

# System-Focused Event Investigation and Analysis Guide

## Communication and Optimal Resolution Toolkit

**Purpose:** To help teams adopt a system-focused approach to event investigation and analysis.

**Who should use this tool?** Event Reporting, Investigation, and Analysis Team.

**How to use this tool:** Review the guide information when developing and implementing a systems approach to event investigation and analysis.

### Table of Contents

Introduction .....	2
A Systems Approach .....	2
Event Review Process .....	5
Activation of the CANDOR Response Team/Preliminary Review .....	6
Identifying the Core Team.....	7
In-depth Event Investigation and Analysis .....	8
Confirmation and Consensus Meeting.....	11
Solutions Meeting.....	13
Followup.....	15
Appendix A: Five Whys.....	16
Appendix B: Detailed Review Timeline.....	17
Appendix C: Visual Model.....	19
Appendix D: CANDOR Tool.....	20
Appendix E: Confirmation and Consensus Meeting Announcement Template .....	25
Appendix F: Solutions Meeting Announcement Template .....	26
Appendix G: Data Measurement Plan .....	27
Appendix H: Hierarchy of Solutions .....	28
Appendix I: Glossary .....	29



## Introduction

In most hospitals across the country, many of the recommendations that come from root cause analyses of adverse events focus on re-education, re-training, disciplinary actions, or the creation of new policies. However, safety science shows that these types of recommendations do not consistently lead to sustained improvements in the quality and safety of care delivered to patients.

This guide provides a standardized structure for facilitating an event review, understanding true contributing factors, and arriving at effective and sustainable solutions. To help achieve these goals, this document provides the following guidance and tools:

1. A name change of the overall process from “root cause analyses” to “event investigation and analysis.”
2. A pre-scripted immediate response to events, along with a tightened timeline for event reviews.
3. A two-meeting structure with the bulk of the information being gathered prior to the first meeting.
4. A change in the name of the meetings from “root cause analyses meeting” to “confirmation and consensus meeting” and “solutions meeting.”
5. Updated language including “event investigation and analysis” to reflect a systems-based approach and “contributing factors” instead of “root causes.”
6. Standard templates for all stages of the event investigation and analysis process.

Incorporating these structured fundamentals into practice should further develop skills necessary for conducting successful event reviews, improve discovery and learning, and lead to the development and implementation of sustainable and effective solutions.

## A Systems Approach

The sole objective of the event investigation and analysis of an adverse event or near miss is the prevention of future adverse events. This activity should not be used to assign blame or liability.

The premise of a systems approach to event investigation and analysis is that while adjusting individual performance may appear to resolve a case, it does not ensure the event won't happen again; human errors are abundant and inevitably repeated. If the focus is on the process and the system factors that facilitated the error, the process can be adjusted to minimize human error, resulting in fewer opportunities to err again.

When an adverse event occurs, too often, the focus is on an individual's performance and is corrected with discipline, counseling, or retraining. This response is ineffective in improving quality of care and patient safety for several reasons.

- First, it diverts attention away from factors in the system (other than the involved individual) that might have contributed to, facilitated, or even caused the adverse event. If these factors can be identified and modified, the chance of similar events can be reduced.
- Second, focusing blame on a particular individual does not prevent other individuals from making the same error.
- Third, the focus on individual blame creates a culture where staff fear punishment and may try to hide adverse events, unsafe conditions, and near misses rather than reporting the hazards to help improve the system. Unless health care leaders are aware of repeatable events, hazards, and unsafe conditions, they cannot take steps toward reducing them.

Other high-risk industries, such as aviation, oil and gas, and nuclear power, have become highly reliable and safe largely because they have moved away from the individual-blame approach. Instead, they use a systems approach to maximize safety. The systems approach recognizes that all adverse events have multiple contributing factors, many of which are outside an individual’s control. Once system contributions are identified, steps can be taken to change the latent hazard or contributing factors and avoid repeats of the same event.

A systems approach’s main principle is that most types of human error cannot be eliminated, so the system must be altered for safety and reliability. This does not eliminate the need for highly trained individuals with competency standards.

### Just Culture

When event investigation and analyses are conducted from a systems approach, with a focus on identifying the system factors that contributed to the event, a fair and accountable culture can be established. The fair and accountable culture is not a blame-free culture, as individuals must still be accountable for appropriate training, preparation, and behavior. After a thorough review of the event, the provider’s involvement can be classified into one of the three following behaviors: normal error, at-risk behavior, or reckless behavior. (Table 1)

“People make errors, which lead to accidents. Accidents lead to deaths. The standard solution is to blame the people involved. If we find out who made the errors and punish them, we solve the problem, right? Wrong. The problem is seldom the fault of an individual; it is the fault of the system. Change the people without changing the system and the problems will continue.”

“The Design of Everyday Things,”  
by Don Norman, cognitive scientist  
and usability engineer

**Table 1: Behavior Classification**

Normal Error (Human Error)	At-risk Behavior	Reckless Behavior
<p>Inadvertent action such as a slip, lapse, or mistake</p> <p>Manage by changing:</p> <ul style="list-style-type: none"> <li>■ Processes</li> <li>■ Procedures</li> <li>■ Design</li> <li>■ Environment</li> </ul>	<p>Individual is not educated about potential risk and sees no value in established policies to prevent it</p> <p>Manage by:</p> <ul style="list-style-type: none"> <li>■ Removing incentives for at-risk behaviors</li> <li>■ Creating incentives for positive behaviors</li> <li>■ Educate about potential risks</li> <li>■ Redesign of system factors</li> </ul>	<p>Conscious and deliberate violations of procedures and policies</p> <p>Manage through:</p> <ul style="list-style-type: none"> <li>■ Remedial action</li> <li>■ Punitive action</li> </ul>
<b>Support</b>	<b>Coach</b>	<b>Sanction</b>

Adapted from: Marx D., New York, NY, Columbia University, *Patient Safety and the “Just Culture”: A Primer for Health Care Executives*, 2001

Normal error and at-risk behaviors are treated in a non-punitive, supportive, and protected manner. The event review focuses on uncovering latent hazards or contributing factors that increase pressure or constrain performance. If a normal error has occurred, the provider undoubtedly feels bad and should be supported. Underlying hazards discovered in the review should be changed in ways such as system redesign.

At-risk behaviors should be “coached” and supported, meaning reviewers or peer leaders remind and educate the provider that their practice may lead to an adverse event. Also, leaders should recognize that often people take this route because the sub-optimal working environment is burdensome, and they cannot complete their tasks efficiently or effectively. This is an opportunity to improve processes, procedures, design, and environment.

Reckless behaviors are **unacceptable, very rare, and not tolerated**. Regardless of tenure, status, or position, these behaviors should receive immediate punitive action.

### **Principles of an Event Review**

In other safety critical industries, event reviews are highly routinized and are one of the most important learning opportunities. In addition, learning about system vulnerabilities before they occur is critical.

