Maryland Department of Health and Mental Hygiene
Office of Health Care Quality

Martin O'Malley, Governor
Anthony G. Brown, Lt. Governor
Joshua M. Sharfstein, M.D., Secretary
Patricia Tomsko Nay, M.D., Executive Director

Maryland Hospital Patient Safety Program
Annual Report
Fiscal Year 2013

January 2014

3 COMAR 10.07.06.11 (F)

Table of Contents

Foreword

It is with great pleasure that I present the 2013 Maryland Hospital Patient Safety Program's Annual Report. Since March 15, 2004, Maryland hospitals have reported to the Office of Health Care Quality (OHCQ) any unexpected events in treatment that result in the serious injury or death of a patient. The Maryland Hospital Safety Program continues to be an invaluable source of information for the Department. As in previous years, there is little overlap between the hospitals' self-reported adverse events and complaints received from the public. In FY13, only five reports were received as both a complaint and as an adverse event.

The OHCQ investigates those factors—identified by the hospital in the root cause analysis—that lead to adverse events. Hospitals readily identified bedside, or sharp-end, root causes to adverse events, but were less successful with identifying higher level or latent root causes. If these types of issues are not corrected, there is a risk of recurrence of the same event. The challenge to hospitals is to develop lasting interventions with measurable outcomes that identify and effectively address all identified root causes.

Many hospitals are aware of events that do not meet reporting criteria; however, sometimes these events are still reported because the organization realizes that serious system issues caused errors that could recur with more significant consequences. These hospitals are willing to go above and beyond the regulations so that we can track these events in hopes of preventing them in the future. The actions of these hospitals and their commitment to patient safety are much appreciated by the OHCQ. We realize that patient safety is not the sole responsibility of the patient safety officer or nursing professionals. It must involve the medical staff and governing body. Patient safety only succeeds as a hospital-wide effort with the direction, involvement and support of hospital leadership.

With more changes on the horizon, we recognize hospitals' diligence to stay the course of patient safety and the Department thanks each hospital for your efforts. I would also like to recognize OHCQ's Anne Jones and Renee Webster for their continued dedication to ensuring quality and safe care to all Marylanders.

Sincerely,

Patricia Tomsko Nay, MD

Patricia Tomsko Nay, MD, CMD, CHCQM, FAAFP, FAIHQ, FAAHPM
Executive Director and Acting Medical Director

Executive Summary

The Hospital Patient Safety Report analyzes, both quantitatively and qualitatively, the 223 serious adverse events reported by Maryland hospitals to the Office of Health Care Quality in fiscal year 2013 (July 1, 2012 to June 30, 2013). This report compares FY13 with previous reporting years, both in types of events reported and in the outcomes of those events.

Key findings include:

- Hospitals submitted 223 reports of Level 1 adverse events in FY13, down from 286 reports in FY12.
- Hospitals with over 301 beds reported an average of 4 events each in FY13, down significantly from 6.4 events per hospital in FY12.
- Falls and pressure ulcers continue to make up the majority of the reports received, with 73 and 52 reports, respectively. These two types of events accounted for nearly two-thirds of all reports in FY13.
- Delays in treatment, after averaging 17 reports per year, increased significantly to 28 reports in FY13.
- Inpatient and outpatient attempted and completed suicides, after hitting a high of 16 in FY12, dropped to only 7 in FY13.
- Reports of airway misadventures, which previously averaged 8 reports per year, increased to 12 in FY13. Two-thirds of these reports came from mid-sized hospitals of 201-300 beds.
- Three hospitals were cited for failing to satisfy the RCA requirements of COMAR 10.07.06.06. Commonalities among submitted poor quality root cause analyses include: A focus on what happened, rather than why; lack of identified causality and defined root causes; and ineffective interventions aimed at the bedside with no monitoring to determine the outcomes of the interventions.

These key findings have informed the recommendations contained in this report. These recommendations include:

- Our largest hospitals should reevaluate their patient safety programs to ensure they are capturing and reporting all reportable adverse events.
- One way to decrease delays in treatment is to provide timely intervention, such as by supervisors who are actively engaged with assessing the well-being and the care being provided to all patients on the unit. Among other interventions, supervisors can activate the chain of command and facilitate timely assessments and definitive treatment.
- Hospital processes should be standardized as much as possible across similar care areas. For instance, the obstetrical operating suite should have the same policies for counting equipment as the general OR.
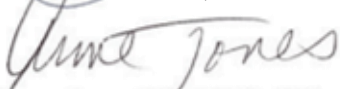
- Hospitals should consider requesting that anesthesia providers evaluate the airways of patients with known or suspected difficult airways upon admission, rather than waiting and being unprepared for emergency interventions.
- Assessments and updates of skills such as dysrhythmia identification must occur periodically, not just at the time of hire.
- Hospitals must proactively address the contributing factors that are common in medication errors, including communication failures, lack of effective medication reconciliation, dosage calculation failures, and complacency.
- Root cause analysis teams must pay more attention to the role of staff supervision (or the lack thereof) in the adverse events. Many adverse events could be averted with timely interventions.
- Hospital leaders should participate in the root cause analysis process to gain valuable insight into the challenges faced by patients and by front line staff. Leadership participation also lets the staff know that administration supports the root cause analysis process. Most adverse events require some analysis of latent issues that hospital leadership is in a better position to rectify.

As always, we are available for questions or comments.

Sincerely,

Renee B. Webster, Assistant Director

Anne Jones RN, BSN, MA, Nurse Surveyor II

Maryland Hospital Patient Safety Program Analysis

Fiscal year 2013 (July 1, 2012 to June 30, 2013) marked the ninth year of the Maryland Patient Safety Program. Hospital reports of Level 1 Adverse Events decreased in FY13, most notably in our largest hospitals, those with over 301 beds. Hospitals reported 286 Level 1 Adverse Events in FY12 and 223 events in FY13.

As in past years, this report includes several comparisons of the current year with previous reporting years. It remains difficult to quantify improvements in quality and safety, but the Office of Health Care Quality has identified improvement in individual hospitals, particularly in the rates of falls and pressure ulcers. Many hospitals continue to struggle with implementing effective, lasting interventions and with measuring outcomes, but this report includes some creative corrective actions and better practices.

While most hospitals have integrated the reporting and analysis requirements of COMAR 10.07.06 into their risk, adverse and sentinel event management programs, a few hospitals still struggle with identifying and critically reviewing adverse events. Further, many hospitals struggle to ensure that staff and leadership buy-in to making lasting changes following close calls or patient injuries.

MANDATORY REPORTING OF ADVERSE EVENTS

A Level 1 Adverse Event is defined in COMAR 10.07.06 as any event that causes death or serious disability.[1] Since the enactment of the Maryland Patient Safety Program regulations on March 15, 2004, through June 30, 2013, a total of 1993 Level 1 Adverse Events have been reported by Maryland hospitals. In comparing reporting rates for specific adverse event categories from FY13 to prior years:

- The percentage of delays in treatment increased significantly from 3% of total events in FY12 to 15% in FY13.
- The percentage of Level 1 events for maternal/neonatal deaths and injuries has again dropped, from a high in FY11 of 4% of total events to 2% in FY12 and now to 1.5% in FY13.
- The percentage of airway misadventures increased from 2.5% in FY12 to 6% in FY13.
- Falls and healthcare acquired pressure ulcers (HAPU) accounted for 64% of the Level 1 events reported in FY13. This percentage has remained stable for three years.
- Reported attempted suicides dropped significantly, from 6% in FY12 to 3.5% in FY13. Even better is that only two of the seven reported in FY13 were successful

---

[1] Serious disability is defined in COMAR 10.07.06.02B(11) as a physical or mental impairment that substantially limits one or more major life activities of an individual lasting more than seven days or is present at the time of discharge.

suicides. Both suicides occurred post-discharge. In FY12, successful suicides numbered 15 of the 16 reports received from hospitals.

Since March 15, 2004, a total of 440 events that did not meet the criteria for a reportable event[2] under COMAR 10.07.06 were reported by hospitals. Sixty-three of these non-Level 1 events were reported to the Department in FY13. Some of these were initially reported as Level 1 events but were downgraded after further review by the hospital or the Department. Additionally, many hospitals have also reported events that they are aware do not meet the criteria for mandatory reporting and are not Level 1 Adverse Events. These hospitals have reported these events because they realize that serious system problems caused the errors and could occur again with more significant consequences. Burns that occur in the OR do not usually cause Level 1 injuries but many hospitals report these events when they occur even if the injuries are minor. Retained foreign bodies that are removed within hours of surgery and wrong site procedures that do not harm patients are also reported by hospitals regardless of the presence of serious disability or death. Over the years, we have also received several reports of alleged sexual assaults occurring in hospitals. While most of these reports have turned out to be unfounded or not proved, it is better for all concerned if the Office of Health Care Quality is informed of these types of allegations by the hospitals, rather than the media. The OHCQ appreciates the willingness of hospitals to go beyond the letter of the law so we can track events that should never happen, even if there is no evidence of injury or if the injury is relatively minor.

