. intravenous syringe
- Medication is not ready-to-use in unit-dose
- Wrong label
- Label has missing/confusing information
- Label did not generate; medication is not prepared
- Medication unavailable in pharmacy

4.K
Medication is delivered to the patient's unit.

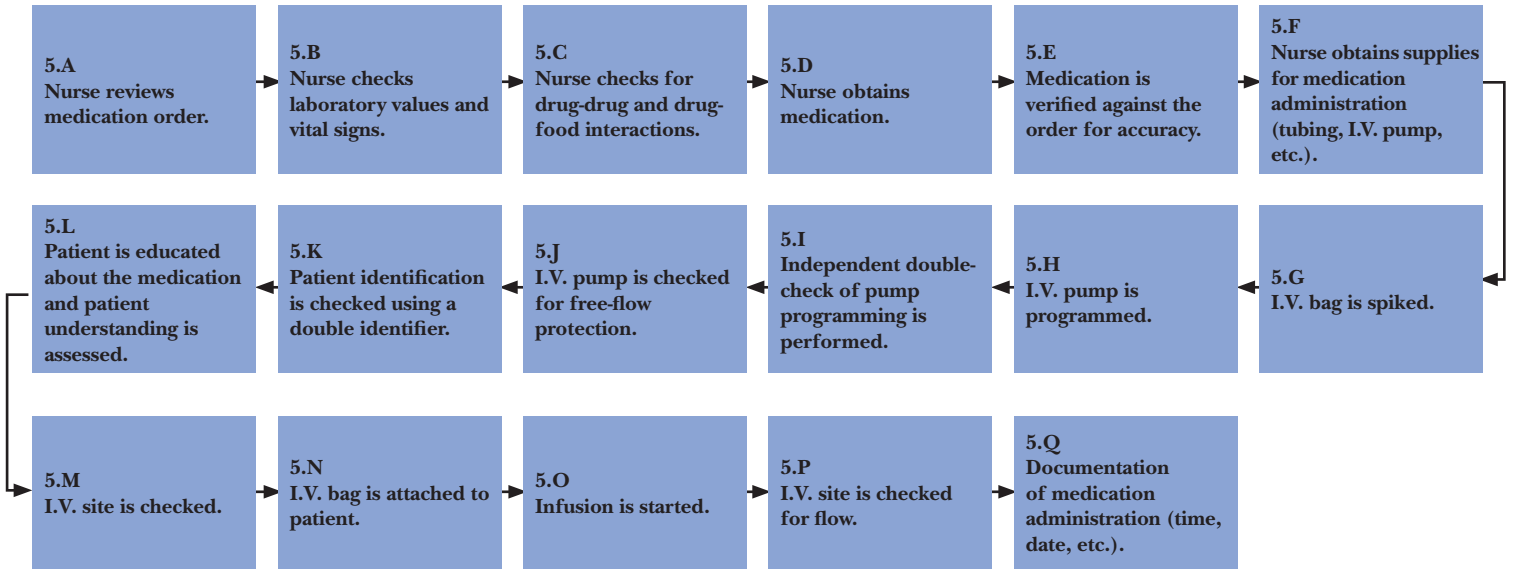
Failure Modes

- Medication delivered to wrong patient/unit
- Delivery of medication into incorrect ADC pocket
- Expired medication delivered
- Delivery system "down"
- Medication left unsecured
- Medication never delivered

Sample FMEA – Medication Use Process for Initiating I.V. Heparin Infusion *cont.*

I. Process Step: **Step 5: Administration**

II. Sub-process



III. Possible Failure Modes for Sub-process Steps 5.D, 5.F, 5.I

5.D
Nurse obtains medication.

Failure Modes

- Wrong medication or concentration obtained
- Medication obtained from stock prior to pharmacist review

5.H
I.V. pump is programmed.

Failure Modes

- Wrong pump
- Wrong duration
- Wrong dose programmed (mL instead of units)
- Wrong rate
- Wrong mode
- Pump program over-ridden; pump drug library not used

5.O
Infusion is started.