Event reviews include all of the following guiding principles:

1. All information is protected under the organization’s bylaws and policies governing peer review and patient safety.
2. Quick reaction and review is essential. Details are lost quickly in memory. The most effective event investigation and analyses are conducted as quickly as possible after the event, including a review of the site of the event. Be sure to follow hospital confidentiality guidelines.
3. Trained event reviewers are essential to gain an understanding of the system as a whole and to conduct in-depth interviews with knowledgeable parties. Trained reviewers are able to gather information about aspects of the system that may not initially be seen as important to the event.
4. Interviews are conducted individually, typically with one or two members of the review team. Larger groups of interviewers (three or more) are less likely to facilitate full transparency about the adverse event.
  - Those being interviewed should not be accompanied by a supervisor; a supervisor’s presence may make the interviewee less likely to reveal true workflow patterns for fear that he or she may be punished for not following protocol. The goal is to provide a comfortable, protected, one-on-one interview in which the interviewee feels free to speak openly.
  - It may be helpful to get feedback from those familiar with the process before talking to the individual who actually participated in the event. This allows the interviewer to gain a better understanding of the process prior to conducting interviews, which may be emotionally charged or challenging.
5. The organization’s leadership provides attention and resources.
6. The patient/family are involved in the interview process because they often are the only people present throughout the entire course of events.

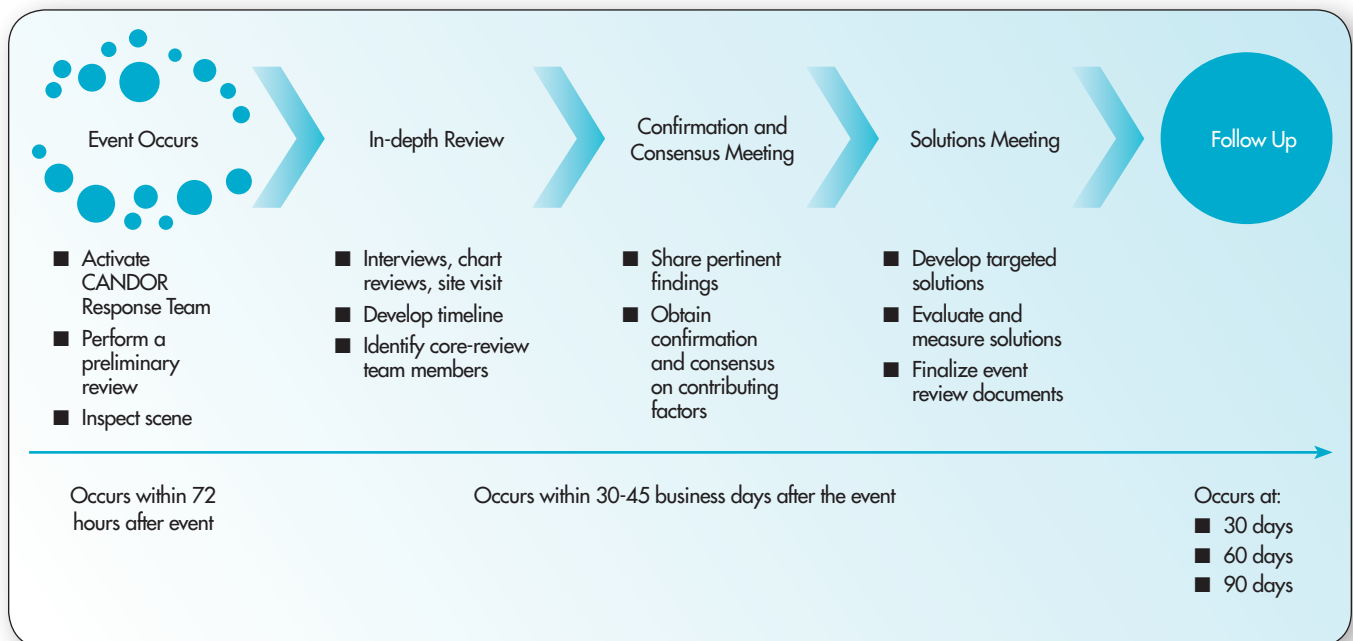
7. A fair and accountable culture should be emphasized with interviewees. The goal is fact finding, not fault finding.

- Research has shown that the first few minutes of an encounter can change perceptions of that encounter drastically.<sup>1</sup>
- Each interaction with patients, family, or staff is an opportunity to reinforce just culture and systems thinking.

“You cannot change the human condition. But you can change the conditions in which humans work.”

James Reason, professor of psychology at the University of Manchester

## Event Review Process



<sup>1</sup>See Hackman JR. “Leading teams: Setting the stage for great performances.” Boston: Harvard Business School Press; 2002.

## Activation of the CANDOR Response Team/Preliminary Review

In the initial stage of an event review, it is critical to establish a culture of safety and ensure that accurate information is gathered in a timely manner. It is recommended that the organization identify a group of individuals who can be immediately available when an event occurs (i.e., within minutes to hours). This team is trained to meet the immediate needs of the patient, family, and caregivers. The CANDOR Response Team, in conjunction with the frontline caregivers, immediately begins open, honest, and supportive communication with patients and family members affected by an event to support and successfully meet their short- and long-term needs. In addition, the CANDOR Response Team provides emotional support to the caregiver and activates the Care for Caregiver program.

The CANDOR Response Team is responsible for conducting a preliminary review, which should occur within hours of the event, if not sooner. The preliminary review should occur at the event location. The preliminary review is crucial and serves several functions:

1. Identifies and addresses the immediate needs of the patient and family.
2. Identifies and addresses the immediate needs of the caregivers.
3. Obtains time-sensitive information (e.g., rhythm strips, broken equipment, and devices).
4. Initiates a billing hold.
5. Begins to identify individuals who will make up a second team, the core team.

**The preliminary review must be conducted within the framework of fair and accountable culture and must:**

- Seek facts, not fault.
- Avoid hindsight bias.
- Show support.
- Emphasize an understanding of each person's perspective at the time, including available information, other demands on their attention and constraints.

When arriving at the site of the event, observe everything, including:

- Environment
- People
- Teams
- Noise
- Temperature
- Busy-ness (volume, census, acuity)
- Technology
- Organization of the environment

Upon arrival at the event location, attempt to understand “the whole” before examining each part. Many different aspects of the context may seem memorable initially, but are ultimately difficult to remember, so take notes. Explain to people why you are taking notes. Draw a diagram of the physical layout, and add any important findings that you notice as this may help others understand the event.

Collect all time-sensitive information from the electronic medical record (EMR) or other clinical information sources, as they may be important (e.g., paper medical record, labs, imaging, page operator records, rhythm strips, and specific equipment). Gather these items immediately; you may not be able to duplicate that information at a later point in time. If a medical device was involved, take it out of service for further evaluation and collect all peripherals (such as the drip set and tubing with the infusion pump).

The preliminary review is not meant to take the place of the in-depth review. It is an opportunity to respond to the immediate needs of those involved, gather time-sensitive materials, and begin building a trusting relationship required to move effectively through the event review.

## Identifying the Core Team

During or shortly after the preliminary review, the core team should be established by the primary event reviewer. At minimum, this team should include the primary reviewer, an executive sponsor, and administrative support. The type of event, the preliminary review, and other information gathered will help to guide and identify additional members. Additional core team members could include those who are knowledgeable about the context of work or are in a position to effect the final solutions, such as risk management, safety leaders, clinical leaders from impacted areas, peer/colleagues in the appropriate domain, department chairs, patient and family, or a member of the family advisory council. The individuals selected will also participate in the confirmation and consensus meeting.