CLASSIFICATION OF EVENTS

OHCQ's Patient Safety Program continues to classify the types of Level 1 Adverse Events in our database using the National Quality Forum's "Serious Reportable Events."[3] This is a nationally known classification of events used by several state reporting systems as their criteria for reporting. Since the National Quality Forum (NQF) system is nationally recognized, it enables the OHCQ to compare its data with other state reporting systems. Since the Maryland Patient Safety Program is focused on patient outcomes and the OHCQ does not define or limit the types of events reported by hospitals, we have supplemented the NQF list with other types of frequently reported events. These additional classifications include:

- death or serious disability related to the use of anticoagulants;
- death or serious disability related to the failure to maintain a patient's airway;
- death or serious disability as result of an unanticipated complication;
- death or serious disability related to a delay in treatment,
- death or serious disability related to a healthcare associated infection
- unanticipated fetal or neonatal death or injury; and
- misdiagnosis.

---

[2] Under COMAR 10.07.06. 02 B (4) the hospitals are required to report all events defined as Level 1 adverse events which result in death or a serious disability to the patient.
[3] National Quality Forum. "Serious Reportable Events in Healthcare—2006 Update." Washington DC: 2007

While there is likely some underreporting, especially of non-lethal events, as reflected in the wide variability seen in numbers of events reported by very similar hospitals, there is heightened awareness among the general public, other Maryland and Federal government payer organizations, and the hospitals about the importance of identifying and addressing safety issues. Several agencies now have mandatory reporting of quality and safety data, including infection rates and core measure data to the Maryland Health Care Commission. Additionally, the work of the Maryland Health Services Cost Review Commission in incorporating rates of Potentially Preventable Complications (PPC) and Potentially Preventable Readmissions into the hospital rate setting process almost certainly has resulted in additional quality review of patient care and potential adverse events.

Maryland hospitals are categorized as acute general, psychiatric, chronic, children's, and rehabilitation. Acute general hospitals account for 67% of all the licensed Maryland hospitals, and reported 90% of the Level 1 Adverse Events in FY13. Non-psychiatric specialty hospitals accounted for 7.5% of reports and psychiatric hospitals accounted for the remaining 2.5%. The number of reports from acute care hospitals is indicative of the acuity of patients served in these hospitals as well as the more invasive and complex services provided in acute care hospitals. The 20 hospitals with less than 100 beds reported 18 Level 1 Adverse Events in FY13. Half of the hospitals with less than 100 beds are specialty hospitals serving chronic, psychiatric, rehabilitation, or child populations and traditionally have a lower rate of reporting adverse events. During FY13, 49 of 63 hospitals reported at least one Level 1 Adverse Event. An overview of the types and sizes of hospitals licensed in Maryland is provided in Appendix A.

For the first time, reporting rates dropped over all hospital sizes except smaller hospitals with 101 to 200 beds. Table 1 identifies the average number of Level 1 Adverse Events reported per hospital.

Table 1: FY13 – Level 1 Adverse Events

FY13 Level 1 Adverse Events			
NUMBER OF LICENSED BEDS	**Number of hospitals**	**Average reports per hospital FY12**	**Average reports per hospital FY13**
301 or more beds	12	6.4	4.0
201 – 300 beds	18	6.2	5.5
101 – 200 beds	13	3.4	3.9
Less than 100 beds	20	1.1	0.9

We are not sure what accounts for this significant change from previous years. Considering their size and the complexity of services in the large acute general hospitals, it is difficult to reconcile that fewer events have occurred in these hospitals. One consideration is that three of the 12 largest hospitals are psychiatric hospitals, which historically report fewer adverse events due to the nature of the facilities.

A look at the types of reports submitted by mid-sized and larger hospitals may offer some clues. Hospitals with 101 to 200 beds reported:

- Four of 11 retained foreign bodies
- One of the attempted suicides
- Twenty percent of the healthcare associated pressure ulcers (HAPUs)
- Twenty percent of falls
- One of the 12 medication errors
- One of the two neonatal injuries
- Sixteen percent of the airway events
- Twenty percent of the delays in treatment

If we compare the above list with events reported by hospitals with 201 to 300 beds, we find:

- Three of the seven reported suicide attempts
- Two retentions of foreign bodies (RFBs)
- One third of the delays in treatment
- Forty-one percent of the falls
- One third of medication errors
- One half of all airway misadventures
- Two thirds of HAPU
- One half of reported healthcare associated infections (HAIs)

Reports for hospitals with over 300 beds included:

- Fifty percent of medication errors
- Three RFBs
- Eight percent of HAPUs
- One third of the delays in treatment and the airway misadventures
- Twenty-five percent of the falls

The range of number of reports from all hospitals with over 100 beds is from one to 12 events. No hospital reported more than 12 events. We are not sure what it means that midsized hospitals reported one half of all airway events and two thirds of all pressure ulcers. Both types of events will be discussed later in this document.

Table two shows the numbers of events reported for the past three fiscal years. For FY13, reports of injurious delays in treatment, airway misadventures, and HAIs increased, while reports of maternal-child injuries associated with the birth process, OR events, falls, and pressure ulcers decreased.

Table 2: Types of Events Reported
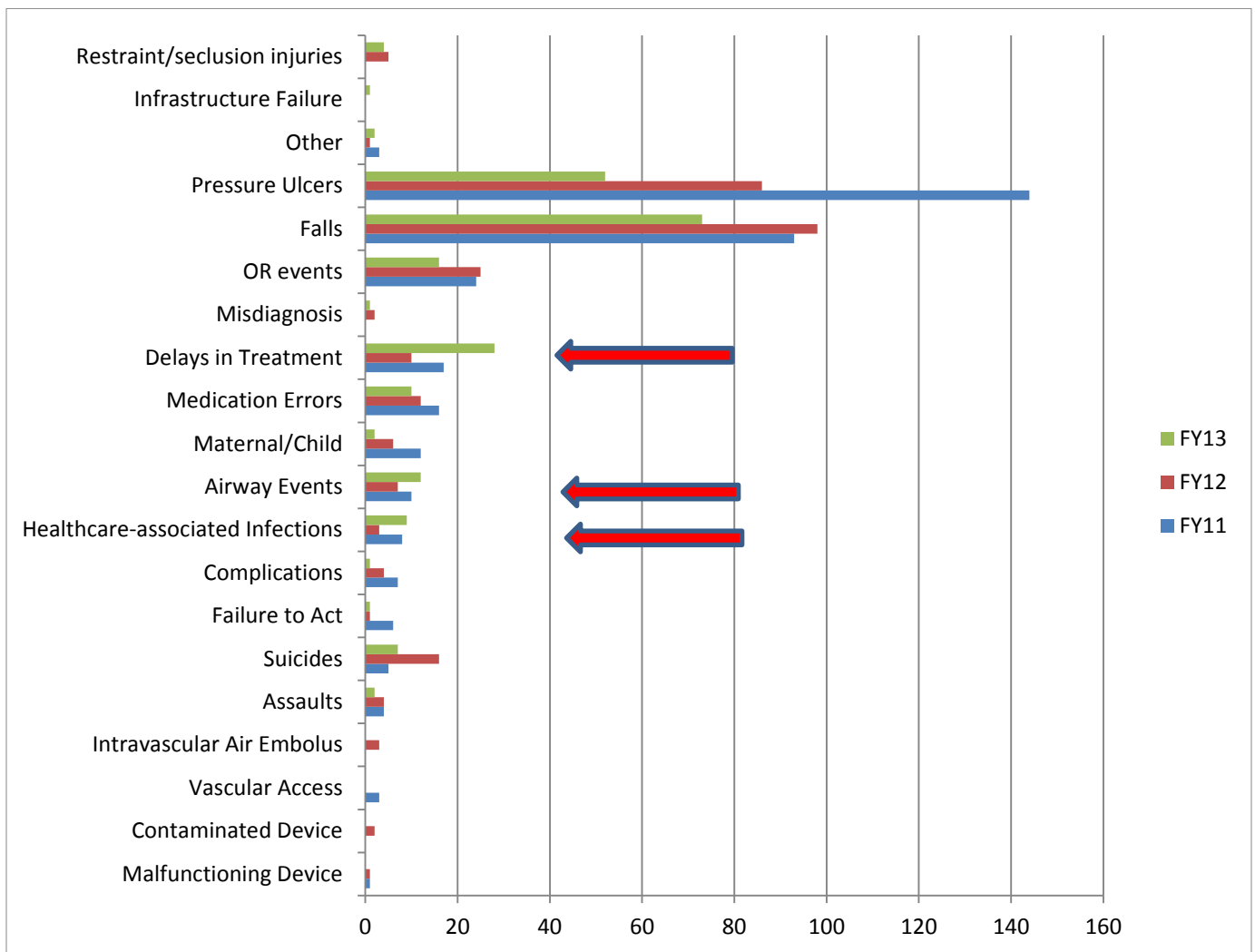
Reporting Adverse Events

