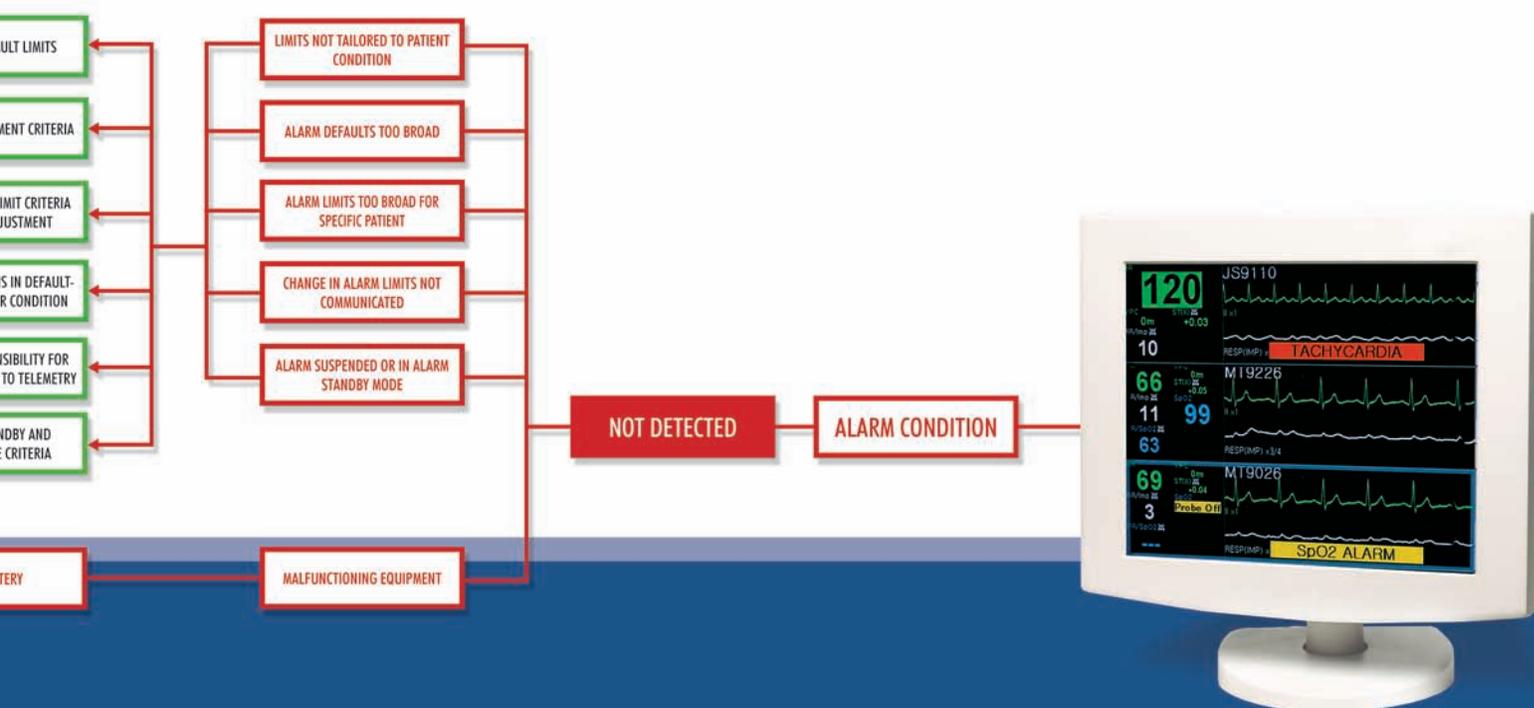


ALARM INTERVENTIONS DURING MEDICAL TELEMETRY MONITORING

A Failure Mode & Effects Analysis



A Pennsylvania Patient Safety Advisory Supplementary Review

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Pennsylvania Patient Safety Authority

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EXECUTIVE SUMMARY

The Pennsylvania Patient Safety Reporting System (PA-PSRS), a statewide adverse event and near miss reporting system of the Pennsylvania Patient Safety Authority, received 277 reports related to alarm response during medical telemetry monitoring between June 2004 and October 2006. All the reports described events in which patients were not consistently monitored for physiologic condition, and three events resulted in patient death.

Telemetry physiologic monitoring systems generate visual and audible alarm signals based on changes in patient physiologic conditions that violate established alarm criteria for a specific patient or a particular patient population. A key function of monitoring systems is to alert appropriate staff to the change in patient condition so that staff can promptly intervene with the appropriate care.

Prompted by the reports—especially because three involved patient death—PA-PSRS analysts conducted a failure mode and effects analysis (FMEA) to help healthcare facilities better understand the FMEA process and use the lessons learned and our remediation results as guidance in developing facility-specific process remediation strategies for similar alarm response events. FMEA is a proactive risk assessment method used to evaluate a system or process in order to identify potential failures and develop and implement mitigation strategies to reduce or eliminate failures before they occur.

Our FMEA focused on the stage in the telemetry monitoring process specific to alarm intervention in response to a change in patient physiologic condition. The high-priority failure modes that we targeted for mitigation include the following:

- Patient misidentification
- Human/equipment error (i.e., telemetry transceiver not connected to patient, signal drop out)
- Alarm condition not detected
- Alarm condition not detected by electrocardiography (ECG)-qualified staff
- ECG-qualified staff not available
- Detection of alarm condition delayed
- Verification of alarm condition delayed
- Locating patient delayed
- Intervention for alarm condition delayed

The high-priority failure modes listed above represent the core failure modes for the 29-step telemetry monitoring process we reviewed. Many of the failure modes were duplicated for the various process steps.

The common mitigation strategies that we developed, which can be implemented for several of the different failure modes we analyzed, include the following:

- Placing slave displays and alarm enunciators in strategic locations throughout a telemetry care area
- Developing a protocol for setting the volume level of an alarm to higher than the minimum audible level that can be heard in a typical environmental noise level for given care area (The volume level setting will be specific to the noise level for each healthcare facility's care area environment.)
- Developing standardized practices for periodic ECG-electrode and lead-set inspection and replacement and proper electrode-site skin preparation
- Developing a protocol that requires prompt response for *all* alarm conditions (low-, medium-, high-priority alarms)
- Developing a protocol that establishes alarm limit default settings based on a particular patient population in a given care area
- Developing protocols that establish criteria for when and how to adjust alarm default limits per patient condition
- Developing protocols to delineate responsibility for primary alarm response and to establish tiers of backup alarm coverage

The results we obtained from our FMEA process can be used by healthcare facilities to understand their respective telemetry monitoring alarm response processes and similar process failures and as guidance in developing facility-specific risk reduction strategies.

INTRODUCTION

Telemetry physiologic monitoring systems generate visual and audible alarm signals based on changes in patient physiologic conditions that exceed alarm limits established for a specific patient or a particular patient population. A key function of the monitoring systems is to alert the appropriate staff to the change in patient condition so that they may intervene with the appropriate care. When a clinician does not respond or delays response to an alarm, appropriate patient care may be compromised, possibly resulting in a poor patient outcome. The Pennsylvania Patient Safety Reporting System (PA-PSRS) conducted a failure mode and effects analysis (FMEA) to help healthcare facilities better understand the FMEA process and to use the lessons learned and our remediation results as guidance in developing facility-specific process remediation strategies for similar alarm response events.

We chose our high-risk process to be alarm intervention in response to a change in patient physiologic condition specific to medical telemetry monitoring. By limiting our process to alarm interventions with telemetry monitoring, we felt we could better manage the project. We used a flowchart to diagram our telemetry process steps. Our topic resulted in a 29-step process with branches based on various decision points in the process. Once the process steps were established, we devised potential failure modes for each step. During our brainstorming sessions, everyone contributed to a list of conceivable ways the process could break down.

We developed a FMEA worksheet to document the project. The information included in the worksheet consisted of categories of steps in the analyzed process, potential failure modes, the potential effects, and ratings in order to prioritize the failure modes. Prioritizing the failure modes allowed us to focus on developing mitigation strategies for the highest-risk process or subprocess in order to redesign the clinical process. The following factors were used in prioritizing the failure modes:

- Probability of occurrence: How likely is the failure to occur?
- Severity: How serious are the consequences of this failure to the patient?
- Detectability: How likely is the failure to be recognized prior to causing harm to the patient?

After the highest-priority failure modes were established, we determined the basic factors that would lead to the failures—the root causes. Root-cause analysis (RCA) is typically a reactive approach to an adverse or sentinel event; however, the principles can be applied proactively. The elements we considered when contemplating root causes included the following:²

- Contributing human factors
- Equipment-related problems
- Environmental factors

- Staffing concerns
- Communication issues
- Work environment culture (e.g., staff are afraid to ask for help)
- Technology management (e.g., who is responsible for IT?)

Once the root causes were identified, we developed mitigation strategies for the highest-priority failure modes in order to redesign or “design out” the potential risks in the alarm response process. Factors that we used to develop mitigation strategies included minimizing the choices available to (and ultimately the decisions made by) the staff, maximizing communication between the staff, and eliminating variability by standardizing procedures, supplies, and equipment. See the “Methods” section on page 11 for a brief discussion on our FMEA methodology.

DATA FROM PA-PSRS

From a review of 328 reports submitted to PA-PSRS between June 2004 and October 2006 related to alarm response during medical telemetry physiologic monitoring, we found 277 reports that were relevant to our FMEA topic, with three that resulted in patient death. The reports were categorized to better understand the scope of the problems associated with telemetry. Some of the reports overlap categories; however, we included each report only once in each category. Event descriptions from some of the reports submitted to PA-PSRS are provided within each category description below.

We established nine categories, listed below, that best described the types of telemetry-related reports submitted to PA-PSRS. The number in parentheses is the percentage of the 277 reports analyzed within each category.

- Telemetry transceiver not connected, delayed in connecting to patient, or taken off without orders (66.9%)
- Telemetry physiologic data not received or not recorded at the central station (12.7%)
- Telemetry physiologic data inaccurate or patients' transceivers or information switched (7.6%)
- Battery issues (3.6%)
- Leads-off (3.3%)
- Lacking or missed communication between clinicians (2.2%)
- Alarm limits changed, alarm turned off, or alarm volume turned down or off (1.8%)
- Telemetry monitor in standby mode (1.5%)
- Delayed clinical response to alarm condition (0.4%)

The nine categories and event descriptions are as follows:

Telemetry transceiver not connected to, delayed in connecting to, or taken off patient without orders. This category captures PA-PSRS reports in which a physician's orders for telemetry physiologic monitoring were written or verbalized but the telemetry transceiver was not connected to, was delayed in being connected to or was disconnected from patients without orders.

[Female patient] admitted from [hospital] via EMS for c/o unsteady gait and increased temperature of 102.5° as reported by staff. . . Nurse placed bed alarms on at 10:45 p.m. At 1:05 a.m., patient found by staff to be off monitor, pulseless, and apneic. Arrest team notified. Despite best efforts, patient ceased to breathe. After root-cause analysis performed, recognized as a Serious Event due to the lapse in monitoring. Disclosure will be sent.

During chart check, found orders for telemetry, but monitor was never placed. Patient admitted at 3:00 p.m. and placed on monitor at 2:30 a.m.

Patient admitted to [cardiac care unit] with [congestive heart failure] exacerbation. Chest x-ray was ordered. Transporter removed the patient from telemetry without informing staff. Patient returned to the unit in stable condition. No injury to patient.