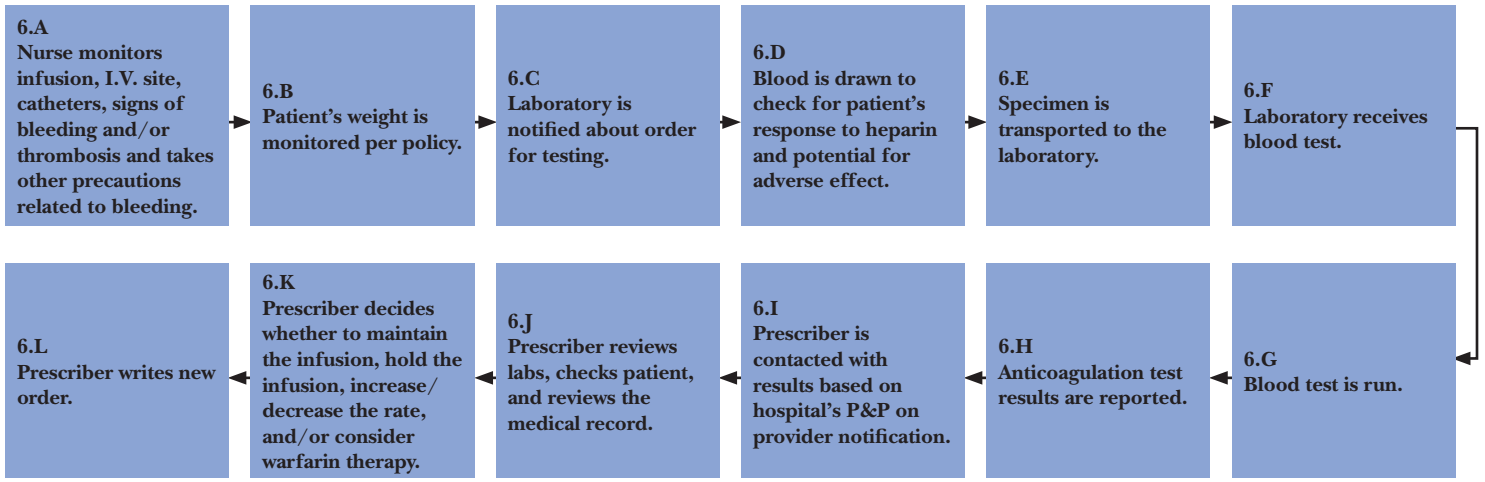
Failure Modes

- No I.V. access
- Obstructed flow of I.V. solution
- Forgot to start the infusion
- Free-flowing infusion
- Wrong patient, drug, concentration, dose, rate, route, time
- Change in pump setting by patient or family
- Equipment failure; medication not given
- Y-site incompatibility precipitation

Sample FMEA – Medication Use Process for Initiating I.V. Heparin Infusion *cont.*

I. Process Step: **Step 6: Monitoring**

II. Sub-process



III. Possible Failure Modes for Sub-process Steps 6.C, 6.D, 6.H, 6.K

6.C
Laboratory is notified about order for testing.

Failure Modes

- Failure to notify laboratory about testing order
- Wrong time for test indicated
- Delayed notification sent to laboratory
- Wrong test ordered

6.D
Blood is drawn to check for patient's response to heparin and potential for adverse effect.

Failure Modes

- Blood is drawn too early or too late with respect to dose given
- Blood is drawn using wrong tube
- Insufficient quantity of blood to run the test
- Blood not drawn due to difficult venous access

6.H
Anticoagulation test results are reported.

Failure Modes

- Lab equipment not properly calibrated
- Lab reference range is not reflective of patients on heparin
- Failure to notify provider about abnormal labs according to policy
- Delay in reporting
- Reporting protocol not followed accurately (i.e., left a message)

6.K
Prescriber decides whether to maintain the infusion, hold the infusion, increase/decrease the rate, and/or consider warfarin therapy.

Failure Modes

- Decision to change therapy based on erroneous laboratory data
- Decision to change therapy not documented in the chart
- Decision to change therapy not communicated to other providers caring for patient
- Decision to delay initiation of warfarin results in increasing length of stay

IV. For each failure mode, calculate the risk priority number (RPN) or criticality index, by estimating the frequency, severity, and likelihood of detecting the failure before the failure reaches the patient. *An example is given below.*

Frequency or probability of the failure occurring (F)	X	Severity of the failure (S)	X	Detectability or likelihood the failure will be detected before it reaches the patient (D)	=	Risk Priority Number (RPN) or Criticality Index

Probability or Frequency Probability Rating (F)

- Remote (F=1): one in 10,000; no known occurrence (may happen some time in 5–30 years).
- Low (F=2, 3, 4): one in 5,000; possible occurrence (may happen some time in 2–5 years).
- Moderate (F=5, 6): one in 200; documented but infrequent (may happen several times in 1–2 years).
- High (F=7, 8): one in 50–100 (F=7); 1 in 50 (F=8); documented and frequent.
- Very high (F=9, 10): one in 20 (F=9); 1 in 10 (F=10); documented; almost certain to occur.