COMAR 10.07.06, Patient Safety Programs, mandates reporting adverse events within five days after the hospital becomes aware of the event. When reporting events, the following information should be provided:

- Patient's age or date of birth
- Date of admission

- Date of event
- Type of event (fall, medication error, etc.)
- Type of injury (death, fractured hip, etc.)
- Anticipated outcome for the patient (surgery, loss of limb, anoxic injury, etc.), and
- If disclosure was made to the patient and/or family.

Event Details

INFORMATION TECHNOLOGY MEDIATED ADVERSE EVENTS

As electronic medical record (EMR) use continues to increase, hospitals are finding that some features of EMRs unintentionally contribute to patient harm. For FY13, the Office of Health Care Quality received numerous reports of adverse events in which IT system omissions or glitches contributed to adverse events.

Many of the reports received in FY13 indicating an EMR contribution to the event were falls, probably because falls are our most reported event type. For instance:

One hospital using an electronic "Ticket to Ride" hand-off tool did not realize that the tool automatically defaulted to low fall risk, until a patient suffered a serious fall in the radiology department. They also had no practice whereby the patient's nurse double checks the information on the "Ticket to Ride" prior to handing off the patient.

Several hospitals found that their electronic fall risk assessments did not define the elements being scored and did not connect interventions to the risk score. In one hospital, installation of an unrelated patch led to the automatic re-install of a previous version of the fall risk assessment tool that overwrote the more thorough current version. Unfortunately, it took a patient injury before this problem was discovered.

Maryland hospitals have found that their critical values screens and policies do not include radiology or cardiac diagnostic findings, so designing the EMR to flag these results was not seen as important. The inability to access pending tests or results has led to delays in treatment, inappropriate discharges, and futile surgeries. For instance: One patient had a carotid ultrasound done but was discharged without anyone looking at the results. The EMR did not flag the test results as critical, even though the patient showed a greater than 90 percent blockage on one side. The patient died a week later after suffering a massive cerebrovascular accident (CVA, or stroke).

In another event, a patient who had not seen a doctor for decades, and was taking no medications, arrested and died unexpectedly during elective surgery. He had had a cardiac work-up before surgery which showed a severely compromised heart muscle. No one accessed the results of testing before taking the patient to surgery. The anesthesiologist was unaware that the tests had been done, and the surgeon was so sure the patient was not compromised that she did not look at the results prior to surgery. The surgeon also assumed that cardiology testing would

notify her if the results were abnormal, even though non-lab diagnostic tests were not on this hospital's list of critical values.

Unintended automatic changes to orders in the EMRs have also lead to bad outcomes. One patient suffered a fatal aspiration under the following circumstances: The speech-language pathologist recommended a pureed diet after the patient failed a swallowing evaluation. Two days later, a nurse noted that the patient should be on a calorie-controlled diet and obtained a new order. Entering the new order for calorie controlled overrode the existing pureed order and the patient aspirated while eating a regular consistency meal. Hospitals should examine their EMR to determine if the EMR differentiates between the content and consistency of diets in diet orders, or if a change in content triggers an unwanted change in consistency.

Another IT-related problem included a premature infant who developed a sight-limiting eye infection in the neonatal intensive care unit of one hospital. One of the contributing factors was that the EMR contained no place to document, or prompt for, routine eye assessments and care.

An EMR-related issue contributed to a patient in the emergency department (ED) suffering a severe medication error when the physician wrote the medication order on the wrong patient's EMR. The EMR in use in this ED allowed for multiple patient records to be open at one time. The physician had not double checked which patient's record was uppermost at the moment she wrote the order.

Clearly, staff should ensure that they are as accurate as possible when using the EMR, or any medical record format. However, they should not have to worry about being set up for a medical error by an electronic system that makes it harder to do the right thing. In all of these events, the EMRs functioned exactly as programmed, it just wasn't good enough. Medical personnel are used to employing work-arounds to compensate for less than perfect working conditions, but it would seem that work-arounds should not be necessary in an electronic system that is presumably designed for the use of distracted and multi-tasking clinicians in complex medical environments. Based on these incidents, hospitals should examine their electronic systems to determine if:

- Lab and diagnostic systems send an automatic prompt to the ordering physician when the results are entered into the EMR;
- Before posting, discharge summaries flag pending results and the current medication list;
- Risk assessments are tied to recommended interventions; and
- Each section of the EMR is hot-linked to the appropriate policy on the hospital's intranet. For instance, the page on which the initial skin assessment is entered links to the hospital's policy for pressure ulcer prevention.

Further, if a system allows for more than one patient's record to be opened at a time, the hospital should determine if it is readily apparent which patient's record is being accessed.

Because of the large sums of money spent on electronic systems, hospitals, especially our larger systems, are in a position to demand functionality from manufacturers and programmers that make sense for safe care.

DELAYS IN TREATMENT

The OHCQ defines delays in treatment as untimely assessments of evolving symptoms or changes in a patient's condition, and/or a delay in definitive treatment. Delays in treatment, perhaps more than other types of adverse events, involve a cascade of poor decisions made by multiple caregivers. Ineffective communication, erroneous role assumptions, knowledge deficits, complacency, inexperience, and passive supervision all contribute to the serious delays in treatment reported to this office. Nearly every delay in treatment occurs because one or more caregivers failed to understand the seriousness of the patient's symptoms. If the bedside nurse does not understand the significance of post-operative bleeding, for example, he will not understand how the patient's rapid heart rate might signal a dangerous change in condition. Since he can't correlate the patient's symptoms, he will not know what other assessments to make, and any communication about the patient's condition to the physician will be ineffective and likely to focus on a less serious symptom. If you couple the nurse's knowledge deficit, usually based on inexperience, with a hospitalist or physician assistant who do not know the patient and are likely feeling pulled in six directions at once, along with a nursing charge nurse or supervisor who thinks no news is good news, on the night shift, you have a recipe for a disastrous outcome.

There were 28 Level 1 delays in treatment reported in FY13 with 24 fatalities – more than 10% of all the events reported in FY13. This number is quite an increase from the ten serious delays in treatment reported in FY12 and the highest number reported for any year since mandatory adverse event reporting began in 2004. Fully half of the reported events involved failing to respond timely to physiologic monitor alarms. Five of the reports related to failing to act upon critical values and the rest were divided between delays in taking patients to the OR, delays in transferring sick patients to the intensive care unit (ICU), failing to monitor ICU patients when they are off the unit for testing, and delays in treatment occurring to ED patients. The bad outcomes having to do with delayed transfers were delays in decision making—not delays in logistics.

Complacency and alarm fatigue are the primary causative factors for delays in responding to alarms. Alarm fatigue has been studied extensively in the patient safety literature and occurs when there are too many competing alarms, when serious alarms sound so similar to alarms signifying non-critical conditions, and when there are multiple false alarms, among other reasons. In fact, ECRI named alarm management the top technological hazard for 2013[4] and alarm management is a Joint Commission National Patient Safety Goal for 2014,[5] after having retired this goal in 2005. However, we have noticed that, along with alarm fatigue, complacency with many common practices and policies surrounding setting alarm parameters, using phones

---

[4] www.ecri.org/2013hazards

[5] Report 1 Requirement, Rationale, Reference Issue 5, December 11, 2013 Page 2 www.jointcommission.org

and beepers to notify nurses of alarms, and remote telemetry monitoring also feature significantly in Maryland-reported alarm events. Many of monitor-related delays occur at change of shift. The nurses about to leave have given up their phones and beepers but the oncoming nurses have not picked them up yet. Several hospitals change out all the batteries and reset the phones during change of shift. This practice leaves a period of time during which the telemetry or remote monitor technician may not be able to contact anyone on the unit if a patient develops a life-threatening dysrhythmia. Complacency arises when this type of flawed process works for a while with no adverse outcomes. The telemetry tech calls the unit clerk, who notifies the charge nurse, who responds to the patient. Eventually it happens that the unit clerk is new and does not understand the significance of the phone call from the telemetry tech, or the clerk gets six phone calls at once, the charge nurse is not available or is likewise distracted, and the patient suffers a preventable adverse event. Unfortunately, the inherent dangerousness of the ingrained process does not become apparent until a patient suffers a bad outcome.