Patient transferred from emergency department to med/surg unit without being monitored. Order was for telemetry.

Telemetry physiologic data not received or recorded at the central station. This category captures PA-PSRS reports in which telemetry transceivers were connected to patients but the patient demographic or physiologic data was not recorded in the physiologic monitoring system.

Telemetry-monitored patient with history of a fall, [who] arrested. Resuscitation efforts were not successful. After the arrest, it was noted that the monitor was not recording for approximately one hour prior to arrest.

Telemetry had been ordered to be placed on the patient at 1:30 a.m. At 3:20 a.m., it was discovered that the patient's telemetry monitor was not recording due to the method of computer entry. Entry was corrected and monitor began to trace the patient.

[Female patient] admitted to observation for chest pain, unknown etiology. Went to a medical unit and was to be placed on telemetry monitoring. Monitor was placed on patient; however, the unit was not turned on in [the intensive care unit (ICU)] where the actual monitoring is viewed. It was discovered approximately 10 hours later.

Patient on tele but not programmed to central desk (5:00 p.m. to 7:45 p.m.).

At change of shift, realized patient's telemetry monitor was not showing up on tele. Tele was connected to patient but not put into system.

Telemetry physiologic data inaccurate or patients' transceivers or information switched. This category captures PA-PSRS reports in which patient demographic information was inaccurate, demographic information was switched between patients, or telemetry transceivers were switched between patients.

When patient was transferred to another room at 3:58 p.m., the patient was not moved on the telemetry computer. [Two days later] discovered at 8:00 a.m.

Telemetry was placed on wrong patient.

Two-bed room. Both patients being monitored on telemetry. This patient was assigned and connected to monitor. However, incorrect monitor number entered into telemetry system for this patient. [As a] result, two patients (same room) assigned same number. Both patients had same number transcribed onto telemetry strips. Several shifts lapsed prior to error being noted . . . Error corrected. New slips made available for staff to review and initial. No harm. No arrhythmia(s) on either patient.

Patient entered into telemetry system under the wrong name. Patient having episodes of tachycardia. Tele strips were labeled with wrong patient name.

Patient admitted via the [emergency room (ER)]. Telemetry pack applied in ER and patient transferred to PCU [sic]—bed A. The patient received was to be placed in bed B. patient identified and paperwork corrected on admission. At 3:30 a.m., the patient in bed B has a bradycardic episode. Staff identified that the telemetry packs were not corrected on admission and rate reported was on patient in bed A.

Battery issues. This category captures PA-PSRS reports in which telemetry transceivers were connected to patients, but physiologic data was not obtained due to various battery problems such as no batteries in the transceivers, batteries installed incorrectly (e.g., backwards), or batteries depleted.

Patient arrived on unit at 1:10 p.m., was connected to telemetry unit as ordered, no battery inserted. Battery inserted at 2:45 when recognized by telemetry tech. Patient not monitored on telemetry for approximately 1.5 hrs.

Initial printout for telemetry received Monday at 12:17 a.m. Since 11:00 p.m. Sunday, this patient has been hooked up to telemetry but no reading. Nurse on unit was called and confirmed patient was hooked to telemetry, but when box was checked the battery was placed incorrectly.

Patient admitted to telemetry (med-surg) unit. Telemetry pack placed on patient but not activated. When new batteries were placed in pack, monitor worked.

Leads-off. This category captures PA-PSRS reports in which telemetry transceivers were connected to patients, but the electrodes or lead wires were intentionally or unintentionally disconnected from patients.

Patient admitted with chest pain and [shortness of breath] . . . Was on a monitored unit. At 3:25 a.m., patient's nurse noticed the leads were off and on checking the patient found him in the bathroom unresponsive. Resuscitation efforts were unsuccessful. Monitor showed patient's leads had come off at 2:32 a.m. Patient's primary nurse had been in the next room caring for another patient. Other staff were with their patients.

. . . at 7:50 a.m. ICU director was doing rounds, found monitor (cardiac) disconnected, and noted it was off for 44 minutes. Night shift and AM shift RN sitting at desk, stated aware of loose leads but patient OK because pulse ox wave form per O₂ Sat monitor stable.

Patient said that his telemetry monitor came off (the leads) during the night. No one reapplied it, so he took the monitor off and laid it on the shelf next to his bed. This was reported to doctor, covering for [another] doctor.

Patient noted to be off tele (leads disconnected) by monitor tech. Tech notified nursing who was busy at the time and forgot to connect patient. Monitor off for 1 hour and 23 minutes per monitor tech.

Lacking or missed communication between clinicians. This category captures PA-PSRS reports in which communication errors between clinical staff resulted in physiologic monitoring alarms

not being addressed (e.g., monitor tech not notifying nurse of patient's physiologic alarm condition).

Patient was in sustained V-tachy for 10 minutes before RN was notified by telemetry tech. Physician aware. [Vital signs stable.] Transferred to critical care for observation.

Surgical patient was scheduled for a procedure, and telemetry was removed for that test to be performed. When the unit was notified that the telemetry was removed, the response from the unit was that they were unaware that the patient was supposed to be on telemetry. Error noted and corrected.

Upon making rounds, physician interrogated the stored alarms and found patient had a 4.2-second pause that was not picked up for 3 shifts after initial event occurred. Patient scheduled for permanent pacemaker. . . .

Alarm limits changed, alarm turned off, or alarm volume turned down or off. This category captures PA-PSRS reports in which physiologic monitoring system alarm limits were originally configured inappropriately or changed for the clinical condition of patients or the alarm volume was turned down to an inaudible level or turned off.

Monitor tech was doing wave review and noted patient had frequent pauses but did not alarm. Checked arrhythmia alarms and noticed pause alarm turned off, also noted heart rate turned down to 37. No RN signed for this.

Patient with apparent ARF [sic] and bilateral hand pain from cryoglobulinemia. Alarm limits per policy is [sic] 90-160 systolic. A-line upper limit was set to 185 and [systolic blood pressure] upper limit set at 175. Error noted and corrected.

Telemetry monitor in standby mode. This category captures PA-PSRS reports in which the telemetry physiologic monitoring system was placed in standby mode, which halts capturing patient physiologic data. This mode is used when, for example, a patient temporarily leaves a care area for a procedure in a different area of the healthcare facility. The problem occurs when the monitor is not reinstated when the patient returns to the monitored care area.

Telemetry monitor found to be on standby at 11:09 p.m. Had been on standby since 11:09 a.m.

Patient off the floor and when returned to floor his telemetry monitoring was on standby for five hours. Patient, family, nursing supervisor, and telemetry supervisor aware.

Delayed clinical response to alarm condition. This category captures PA-PSRS reports in which there was a delayed clinician response to a patient's physiologic alarm condition.

Patient who was on telemetry monitoring system and continuous pulse oximetry was found in room to be bradycardic with no respirations. System was alarming during event. Code called, patient resuscitated and transferred to ICU.

As can be seen in Table 1, the greatest problem surrounding medical telemetry physiologic monitoring, based on reports from Pennsylvania healthcare facilities, is that patients are not consistently monitored when admitted to a telemetry care area.

Reported Event	Number of Reported Events	Percent of Total Reports (%)	Number of Events Resulting in No Patient Harm	Number of Events Resulting in Patient Harm without Patient Death	Number of Events Resulting in Patient Death
Telemetry transceiver not connected to, delayed in connecting to, or taken off patient without orders	185	66.9	183	2	0
Telemetry physiologic data not received or not recorded at the central station	36	12.7	35	0	1
Telemetry physiologic data inaccurate or patients' transceivers or information switched	21	7.6	20	1	0
Battery issues	10	3.6	10	0	0
Leads-off	9	3.3	6	1	2
Lacking or missed communication between clinicians	6	2.2	6	0	0
Alarm limits changed, alarm turned off, or alarm volume turned down or off	5	1.8	5	0	0
Telemetry monitor in standby mode	4	1.5	3	1	0
Delayed clinical response to alarm condition	1	0.4	1	0	0
Total	277	100	269 (97.1%)	5 (1.8%)	3 (1.1%)

Table 1. Breakdown by Category of the Number of PA-PSRS Reports and Respective Patient Harm Related to Alarm Intervention in Response to Change in Patient Physiologic Condition during Medical Telemetry.

Columns 4, 5, and 6 in Table 1 indicate the number of reports and percentage of the total number of reports in each category of the patient harm level. The harm level for each column is broken down as follows:¹

- No Patient Harm
 - Circumstances occurred that could cause adverse events.
 - An event occurred but did not reach the individual (“near miss”) because of active recovery efforts by caregivers.

- An event occurred that reached the individual but did not cause harm and did not require increased monitoring.
- An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm.
- Patient Harm
 - An event occurred that contributed to or resulted in temporary harm and required treatment or intervention.
 - An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization.
 - An event occurred that contributed to or resulted in permanent harm.
 - An event occurred that resulted in a near-death event (i.e., required ICU care or other intervention necessary to sustain life).
- Patient Death
 - An event occurred that contributed to or resulted in death.

Of the 277 reported events, approximately 97% did not result in harm to patients, approximately 2% resulted in harm and approximately 1% resulted in death to patients.

Note

1. Pennsylvania Patient Safety Authority. Training manual and user's guide: using the Pennsylvania Patient Safety Reporting System (PA-PSRS). Version 4.0. Pennsylvania Patient Safety Authority; Harrisburg (PA); 2005 Nov.

METHODS

Our FMEA process was based on the guidelines established by the Joint Commission, outlined in its book *Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction*, and published in 2002 by Joint Commission Resources, Inc. The Joint Commission established an eight-step process, as follows:¹

1. Select a high-risk process, and assemble a team.
2. Diagram the process.
3. Brainstorm potential failure modes, and determine their effects.
4. Prioritize failure modes.
5. Identify root causes of failure modes.
6. Redesign the process (develop mitigation strategies).
7. Analyze and test the new process.
8. Implement and monitor the redesigned process.

However, we only followed the first six of the eight steps in the Joint Commission's process; we are not a healthcare facility and therefore would be unable to test or implement any mitigation strategies we developed.

Selecting a High-Risk Process and Assembling a Team

We chose clinician response to an alarm condition due to a change in patient physiologic condition because the PA-PRSR program has received many reports specific to this scenario, including three reports of patient death related to not being monitored. We believed that by focusing only on alarm response specific to medical telemetry, we could more effectively develop mitigation strategies. We also decided to focus on care-area-based telemetry monitoring in areas such as medical/surgical (med/surg) and intermediate/step-down units. We exclude the emergency and intensive/critical care areas, as well as centralized remote monitoring (i.e., “war room”). Our team consisted of seven members: a project manager, three clinical nurses with risk management backgrounds, two biomedical engineers, a consultant with extensive expertise in clinical alarm response policies and protocols, and an IT specialist. The diversity of the group fit well with the clinical alarm topic to be analyzed.

Diagramming the Process

Once the process to be analyzed was selected and the team was established, we set out to map the steps in the process using a flowchart format. We concentrated our efforts on basic and realistic telemetry monitoring processes that would be applicable to most facilities. Appendix B on pages 33 to 34 shows the final flowchart. We agreed to start the process at the point at which

a patient is being monitored via telemetry then move to the point at which a patient experiences clinically significant physiologic changes, which addressed the problems of alarm intervention.