It is important to ensure that there is consistent communication with the team. Regular communication will create more buy-in, identify better solutions, and avoid potential pitfalls. The following is a list of responsibilities for the core team:

1. The primary reviewer:
  - a. Manages the event review.
  - b. Facilitates interviews with frontline staff and content experts.
  - c. Compiles the content for documentation of the event.
  - d. Determines suspected causal factors for the event and presents to other core team members in preparation for the confirmation and consensus meeting.
  - e. Conducts/facilitates the confirmation and consensus and solutions meetings.
  - f. Ensures the quality of the final documentation.
2. The executive sponsor (CMO, CNO, or other senior leader):
  - a. Provides guidance and assistance in making sure staff is available for interviews and meetings.
  - b. Ensures roadblocks are removed and adequate resources are supplied to complete the review and implement solutions.
3. The administrative support:
  - a. Makes appointments.
  - b. Sets up meetings and interviews.
  - c. Keeps the documentation organized.

Based on the preliminary event report, the core team will begin to consider which types of subject experts to reach out to for guidance. These subject experts will inform the core team. Examples of subject experts include individuals in the following areas:

- a. Biomedical engineering
- b. Facilities
- c. Human factors or other system safety engineering field
- d. Information technology
- e. Medical and surgical specialties
- f. Nursing
- g. Pharmacy
- h. Risk management

## In-depth Event Investigation and Analysis

Once the preliminary review is complete and the core team is identified, the in-depth event investigation and analysis begins. This review:

1. Provides a deep and thorough understanding of the event: if individual interviews, appropriate information gathering, and observations occur within days of the event, it is more likely that the reviewer will discover contributing factors.
2. Impacts safety culture: with the right approach to interviews and observations, the event reviewer will model to staff that safety and risk leaders are focused on the systems issues that need to be fixed, contributing to an open safety culture.
3. Supports care for the caregiver: demonstrates concern about the impact on the caregiver, supports them, and identifies individuals who require further support or intervention.
4. Engages patients and families: demonstrates an ongoing commitment to patient and family members, connects them to safety and risk leaders, and keeps them informed of findings.

Please note that the bulk of the time and effort of the event review process should occur during the in-depth investigation and analysis. If done well, the resulting information will lead to effective, targeted, implementable, and sustainable solutions.

### Conducting an Effective In-Depth Event Investigation and Analysis

An effective in-depth event investigation and analysis includes conducting interviews and understanding the context in which the event took place (observations), reviewing all pertinent records, and developing a chronological timeline that leads up to the actual event. These steps do not have to be sequential and are most effective when conducted iteratively.

#### Interviews

Essential pieces of information are obtained through confidential interviews with individuals involved in the event and should be a major focus of the in-depth event investigation and analysis. Confidentiality is critical. Ideally the interviews should be one-on-one; there should be no more than two reviewers present in an interview. Some reviewers have found that having a “note taker” is extremely helpful so that the main interviewer can concentrate on the conversation, rather than on taking adequate notes.



Consider interviewing others who were around, but not directly involved in the event. It is important to understand how the work is normally performed, and those not involved can often give great insight into the normal work flow, environment (e.g., physical layout, noise, lighting), technology that is used and how it works, etc. It may be helpful to interview those directly involved with the incident after understanding others' perceptions of the event. However, order of the interviews is not critical, as it is more important to talk to people when and where it is convenient for them.

All interviews should have an introduction. This is especially important for individuals who were directly involved in the event. For individuals who are involved in clinical care (e.g., nurses), speak with the supervisor to ensure interviewee availability and clinical coverage. It is important to coach the supervisor so that the purpose of the interview is communicated appropriately. Supervisors should be coached to stress to employees that the goal of the interviews is to gain accurate knowledge of the details of the event without blaming the individual. It is essential that employees feel comfortable sharing openly, as that will lead to a more accurate assessment of what caused the event.

A private, quiet setting should be used for the interview, and it should be conducted when both parties have at least 30–60 minutes.

Initial steps:

1. Introduce yourself and your role.
2. If possible, offer a glass of water or cup of tea.
3. Stress that the purpose of the interview is to learn more about what happened and how to make the system safer for others.
4. State the anticipated length of the interview.

Two possible ways to start the interview:

- 1) "Thank you for your willingness to help us learn. Can you tell me about your understanding of what happened?"
- 2) "I would like to learn more about what happened. We are trying to identify system factors that might have contributed to the event or facilitated an error. Can you tell me the story?"

## Questions

The interviewer should ask followup questions as necessary to obtain a sufficient level of detail. All questions should be neutral, simple, and positive. Positive phrasing means "do you remember..." rather than "you wouldn't remember whether..." The interview questions are an opportunity to focus on system factors—help the individual understand they are part of a larger system and that to make the system safer, it is essential to understand the individual's viewpoint.

There are multiple opportunities for bias, with the two main biases being anchoring bias and hindsight bias. Humans tend to have these biases no matter their training. Therefore, the main way to mitigate them is to be aware of them.

Questions should cover:

1. Aspects of the organization (e.g., staffing, policies, and procedures)
2. Technology involved (e.g., any usability issues, downtime, individual knowledge gaps)
3. Interactions with equipment (e.g., beds, pumps, other equipment)
4. Physical environment (e.g. time of day, day of week, temperature, light or dark, room layout, noise)
5. Supervision (e.g., leadership or management involvement/resources or lack thereof)

6. Teamwork (e.g., how long has this team worked together, and do they have thoughts about strengths or weaknesses of this team?)
7. Communication (e.g., were there barriers to communication?)
8. The task itself (e.g., how frequently is this task conducted? Were staff adequately trained? What is the normal way it is done? Were there deviations? Why?)
9. Any unusual aspects of the patient (e.g., unexpected patient complications, conditions. How would they describe their interaction with the patient? Any other aspects or concerns?)

This is not a comprehensive list, but it serves as a starting point.

Reviewers should use active listening skills and repetitively stress the point of the interview is fact finding not fault finding. Active listening means you remain focused on what the interviewee is saying, avoid interrupting or preparing your next question while they are speaking. Repeating back or asking for clarification about what they have said helps people engage in this type of listening.

### **Five Whys**

Utilizing a “five whys” technique may be helpful. Asking the question “why” multiple times helps to get to the main contributing factors of an event. Very often the answer to a question will lead you to another question. Though the technique is called “five whys,” you may need to ask the question fewer or greater than five times before you find the issue related to a problem. An interviewer should not accept these responses as the final result and always follow up with a “why” question:

- Human error – Ask questions such as “Why was there human error? Was there a distraction? Was the person fatigued? Was the person not properly oriented or trained to perform the task at hand?”
- Device failure – Why did the device fail? Was this the first time it failed? What was its preventive maintenance and/or repair history? Was this a new device? Was the person using the device properly trained?
- Process deviation – Why did the person deviate from the process?

(Examples of specific “five whys” questions can be found in Appendix A)

### **Identifying Essential Interviews**

The snowballing technique can be helpful to identify and interview the right people to gain a thorough understanding of the event. Start with the key stakeholders, those who know the process, supervisors, those who interact with the process, and those involved in the event.