Additionally, hospitals have reported a lack of accountability, both in individual clinicians as well as in hospital systems that do not hold people accountable for following policies and reporting and responding to monitor alarms. All of the reported monitor events involved misunderstanding the importance of abnormal monitor rhythms and/or downgrading the importance of abnormal monitor rhythms based on assumptions made about the patient, for instance, assuming that the patient is well, based on an assessment made minutes to hours prior to the alarm.

Some examples of delays in responding to monitor alarms include: A patient died in the ICU while his assigned nurse, who had been contracted to work several weeks in the ICU, was on break. The nurse had reported off to another nurse, who got busy and was too far away to see the patient or hear the alarms. Because the patient had a pacemaker, and the alarm parameters had not been set to compensate for the pacemaker rhythm, no alarms sounded when he lost his native heart rate, nor did the remote monitoring tech notice. The covering nurse was too far away to hear the pulse oximetry alarm, which could only be heard in the room. During the root cause analysis (RCA), the hospital determined that, among other problems, an old hospital policy forbid contracted nurses from carrying an alarm beeper and that had been the practice on this unit for years with no one recognizing the inherent danger in this policy.

In another event, a telemetry tech called a nurse on the telemetry unit and said that her patient was alarming "leads off." The nurse was short-tempered with the tech and replied that she had just been in the room and the patient was fine. The patient continued to alarm "leads off," and after another 20 minutes. The tech then called the nurse back to say that the patient was now alarming "low battery." When the nurse arrived in the room with the new batteries, she found the patient cold and pulseless. A review of the monitor history showed that the patient had a progressively slower heart rate over ten minutes culminating in no heart rate for 30 minutes before the nurse responded to the room. The RCA determined that the culture of this unit was such that the techs were afraid to call the nurses because they felt the nurses were rude to them, the techs were not empowered to call codes based on the rhythms they see on the monitors, and there was little to no accountability among the nurses for answering alarms in a timely manner.

A patient with a newly diagnosed degenerative musculoskeletal disease was transferred to a telemetry unit when she started deteriorating after a week on a medical unit during which she had no nutrition due to her inability to swallow. Her peripheral IV had come out and the nurse on the night shift could not restart it, although she did not try to get any help to get it restarted. The patient demonstrated a very low blood pressure yet there was no urgency in restarting her IV and the nurse was afraid of calling the attending at night. The nurse went on break and did not hand-off her patients to another nurse. During this time, the patient started alarming "leads off." This lasted for over an hour before anyone responded and by that time, it was too late to resuscitate her. The RCA stated that the hospital planned on putting a visual alarm system in the hallway of the unit. This corrective action was good, but it did not address all of the other problems with this patient's care, such as accountability, supervision, communication, hand-offs, and either a possible disruptive physician or a non-assertive nurse.

Another patient on a telemetry unit also died after a prolonged "leads off" alarm. On this unit, the RNs were so dependent on the telemetry techs alerting them to problems that they had gotten out of the habit of checking the monitors for their own patients. The RCA also found that the RNs were assessed for rhythm recognition competence only during orientation. They had no annual or periodic updates or competence assessments with which the nursing staff could maintain their skills.

ECRI, in their publication about the top technological hazards of 2013, offers some concrete steps to reduce adverse alarm events:[6]

- Evaluate how alarms (including alarm management technologies that collect and forward alarms to clinicians) are used in your facility.
- Assess the configuration of the system and the full complement of equipment in use, including physiologic monitors, bed alarms, nurse-call systems, infusion pumps, and ventilators. Evaluate the parameters monitored by each device.
- Evaluate staffing patterns, patient characteristics, and care models of each unit using alarmed devices.
- How are alarms managed by the medical device itself? What parameters are monitored? Is the priority level of each alarm unambiguous? Can the devices be configured for individual patient needs?
- Does the alarm management system in use forward all alarms to the clinician or does the device allow filters so that only the high priority (as determined by pre-set protocols) alarms are sent? Does the device (phone, beeper, etc.) receiving the alarm display with sufficient clarity to allow the receiving clinician to determine the severity?
- Evaluate how alarms are tracked throughout the system. Are logs available that track who is alarming, for what reason, and for how long? Does the log indicate what alarm was sent to the clinician's handheld device and when the alarm was acknowledged?

---

[6] www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx

- For each area which uses monitors, assess the overall alarm load, the configuration of the equipment, and whether the physical layout of the unit helps or hinders the staff's ability to see and hear alarms.
- Assess policies and procedures for the following: Protocols should define the default settings for each unit, including which alarms are to be used and which are priority alarms. Protocols should include criteria to guide clinicians in how and when to set patient-specific parameters that differ from the defaults, and should define who is primarily and secondarily responsible for responding to alarms. Protocols should also address the hand off and configuration of the individually assigned phones or beepers. ECRI recommends that alarm silencing, modification, and disabling should be strongly password protected and restricted to a few key supervisory staff.

Of course, after performing all of these assessments, we recommend fixing them as much as possible. The truly critical alarms should be visibly and audibly different from all other alarms. According to the adverse event reports, it is most often the "Leads Off" alarm that is problematic. Monitoring equipment should be set up and used in ways that minimize so-called nuisance alarms. Obviously, staff must be trained on all of the functionality of the monitoring systems so they know how to read the monitor and understand the difference between alarms. Monitoring systems should employ redundant notification processes for critical alarms, such as a visual cue in the hall and at the nurse's station as well as an audible alarm in the room and in the hall. The system should provide that calls from the remote monitor techs about critical alarms automatically go to the charge nurse as well as the patient's nurse.

As noted, failure to understand the seriousness of a patient's changing condition is evident in nearly all delays in treatment. For instance: An elderly patient with very poor circulation and cardiac status had a repeat surgery to try to restore circulation to his legs. He complained of chest pain and had a dangerously irregular rhythm while in the recovery room so he was admitted to a telemetry unit on an anticoagulant and nitroglycerin for the chest pain. Nitroglycerin relaxes the blood vessels and allows the heart muscle to work easier. The patient had massive bleeding from his leg incision overnight. The nurse failed to recognize that the bleeding was a significant finding, which, even in a healthy person should have been addressed, but was really dangerous for this patient's already stressed heart. The surgeon had ordered routine lab work, which meant the patient's blood counts and coagulation status were not checked until around 7 AM. The nurse did not notify the surgeon of the change in the patient's condition until after the blood was drawn. The patient arrested and died before the blood work results were available.

A young post-operative appendectomy patient suffered a fatal delay in treatment when his persistent low blood pressure was treated for more than 24 hours with fluid boluses. For 12 of those hours, he was managed overnight by a nurse who was texting the patient's vital signs to the physician assistant, who ordered fluid boluses but did not examine the patient. The patient finally deteriorated enough to be taken back to surgery on day two, where it was found that he had a non-survivable compromise to the circulation to his entire bowel. There was an unmet obligation of the physician assistant to examine a post-operative patient with unstable vital signs or call the

surgeon. Hospitals should determine whether texted orders are covered by hospital policy. It is important to know if texting identifiable patient information happens in your hospital and if the hospital's HIPAA policy is current with regards to the latest electronic communication devices. Hospital may also need to consider if there is a HIPAA-compliant means to transmit photos such as the pictures of the amount of post-operative bleeding.

Another patient suffered a fatal cardiac arrest in the radiology department when she was sent from the ICU with no monitor or nurse in attendance. She had had very labile vital signs for two days yet the nurse caring for her got an order from the physician to send the patient in a wheelchair with no clinical support or monitor. The radiology department was not told that the patient was quite sick and so the radiology technician left the patient alone for a few minutes while setting up the room. When she went to retrieve the patient, she found the patient pulseless and non-responsive. A code was called but the patient did not survive. There was no reason the diagnostic test ordered for the patient could not have been done at the bedside in the ICU. The RCA team found that ancillary testing departments like radiology, ultrasound, vascular studies, etc. had not defined which tests could be done at the bedside and which had to be done in the department and the choice was left up to the ordering physician. As part of the hospital's corrective actions, the ancillary testing departments created a list of tests that <u>had</u> to be done in the department, and posted this list in patient care areas. The list of test that had to done in the departments was much shorter than the list of tests that can be done at the bedside.