Brainstorming Potential Failure Modes and Determining Their Effects

After the process steps were established, we came up with potential failure modes for each of the process steps. All ideas were recorded to be analyzed later in the process. The main focus was to develop as many failure modes as possible in the time allotted. We also determined the potential effects or results of the failure modes as they relate to patient outcomes.

At this point, we developed a FMEA worksheet to organize and track our progress. Information was added to the worksheet after each meeting as the FMEA process progressed. In addition to categorizing and documenting the steps in the analyzed process, the potential failure modes, and the potential effects, the worksheet also included ratings to prioritize the failure modes.

Prioritizing the Failure Modes

Prioritizing the failure modes allows the team to focus its energy on developing mitigation strategies to address the causes of the highest risk failure modes. The following rating criteria were used in prioritizing the failure modes:²

- Probability of occurrence: How likely is the failure to occur?
- Detectability: How easily is the failure likely to be recognized prior to causing harm to the patient?
- Severity: How serious are the consequences of this failure to the patient?

A five-point rating scale was used to rate each of the criteria as follows:^{*}

- Probability of occurrence
 - 1: remote or nonexistent
 - 2: low
 - 3: moderate
 - 4: high
 - 5: very high
- Detectability
 - 1: certain to be detected
 - 2: high likelihood of detection
 - 3: moderate likelihood of detection

^{*} Based on the FMEA rating scale established by the Partnership for Patient Care Health Care Improvement Foundation.

- 4: low likelihood of detection
- 5: almost certain not to be detected
- Severity
 - 1: minor or no effect
 - 2: moderate effect
 - 3: minor injury
 - 4: major injury
 - 5: severe outcome

Probability of occurrence and detectability ratings are based on the particular failure mode; severity ratings are based on the effects of the failure mode. For more detailed information on the rating scale, see Appendix A on pages 31 and 32.

The rating scores were used to determine the failure mode risk priority number (RPN). The RPN represents a numeric value for the most critical failure modes to address. The RPN is obtained by multiplying each of the rating scores. For example, a probability of occurrence score of 3, a detectability score of 4, and a severity score of 5 would yield a RPN of 60. At minimum, a high RPN value indicates that a particular failure mode requires further analysis by the FMEA team. The RPN value may not always be the only factor used to dictate which failure mode(s) we addressed. The knowledge and experience of the FMEA team members may also be used in conjunction with the RPN to determine which high-priority failure modes to address. Staff often have insights into a process that cannot be represented by a number only.

Identifying the Root Causes of the Failure Modes

After the highest-priority failure modes were established, the next step was to determine the basic factors that would lead to the failures—the root causes. RCA is typically a reactive approach to an adverse or sentinel event; however, the principles can be applied proactively. The elements we considered when contemplating root causes included the following:²

- Contributing human factors
- Equipment-related problems
- Environmental factors
- Staffing concerns
- Communication issues
- Work environment culture (e.g., staff are afraid to ask for help)
- Technology management (e.g., who is responsible for IT?)

Redesigning the Process

Once the root causes were identified, we concentrated on developing mitigation strategies to address the causes of the highest-priority failure modes in order to redesign or “design out” the potential risks in the alarm response process or its underlying systems. Factors that we used to develop mitigation strategies included minimizing choices for (and ultimately the decisions made by) the staff, optimizing the effectiveness of communication between the staff, and eliminating variability by standardizing on procedures, supplies, and equipment.

Notes

1. Joint Commission. Failure mode and effects analysis in health care: proactive risk reduction. Chicago (IL): Joint Commission Resources, Inc.; 2002.
2. Partnership for Patient Care (Delaware Valley Healthcare Council, ECRI Institute, Health Care Improvement Foundation, Independence Blue Cross). Failure mode and effects analysis: a practical guide. 2006.

PA-PSRS FMEA RESULTS

We developed a 29-step clinical telemetry process for alarm interventions in response to a change in a patient's physiologic condition. We used a flowchart to diagram process steps. The flowchart appears in Appendix B on page 33.

The overall clinical process flows from the point at which a patient is being monitored via telemetry to the time a nurse acknowledges an alarm condition and intervenes as appropriate. We included steps typically encountered when a change in a patient's physiologic condition occurs. Therefore, we excluded steps in the telemetry monitoring process that would typically occur before the patient's physiologic condition changed, such as a physician ordering telemetry monitoring for a patient and a nurse reviewing the order, among others. Without those added steps, we realized that the scope of the topic would be tractable to effectively and efficiently develop failure modes and mitigation strategies.

Once the patient's physiologic condition changes (step 2 in the flowchart), the next steps involve the physiologic monitoring system detecting the alarm condition and generating visual and audible alarm notification to alert clinical staff (steps 3 and 4). From there, a staff member detects the alarm condition and takes some action to resolve the condition. The staff member could be an electrocardiography (ECG)-qualified nurse or a nonqualified staff member. An ECG-qualified nurse is trained in interpreting the physical parameters of the patient (e.g., ECG rate and waveform, oxygen saturation level). The qualified nurse then verifies the alarm condition on the central station display and determines the appropriate level of response. Based on the patient's condition, the appropriate response could range from simply silencing the alarm to administering treatment. For a comprehensive look at the sequence of events for the ECG-qualified staff member detecting an alarm condition, see steps 5A through 29A in the flowchart in Appendix B.

In the event that a nonqualified staff member (e.g., a ward clerk) detects an alarm condition prior to a nurse detecting the alarm, the nonqualified staff member notifies the patient's primary care nurse. If the primary care nurse is not available (e.g., tending to a different patient), the nonqualified staff member notifies an alternate care nurse. Whether the primary or alternate care nurse is notified, the sequence of events is similar. Either care nurse acknowledges the alarm condition, assesses the patient's condition, and intervenes as appropriate. For a comprehensive look at the sequence of events for the nonqualified staff member detecting an alarm condition, see steps 5B through 16B in the flowchart in Appendix B.

We determined the RPN for each failure mode by multiplying our rating scores for probability of occurrence, detectability, and severity. We developed mitigation strategies for the high-priority failure modes (i.e., RPN scores of 60 and greater). The worksheet in Appendix C on page 35

shows the steps with the respective high-priority failure modes, RPN scores, potential causes, and mitigation strategies.

Many of the process steps were similar, but with different clinical staff performing the steps. For example, some of the steps in our process included a primary care nurse and an alternative care nurse; if a primary care nurse was not available to respond to an alarm condition, then an alternative care nurse was notified of the alarm. Their roles and responses are similar, therefore, many of the failure modes, potential effects, and mitigation strategies were duplicated. As such, we will only discuss each of the high-priority failure modes once. The mitigation strategies for the high-priority failure modes can then be applied to the duplicate failure modes.

In general, many of the failure modes resulted in similar potential effects. The effects common to many of the failure modes are briefly described below.

Poor patient outcome. A detrimental physical or psychological complication of a patient that results from a potential failure mode of a process. For example, treatment is not provided to a patient when an alarm condition is not detected by staff.

Staff inefficiency. Process steps are repeated or efforts duplicated due to a process breakdown, such as patient misidentification. For example, treatment given to an incorrect patient will need to be rendered to the correct patient once the misidentification is discovered.

Intervention on wrong patient. Clinical response to an alarm condition is rendered to the wrong patient.

Delay in intervention. Clinical response to an alarm condition is not made in a timely manner.

Patient physiologic change undetected. The change in a patient's physiologic condition (e.g., increased heart rate) goes unnoticed by the telemetry system equipment or by the clinical staff.

Downstream negative effects. Effects that do not necessarily result in harm to the patient may have a detrimental impact on staff morale, patient satisfaction, or hospital reputation. These include the following:

- Increased length of patient stay
- Litigation
- Increased cost of care
- Loss of staff confidence in telemetry monitoring
- Loss of physician confidence in the care provided in the telemetry care area
- Loss of patient confidence in care
- Decreased staff morale

High-Priority Failure Modes, Root Causes, and Mitigation Strategies

Patient Monitored Via Telemetry (Step 1)

Our analysis for reasons a patient would not be monitored identified two high-priority failure modes: *patient misidentification* and *human/equipment error* (e.g., not connected to a telemetry transceiver).

The RPNs for patient misidentification and human/equipment error were 60 and 80, respectively. The severity and detectability scores for each mode were the same; however, we scored the probability of occurrence differently. The probability of occurrence for human/equipment error (4) was slightly higher than for patient misidentification (3) resulting in the higher RPN for the human/equipment error.

We identified four possible root causes for patient misidentification, as follows:

- Patient identifiers not checked
- Telemetry transceiver connected to the correct patient, but the central station monitoring system configured with incorrect patient demographics
- Incorrect telemetry transceiver on the patient
- Inadequate differentiation of patient identifiers (e.g., similar names)

Patient identifiers not checked. Two mitigation strategies for patient misidentification are developing a patient identification policy that includes standardizing on two identifiers (and reinforcing clinician compliance through education) and developing a protocol for checking identifiers by the admitting nurse or the staff applying the telemetry transceiver to the patient on admission to the telemetry department. Delineation of responsibility for checking identifiers should be clearly established.

Telemetry transceiver connected to the correct patient, but the central station monitoring system configured with the incorrect patient demographics. We established two ways to guard against incorrect patient demographics. One is to implement a protocol in which staff applying the telemetry transceiver reconcile the transceiver identifier against the patient identifier configured in the central station monitoring system for a particular patient. This protocol can also be established so that the primary care nurse can reconcile the correct transceiver to the patient during an initial assessment of the patient. A second way is to use technology to reconcile the correct transceiver with the correct patient. For example, facilities in need of replacing existing telemetry physiologic monitoring systems should consider systems that incorporate a display screen with patient identifiers on the telemetry transceiver that can be matched to information configured in the central station monitoring system. Because of the expense of a new telemetry

system, we do not recommend that facilities replace existing telemetry physiologic monitoring systems solely as a mitigation strategy against incorrect patient demographics.

Incorrect telemetry transceiver on the patient. Reconciliation between the transceiver identifier and patient identifier at the central station, as described above, also apply to this failure mode.

Inadequate differentiation of patient identifiers (e.g., similar names). Healthcare facilities may often have patients with the same first and last names in the same care area, leading to misidentification of patients. Mitigation strategies include establishing unique identifiers for each patient, geographically separating patients, and assigning separate nurses to patients with similar names. An example of a unique identifier could be using patient initials or the first few letters of patients' last name along with a numbering sequence. For example, two patients named John Smith could be represented by the identifiers js123 and smi321.

We established four causes of human/equipment error, which are as follows:

- Breakdown in communication
- Malfunctioning equipment
- Signal loss
- Electromagnetic interference (EMI)

We further focused the causes into subcauses in order to develop effective remediation strategies. For example, breakdown in communication is a very broad topic. We realized that establishing mitigation strategies would be very difficult without first understanding the reasons for communication problems. Malfunctioning equipment and signal loss also need further refinement; however, refinement of EMI would have been much too complex because there are a numerous reasons for EMI to occur, some of which are not easily controllable. Therefore, we did not break down causes of EMI.