Next, from information gained in these initial interviews, identify and interview other pertinent individuals who might shed light on the systems breakdown. For example, the anesthesiologist may mention that the sterile supply supervisor always seems concerned about ENT cases. Set up a meeting with the sterile supply supervisor and ask “why?”

### **Understanding the context**

During the in-depth investigation and analysis, learn about the processes involved in the work around the event. Understanding how people actually do their work, not assuming, is key to understanding causal factors that led to the event. The environment, the technology, the information, and the processes are all critical clues to the context in which the event occurred. Understanding the context is best done through observations of normal work flow in the environment where the event occurred.

When visiting, ask people to walk through all the steps that comprise the process and explain to the people around

you why you are taking notes. Listen, observe, and ask questions so you can explain the process exactly to another person. Take pictures to clarify a process (e.g., layout of a unit that puts patients out of sight line). Be sure to follow all hospital confidentiality guidelines.

## **Timeline**

The in-depth investigation and analysis includes establishing a timeline of the activities that led up to the event. This should be a date and time process map of key moments, along with any pertinent post-event moments. An example of a timeline is included in Appendix B.

The timeline serves as a basic unifying document for the event review teams. It is a “living document” and may change multiple times throughout the event review process. It includes factual statements of those involved, as well as the dates and the times of those occurrences that led up to the event according to the medical record.

## **What is the output from the in-depth investigation and analysis?**

If there is more than one interviewer on the team, a team meeting may be needed to develop a common timeline and to pool information.

The outputs from the in-depth investigation are:

1. Pertinent interview quotes, notes.
2. Preliminary findings (patient’s current condition and needs, caregiver’s needs, drawings, photos, findings, etc.).
3. Detailed review timeline (should include working conditions, processes, people, environment, etc., and pertinent interview perspectives and findings).
4. Copies of objective data (medical records, EMR audit trails, paging records, labs, imaging reports, and all other time stamped audits, etc.).
5. A visual model (Appendix C) of what the event reviewer(s) believe are the contributing factors (to be proposed and discussed at the consensus meeting). The visual model demonstrates the complexity of the event by incorporating all of the causal factors that led up to the event.
6. The question and the findings/comments section of the CANDOR tool. (Appendix D)

The in-depth investigation should yield a very coherent story of the event. This information is the starting point in determining the contributing factors.

## **Confirmation and Consensus Meeting**

The confirmation and consensus (CC) meeting is an opportunity for the core team and event stakeholders to understand the event. Stakeholders may include risk managers, safety leaders, clinical leaders from impacted areas, other content experts, department chairs, patient and family members, or family advisory council members. This meeting should NOT be a review of the event. All attendees of the confirmation and consensus meeting should receive the detailed review timeline (Appendix B) before the meeting and prepare questions. This meeting should clarify aspects of the in-depth investigation, but that should not be the focus. The goal of the meeting is to confirm contributing factors (found in the in-depth investigation) and to build consensus around these factors. It is an opportunity for everyone to understand the event, why it occurred, and confirm contributing factors.

## **Conducting an Effective Confirmation and Consensus Meeting**

When creating meeting invitations for the confirmation and consensus meeting, the event reviewer should refer to the confirmation and consensus meeting announcement template (Appendix E) to standardize instructions. At the beginning of the meeting, it is recommended to use key elements of Example 1 below.

### **Example 1: Meeting Introduction (to be read in the meeting)**

Thank you for coming. Just to remind everyone, the purpose of this meeting is to understand the system contributions to this event and to make sure that all the facts are understood. It is not a meeting to find fault or assign blame. The expectation is that everyone in attendance will contribute to a better understanding of the event, and will make the system safer for caregivers and patients in the future. We will not use this meeting to reinvestigate the event.

As the reviewer, I have conducted interviews with [XXX -- whoever the interviews have been conducted with], have visited the unit, and [XXX -- whatever else has been done].

In this meeting, our goal is to come to consensus around the main contributing factors to this event. To do this, we will walk through the event together as a team, and confirm that these are appropriate contributing factors to address.

Key Elements:

- Thanks for attending.
- This meeting will focus on contributing processes and procedures, not individual fault or blame.
- Everyone at the table is an expert in their area and should add to the understanding to create a safer system.
- The investigation is complete:
  - Interviews have been conducted with...
  - Units have been observed...
- The goal is to confirm the contributing factors that need to be addressed.

The reviewer should briefly go through the timeline and include pertinent findings. Next, the reviewer should refer to the visual model. The visual model provides a graphical representation of the causal factors that contributed to the event. The reviewer will then share the CANDOR tool which explores contributing factors. Finally, the group will confirm each causal factor. These factors are the focus of the solutions meeting. The meeting should be 60 minutes long, and minutes should be sent to the entire team for approval.

### **Confirmation and Consensus Meeting Outputs**

1. Visual model (Appendix C) with the list of contributing factors
2. Completed CANDOR tool (with the exception of the solutions) (Appendix D)
3. Scheduled solutions meeting not later than 2 weeks after this meeting

## Solutions Meeting

When creating meeting invitations for the solutions meeting, the event reviewer should refer to the solutions meeting announcement template to standardize instructions (Appendix F). At the beginning of the meeting, it is recommended to use key elements of the Example 2 below.

### Example 2: Meeting Introduction (to be read in the meeting)

Thank you for coming. Just to remind everyone, this is our solutions meeting for [brief description of event]. The purpose of this meeting is to develop solutions and measurement strategies for these solutions. It is not a meeting to reinvestigate the event. We will only focus on solutions that pertain to the contributing factors highlighted in the CC meeting. At the end of this meeting, we will walk away with specific process changes and measures to evaluate these changes.

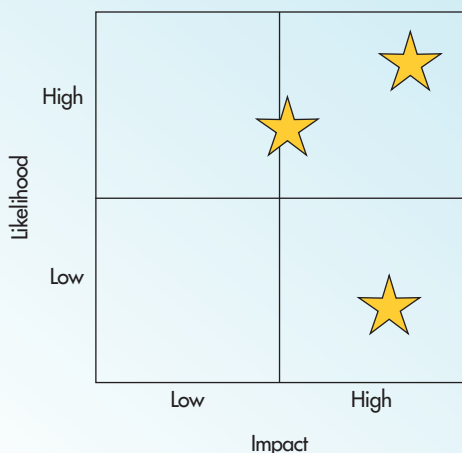
The expectation is that everyone in attendance will contribute to a better understanding of the event, and will make the system safer for caregivers and patients in the future.

Key Elements:

- Brief description of the event.
- Meeting purpose is to develop solutions and strategies related to the contributing factors.
- No reinvestigation of the event.
- The goal is to create specific process change recommendations and create measures to evaluate their effectiveness.

The solutions meeting will develop targeted solutions for the contributing factors to the event, to determine appropriate measurement strategies, and to create a plan and assign responsibility for deliverables. Solutions should focus on the most critical contributing factors of the event, determined during the confirmation and consensus meeting. To determine which contributing factors are most critical, chart the factors evaluating impact and likelihood of occurrence (see Example 3 below).