Among the delays occurring in hospital EDs, an elderly patient with dementia was brought to the ED with gastrointestinal bleeding. His hemoglobin and hematocrit were dangerously low at 6/24 (normal hemoglobin for males is 13-17 and normal hematocrit is 41-53). The staff exhibited no urgency in getting consent to administer blood from a family member and ten hours elapsed before two physicians filled out an incapacity statement (stating that the patient was not competent to grant consent for blood and the administration of blood was an emergency) and blood was ordered. The patient's hemoglobin and hematocrit were 5.2 and 17 at that time. The patient arrested just as the first unit of blood was started and could not be resuscitated. This patient was essentially ignored to death. The patient's nurse failed to activate the chain of command and the ED charge nurse did not assist in facilitating the appropriate care.

In another ED event, a disabled child was brought to the ED by his parents with nausea and vomiting. The child was triaged and sent back to the lobby. The physician in triage wrote orders, which were not carried out because the patient was not physically in a bed. After three hours in the waiting room, the child started vomiting massive amounts of fecal matter and died shortly after getting to a bed in the main ED. Because of his disabilities, this child should have had a higher triage priority and there should have been some way to start the diagnostic process regardless of his physical location.

One patient died in the ED during the fourth hour of a delay in going to the OR to repair a subdural hematoma (a bleed inside the skull). The hospital had several archaic policies that led to the delay. The neurosurgeon had to call the general surgeon to ask if his emergency case could bump the previously scheduled elective case. Since there was no urgency on the part of the OR

staff, it took a couple hours to gather the equipment for the case. The neurosurgeon kept calling the clerical staff instead of the charge nurse. Consequently, this emergency evacuation of the hematoma was not even posted on the schedule for four hours. The patient's neurological status had deteriorated so much during that time that surgery was no longer viable. It could not be determined why the charge nurses of the ED and the OR were not involved and did not facilitate the patient's immediate transfer to the OR. These issues were not addressed in the RCA.

Some delays in treatment start in the ED and follow the patient. One patient presented to the ED with signs of an acute cerebrovascular accident (CVA, or stroke). Since she could not swallow, she did not get any of the oral medications ordered by the ED physician assistant but no one told the physician assistant that the patient had not gotten the medications and the patient was not seen by a physician while in the ED. When the patient was transferred to the medical floor, the ED neglected to include her stroke score (a measurement of the severity of the CVA) so when the floor nurse did the evaluation and the score was two times the score in the ED, he had no way of knowing that was a critical piece of information. Because of a name mix up, the patient was assigned to the wrong physician, so when the nurse called the physician in the middle of the night, he refused to come see the patient. The on-call specialist was in surgery at another hospital and could not see the patient until the morning, by which time it was too late. This hospital had an agreement with a regional referral center to accept stroke patients but no one caring for this patient knew that.

There are many steps that hospitals can take to compensate for deficits in experience and critical thinking among the bedside staff. As has been mentioned in prior reports, supervisory processes must become more active. In all of the above delays in treatment, the timely intervention by a more experienced and assertive clinician would likely have changed the outcome. Very few of the RCAs submitted for these events, or really for any event type, mention the charge nurse or supervisor. It is apparent that while patients are being mismanaged, sometimes for hours, the charge nurse or the supervisor was not involved. It is unlikely that the supervisors in an organization are so ineffectual that no one thinks to involve them in complex care situations. While it sometimes seems so to those of us that review the reported events and RCAs, these adverse events are not occurring in deserted hospitals. If the bedside nurse is not reaching out to the charge nurse, the charge nurse has a duty to look for ways to intervene. He or she has a responsibility to make rounds on each patient during the shift to identify problems early. A hospital's charge nurses should be aware of those staff members that may need some extra help in sorting out a change in their patient's symptoms and must oversee the care provided by float nurses and agency or contracted nurses. When performing an RCA, hospitals should review these supervisory issues. Questions regarding why charge nurses are not more proactive should be asked and examined in every RCA.

Many, if not most, of our hospitals have implemented some sort of rapid response team (RRT) to quickly evaluate and intervene in situations where the patient's symptoms indicate a need for a higher level of care. However, RRTs are only effective if someone actually calls them. That action takes a recognition that the patient is in trouble. Charge nurses, supervisory personnel, and more experienced peers are the first line of assistance, but they have to look for

those situations when assistance is needed, even if the bedside nurse does not recognize the need to ask for assistance.

For instance, a patient was admitted to a telemetry unit from the ED with stroke symptoms. His nurse that night was a float nurse from a medical unit. During the night, the patient started complaining of a severe headache, showed facial drooping, and vomited several times. The nurse did not deviate from the every-four-hours vital signs and assessment schedule in use on the medical unit, but she was not cognizant of the meaning and seriousness of the headache and facial drooping symptoms. When the nurse called the physician assistant in the middle of the night, she only reported the vomiting. Since the physician assistant did not know the patient, she ordered an antiemetic. It was not until the attending physician saw the patient during the day that a repeat head MRI was done, which showed a large extension of the stroke with corresponding brain damage. The patient did not survive, and again there was no indication that the charge nurse was involved in the patient's care. He or she knew this nurse came from a unit with a lower level of acuity, yet assigned a new patient with an evolving cerebral vascular accident (CVA) to the float nurse, then failed to provide sufficient guidance and timely intervention. In the FY12 Annual Report, we noted that one hospital had created short pamphlets about each unit with the general type of patient diagnosis found on the unit along with the expectations for assessments and care. The pamphlets were to be given to float or agency nurses who were not familiar with the unit. Having that type of information may have helped this patient because at least the nurse would have known what was expected in terms of assessments, and she may have been better informed about the kind of symptoms to watch for in that patient population.

In regards to the medical staff, hospitalists and physician assistants that cover for attending physicians, especially at night, must be confident that they can get the help they need. This report and previous annual reports have cited multiple incidents where events or close calls were associated with the failure of a mid-level provider to go up the chain of command. The culture in a hospital's organization should not put subtle pressure on the physician assistants (by over-reliance) to overstep the bounds of their supervisory agreements. Physicians who are less likely to be cooperative with middle-of-the-night phone calls from hospitalists, mid-level providers, or nurses, may contribute to this over-reliance. When a hospital becomes aware of these issues, the medical staff leadership must address these problems directly with the physicians involved under the hospital's disruptive physician policy. The chain of command is intended to address these difficult care issues and staff should know when and how to access supervisory staff.

AIRWAY EVENTS

The number of adverse events associated with failing to establish and maintain a patent airway increased from an average of eight per year to 12 reports in FY13. There were three types of patient outcomes from the airway events—death (9/12), permanent anoxic brain injury (2/12), and one prolonged hospitalization following an emergency tracheostomy. Two patients aspirated, seven patients who were known to have difficult airways died during code situations, and there

were three events reported in which a delay in intubation created an emergency situation during which the patients could not be intubated.

One patient who aspirated and died was the aforementioned patient whose new order for a calorie controlled diet overwrote the previous order for pureed consistency. The other aspiration patient was given a gallon of liquid contrast medium through a feeding tube prior to an abdominal CT. His tube feedings had not been stopped and he had also received a dose of pain medication just prior to the test. He was initially restless, then settled down and the test was completed. When the patient was brought out of the scanner, he was pulseless and not breathing. During the code, copious amounts of tube feeding and liquid contrast were suctioned from the patient's airway. He did not survive.

Three of the patients with known difficult airways were individuals with intellectual disabilities. These patients also had other anatomic anomalies such as cleft palate that made oral intubation impossible. However, airway difficulties should have been anticipated in these patients. Hospitals should consider establishing a process whereby patients with obvious or suspected facial or airway anomalies are evaluated by anesthesia or an ear, nose, and throat physician upon admission, so that provisions can be made, and their medical records flagged, in the event of a problem. One of these patients received a dose of sedation on an inpatient psychiatric unit and suddenly stopped breathing. No assessment of his airway or oral anomalies had been made, and the psychiatric unit was not equipped with a difficult airway kit. An airway assessment could become part of the other anticipatory risk assessments done on admission, such as nutrition, pressure ulcers, and falls.