Breakdown in communication. We developed a number of causes that contribute to a breakdown in communication. Confusion regarding orders for telemetry monitoring is a key factor in contributing to communication problems. Telemetry monitoring orders are either in written or verbal form. Problems may arise when written orders are not available, or when verbal orders are generated but not converted to written orders and placed in patient charts. In some cases, standing orders for telemetry monitoring may not exist. Reducing or eliminating confusion with telemetry orders may be accomplished by developing telemetry monitoring protocols that incorporate standing orders for placing patients on telemetry monitoring, which could include eliminating or limiting the use of verbal orders.

Other factors in communication breakdown include an unclear delineation of responsibility for staff for initiating telemetry monitoring and failure to reinstate a patient whose telemetry transceiver was placed in standby mode (e.g., when leaving the care area for a radiology

procedure). A failure in appropriate patient monitoring may be the result of missed steps in placing patients on telemetry monitoring, which can be reduced or eliminated by incorporating a protocol to include the appropriate steps for placing patients on telemetry monitoring. Typical steps in placing patients on telemetry monitoring include electrode preparation and application, inputting patient information to the monitoring system, and setting and verifying appropriate alarm limits for specific patient conditions. Mitigation strategies, as part of a telemetry protocol that we developed to address failing to reinstate a patient into the monitoring system from standby mode, include developing a checklist for handoffs between staff members (e.g., nurse to transporter); limiting the use of the standby mode to specific, appropriate circumstances; and verifying patient physiologic waveform and numerics at the central station each time the patient is removed from the standby mode. Additionally, facilities in need of replacing an existing telemetry physiologic monitoring system should consider systems that incorporate an automatic mechanism that enables patient monitoring from the standby mode when the patient is connected or reconnected to the telemetry transceiver or reenters the telemetry care area (i.e., is within the wireless range of the telemetry system). However, we do not recommend that facilities replace existing telemetry physiologic monitoring systems solely for enabling automatic patient monitoring from the standby mode.

Malfunctioning equipment. Based on the majority of PA-PSRS reports related to telemetry system malfunctions and our FMEA team's experience with telemetry systems, we identified two root causes for the malfunctions: problems with the telemetry transceiver battery and random device failure. From 11 telemetry monitoring PA-PSRS reports related to battery problems, 4 indicated that the telemetry transceivers did not have batteries, 3 indicated that the transceivers had dead or low batteries, and 3 indicated that the batteries were placed incorrectly (e.g., backwards) in the transceivers. Although we did not receive PA-PSRS reports related to random device failures such as a display screen "blinking out," from the experience of our team's biomedical engineers, we understood that device failures occur and need to be addressed as part of any failure mode and mitigation strategy process.

Some of the causes that we developed for a transceiver with a dead or low battery include:

- Lax or missing protocol for replacing batteries
- Undetected low-battery alarm due to the architectural layout of the building, staff distraction, staff not close enough to hear or see a low-battery alarm condition, or low-battery alarm volume is turned down or off
- Lack of battery supplies in the telemetry care area

We identified the need for a protocol to address periodic battery replacement. The protocol also addressed who replaces the batteries (e.g., nursing, biomedical engineering), how often the battery is replaced (e.g., every shift, every 24 hours), and the par-level quantity of replacement batteries maintained in the telemetry department. Monitor slave displays and enunciators placed

in strategic locations in the telemetry department were also considered for facilities with a challenging architectural layout or for staff that are often not within hearing of the central station, hindering detection of a low-battery alarm condition. Additionally, protocols should be in place to configure the telemetry monitoring system to prevent the audibility of the low-battery alarm from being turned down or off and to set a minimum audible volume level standard.

Other methods to ensure that the patient is being monitored include verifying patient physiologic waveforms and numerics at the central station to confirm proper battery placement, in-service competency training on the telemetry monitoring system (e.g., proper battery placement), and acquiring telemetry transceivers that function irrespective of how the battery is placed or that prevent improper insertion of the battery. Again, we do not recommend that facilities replace existing telemetry physiologic monitoring systems solely as a mitigation strategy for incorrect battery placement.

Signal loss. The three main causes for a signal loss condition that would hinder patient physiologic monitoring are leads-off, the patient out of the wireless range of the telemetry monitoring system, and signal dead-spots. Leads-off, typically considered a low-priority alarm response, refers to a condition in which the monitoring electrodes or electrode lead-wires become disconnected from the patient or telemetry transceiver.

Telemetry transceivers are wirelessly connected to the central station monitor. The operating range of the telemetry system depends on its configuration (e.g., the quantity and location of wireless access points or antennae) and is specific to each healthcare facility. For example, the wireless range may encompass only a telemetry care area (e.g., med/surg), extend to other departments such as radiology, or be facilitywide. Most facilities' telemetry monitoring systems are configured for department-level wireless coverage; therefore, patient physiologic data is not captured when the telemetry transceiver (i.e., the patient) is outside the wireless range of the system. Depending on the architectural layout of a facility or the type, quantity, or location of telemetry antennae or wireless access points, areas of signal dropout may occur.

A leads-off condition can occur due to worn or loose electrodes, poor electrode-site preparation, patient sweat, and inadvertent or purposeful electrode or lead-wire disconnection. As a risk reduction strategy, we identified the need for a protocol making leads-off alarms a higher-priority response by clinicians. Although often considered a low-priority response, the leads-off condition means that potentially vital patient physiologic data is not being captured, potentially resulting in serious consequences for the patient. We also identified the need for standardized protocols for periodic electrode replacement with regular inspection of the lead sets and ensuring proper patient skin preparation at the electrode site by clinical staff. Additionally, in situations of poor electrode performance (e.g., diaphoretic patients), we decided that trialing different types of electrodes that are designed to resist certain skin conditions, such as excessive perspiration,

could alleviate the problem. Once specific types of electrodes have been accepted, minimum inventory stocking levels would be established.

We defined events in which patients with telemetry transceivers are out of the wireless range of the telemetry system as either intentional or unintentional. Most often, a situation we defined as a patient intentionally outside of wireless range of the telemetry system is due to the patient being transported to a different department in the facility (e.g., radiology) for a procedure. The telemetry system would be placed in standby mode while the patient was away from the department (this scenario is discussed on page 8). A situation in which a patient is unintentionally outside the wireless range is typically due to the patient leaving the telemetry care area without the knowledge of clinical staff (e.g., to smoke a cigarette). In this situation, the patient's transceiver would not be placed in the standby mode, resulting in the patient not being monitored.

While it is difficult to police patients in a busy care area, we determined that the best remediation approach would be to educate patients to remain within the range of the telemetry care area. Alternatives to leaving the care area, such as nicotine patches for smokers, could be offered to patients. However, the advantages of alternatives to patients leaving the telemetry care area should be weighed against any detrimental effects of the alternatives themselves. For example, offering a nicotine patch to a patient who is a chronic and persistent smoker could result in a nicotine overdose should the patient get away to smoke a cigarette. The best approach for addressing areas with signal dead-spots is to increase the number of telemetry antennae or access points or to reposition existing antennae or access points to improve coverage in those areas.

Monitoring System Detects Alarm Condition

We developed a number of failure modes for this step; however, our analysis resulted in only one high-priority failure mode, *alarm condition not detected*. The RPN for this high-priority failure mode was 60, derived from a probability of occurrence score of 4, a detectability score of 3, and a severity score of 5. We identified six possible causes for an alarm condition not detected by the monitoring system, as follows:

- Alarm limits not tailored to the patient condition
- Alarm limits change not communicated
- Default alarm limits too broad
- Specific patient alarm limits too broad
- Alarm suspended or monitor placed in alarm standby mode
- Malfunctioning equipment

Alarm limits not tailored to the patient condition. Specific alarm limits (i.e., nondefault) should be selected based on patient physiologic condition. For example, a care area (e.g., ICU)

with a policy that sets default low- and high-heart rate limits at 50 and 110 beats per minute (bpm), respectively, may encounter a patient with a normal heart rate of 50 bpm. The high-heart rate alarm limit may need to be decreased to ensure that a heart rate of 100 bpm, for example, will activate an alarm as this rate may be high for that patient.¹

Two key mitigation strategies to address specific alarm limits in a given care area are establishing criteria for adjusting default limits per patient physiologic condition and training nursing staff about the criteria and the steps. Other steps include establishing appropriate default limits based on a particular patient population in specific care areas (ICU versus med/surg) and getting physician feedback to changing default limits per patient physiologic condition.

Alarm limits change not communicated. Clinical alarm limits for a particular patient may be changed during a nursing shift due to a change in the patient's physiologic condition but then not communicated to the next shift or to nurses on the same shift. We determined that a handoff (e.g., between nursing shifts or nurses on the same shift) communication checklist, including alarm limit changes, would eliminate this problem.

Default alarm limits too broad. Default alarm limit settings should be determined based on the type of patient population of a particular care area; however, limits set too broadly will not capture potentially significant changes in patient physiologic conditions. Mitigation strategies include establishing default limits based on the particular patient population in specific care areas, establishing criteria for when and training nursing staff how to adjust default limits based on patient condition, and incorporating physician feedback on changing default limits per patient condition.

Specific patient alarm limits too broad. This cause is similar to that above for default alarm limits set too broadly and has the same mitigation strategies: establishing default limits based on particular patient population in specific care areas, establishing criteria for when and training nursing staff how to adjust default limits based on patient condition, and incorporating physician feedback on changing default limits per patient condition.

Alarm suspended or monitor placed in alarm standby mode. In developing root causes and mitigation strategies for when a monitoring system detects an alarm condition, we identified an important difference between alarm suspend and alarm standby mode. Some clinicians use these terms interchangeably. We defined them as follows:²

- Alarm *suspend* inactivates the alarm for a specific time, which is user configurable (e.g., three minutes). Alarm suspend may also be referred to as “alarm paused.”
- Alarm *standby* defeats the monitor alarm system, and sometimes stops physiologic parameter acquisition usually until a clinician manually restarts monitoring.

Alarm suspend is typically more appropriate for situations in which patients will remain connected to the telemetry transceiver in the telemetry care area, but may generate false alarms, for example, from a clinician reapplying electrodes. Alarm standby mode is appropriate for patients who are removed from the transceiver (e.g., when being temporarily transported to radiology) but will occupy the same bed when returning to the telemetry care area. Two mitigation strategies we developed are establishing criteria for when it is appropriate to use alarm suspend or alarm standby mode and delineating responsibility for placing the patient back into the telemetry systems when returning to the care area.

Malfunctioning equipment. Reconciliation for malfunctioning equipment as described on page 19 also apply to this failure mode.

ECG-Qualified Staff (e.g., Nurse) Detects Alarm Condition

We defined ECG-qualified staff as clinicians trained to understand and interpret patient ECG physiologic data (e.g., heart rate, ECG signal waveform). Our analysis resulted in three high-priority failure modes: *alarm condition not detected by ECG-qualified staff*, *ECG-qualified staff not available*, and *detection of alarm condition delayed*. The failure mode *alarm condition not detected by ECG-qualified staff* generated the highest RPN of the three modes. We rated the probability of occurrence a score of 5, the detectability a score of 3, and the severity 5 for an RPN value of 75. The other two failure modes each rated in a score of 60.

Alarm condition not detected by ECG-qualified staff. We further developed two underlying causes for *alarm condition not detected by ECG-qualified staff*, as follows:

- Alarm is not heard.
- Staff is desensitized to alarms.