### Example 3: Chart to Determine Critical Factors



Choosing the right attendees for this meeting is important. A solution will require a fundamental change in a process, and there may be some resistance to change. It is essential to identify all the groups affected by the change, understand the amount of work required for the successful implementation of the change, set priorities, and develop effective communication plans. Attendees at the solutions meeting should be the core team, key stakeholders (as defined earlier), and frontline staff. Individuals who are able to make decisions about allocating resources should be present, too. The executive sponsor can serve in this role, but others may be needed. Safety experts and other content experts may be included, as well as patients and family members.

Although the solutions meeting should allow for clarifications to the contributing factors, it should not be a focus, and time should not be spent reviewing the event. The agreed-upon visual model will keep the team focused. For each critical contributing factor determined in the CC meeting, solutions are discussed, responsibility is given to appropriate individuals involved, and measurement strategies are finalized.

This meeting should last 60-90 minutes. Meeting minutes should be sent out for approval by members.

## Evaluating Solutions

It is important to evaluate the strength of solutions (measured in effectiveness and sustainability), and develop a way to measure and track their effectiveness.

### Measurement

Solutions cannot be evaluated as effective if a measurement tool is not available. It is the responsibility of the attendees at the solutions meeting to develop solutions, but the core team is responsible for developing the measurement strategies. Individual team members should take ownership of each corrective action and measurement. The intervention should be measured through observations, audits, or other data collection methods. A template for measurement is provided in Appendix G.

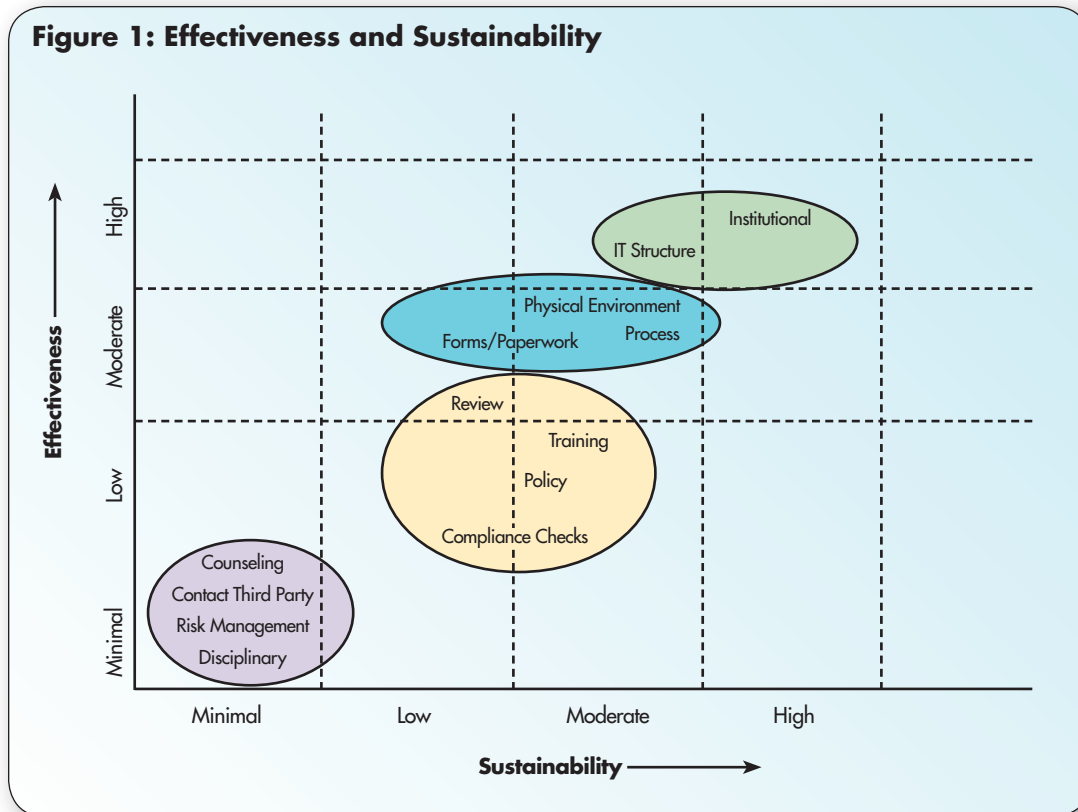
Remember that, once implemented, it is possible that a solution can actually have significant negative unintended consequences—the measurement strategy can help reveal this issue and gives the owners of the solution an opportunity to refine or change the intervention.

## Evaluating the Strength of Your Solutions

A method for evaluating the strength of the solutions is provided in Figure 1. This figure shows multiple categories of solutions that have varying levels of sustainability and effectiveness (each category is defined in Appendix H).

Each proposed solution should be evaluated for both sustainability and effectiveness. The solutions meeting should determine which colored circle is appropriate (Figure 1). ***Evaluate solutions if they are low on the effective or sustainability portion of the graph.*** However, some solutions, though less effective or sustainable (such as compliance checks, training, or review) may be useful in the short term if longer-term solutions will not be introduced until later.

There will never be a recipe for the perfect set of solutions to a specific hazard. In addition, asking the right questions of the right people won't automatically produce the most effective solutions. However, ***avoiding*** those solutions that are focused solely on individuals (those in the red circle) and using the approach above will help move an event review team toward systems-based solutions, which will be most effective in the long term. Appendixes H and I will help define the categories and solutions in Figure 1.



Hettinger AZ, Fairbanks RJ, Hegde S, et al. *An evidence-based toolkit for the development of effective and sustainable root cause analysis system safety solutions.* J Healthc Risk Manag. 2013;33(2):11-20.

### What Are the Outputs From the Solutions Meeting?

1. Completed CANDOR process tool with assigned solutions for each critical contributing factor that have been evaluated for effectiveness
2. Measurement plan for each solution (Appendix G: Data Measurement Plan)
3. Long-term responsible party (Appendix G: Data Measurement Plan)
4. Scheduled 30-, 60-, and 90-day followup meetings to evaluate solutions

### Followup

After the solutions meeting, all the documentation should be finalized. Followup meetings at 30-day intervals and communications should be planned in advance to ensure compliance and effectiveness of the implemented solutions to the critical contributing factors.

Please keep in mind that the team may find that a solution is not effective. The followup meetings serve as an opportunity to develop new strategies to address such issues. If, during a meeting, a new solution is developed to address an ineffective solution, the followup schedule of 30-, 60-, and 90-day meetings will apply to that newly developed solution. It is also important to update the patient and family on the progress being made at the 30-, 60-, and 90-day meetings.



# Appendixes

## Appendix A: Five Whys

In this example, there is only one path shown, but answers can create multiple paths and more questions.

**Event Summary:** The wrong concentration of potassium (K+) was used in the compounding of TPN. This was discovered almost 2 months later.

**1st Why:** *Why was this concentration of K+ used in the compounding process of TPN?*

When the drug was brought into the facility, it was a different concentration from what had been used in the past, but was entered into the database by the pharmacy technician under the same barcode as the previous concentration.

**2nd Why:** *Why was the concentration different?*

There has been a drug shortage of the concentration that we typically use, and we had no choice but to order a different concentration.