Two patients with difficult airways extubated themselves and could not be reintubated. Both patients had tracheostomy set-ups and difficult airway kits at the bedside but neither was used in one of the self-extubations, and the available equipment was the wrong size for the other patient, who was an adult with a child-sized airway.

Two of the patients who died during code situations when the available staff could not establish an airway had had pre-existing tracheotomies. In both cases, the responders to the code were unaware of this fact and attempted multiple times to orally intubate these patients before becoming aware of the existence of the stoma. One of the RCAs found that resuscitation efforts in the hospital were led by residents and medical students who were not adept at crowd control, creating a scene that was too noisy and chaotic for effective communication.

Among the delays in intubation were two patients who presented to EDs with oral swelling from medication reactions. One patient waited one and a half hours to be evaluated by an anesthesiologist, who did not feel the patient needed to be intubated. The patient continued to deteriorate for another hour before she was seen by an ear, nose, and throat (ENT) physician. By this time, her airway was severely compromised and she could not be intubated orally. An emergency tracheostomy was then done, which resulted in collapsed lungs, insertion of two chest tubes and a prolonged stay in the ICU. Again, the ED charge nurse was not involved while this patient deteriorated to the point that she needed emergency surgical intervention.

Another patient came to the hospital with an airway compromised by a very large goiter (an enlarged thyroid gland). He was started on Lovenox (an anticoagulant) because he was suspected of having a blood clot in his lung, although testing was negative. After two days on the anticoagulant, he was taken to surgery for removal of his thyroid. That night, while on a telemetry unit, he started complaining of throat tightness. He was seen by the physician assistant who ordered pain medication. An hour later, the patient again complained of a choking feeling and tightness in his throat. The physician assistant ordered a CT of the neck. The patient was taken for the CT with no monitor other than telemetry, and laid flat for the test. This patient was also initially very restless during the CT but was very lethargic by the end of the test. The transporter noticed the patient was not breathing while in the elevator going back to the floor. The patient was initially resuscitated but had suffered a profound anoxic brain injury and was taken off life support several days later at his family's request. The RCA determined that the physician assistant and the nurses were leery about calling the surgeon in the middle of the night because they "knew" he would be mad and would just say that the patient was feeling the bandage around his neck, not really airway compromise. Like many hospitals, this hospital relies on physician assistants to cover the hospital at night. Physician assistants are not licensed independent practitioners; they work under a supervisory agreement with a physician who must be readily available for consultation and assistance. The physician assistants should be the start of the chain of command, not the end. Based on the RCA it appears the physician assistant and the nurse were the only two people on this unit that night. There was no evidence that the hospital considered the fact that someone with more experience could have been contacted to intervene.

SURGICAL EVENTS

Eleven Level 1 events reported in FY13 were associated with the post-surgical retention of foreign bodies (RFB), along with seven RFBs that caused Level 2 injuries that required intervention but did not cause serious disability. Eighteen RFBs is too many considering the attention given to this problem over the past decade. Most of the reported events coincide with the literature about RFBs in that they occurred during emergency abdominal procedures, or during complex abdominal procedures with multiple personnel changes. Maryland hospitals have reported two cases of guide wires left behind after cardiac catheterizations. One patient had a retained sponge following a Cesarean section delivery that resulted in an abscessed ovary several months later. The hospital's RCA found that none of the packs of sponges used in the Labor and Delivery ORs had radiopaque tags, and they were packaged in a different quantity than the main OR.

One hospital reported a RFB from the use of a new piece of equipment. Most of the staff that were to use this piece of equipment were not trained on its use, and since it was for a trial use, did not contain directions. The piece of equipment that was being trialed, a temperature probe used during cardiac procedures, looked sufficiently similar to the old temperature probes that it was inserted in the same way, resulting in the retention of a plastic stiffener in the patient's esophagus. Since the stiffener was never meant to be inserted into a patient, it was not

radiopaque and did not show up on x-rays. The patient was discharged, and spent the next two months trying to find the source of his gastric distress. The RFB was finally found and removed during an upper gastrointestinal endoscopic procedure.

In FY12, the Office of Health Care Quality noted a trend in reports of retained objects inserted into the vagina to preserve pneumoperitoneum during laparoscopic procedures. In abdominal and pelvic laparoscopic surgery, an inert gas, usually CO_2, is insufflated into the abdominal cavity to increase the surgeon's work space and visibility. During gynecological procedures in particular, the gas must be blocked from escaping prematurely through the vagina. The choice of object with which to accomplish this seems to be an individual decision on the part of the surgeon; one reported event involved an inflated surgical glove wrapped in a towel; other items used include the bulbs from the end of syringes. Since these objects are not counted as instruments, there is no double check to ensure they have been removed. These types of RFBs have been reported to cause infections, discomfort, and difficulty urinating and, according to the COMAR, are Level 2 events, which require the hospital to perform a RCA, but the hospital is not required to submit the RCA to the office. Regardless of the level of these events, these events are serious and system changes should be implemented to prevent their recurrence. Six of the seven Level 2 RFBs were devices retained in the vaginal vault.

The number of reports of wrong side surgeries, wrong patient surgeries, and wrong procedures dropped significantly in FY13 to one each. One hospital reported surgery on the wrong finger, because the finger was marked on the dorsal surface, and then turned over for surgery. The incorrect kidney was removed in another patient who had had a previous stent placed in one kidney. The nephrectomy was performed by different surgeon based on unclear documentation, and no imaging was asked for or available during surgery. Another hospital performed a circumcision on an infant whose parent had not consented.

MEDICATION ERRORS

In FY13, the Department received 12 reports of medication errors leading to death or serious disability including one each untreated hypoglycemia and anticoagulation events. This is consistent with reports of 12 Level 1 medication errors received in FY12. There were six deaths associated with the reported medication errors. Four of the events involved over-sedation of patients; one from the order entered on the incorrect medical record, one a patient who was a long-term narcotic user for back pain who demanded narcotics and was given a rather hefty dose of Dilaudid (a narcotic pain reliever) prior to a MRI, a terminally ill patient who had a morphine IV (a narcotic pain reliever) hung by a nurse who thought the concentration was 1:1 (1 mg of morphine to 1 ml of IV fluid) when the concentration was actually 10:1, and the fourth patient who was given too much sedation during a procedure done at the bedside in the ICU.

An oncology patient got five times the dose of chemotherapy she should have had after her physician entered the incorrect order and it was dispensed by the pharmacist and delivered via IV by the RN without any sort of double check on the dose.

One child who was on a complicated circulatory support regimen died after a temporary pharmacist unfamiliar with the regimen used the wrong concentration of an anticoagulant to draw up bolus doses to be given. The child received 10 times the dose of anticoagulant she needed.

A patient died in an ICU of untreated hypoglycemia when she was assigned to a nurse who felt her assignment was too heavy and did not assess or treat the patient. The patient had been transferred into the ICU because her glucose dropped precipitously on a medical floor. When the RN tried to refuse the assignment, the charge nurse did not know what to do and did not call anyone else who could have provided guidance. The RN finally accepted the assignment but then did nothing for the patient until she arrested with undetectable blood glucose.

Two patients suffered medication errors in the ED. One patient was adamant that she was having an allergic reaction and demanded epinephrine. In an effort to placate the patient, even though she had no symptoms of an allergic reaction, the physician ordered a sub-therapeutic dose of epinephrine to be injected just below the skin. Even though this was not an emergency situation, the order was verbal, thus not entered into the chart. The ED RN, who was unfamiliar with epinephrine and did not consider it a high alert medication, drew up a larger than normal, (and larger than ordered) dose from a multidose vial of epinephrine and injected it directly into the patient's vein through her IV. The patient immediately went into acute pulmonary edema (fluid flooded into her lungs) and then had an acute myocardial infarction (heart attack). She eventually recovered. The pharmacy immediately removed all the multi-dose vials of epinephrine from the ED.