The reasons for an alarm not being heard by the clinical staff are similar to those for malfunctioning equipment described on page 19, such as the architectural layout of the building, staff distracted or not within hearing of the alarm, and alarm volume level turned down or off. Another reason, which was not part of equipment malfunction, was the diffuse responsibility of clinical staff. Therefore, the mitigation strategies are similar. Providing monitor slave displays and enunciators in strategic locations of the care area will combat alarms not heard because of the architectural layout of the building, staff distraction, or staff not in close proximity to the central station. Staff distractions or staff out of hearing of the alarm can also be alleviated by delineating responsibility for primary alarm response and establishing tiers of backup coverage in the event the primary care nurse is unable to respond to the alarm.

Desensitization to alarms can often be attributed to exposure to too many alarms, especially low-priority alarms. Leads-off alarms are considered low-priority alarms by many healthcare facilities and physiologic monitoring system manufacturers. Too many alarms may be the result

of unnecessary alarm conditions or nuisance alarms, such as when the alarm limits are not tailored to the patient condition (see the discussion “Monitoring System Detects Alarm Condition” on page 19), or the alarm default limits are set too narrowly. Methods to reduce unnecessary alarm conditions include periodically replacing patient electrodes, regularly inspecting the lead sets, checking the integrity of the electrodes and lead sets for leads-off alarm conditions, and adhering to proper patient skin preparation prior to placing the electrodes. For poor performing electrodes (e.g., due to patient sweating), trial or maintain a minimum inventory level of different types of electrodes (e.g., moisture resistant).

Establish criteria for adjusting alarm limits according to patient condition, for when it is appropriate to place a monitor in alarm standby mode or to suspend an alarm, and for the need to place patients on telemetry monitoring (i.e., does the patient’s condition truly warrant monitoring). Additionally, alternative strategies for alarm notification (e.g., a paging system) may be considered to target alarms to clinical staff with responsibility for specific alarm conditions. Establishing a policy that *all* alarm conditions require prompt response may eliminate poor or no responses to low-priority alarms.

ECG-qualified staff not available. The reasons we developed for a ECG-qualified staff member not available to respond to an alarm condition include the staff member is performing other tasks in areas away from the patient, the staff member is on break, and the staff member may be unclear of his or her role in responding to an alarm condition. The remediation strategy we developed to ensure a prompt response by an ECG-qualified staff member is to establish tiers of alarm response coverage. For example, if the primary care nurse is unavailable during an alarm condition, an alternate care nurse responds; if an alternate nurse is unavailable, a nurse manager responds.

Detection of an alarm condition delayed. The reasons we list for a delay in detecting alarms are similar to those we developed for alarm condition not detected by ECG-qualified staff: alarms are not being heard and staff are desensitized to alarms. Additionally, we included the following reasons: the ECG-qualified staff member is tending to the needs of another patient at a bedside away from the patient experiencing an alarm condition, and no backup plans for alarm coverage exist. As with many of the high-priority failure modes discussed above, the alarm not being heard is attributable to the architectural layout of the building, staff being distracted or not within hearing, diffuse staff responsibility, and alarm volume level turned down or off. Staff desensitization is the result of exposure to too many alarms and the diminished urgency of low-priority alarms.

Slave displays and enunciators placed in strategic locations of the care area may reduce the negative effect of poor architectural layout of the building and staff not within hearing of an alarm. Delineating responsibility for primary alarm response and establishing tiers of backup coverage should increase alarm detection by staff. As was discussed on page 19, too many

alarms may be the result of unnecessary alarm conditions, such as result when alarm limits are not tailored to the patient condition or default limits are too narrow. Efforts toward reducing unnecessary alarm conditions include periodically replacing patient electrodes, regularly inspecting the lead sets, checking the integrity of the electrodes and lead sets for leads-off alarm conditions, and adhering to proper patient skin preparation procedures prior to placing the electrodes. For poor performing electrodes (e.g., due to patient sweating) trial or maintain a minimum inventory level of different types of electrodes (e.g., moisture resistant).

Establish criteria for adjusting alarm limits according to patient condition, for when it is appropriate to place a monitor in alarm standby mode or to suspend an alarm, and for the need to place patients on telemetry monitoring. Additionally, alternative strategies for alarm notification (e.g., a paging system) may be considered to target alarms to clinical staff with responsibility for specific alarm conditions. Establishing a policy that *all* alarm conditions require prompt response may eliminate poor or no responses to low-priority alarms.

Qualified Staff Verifies Alarm Condition on Telemetry Display

We consider verifying an alarm condition as a qualified staff member (i.e., someone who understands and can interpret physiologic data) acknowledging the alarm and viewing the telemetry central station or slave display. Our analysis resulted in only one high-priority failure mode, *delay in verification of the alarm condition*. The RPN for this high-priority failure mode was 60, derived from a probability of occurrence score of 4, a detectability score of 3, and a severity score of 5. We identified six possible root causes for an alarm condition not being detected by the monitoring system, as follows:

- Nurse unable to leave different patient's bedside
- Diffuse responsibility alarm verification
- No backup plans for alarm verification
- Inadequate tiers of coverage
- Urgency of response to low-priority alarms is inadequate

Nurse unable to leave different patient's bedside. Verification of an alarm condition may be hindered by a busy nursing staff. For example, during the day-nursing shift, the nurse-to-patient ratio may be 1 nurse to 4 or 6 patients and during the evening shift the ratio may be 1 nurse to 10 patients. It is very likely that alarm conditions for more than one patient will exist simultaneously, and it is impossible for a primary care nurse to respond to more than one alarm at the same time. One way to address this is to establish tiers of backup coverage for responding to an alarm condition. For example, if the primary care nurse is unavailable during an alarm condition, an alternate care nurse responds; if an alternate nurse is unavailable, a nurse manager responds. Other strategies include placing slave displays in each of the patient rooms or

providing handheld monitors for staff to allow remote viewing of alarm conditions with physiologic data for other patients.

Diffuse responsibility for alarm verification. Nurse to patient ratios and the concurrent responsibilities of the nursing staff may significantly hinder verification of patient alarm conditions. A method to help ensure verification of alarms is to clearly delineate responsibility for primary alarm response and to establish tiers of backup coverage.

No backup plans for alarm verification. Without a clear protocol in place to provide secondary and/or tertiary alarm response coverage, alarm verification may not occur or could be significantly delayed, resulting in detrimental effects to patient health. We, therefore, decided that a protocol must be established for delineation of responsibility for primary alarm response and establishing appropriate tiers of backup coverage.

Inadequate tiers of coverage. As with the root causes above, we maintain that a tiered approach for alarm response coverage will help to ensure a prompt and adequate response to an alarm condition.

Urgency of response to low-priority alarms is inadequate. Many healthcare facilities and telemetry system manufacturers categorize alarms by priority level. For instance, a leads-off alarm is often designated low priority. In fact, priority level telemetry systems use different visual and audible alarm indicators for different priority level alarms. For example, a low-priority leads-off alarm will have a different visual and audible indicator than a high-priority alarm, such as asystole, to distinguish between the two. Knowing that a certain alarm indicator (e.g., a specific audible tone) is a low priority may create a sense of confirmation bias resulting in a lack of urgency in responding to the alarm condition.

As a risk reduction strategy, we developed a protocol requiring leads-off alarms a high-priority response from clinicians. Although leads-off is often considered a low-priority alarm, we considered it a high-priority since the leads-off condition means that potentially vital patient physiologic data is not being acquired, possibly resulting in serious consequences for the patient.

Primary or Alternative Care Nurse Locates the Patient (Steps 12A, 27A, 9B, 14B)

Once an alarm condition has been verified, the primary care nurse—or alternative nurse depending on the response scenario—then locates the patient to tend to the alarm condition. In our analysis, we established one high-priority failure mode: *delay in locating the patient*. The RPN for this high-priority failure mode was 60, derived from a probability of occurrence score of 4, a detectability score of 3, and a severity score of 5. The one obvious cause is that the patient is outside (away) from the patient room. We established a “sweep” protocol to remedy this scenario. A sweep protocol can rapidly cover an area to locate a patient in the care area by

delineating responsibility to the clinical staff searching certain areas within the department (i.e., who searches which rooms) and the order in which rooms are searched.

Primary or Alternative Care Nurse Intervenes as Appropriate (Steps 14A, 29A, 11B, 16B)

After the patient has been located, the nurse then intervenes as appropriate in response to the alarm condition, such as reapplying or replacing ECG electrode leads for a leads-off alarm. We established one high-priority failure mode in which intervention may be hindered: a *delay in intervention*. The RPN for this failure mode is 60 (probability of occurrence is 4, detectability is 3, severity is 5). Although the RPN is on the low end of our RPN score inclusion criteria, we chose to develop mitigation strategies for it because of the serious potential for a negative patient outcome.

Delay in intervention. The three root causes we developed for the delay in intervention scenario are inappropriate assumptions, lack of available equipment or supplies, and competing priorities of the clinical staff with regard to other patients.

Inappropriate assumptions. A clinical staff member, assuming another staff member responded to a patient alarm condition without verification, may delay in intervention of care. Reinforcing alarm verification protocols through staff education and training will help to reduce the likelihood of a delayed intervention.

Lack of availability of equipment or supplies. Adequate inventory levels of equipment or supplies must be maintained in each care area and the central supply department of healthcare facilities in order to provide prompt and appropriate care when patient physiologic conditions require it. Missing equipment or supplies may significantly delay intervention while clinical staff search for needed items. We established a policy to set and maintain inventory restocking triggers. By increasing the par-level restocking quantity for supply items that are often unavailable, a facility can help ensure that an adequate supply is available before the items need to be reordered and that staff not use emergency supplies (e.g., crash cart) for routine use, and that responsibility be delineated for checking supply inventory levels and expiration dates.

Competing priorities of the clinical staff with regard to other patients. The demands on the nursing staff can be significant due to a low nurse-to-patient ratio or the clinical needs of a seriously ill patient. One way to meet the competing needs of patients is to establish tiers of backup coverage in response to an alarm condition. For example, if the primary care nurse is unavailable during an alarm condition, an alternate care nurse responds; if an alternate nurse is unavailable, a nurse manager responds. Other strategies include placing slave displays in each of the patient rooms or using handheld monitors to allow staff to remotely view alarm conditions with physiologic data for other patients.

Notes

1. ECRI Institute. The hazards of alarm overload. Keeping excessive physiologic monitoring alarms from impeding care. *Health Devices* 2007 Mar;36(3):73-83.
2. Joint Commission. Failure mode and effects analysis in health care: proactive risk reduction. Chicago (IL): Joint Commission Resources, Inc.; 2002.

CONCLUSIONS

Our retrospective review of reports submitted to PA-PSRS regarding failures in telemetry physiologic monitoring of patients demonstrates that patients are not consistently monitored when admitted to a telemetry care area. That inconsistency often results in missed or delayed intervention by clinical staff to a change in a patient's physiologic condition. With more consistent physiologic monitoring, staff would have been alerted to that change in the patient's condition by the activation of an alarm from the telemetry monitoring system.

We found that many of the potential failure modes and their respective causes were identical in the steps of our telemetry process. Concentrating on the highest-priority failure modes and the common causes that apply to multiple failure modes led to strategies that would have the greatest benefit to patient safety.

Mitigation strategies to reduce risk associated with potential failure modes varied, but the majority of failure modes could be reduced or eliminated by developing and implementing new or revised policies and protocols as opposed to changes in technologies. Many of the policies and protocols that we developed could be applied to many different failure modes.