**3rd Why:** *Why did the pharmacy technician enter the drug as the previous concentration?*

There was a breakdown in communication, and she wasn't told when a different concentration had been ordered or that a different concentration had been received. We've always used the same concentration. Also, the labels are very similar and the print is very small. She didn't realize it was a different label when she manually entered it into our database.

**4th Why:** *Why was the drug information being entered manually?*

Our computer system is not connected to the National Drug Database, so we can't simply scan the bottle and have the information entered automatically. We have to enter every drug into our database manually. If someone misreads a label or makes a typing error, we do not have accurate information in our database. Our database only knows what we tell it. In this case, the drug was entered as the wrong concentration. So, we had a case of "garbage in, garbage out."

**5th Why:** *Why do you think the pharmacists or technicians who put the drugs on the compounder did not notice that the concentration was different?*

If we do not have accurate information in our database, our redundant safety measure of scanning the bottles to make sure we have the right medication doesn't work. In this case, the database was confirming incorrect information. Also, when the bottles are on the compounder they are upside down, so that makes them even more difficult to read. Some manufacturers put the concentration information on the bottle upside down, but this manufacturer doesn't.

If the interviewer stopped after getting the answer to the first why, one might conclude that the root cause is that the person entering the data into the system was not vigilant. If the person stopped after the 3rd why, one might conclude that the root cause was a breakdown in communication. However, if one continues asking why, it becomes apparent that there were several root causes that included poor technology for supporting the tasks, poor medication labeling processes that are not optimal for the medication shortages, and a reliance on using people to double-check that technology is working properly.



## Appendix B: Detailed Review Timeline

Event Type: \_\_\_\_\_

Individuals Interviewed: \_\_\_\_\_

Name	Title/Role
Nurse #1	Charge nurse
Nurse #2	RN
CNA X	Nursing tech
Manager MS	Manager

### Pertinent Interview Findings

There was only one certified nursing assistant (CNA) that day, as the other CNA called in sick. The charge nurse usually doesn't take patient assignments; however, the emergency department was on bypass and leaders instructed all of the nursing units to make EVERY bed available.

Nurse #1 and Nurse #2 both said they were speaking to the tech at the same time while she was passing in the hall, because both of their patients needed blood draws. They had both received their admissions right around the same time.

The nursing manager thought it was a safety issue to fill all the beds in the department, as they were not adequately staffed. However, she felt pressure from senior leaders to comply with the request and did not speak up.

The blood glucose sheet that contains the patient's name, room number, medical record number, and date of birth was not used. Instead, a scrap piece of paper was used to record the results. This is common practice on this unit to save time, since the blood glucose sheets are rarely stocked, and they are located behind the nursing station, which is at one end of the unit.

The CNA referred to both of the patients as "your patient" when providing each nurse with results. There was an opportunity to ask a clarifying question of the tech and nurses about patient identification practices on the unit.

### **Timeline of Event:**

March 12, 2014 (0900) RN#1 received report from ED on patient Mrs. Jones in SBAR format. Mrs. Jones was admitted with uncontrolled diabetes. Patient admits she is non-compliant with diet and medications. Last blood sugar level at 0800 was 641. Ten units of insulin were administered in the ED. RN#2 received report from ED on patient Mr. Smith in SBAR format. Mr. Smith was being admitted with chest pain, dizziness, and hyperglycemia. Last set of vitals indicated that his blood sugar was 245. Four units of insulin were administered in the ED.

(0930) Mrs. Jones arrived to 3North and placed into room 332. RN#1 obtained the admission information and instructed the CNA to repeat the blood sugar and obtain a set of baseline vitals.

(0935) Mr. Smith arrived to 3North and placed into room 333. RN#2 obtained the admission information and instructed the same CNA to obtain a set of baseline vitals and to repeat the blood sugar.

(0945) The CNA reports back to RN#1 the following: “Your new patient’s blood sugar was 149, the blood pressure was 145/100, the heart rate was 85, and the respirations were 10.”

(0947) The CNA reports back to RN#2 the following: “Your new patient’s blood sugar was 525, the blood pressure was 132/80, the heart rate was 70, and the respirations were 10.”

(0950) RN#2 administers 10 units of insulin to Mr. Smith for a reported blood sugar of 525. She then instructs the CNA to repeat the blood sugar within 20 minutes.

(1010) The CNA proceeds to room 333 and finds Mr. Smith unconscious. The CNA immediately pulls the cord for help.

(1011) The rapid response team arrives. Mr. Smith’s glucose was 32.

(1011) 1 mg glucagon was administered.

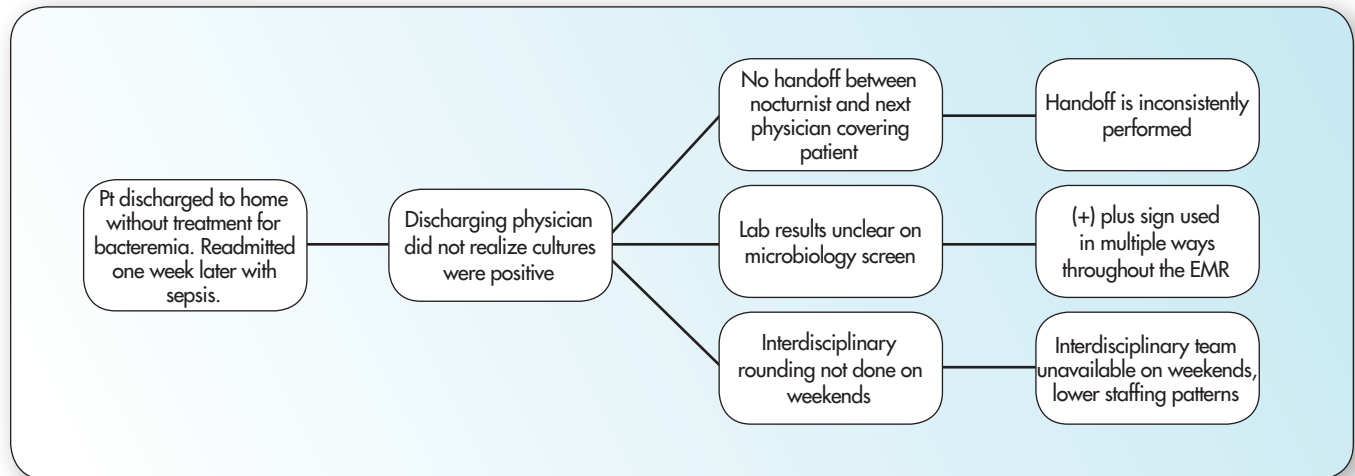
(1021) 25mL D50W IV push given and Mr. Smith was transferred to ICU for observation.

March 14, 2014 (1032) Mr. Smith transferred back to 3 North, events unremarkable.

March 15, 2014 Mr. Smith discharged home.