CAUSATION

Table 3: Causative Factors for Four Event Types
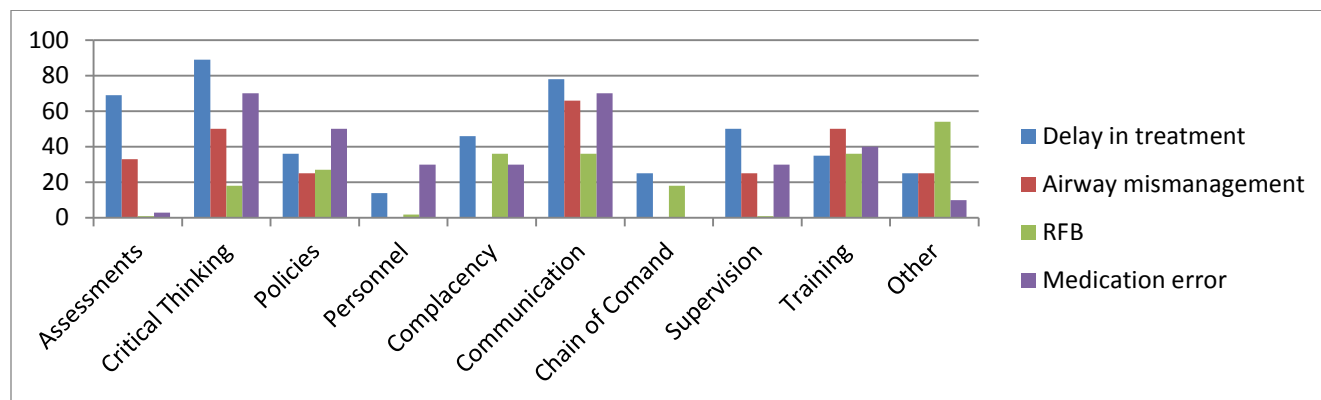
As discussed, critical thinking is the prime causative factor in delays in treatment, followed closely by assessments, communication and supervision. While training is noted as a causative factor in nearly all RCAs, and is the most popular corrective action, it is difficult to see how retraining skilled professionals will prevent similar events from happening. Many of the reported delays, medication errors, and RFBs were ultimately failures of basic, generic, hospital

procedures such as hand-offs, on-call systems, supervision, role delineation, and personal accountability. Many of the airway events shared these causative factors but also had a technical component.

HEALTHCARE ASSOCIATED INFECTIONS

After several years of only receiving two or three reports of healthcare associated infections (HAIs) per year, nine HAIs were reported in FY13. Since COMAR 10.07.06, Patient Safety Programs, requires reporting of HAIs only when the patient is seriously injured or dies, the majority of the received reports are those in which it is fairly clear that the HAI was the cause of death or disability. Maryland hospitals continue to work very hard to eliminate central-line associated blood-stream infections (CLABSIs), ventilator-associated pneumonias (VAP), and catheter-associated urinary tract infections (CAUTI). We have seen rates for these types of infections drop to zero or near zero in many hospitals. Unfortunately, other opportunistic infections crop up in hospitalized patients. Several of the reports received in FY13 involved Clostridium difficile (C. diff) infections. C. diff occurs when the normal flora in the intestinal tract is wiped out, usually by antibiotics. C. diff causes severe diarrhea and is very difficult to get rid of in a hospital environment, requiring patient isolation and special cleaning procedures for rooms and equipment.

Five of the nine reported HAIs were fatal and include three infants born prematurely who died of CLABSIs; another patient died of C. diff infection, and the fifth patient died from sepsis associated with a peripheral IV that had been inserted in the ED, then went unnoticed for five days, until the patient developed a vein inflammation (phlebitis) which progressed to pneumonia followed by sepsis and then death.

Another patient developed C. diff colitis when an upgrade to the hospital's EMR overrode the automatic stop orders for antibiotics and no one noticed that the patient was on antibiotics far longer than recommended.

Reports of HAI resulting in death or serious disability are often not reported to the department for weeks after the care was rendered. Further complicating the reporting of healthcare acquired infections are factors identified in previous annual reports. These include the short length of patient stays in hospitals; HAIs may not be apparent at discharge and the patient may be treated for the infection at the doctor's office postoperatively or at another hospital, making it difficult if not impossible to capture this information. Confirmatory laboratory cultures may take several days to identify the infection. Therefore, HAIs may not be communicated in a timely manner to the hospital's patient safety officer or to the Department. Infection control regulations added to COMAR 10.07.01 in 2008 require collaboration between the hospital's infection control practitioner and the patient safety/quality assurance departments. The CMS Condition of Participation (COP) for Infection Control also requires interaction between the hospital's governing body, infection control, and quality assurance departments.

PRESSURE ULCERS AND FALLS

Pressure ulcers and falls accounted for 62% of all events reported in FY13. Reports of patients who developed stage III and IV pressure ulcers after admission dropped from 30% in FY12 to 26% of all the Level 1 reports received by the Department in FY13. The outcomes to the patient reported most frequently when pressure ulcers occur are medical intervention and extended lengths of stay. Thus far, no reported pressure ulcer has resulted in death. The causes of pressure ulcers are multi-factorial, and the prevention and treatment of pressure ulcers remains a priority for most hospitals. A unique action taken by one hospital, after having two patients develop deep tissue injuries (DTIs) due to their refusal to be turned and repositioned, was to show pictures of stage III and IV HAPUs to patients who refuse these basic interventions.

Falls resulting in death or serious disability to the patient remain the most often reported, adverse event, and increased somewhat in FY13, from 34% of the Level 1 reports in FY12 to 36% in FY13. Six of the 73 falls reported in FY13 resulted in death (8.2%). This is slightly lower than the death rate of 9.2% in FY12. All of the deaths were caused by head injuries suffered during the falls. According to the Centers for Disease Control (CDC), falls are the leading cause of injury-related deaths in those 65 and older, and most fractures in older adults are caused by falls.[7] Please see Appendix E for a breakdown of the outcomes of the events reported in FY13.

Table 4: Identified Causes of Falls with Injuries

---
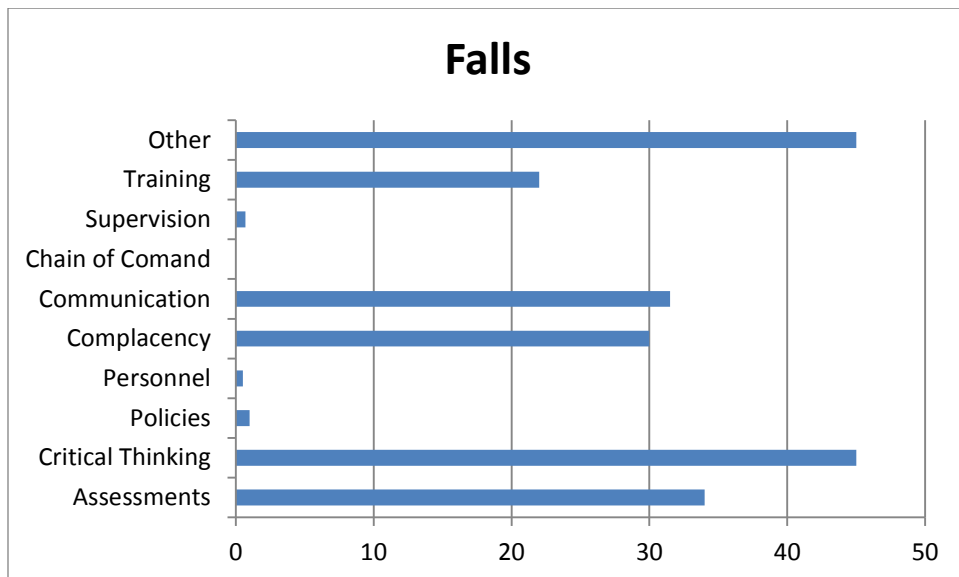
[7] Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Web–based Injury Statistics Query and Reporting System (WISQARS)

The "Other" category refers to those alert and oriented patients who are not seen as a fall risk until they get up and fall. We still find staff that are not trained in effectively using bed alarms and other interventions. Of course, ineffective and incomplete communication is a contributing factor to many falls. We find poor communication to be a factor especially during hand-offs between shifts and between departments; when patients are sent for tests and the receiving department is not made aware of the patient's fall risk. Assessments that either downplay the risk or fail to link interventions to risk scores are a factor in many falls. As in many other events, a failure of critical thinking is a major contributing factor to many of the reported falls. For instance, an elderly demented patient fell out of bed after a nurse put her on the bedpan, left the bed in an elevated position, and pulled the privacy curtain around the bed. The patient hit her head when she fell and died.

For alert and oriented patients who refuse to turn or get up, or refuse to use assistive or other fall prevention devices such as call bells, etc., hospitals may want to educate and inform the patient of the likely consequences of not cooperating with interventions, including showing pictures of pressure ulcers and statistics about falls, and get a signature on an informed refusal of care. Obviously, competent patients have the right to refuse care, and it is incumbent on the hospitals to eliminate or control obstacles to compliance (pain, etc.), but it is time to take fall prevention and pressure ulcer prevention as seriously as we take leaving against medical advice because refusing medically advised interventions may also cause dire outcomes.