The common mitigation strategies affecting patient safety that we developed and that can be implemented for many of the different failure modes we analyzed are as follows:

- Placing slave displays and enunciators in strategic locations throughout a care area.
- Developing a protocol for setting the volume of an alarm to a minimum audible level that can be heard in a typical environmental noise level for given care area.
- Developing standardized practices for periodic electrode and lead-set inspection and replacement and proper electrode-site skin preparation.
- Developing a protocol that requires prompt response for *all* alarm conditions (low- or high-priority alarms).
- Developing a protocol that establishes alarm limit default settings based on a particular patient population in a given care area.
- Developing protocols that establish criteria for when and how to adjust alarm default limits according to patient condition.
- Developing protocols to delineate responsibility for primary alarm response and establishing tiers of backup alarm coverage.

The intent of our FMEA exercise was to give healthcare facilities an opportunity to gain an understanding of the FMEA process as it is applied to healthcare and to provide the results from our data that facilities can consider using as a framework for developing facility-specific policies and protocols to reduce risks associated with alarm intervention in response to changes in patient physiologic conditions during telemetry.

APPENDIX A: RISK PRIORITY RATING SCALE

Probability of Occurrence

Rating	Description	Definition
1	Remote to nonexistent	Little or no occurrence, highly unlikely
2	Low	Possible, but problem occurs in isolated cases
3	Moderate	Documented, but infrequent; problem has a reasonable chance to occur
4	High	Documented, frequent; problem occurs regularly or within a short time period
5	Very high	Documented, almost inevitable

Detectability

Rating	Description	Definition
1	Certain to be detected	Almost always detected immediately
2	High	Likely to be detected
3	Moderate	Moderately likely to be detected
4	Low	Unlikely to be detected
5	Almost certain not to be detected	Detection not possible

A lower detectability score reflects a greater likelihood that the failure mode will be detected before harm reaches the patient, and a higher score reflects a lower probability that the failure mode will be detected.

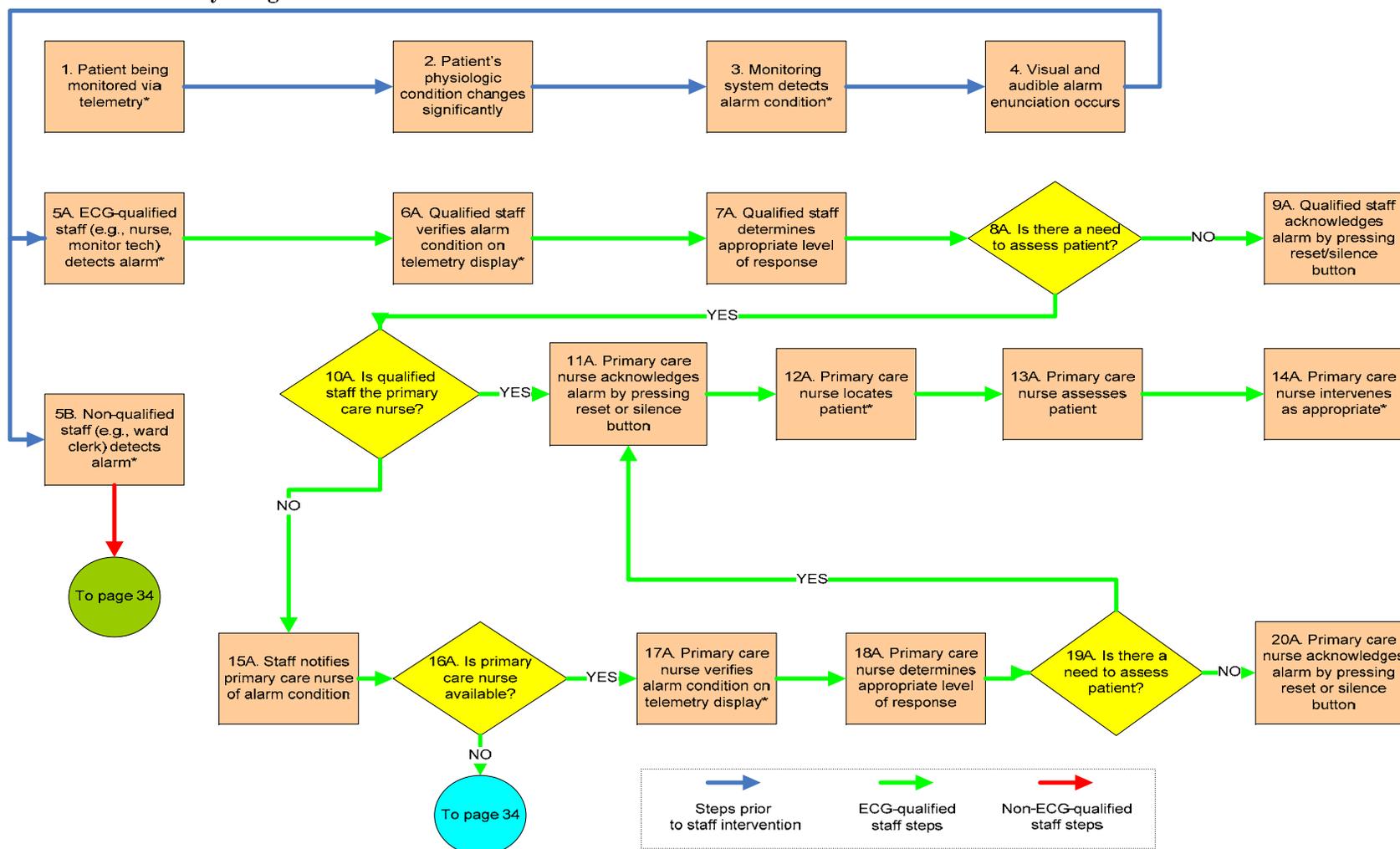
Severity

Rating	Description	Definition
1	Minor or no effect	Would not be noticeable to the patient; would not affect the process
2	Moderate effect	May affect the patient; would affect the process
3	Minor injury	Would result in minor physical or psychological injury to the patient; would affect the process
4	Major injury	Dangerous; would result in major injury to the patient (e.g., loss of limb, loss of function); would affect the process
5	Severe or terminal outcome	Very dangerous; would result in potential death; would affect the process

For severity, the effect is rated, not the failure mode. The ratings are based on the risk of injury to the patient and the significance of the injury resulting from the effect of the failure mode. Severity ratings are subjective; as such, FMEA teams should also use experience and professional judgment in determining severity ratings.

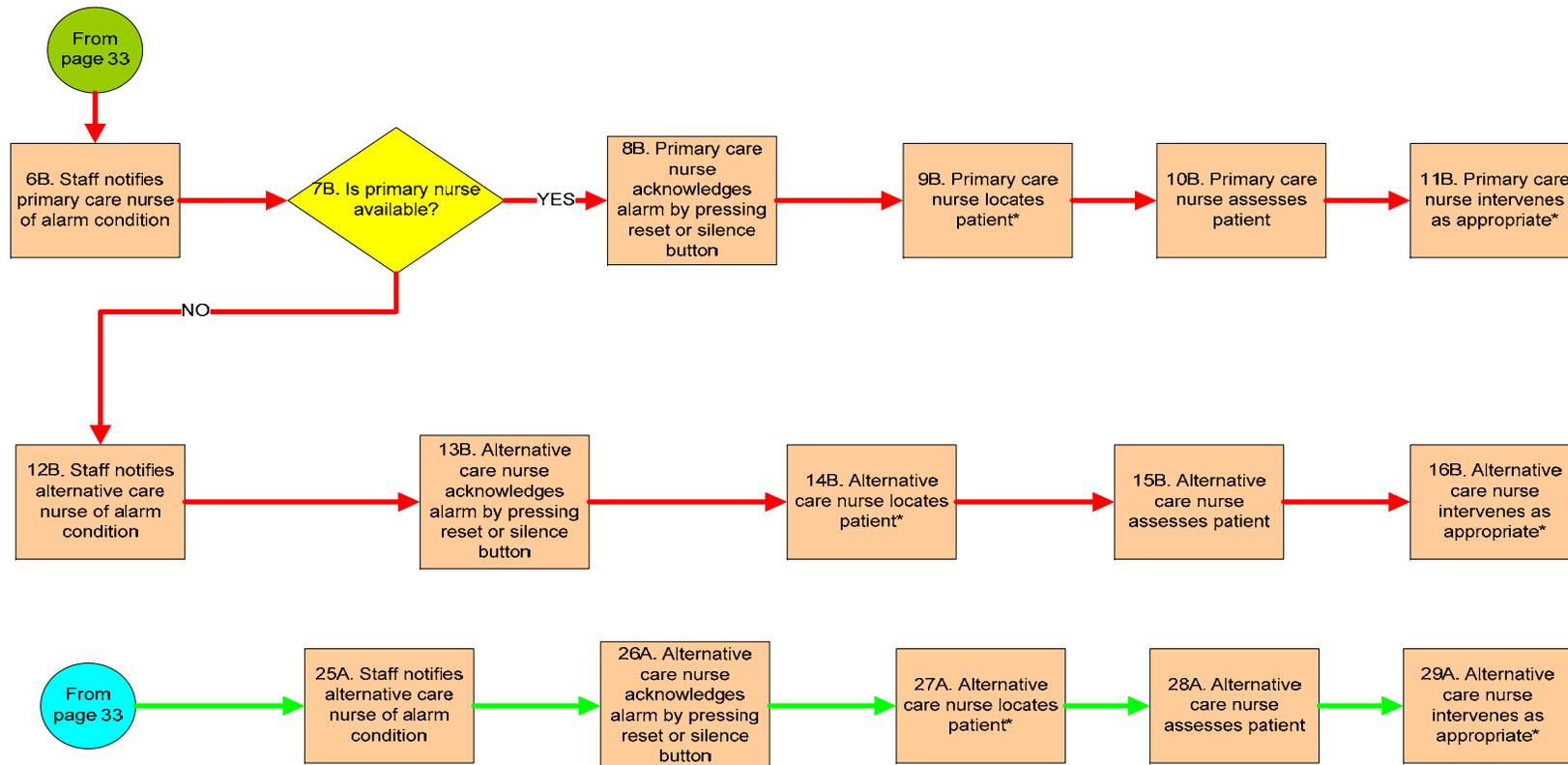
APPENDIX B: ALARM INTERVENTION FLOWCHART

Alarm Interventions in Response to Change in Patient Physiologic Condition



*Indicates steps that were addressed as high-priority failure modes during this FMEA process (see corresponding steps in Appendix C).

Alarm Interventions in Response to Change in Patient Physiologic Condition (continued)



*Indicates steps that were addressed as high-priority failure modes during this FMEA process (see corresponding steps in Appendix C).