## Appendix C: Visual Model

The model below is one major output from the in-depth review findings. This format helps to utilize the information found in the investigation to understand why the event occurred. The boxes represent different categories of contributing factors. **The major contributing factors are the focus of the solutions meeting.**



## Appendix D: CANDOR Tool

Process	Questions to Review	Y/N	Contributing or Causal Factor Y/N	Findings/ Comments
Communication	<ul style="list-style-type: none"> <li>■ Did all caregivers have access to all pertinent information needed to make the best decisions for the patient? (e.g., medical record, laboratory results, imaging, past medical history, test results, EHR)</li> <li>■ If not, why?</li> <li>■ Could this type of communication failure occur in the future during normal working conditions?</li> <li>■ If yes, why?</li> </ul>			
Communication	<ul style="list-style-type: none"> <li>■ Was the medical record accurate and up to date, including necessary laboratory results, imaging, and test results?</li> <li>■ If not, why?</li> <li>■ Was it accessible and visible to the provider? How many charts were open? Was the software/system running properly?</li> </ul>			
Communication	<ul style="list-style-type: none"> <li>■ Are there any barriers to communication?</li> <li>■ If yes, what are they? Why did they occur?</li> <li>■ Is there any opportunity to overcome the barriers?</li> <li>■ If not, why?</li> </ul>			
Communication	<ul style="list-style-type: none"> <li>■ Were staffing levels appropriate?</li> <li>■ Were caregivers properly trained?</li> </ul>			
Communication	<ul style="list-style-type: none"> <li>■ Was there something that prevented information from being communicated effectively to the entire team in a timely manner?</li> </ul>			
Communication	<ul style="list-style-type: none"> <li>■ Was there a handoff involved in the event? What happened during the handoff? Was there anything that happened during the handoff that may have contributed to the event?</li> </ul>			
Physical Environment	<ul style="list-style-type: none"> <li>■ Describe the physical environment.</li> <li>■ Was the physical environment conducive to providing safe care for this patient/ procedure/event (e.g., lighting, overhead paging, security, uneven or slippery surfaces, visitors, emergency power, noise, alarm fatigue)?</li> </ul>			

Process	Questions to Review	Y/N	Contributing or Causal Factor Y/N	Findings/ Comments
Physical Environment	<ul style="list-style-type: none"> <li>■ Was this a direct result of a natural disaster, and if so, is there an emergency response plan? Is emergency equipment tested on a regular basis?</li> </ul>			
Equipment Device Failure	<ul style="list-style-type: none"> <li>■ Was all necessary equipment available?</li> <li>■ Did staff know where to find the equipment needed?</li> </ul>			
Equipment Device Failure	<ul style="list-style-type: none"> <li>■ Was all equipment functioning properly?</li> <li>■ Was the preventive maintenance and testing up to date?</li> <li>■ Were there features of the device that made it difficult for users to understand how to properly operate the device?</li> <li>■ Were there features of the device that facilitated error?</li> <li>■ What was the training regimen for this device?</li> <li>■ Have others (internal and external) reported problems with the device?</li> </ul>			
Equipment Device Failure	<ul style="list-style-type: none"> <li>■ If applicable, was this incident reported to the FDA?</li> </ul>			
Equipment Device Failure	<ul style="list-style-type: none"> <li>■ Was there a recall on this device?</li> </ul>			
Care Process	<ul style="list-style-type: none"> <li>■ What are the steps in the process?</li> </ul>			
Care Process	<ul style="list-style-type: none"> <li>■ Were there enough people to do the steps in the process?</li> <li>■ Were they the right people to do those steps?</li> <li>■ Identify the actual staffing ratio. Was it adequate?</li> <li>■ Were any of the involved individuals working extended shifts (longer than 12 hours)?</li> </ul>			

Process	Questions to Review	Y/N	Contributing or Causal Factor Y/N	Findings/ Comments
Care Process	<ul style="list-style-type: none"> <li>■ Did this event take place during a procedure, test, or skilled task?</li> <li>■ If yes, how often are these particular competencies assessed?</li> <li>■ If yes, is there a written protocol that the care provider could have referenced? <ul style="list-style-type: none"> <li>– If yes, was it easily accessible and did the care provider know it was available?</li> <li>– If no, where was it located? Is it commonly requested? Is it commonly used?</li> </ul> </li> </ul>			
Care Process	<ul style="list-style-type: none"> <li>■ Were procedures available, workable, intelligible, and routinely used? If not, why?</li> </ul>			
Care Process	<ul style="list-style-type: none"> <li>■ Could a similarly credentialed person do the same thing in a similar situation with the same information available (considering the environment)?</li> </ul>			
Care Process	<ul style="list-style-type: none"> <li>■ Are there any known deviations from the standard? If so, was the standard known and easily understood? If so, was the standard applicable/feasible to the current work conditions?</li> </ul>			
Care Process	<ul style="list-style-type: none"> <li>■ Was the team familiar with each other?</li> </ul>			
Care Process	<ul style="list-style-type: none"> <li>■ Was there orientation for this individual or team? If yes, what was it like?</li> </ul>			
Policy	<ul style="list-style-type: none"> <li>■ Does a policy or procedure exist to address this process?</li> <li>■ Was the policy followed?</li> <li>■ If not, why?</li> <li>■ Is the policy feasible in the actual context of work?</li> <li>■ Do people know about the policy? Was an appropriate roll out done?</li> <li>■ Do leaders model that behavior? Has the policy been enforced by leaders?</li> <li>■ If the answer to any of these questions is "no" this is a SYSTEMS issue and should be addressed as such.</li> </ul>			

Process	Questions to Review	Y/N	Contributing or Causal Factor Y/N	Findings/ Comments
Culture	<ul style="list-style-type: none"> <li>■ What do you believe are the hospital's/ system's priorities and goals?</li> <li>■ How is patient safety discussed on your unit?</li> <li>■ Did the involved party feel that there were conflicting priorities between keeping the patient safe and other organizational priorities?</li> </ul>			
Culture	<ul style="list-style-type: none"> <li>■ Have leaders established methods to identify risks and provide employees opportunities to make suggestions?</li> <li>■ If yes, how?</li> </ul>			
Culture	<ul style="list-style-type: none"> <li>■ Was this event communicated to the patient and family?</li> <li>■ If yes, who and what was communicated?</li> </ul>			
Culture	<ul style="list-style-type: none"> <li>■ Was leadership contacted?</li> </ul>			
Culture	<ul style="list-style-type: none"> <li>■ Is there any followup care being arranged for the patient and family?</li> </ul>			
Culture	<ul style="list-style-type: none"> <li>■ Was this event placed in the patient safety event reporting system?</li> </ul>			
Culture	<ul style="list-style-type: none"> <li>■ Was this event shared throughout the organization?</li> </ul>			
Future Risks	<ul style="list-style-type: none"> <li>■ Are there other areas in the organization where this could happen?</li> </ul>			
Future Risks	<ul style="list-style-type: none"> <li>■ Are there opportunities to improve trainings, competencies and orientation sessions by including lessons learned from this event?</li> </ul>			

<b>Contributing Factors</b>	<b>Solutions to Contributing Factors</b>	<b>Responsible Position/Title</b>	<b>Implementation Date</b>	<b>Measurement Method</b>
1.				
2.				
3.				
4.				



## Appendix E: Confirmation and Consensus Meeting Announcement Template

As you may know, a patient care incident occurred on (insert date) involving (brief description of event). On behalf of (insert executive sponsor name), we are asking you to participate in our upcoming confirmation and consensus meeting on (insert date, time, and location).

The meeting will last 60 minutes and will be facilitated by (insert person's name). An in-depth review of the event is complete. Please review the enclosed information prior to the meeting.