Severity Rating (based on patient outcomes) (S)

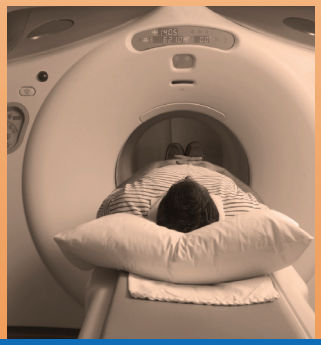
- Minor event (S=1): No injury, increased length of stay, or increased level of care.
- Moderate event (S=4): Increased length of stay or increased level of care for one to two patients.
- Major event (S=7): Permanent lessening of bodily functioning (physiologic or intellectual), disfigurement, surgical intervention required, increased length of stay for three or more patients, increased level of care for three or more patients.
- Catastrophic event (S=10): Death or major permanent loss of function, suicide, rape, hemolytic transfusion reaction, surgery/procedure on the wrong patient or wrong body part, infant abduction, or infant discharge to the wrong family.

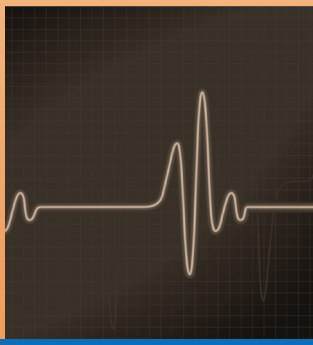
Detectability Rating (D) (change order on these so sequence is from 1 to 9, i.e., very high D=1)

- Remote (D=9): Detection not possible at any point in the system.
- Low (D=7, 8): Low likelihood (one or two in 10) that error will be detected before the product/service reaches the patient.
- Moderate (D=4, 5, 6): Four, five, or six in 10 that error will be detected before the product/service reaches the patient.
- High (D=2, 3): Seven in 10 that error is likely to be detected before product/service reaches the patient.
- Very high (D=1): System will always detect error.

Step in Process	Possible Failure Modes	Frequency	Effect(s) of Failure	Severity	Likelihood of Detection	Criticality Index or RPN	Cause(s) of Failure	Risk-Reduction Strategies
6.H Anti-coagulation test results are reported.	Lab equip-ment not prop-erly calibrated.	2	Incorrect anticoagula-tion status reported	10	7	140	Lack of supervi-sion. Variation in carrying out procedures.	Spot-check supervisory review of equipment calibration. Scheduled equipment control checks.
	Lab reference range does not reflect patients on heparin.	5	Bleeding complica-tions	10	5	250	Incorrect presenta-tion of important lab information.	Indicate therapeutic PTT levels in lab reports.
	Delay in reporting by lab technician.	5	Delay in treatment	10	6	300	Inadequate staffing to make timely reports. Lack of lab staff supervision.	Review staff effectiveness plans (including # of staff as well as competency). Routine rounds by lab supervisor to ensure timely report-ing of results. Built-in reminders.
	Test results reported under wrong patient's name.	2	Improper treatment	10	8	160	Duplicate/sound-alike names. Only name used to identify patient. Specimen labeled incorrectly.	Utilize multiple patient identifiers and include multiple identifiers on specimen label. Bedside labeling of specimen. Bar-coding (long-term solution). Alerts for duplicate names.
	Wrong physi-cian or nursing unit contacted or elevated or sub- therapeu-tic levels.	2	Delay in treatment	10	6	120	Inadequate staff to ensure follow-up. Incorrect patient information (e.g., wrong room number) on lab requisition.	Review staffing effectiveness plans. Develop electronic systems to ensure accuracy of patient informa-tion (e.g., location).
	Failure to notify provider about abnormal values accord-ing to policy.	4	Delay in treatment	10	6	240	Knowledge deficit of reporting criti-cal lab results.	Utilize computer-generated alerts for reporting critical lab results. Periodic QI audit to value follow-up reporting results.
	Reporting protocol not followed accu-rately.	5	Delay in treatment	10	6	300	Knowledge deficit of report-ing critical lab results. Inability to reach provider. Inadequate staff knowledge of policy. Inadequate staffing.	Review staff effectiveness plans (including # of staff as well as competency). Utilize computer-generated alerts for critical value lab results. Reinforce policy requiring documentation of communication to provider. Specify protocol for when the provider cannot be reached.

Note: The rankings in the example are intended for demonstration purposes only. Rankings for frequency, severity, and likelihood of detection will vary from facility to facility based on the reliability of their processes at any given step.



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