APPENDIX C: ALARM INTERVENTION HIGH-PRIORITY FAILURE MODES WORKSHEET

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
1. Patient being monitored via telemetry	1.1 Patient misidentified	3	4	5	60	<p>Patient identifiers not checked</p> <p>Telemetry transceiver on correct patient, but central station configured incorrectly</p> <p>Incorrect telemetry transceiver on patient</p> <p>Inadequate differentiation of patient identifiers (e.g., names are similar)</p>	<p>Develop policy for identifiers (low status)</p> <ul style="list-style-type: none"> ▪ Standardize on using two identifiers ▪ Reinforce using education <p>Develop protocol for checking patient identifier on admission to telemetry department (clearly delineating responsibility and throughout hospital)</p> <p>Require admitting nurse to check patient identifier on admission to telemetry department</p> <p>Develop/revise protocol so that staff applying transceiver reconcile transceiver number against number on central station for particular patient</p> <p>Develop/revise protocol so that the primary care nurse reconciles transceiver number against number on central station for particular patient upon initial assessment</p> <p>Look for systems that offer feedback that transceiver is correct for correct patient</p> <p>Use unique identifiers for each patient</p> <p>Separate patients geographically, assign separate nurse to patients with similar names</p>

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
1. Patient being monitored via telemetry	1.2 Human/equipment error (not put on monitor, signal drop out)	4	4	5	80	<p>Breakdown in communication</p> <ul style="list-style-type: none"> ▪ No standing order ▪ No protocol for telemetry monitoring ▪ No clear delineation of responsibility for monitoring ▪ No written order available ▪ Physician provides verbal order, but nurse did not write down verbal order <ul style="list-style-type: none"> - No standard process for verbal order or verifying and documenting - No policy limiting the use of verbal orders in hospital <p>Patient not reinstated after monitoring system put in standby mode</p> <p>Malfunctioning equipment</p> <ul style="list-style-type: none"> ▪ Dead battery <ul style="list-style-type: none"> - Battery not changed <ul style="list-style-type: none"> o No process in place for routine battery changes o No one heard low-battery alarm o Challenges of architectural layout of building o Staff distracted o Staff out of earshot of alarm o Volume turned down or off - Battery put in telepack incorrectly <ul style="list-style-type: none"> o Lack of training o Poor human factors design o Random device failure <ul style="list-style-type: none"> o Lack of preventive maintenance ▪ Breakdown in repair identification process ▪ Signal loss ▪ Leads off <ul style="list-style-type: none"> - Worn/loose electrode - Poor prep 	<p>Develop and/or revise telemetry protocol</p> <ul style="list-style-type: none"> ▪ Incorporate standing orders for placing patient on telemetry as part of protocol ▪ Incorporate delineation of responsibility for placing patient on telemetry <ul style="list-style-type: none"> - Electrode prep and application - Admission to monitoring system - Setting/verifying of alarm limits ▪ Develop checklist for handoffs between staff (nurse to transporter) ▪ Select telemetry system that automatically enables monitoring when patient is connected/reconnected ▪ Establish protocol for limitation on use of standby mode, protocol for after standby: reinstate patient in system and verify waveform and numerics on central station <p>Establish protocol for periodic battery replacement: determine who replaces battery, how often</p> <p>Address challenging architectural layout of building</p> <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations <p>Address staff distractions</p> <ul style="list-style-type: none"> ▪ Delineate responsibility of primary alarm response, and establish tiers of backup coverage <p>Address staff out of earshot of alarm</p> <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations <p>Address volume turned down/off</p> <ul style="list-style-type: none"> ▪ Configure system to prevent alarm audibility from being turned down too low or off ▪ Create policy for alarms to be set at a minimum audible volume level <p>(Did not mitigate random device failure)</p>

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
1. Patient being monitored via telemetry	1.2 Human/equipment error (not put on monitor, signal drop out) <i>(continued)</i>	4	4	5	80	<ul style="list-style-type: none"> - Sweat - Inadvertent disconnection - Purposeful patient disconnection ▪ Patient out of range Electromagnetic interference	Establish par-levels within the care area, and delineate responsibility for par-level maintenance Acquire telemetry packs with universal battery terminals or prevent improper battery insertion Verify waveform and numerics on central station to confirm proper battery placement Conduct in-service competency training on telemetry system (e.g., proper battery placement) Develop standardized practices (protocol) <ul style="list-style-type: none"> ▪ Increase response priority for leads-off alarm ▪ Perform periodic electrode replacement <ul style="list-style-type: none"> - Conduct regular inspection of lead sets - Require nurses to check the integrity of lead sets and electrodes for leads-off alarm <ul style="list-style-type: none"> o Institute competency checklist - Adhere to proper patient skin prep - Trial different types of electrodes for poor performing electrodes (e.g., due to patient's sweating) Extend mitigation efforts beyond the floor <ul style="list-style-type: none"> ▪ Educate patients to remain within the range of the telemetry unit ▪ Offer alternatives to leaving floor (e.g., nicotine patches for smokers who go off floor to smoke) Eliminate dead spots <ul style="list-style-type: none"> ▪ Increase coverage of antennas (Did not mitigate electromagnetic interference)

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
3. Monitoring system detects alarm condition	3.1 Alarm condition not detected	4	3	5	60	<p>Alarm limits not tailored to patient condition Alarm defaults too broad Alarm limits too broad for specific patient Change in alarm limits not communicated Alarm suspended or in alarm standby mode</p> <p>Malfunctioning equipment</p> <ul style="list-style-type: none"> ▪ Dead battery <ul style="list-style-type: none"> - Battery not changed <ul style="list-style-type: none"> ○ No process in place for routine battery changes ○ No one heard low-battery alarm <ul style="list-style-type: none"> • Challenges of architectural layout of building • Staff distracted • Staff out of earshot of alarm • Volume turned down or off • No supply of batteries - Battery put in telepack incorrectly <ul style="list-style-type: none"> ○ Lack of training ○ Poor human factors design - Random device failure <ul style="list-style-type: none"> ○ Lack of preventive maintenance <p>Breakdown in repair identification process</p>	<p>Establish default limits based on particular patient population in particular care area</p> <p>Establish criteria for when to adjust defaults per patient condition</p> <p>Train nurses about alarm limit criteria and how to adjust alarms per patient condition</p> <p>Consider including physicians in changing defaults limits per patient condition</p> <p>Incorporate alarm limit changes in handoff communication checklist</p> <p>Establish criteria for when suspend or standby mode is appropriate</p> <p>Delineate responsibility for placing patient back on telemetry when returned to care area</p> <p>Establish protocol for periodic battery replacement: who replaces battery, how often</p> <p>Address architectural layout of building</p> <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations <p>Address staff distractions</p> <p>Address staff out of earshot of alarm</p> <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations <p>Address volume turned down/off</p> <ul style="list-style-type: none"> ▪ Configure system to prevent alarm audibility from being turned down too low or off ▪ Create policy for alarms to be set at a minimum audible volume level <p>Establish par-levels within the care area, and delineate responsibility for par-level maintenance</p> <p>Acquire telemetry packs with universal battery terminals to prevent improper battery insertion</p> <p>Verify waveform and numerics on central station to confirm proper battery placement</p> <p>Conduct in-service competency training on telemetry system (e.g., proper battery placement)</p>

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
5A. ECG-qualified staff (e.g., nurse) detects alarm	5A.1 ECG-staff does not detect alarm	5	3	5	75	<p>Alarm is not heard</p> <ul style="list-style-type: none"> ▪ Challenges of architectural layout of building ▪ Staff distractions ▪ Staff out of earshot of alarm <ul style="list-style-type: none"> - Staffing levels - Staff occupied with patients ▪ Diffuse responsibility ▪ Volume turned down/off <p>Staff desensitization to alarms</p> <ul style="list-style-type: none"> ▪ Too many alarms <ul style="list-style-type: none"> - Alarm limits not tailored to patient condition to limit unnecessary alarm - Alarm defaults too narrow 	<p>Address challenges of architectural layout of building</p> <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations <p>Address staff distractions</p> <ul style="list-style-type: none"> ▪ Delineate responsibility for primary alarm response and establish tiers of backup coverage <p>Address staff out of earshot of alarm</p> <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage <p>Focus diffused responsibility</p> <ul style="list-style-type: none"> ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage <p>Address volume turned down/off</p> <ul style="list-style-type: none"> ▪ Require alarms to always be set at adequate level of audibility but not below a certain level based on lockout system feature <p>Address staff desensitization to alarms</p> <ul style="list-style-type: none"> ▪ Reduce nuisance alarms <ul style="list-style-type: none"> - Perform periodic electrode replacement - Conduct regular inspection of lead sets

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
5A. ECG-qualified staff (e.g., nurse) detects alarm	5A.1 ECG-staff does not detect alarm <i>(continued)</i>	5	3	5	75	Diminished sensitivity to low-priority alarms	<ul style="list-style-type: none"> - Require nurses to check the integrity of lead sets and electrodes for leads-off alarm - Institute competency checklist - Adhere to proper patient skin prep - Trial different types of electrodes for poor performing electrodes (e.g., for diaphoretic patient) - Establish criteria for when to adjust default limits per patient condition - Train nurses about alarm limit criteria and how to adjust alarms per patient condition - Establish minimum criteria for patients to be placed on telemetry monitoring - Establish criteria for when suspend or standby mode is appropriate to prevent nuisance alarms - Consider alternative alarm notification strategies to target alarms to those with responsibility for those alarms <ul style="list-style-type: none"> ▪ Increase sensitivity to low-priority alarms <ul style="list-style-type: none"> - All alarms (low and high) require prompt response
5A. ECG-qualified staff (e.g., nurse) detects alarm	5A.3 ECG staff not available	4	3	5	60	Doing other tasks On break Unclear role in alarm response	Establish tiers of alarm coverage response

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
5A. ECG-qualified staff (e.g., nurse) detects alarm	5A.4 Delay in detection	4	3	5	60	<p>Alarm is not heard</p> <ul style="list-style-type: none"> ▪ Challenges of architectural layout of building ▪ Staff distractions ▪ Staff out of earshot of alarm <ul style="list-style-type: none"> - Staffing level - Staff occupied with patients ▪ Diffuse responsibility ▪ Volume turned down/off 	<p>Address challenges of architectural layout of building</p> <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations <p>Address staff distractions</p> <ul style="list-style-type: none"> ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage <p>Address staff out of earshot of alarm</p> <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage <p>Focus diffused responsibility</p> <ul style="list-style-type: none"> ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage <p>Address volume turned down/off</p> <ul style="list-style-type: none"> ▪ Require alarms to always be set at adequate level of audibility but not below a certain level based on lockout system feature

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
5A. ECG-qualified staff (e.g., nurse) detects alarm	5A.4 Delay in detection <i>(continued)</i>	4	3	5	60	<p>Staff desensitization to alarms</p> <ul style="list-style-type: none"> ▪ Too many alarms <ul style="list-style-type: none"> - Alarm limits not tailored to patient condition to limit unnecessary alarm - Alarm defaults too narrow - Alarm limits (specific patient) too narrow ▪ Diminished sensitivity to low-priority alarms <p>Staff at another patient's bedside No backup plans for alarm coverage</p>	<p>Address staff desensitization to alarms</p> <ul style="list-style-type: none"> ▪ Reduce nuisance alarms <ul style="list-style-type: none"> - Perform periodic electrode replacement - Conduct regular inspection of lead sets - Require nurses to check the integrity of lead sets and electrodes for leads off alarm - Institute competency checklist - Adhere to proper patient skin prep - Trial different types of electrodes for poor performing electrodes (e.g., for diaphoretic patient) - Establish criteria for when to adjust default limits per patient condition - Train nurses about alarm limit criteria and how to adjust alarms per patient condition - Establish minimum criteria for patients to be placed on telemetry monitoring - Establish criteria for when suspend or standby mode is appropriate to prevent nuisance alarms - Consider alternative alarm notification strategies to target alarms to those with responsibility for those alarms <p>Increase sensitivity to low-priority alarms</p> <ul style="list-style-type: none"> ▪ All alarms (low and high) require prompt response <p>Delineate responsibility for primary alarm response, and establish tiers of backup coverage</p>