The purpose of this confirmation and consensus meeting is to seek input and to validate and agree on the findings. At the conclusion of this meeting, there will be consensus around contributing factors, which will be the focus of the solutions meeting.

At our organization, we believe in a systems approach to solving problems, and we don't focus on individuals or place blame, as those methods do not improve the safety of our patients. Instead, we look at the process breakdowns. All information is to be treated confidentially.

Your attendance and participation demonstrate your commitment to patient safety and encourage open dialogue and ownership of solutions.

If you have any questions, feel free to contact me.

Thank you in advance for your preparation and attendance at this meeting.

## Appendix F: Solutions Meeting Announcement Template

On behalf of (insert executive sponsor name), we would like you to participate in our upcoming solutions meeting related to (describe safety event).

The solutions meeting will take place at (time) (date) (location).

Your attendance and participation and that of your staff demonstrate your commitment to patient safety and encourage open dialogue and ownership of solutions to help better care for our patients. You were specifically invited because (XXXX).

You are being asked to attend because your presence is essential to develop effective solutions to the contributing and causal factors found during our event review. This meeting is designed to create solutions and develop a plan for implementing these solutions.

The meeting will last approximately 60–90 minutes and will be facilitated by (name, department). The intent of the solutions meeting is to walk away with an actionable plan for safety improvement.

If you have any questions, feel free to contact me by phone (xxx-xxx-xxxx) or email xxxx.xxxx@xxxx.xxx.

Thank you in advance for your preparation and attendance at this solutions meeting.

## Appendix G: Data Measurement Plan

Contributing Factor	Definition/Description	Current State	Goal State	Data Source	How will data be collected?	Who will collect the data?	Proposed dates for measurement	Long-term followup plan	Notes
Bottles upside down	Bottles hung upside down in the TPN process, making it difficult to read	Upside down	In 1 month, no bottles upside down	Compounding unit	Observations- scheduled and random	Sarah Jones	2/10/14- 2/20/14	Random checks performed 1x per week for 6 months	Will observe when bottles are being hung, also will do random checks through the day

## Appendix H: Hierarchy of Solutions

Do solutions meet the following criteria:

- Address the root cause/contributing factor
- Are specific and concrete
- Can be understood and implemented by a reader unfamiliar with the situation
- Will be tested or simulated prior to full implementation (when feasible)
- Based on consultation with process owners

**Recommended Hierarchy of Actions - Adapted From The Department of Veterans Affairs National Center for Patient Safety)**

### **Stronger Actions**

- Architectural/physical plant changes
- New device with usability testing before purchasing
- Engineering control or interlock (forcing functions)
- Simplify the process and remove unnecessary steps
- Standardize equipment or process or caremaps
- Tangible involvement and action by leadership in support of patient safety

### **Intermediate Actions**

- Increase in staffing/decrease in workload
- Software enhancements/modifications
- Eliminate/reduce distractions (sterile medical environment)
- Checklist/cognitive aid
- Eliminate look- and sound-alike medications
- Read back
- Enhanced documentation/communication
- Redundancy

### **Weaker Actions**

- Double checks
- Warnings and labels
- New procedure/memorandum/policy
- Training
- Additional study/analysis

## Appendix I: Glossary

**Adverse safety event:** a deviation from generally accepted performance standards that reaches the patient and results in moderate to severe harm or death.

**Anchoring bias:** the tendency to make all information fit into a preconceived story, causing the interviewer to not seek out disconfirming evidence or make disconfirming evidence fit into the initial story. The initial piece of information is now used to make judgments about all other new information. Interviewers need to consider multiple perspectives and use factual information to uncover contributing factors to an event. If they are anchored, they will only seek evidence that confirms their initial hypothesis about the causes of the event.

**Causal factor:** the suspected or confirmed factors that caused the adverse event. Often, multiple factors must intersect for an adverse event to reach the patient. Labeling one or even several of these factors as “causes” may place undue emphasis on a single specific factor and obscure the overall relationships among different layers and other aspects of system design. The purpose of the event review and analysis is to help clarify the causal factors.

**Contributing factor:** additional elements that contributed to the adverse event, many of which are outside an individual’s control.

**Confirmation and consensus meeting:** a meeting where major stakeholders come together to determine critical contributing factors for a safety event.

**Event review:** the overall process of assessing an adverse safety event to determine contributing factors and develop solutions.

**Hindsight bias:** the tendency for people to exaggerate the likelihood that they could predict the event’s occurrence. In many events, those not involved tend to believe that they could have predicted the event and therefore avoided it. Hindsight bias is commonly driven by a lack of insight into the context of the error, meaning the details of the environment, information available to the provider at the time, and other factors that may not be initially obvious. It means sticking to a single explanation and failing to dig deeper, and it often means blaming others more than they ought to be blamed, simply because you feel like the causes of failure are obvious after the fact. For interviewers, it is important to remember this tendency and to consider the event in context. A systems approach principle is that no one wants to do a bad job; therefore, they thought they were doing their job correctly at the time. It is the interviewer’s job to find out *why*.

**In-depth event review:** the data-gathering phase of an event review, involving conducting interviews, making observations, and building a timeline.

**Latent hazard:** the hidden problems within health care systems that contribute to adverse events.

**Root cause:** the underlying problems that increase the likelihood of errors. In a systems approach, root cause is referred to as contributing factor.

**Solutions meeting:** a meeting where major stakeholders and individuals who are able to make process changes come together to develop solutions and measurement plans for a safety event.

**Stakeholder:** typically managers and people who work in the process, the upstream and downstream departments, the patients, the support staff, and executive leadership. The team should note that not every group needs to be brought to the level of enthusiastic support for successful implementation of the plan.

## Types of Solutions

**Institutional:** changes are large, facility-wide investments that require significant time and resources.

**IT structure:** solutions consist of changes to programs or interfaces that will change a process. These changes have the potential to be highly effective and sustainable if implemented after careful analyses to determine whether the technology supports the users.

**Physical environment:** any change to the environment, such as moving supplies to make them more accessible.

**Process:** solutions that change the workflow to reduce hazards, such as eliminating unnecessary steps. These include the accompanying changes to any protocols and necessary training.

**Forms and paperwork:** new forms or changes to documentation templates and procedures to improve communication and streamline processes.

**Review:** an assessment of a particular system or process with the aim of changing the studied process or environment. Reviews that are performed solely for compliance purposes are not included.

**Training:** educating individuals on new forms or procedures.

**Policy:** either reinforcement of existing policies or an isolated change to a policy that doesn't require significant change to the underlying process, physical environment, or IT system. For the purposes of this toolkit, those policies changes can be bundled as part of those categories.

**Compliance check:** reviews of charts or processes for the purpose of monitoring or regulating a particular process. These solutions often use key words such as audits, chart reviews, and/or secret shoppers to verify that the process in question is being performed according to standards that are put in place.

**Counseling:** typically involve a "development plan," providing "feedback," or a practice committee referral to those involved in the event.

**Contacting third party:** includes hosting manufacturer representatives, motivational speakers, and other consultants.

**Disciplinary:** actions taken toward involved staff members.



AHRQ Pub. No. 16-0020-10-EF  
April 2016

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