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
6A. Qualified staff verifies alarm condition of telemetry display	6A.5 Delay in verification	4	3	5	60	<p>Nurse cannot leave different patient's bedside</p> <p>Diffuse responsibility of verification of alarms No backup plans for alarm verification Inadequate tiers of coverage</p> <p>Urgency of response to low-priority alarms in inadequate</p>	<p>Delineate responsibility for primary alarm response, and establish tiers of backup coverage</p> <p>Locate slave displays in patient rooms</p> <p>Incorporate other technology (e.g., nurse-held monitor)</p> <p>Delineate responsibility for primary alarm response, and establish tiers of backup coverage</p> <p>All alarms (low and high) require prompt response</p>
12A. Primary care nurse locates patient	12A.3 Delay in locating patient	4	3	5	60	Patient is outside (away) from the patient room	<p>Implement "sweep" protocol</p> <ul style="list-style-type: none"> ▪ Locate a patient in the care area by delineating responsibility to the clinical staff searching certain areas within the department (i.e., who searches which rooms) and the order in which rooms are searched
14A. Primary care nurse intervenes as appropriate	14A.4 Delay in intervention	4	3	5	60	<p>Inappropriate assumptions</p> <p>Lack of availability of equipment/supplies</p>	<p>Reinforce alarm verification protocols through staff education and training</p> <p>Implement protocol to set and maintain inventory restocking triggers; for example, increase the par-level restocking quantity for supply items that are often unavailable, require that staff not use emergency supplies (e.g., crash cart) for routine use, and delineate responsibility for checking supply inventory levels and expiration dates</p>

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
14A. Primary care nurse intervenes as appropriate	14A.4 Delay in intervention <i>(continued)</i>	4	3	5	60	Competing priorities with other patients	Delineate responsibility for primary alarm response, and establish tiers of backup coverage Locate slave displays in patient rooms Incorporate other technology (e.g., nurse-held monitor)
17A. Primary care nurse verifies alarm condition on telemetry display	17A.5 Delay in verification	4	3	5	60	Nurse cannot leave different patient's bedside Diffuse responsibility of verification of alarms No backup plans for alarm verification Inadequate tiers of coverage Urgency of response to low-priority alarms in inadequate	Delineate responsibility for primary alarm response, and establish tiers of backup coverage Locate slave displays in patient rooms Incorporate other technology (e.g., nurse-held monitor) Delineate responsibility for primary alarm response, and establish tiers of backup coverage All alarms (low and high) require prompt response
27A. Alternate care nurse locates patient	27A.4 Delay in locating patient	4	3	5	60	Patient is outside (away) from the patient room	Implement "sweep" protocol <ul style="list-style-type: none"> ▪ Locate a patient in the care area by delineating responsibility to the clinical staff searching certain areas within the department (i.e., who searches which rooms) and the order in which rooms are searched

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
29A. Alternate care nurse intervenes as appropriate	29A.4 Delay in intervention	4	3	5	60	<p>Inappropriate assumptions</p> <p>Lack of availability of equipment/supplies</p> <p>Competing priorities with other patients</p>	<p>Reinforce alarm verification protocols through staff education and training</p> <p>Implement protocol to set and maintain inventory restocking triggers; for example, increasing the par-level restocking quantity for supply items that are often unavailable, require that staff not use emergency supplies (e.g., crash cart) for routine use, and delineate responsibility for checking supply inventory levels and expiration dates</p> <p>Delineate responsibility for primary alarm response, and establish tiers of backup coverage</p> <p>Locate slave displays in patient rooms</p> <p>Incorporate other technology (e.g., nurse-held monitor)</p>
5B. Non-ECG-qualified staff (e.g., ward clerk) detects alarm	5B.1 Non-ECG-qualified staff does not detect alarm	5	3	5	75	<p>Alarm is not heard</p> <ul style="list-style-type: none"> ▪ Challenges of architectural layout of building ▪ Staff distractions ▪ Staff out of earshot of alarm <ul style="list-style-type: none"> - Staffing level - Staff occupied with patients ▪ Diffuse responsibility 	<p>Address challenges of architectural layout of building</p> <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations <p>Address staff distractions</p> <ul style="list-style-type: none"> ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage <p>Address staff out of earshot of alarm</p> <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage <p>Focus on diffused responsibility</p> <ul style="list-style-type: none"> ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
5B. Non-ECG-qualified staff (e.g., ward clerk) detects alarm	5B.1 Non-ECG-qualified staff does not detect alarm <i>(continued)</i>	5	3	5	75	<ul style="list-style-type: none"> ▪ Address volume turned down/off <p>Staff desensitization to alarms</p> <ul style="list-style-type: none"> ▪ Too many alarms <ul style="list-style-type: none"> - Alarm limits not tailored to patient condition to limit unnecessary alarm - Alarm defaults too narrow <ul style="list-style-type: none"> ▪ Diminished sensitivity to low-priority alarms 	<p>Address volume turned down/off</p> <ul style="list-style-type: none"> ▪ Require alarms to always be set at adequate level of audibility but not below a certain level based on lockout system feature <p>Address staff desensitization to alarms</p> <ul style="list-style-type: none"> ▪ Reduce nuisance alarms <ul style="list-style-type: none"> - Perform periodic electrode replacement - Conduct regular inspection of lead sets - Require nurses to check the integrity of lead sets and electrodes for leads-off alarm - Institute competency checklist - Adhere to proper patient skin prep - Trial different types of electrodes for poor performing electrodes (e.g., for diaphoretic patient) - Establish criteria for when to adjust default limits per patient condition - Train nurses about alarm limit criteria and how to adjust alarms per patient condition - Establish minimum criteria for patients to be placed on telemetry monitoring - Establish criteria for when suspend or standby mode is appropriate to prevent nuisance alarms - Consider alternative alarm notification strategies to target alarms to those with responsibility for those alarms <ul style="list-style-type: none"> ▪ Increase sensitivity to low-priority alarms <ul style="list-style-type: none"> - All alarms (low and high) require prompt response

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
5B. Non-ECG-qualified staff (e.g., ward clerk) detects alarm	5B.3 Non-ECG-qualified staff not available	4	3	5	60	Doing other tasks On break Unclear role in alarm response	Establish tiers of alarm coverage response
5B. Non-ECG-qualified staff (e.g., ward clerk) detects alarm	5B.4 Delay in detection	4	3	5	60	Alarm is not heard <ul style="list-style-type: none"> ▪ Challenges of architectural layout of building ▪ Staff distractions ▪ Staff out of earshot of alarm <ul style="list-style-type: none"> - Staffing level - Staff occupied with patients ▪ Diffuse responsibility ▪ Volume turned down/off 	Address challenges of architectural layout of building <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations Address staff distractions <ul style="list-style-type: none"> ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage Address staff out of earshot of alarm <ul style="list-style-type: none"> ▪ Place slave displays in strategic locations ▪ Place enunciators in strategic locations ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage Focus on diffused responsibility <ul style="list-style-type: none"> ▪ Delineate responsibility for primary alarm response, and establish tiers of backup coverage Address volume turned down/off <ul style="list-style-type: none"> ▪ Require alarms to always be set at adequate level of audibility but not below a certain level based on lockout system feature

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
5B. Non-ECG-qualified staff (e.g., ward clerk) detects alarm	5B.4 Delay in detection <i>(continued)</i>	4	3	5	60	<p>Staff desensitization to alarms</p> <ul style="list-style-type: none"> ▪ Too many alarms <ul style="list-style-type: none"> - Alarm limits not tailored to patient condition to limit unnecessary alarm - Alarm defaults too narrow ▪ Diminished sensitivity to low-priority alarms <p>Staff at another patient's bedside No backup plans for alarm coverage</p>	<p>Address staff desensitization to alarms</p> <ul style="list-style-type: none"> ▪ Reduce nuisance alarms <ul style="list-style-type: none"> - Perform periodic electrode replacement - Conduct regular inspection of lead sets - Require nurses to check the integrity of lead sets and electrodes for leads-off alarm - Institute competency checklist - Adhere to proper patient skin prep - Trial different types of electrodes for poor performing electrodes (e.g., for diaphoretic patient) - Establish criteria for when to adjust default limits per patient condition - Train nurses about alarm limit criteria and how to adjust alarms per patient condition - Establish minimum criteria for patients to be placed on telemetry monitoring - Establish criteria for when suspend or standby mode is appropriate to prevent nuisance alarms - Consider alternative alarm notification strategies to target alarms to those with responsibility for those alarms ▪ Increase sensitivity to low-priority alarms <ul style="list-style-type: none"> - All alarms (low and high) require prompt response <p>Delineate responsibility for primary alarm response, and establish tiers of backup coverage</p>

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
9B. Primary care nurse locates patient	9B.3 Delay in locating patient	4	3	5	60	Patient is outside (away) from the patient room	Implement “sweep” protocol <ul style="list-style-type: none"> Locate a patient in the care area by delineating responsibility to the clinical staff searching certain areas within the department (i.e., who searches which rooms) and the order in which rooms are searched
11B. Primary care nurse intervenes as appropriate	11B.4 Delay in intervention	4	3	5	60	Inappropriate assumptions Lack of availability of equipment/supplies Competing priorities with other patients	Reinforce alarm verification protocols through staff education and training Implement protocol to set and maintain inventory restocking triggers; for example, increasing the par-level restocking quantity for supply items that are often unavailable, require that staff not use emergency supplies (e.g., crash cart) for routine use, and delineate responsibility for checking supply inventory levels and expiration dates Delineate responsibility for primary alarm response, and establish tiers of backup coverage Locate slave displays in patient rooms Incorporate other technology (e.g., nurse-held monitor)
14B. Alternate care nurse locates patient	14B.3 Delay in locating patient	4	3	5	60	Patient is outside (away) from the patient room	Implement “sweep” protocol <ul style="list-style-type: none"> Locate a patient in the care area by delineating responsibility to the clinical staff searching certain areas within the department (i.e., who searches which rooms) and the order in which rooms are searched

Steps or Links in Process	List All Potential Failure Modes	Probability of Occurrence	Detectability	Severity	Risk Priority Number (RPN)	Potential Causes	Mitigation Strategies (Recommended Redesign)
16B. Alternate care nurse intervenes as appropriate	16B.4 Delay in intervention	4	3	5	60	<p>Inappropriate assumptions</p> <p>Lack of availability of equipment/supplies</p> <p>Competing priorities with other patients</p>	<p>Reinforce alarm verification protocols through staff education and training</p> <p>Implement protocol to set and maintain inventory restocking triggers; for example, increasing the par-level restocking quantity for supply items that are often unavailable, require that staff not use emergency supplies (e.g., crash cart) for routine use, and delineate responsibility for checking supply inventory levels and expiration dates</p> <p>Delineate responsibility for primary alarm response, and establish tiers of backup coverage</p> <p>Locate slave displays in patient rooms</p> <p>Incorporate other technology (e.g., nurse-held monitor)</p>