UNUSUAL EVENTS

Three of the four reported injuries associated with side rails or restraints occurred when patients trapped a limb in the side rail. Two of these patients fractured hips; the other patient fractured his thigh bone near the knee.

Two patients were injured in separate patient-to-patient assaults. One patient lost an eye after being punched in the face. The victim was supposed to have been on line-of-sight observation but no one noticed another patient go into his room. After being injured, the patient was taken to the hospital's ED, where the ED physician refused to see him because he thought the ED did not have to treat inpatients. The patient was eventually transferred to another hospital, where he lost his eye.

In the one report of an infrastructure failure, a patient arrested in the radiology suite and died when he got no oxygen from the resuscitation equipment. The lack of oxygen delivery was not noticed until an arterial blood gas was obtained near the end of the code. Even though the code team immediately switched to a portable oxygen source when the lab results showed a dangerously low blood oxygen level, the patient did not survive. While investigating, facilities personnel opened up the wall to expose the piped-in oxygen system and found that the connection had never been completed between the pipe and the nozzle coming out of the wall.

There were five reported inpatient suicide attempts. Two patients attempted to jump through windows; one failed because the glass was too thick and he sustained a spinal cord injury. The other patient landed on the roof of a lower floor and had to be transferred to a higher

level of care for treatment. One patient suffered a severe anoxic injury when he hanged himself in the bathroom of an inpatient psychiatric unit. His family had notified the nurses that he was suicidal and had a plan. He was placed in a seclusion room, but was still subject to 15-minute checks and the staff left the bathroom door open. It is difficult to understand why hospital staff would think 15-minute checks would be sufficient for a psychotic, suicidal patient deserving of arms-length or line-of-sight observation.

Patient Age and Adverse Events
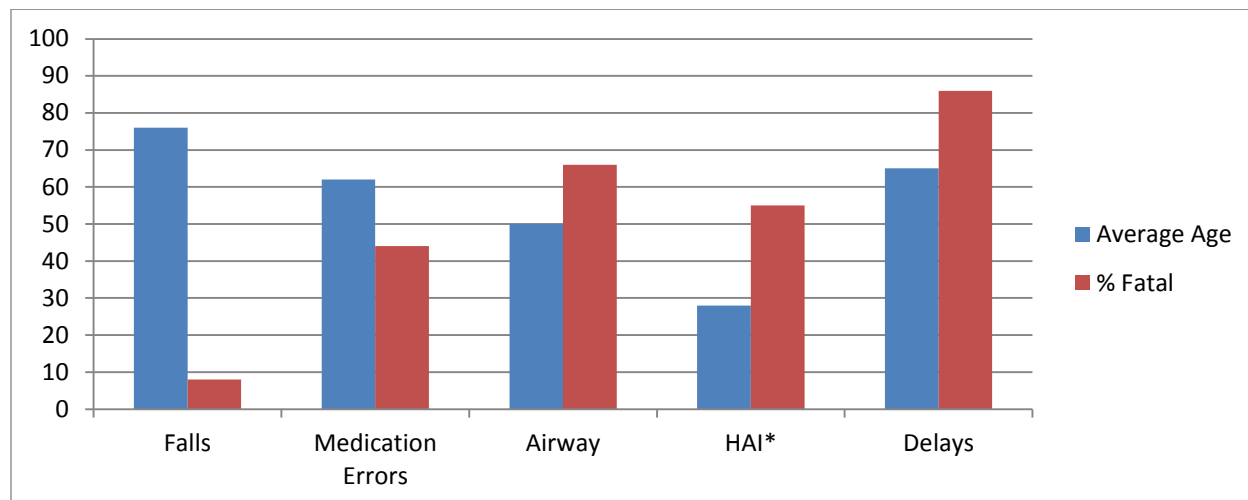
Table 5: Age and Fatality Rate

Table 5 represents the average age for each of the most often reported adverse events for FY13, plus the percentage fatal. *HAIs generally happen to the very young and very old, so the average age is skewed by the fact that 50% of the reported HAIs occurred to patients less than one year old.

Review of Root Cause Analyses

COMAR 10.07.06.06 states:

C. The root cause analysis shall examine the cause and effect of the event through an impartial process by:

> *(1) Analysis of human and other factors;*
> *(2) Analysis of related processes and systems;*
> *(3) Analysis of underlying cause and effect systems through a series of "why" questions;*
> *(4) Identification of risks and possible contributing factors . . .*

In order to comply with the requirements of COMAR 10.07.06, the hospital must submit a root cause analysis for reported Level 1 adverse events that includes an in depth review of the event by a multi-disciplinary team of individuals to determine, through a series of "why" questions, the actual root causes of the event. Root causes are defined by COMAR 10.07.06 as the basic or contributory causal factors that underlie variations in performance.[8] Root causes are generic, in that the causative factors for a given error may occur almost anywhere in patient care

---

[8] COMAR 10.07.06.02 (B)(10)

areas, and may lead to the same or similar outcomes if not fixed. Root cause analyses should focus primarily on systems and processes. The hospital staff must also identify risks and contributing factors for recurrence, and determine what improvements in systems or processes are needed to prevent recurrence.

If an RCA fails to meet one or all of the requirements of COMAR 10.07.06, the Office of Health Care Quality may issue a deficiency statement or may send the hospital an extended review of the RCA identifying exactly which elements of COMAR were not met and providing direction on resources to use to improve the quality of future RCAs. There were several commonalities among these poor-quality RCAs:

1. Each RCA focused on what happened, rather than why, yet they lacked sufficient description of the adverse event to even determine what happened;
2. These seven RCAs lacked defined root causes and the information given was insufficient to establish causality;
3. Probably because causality had not been determined, the interventions lacked specificity and had outcome measurements that were inadequate to determine if the corrective actions had any effect on the problematic process(es); and
4. Hospitals continue to focus on bedside, sharp end, corrective actions for adverse events.

In FY 2013, the Office of Health Care Quality sent out notices to six hospitals regarding seven RCAs that failed to meet all of the requirements of COMAR 10.07.06. Deficiency statements were issued to three hospitals, and new action plans were requested of the other three hospitals. The deficiency statements relate only to a hospital's compliance with COMAR 10.07.06 and do not reference the adverse event except in the most general terms

Example 1: A middle-aged, very debilitated patient with severe protein malnutrition, possible aspiration pneumonia, and ascites (free fluid in the abdomen) was admitted for altered mental status and was sent from the ICU to Radiology for an MRI where the patient aspirated. The patient had been on tube feedings and was given 1 liter of liquid contrast medium per NG tube two hours before and had been given a dose of pain medication about a half-hour before the procedure. She was not monitored because apparently no one knew about MRI-safe portable monitors. She was initially restless but then settled down and the technician was able to complete the test. In reality, she became non-responsive after aspirating. The patient arrested and was initially resuscitated, but arrested again later and died.

The RCA included a timeline explaining what happened and when. The patient's tube feedings had not been stopped prior to the test and the volume and type of contrast medium was probably contraindicated due to her aspiration. The RCA does not explain the following issues:

- The rationale of the physician for ordering this particular contrast, which required such a large volume of fluid be given;

- The MRI technician's failure to know that the hospital has MRI-safe monitors available;
- The reasons for an ICU patient being sent to the MRI suite without clinical support;
- The rationale behind the ICU nurse—who has less than one year experience— sending this patient to the MRI without a monitor or a clinician; and
- The absence of the charge nurse or supervisor in the decision-making process.

The RCA identified no root causes. While it does occasionally happen that a bad outcome might not have an identifiable root cause, it is very rare for a preventable medical error to have no cause. Since this hospital's RCA team failed to identify <u>why</u> any of these errors in judgment and patient management occurred, they were unable to come up with any actionable root causes. The only corrective actions identified in the RCA were education and policy changes and were aimed at the bedside—at the ICU nurse and the MRI tech in particular. If the RCA team had asked all of the why questions, they likely would have arrived at some higher level root causes that needed to be addressed, like supervision, hand-offs, and for peer review, the physician management of this patient.

Example 2: An elderly patient was admitted to a medical-surgical bed with community-acquired pneumonia and untreated chronic obstructive pulmonary disease. After two weeks in the hospital, she developed a fever of 103 F. She was moved to a telemetry-monitored bed and blood cultures were sent to the lab to determine if she had a blood-borne infection. The following day, she was showing signs of sepsis with lethargy, hypoxia (low blood oxygen levels) and low blood pressure. Her family was so concerned that they found an intensivist (a physician with critical care training who covers the patients in the ICU) in the hospital that evaluated her on the telemetry unit and wrote a note in her medical record opining that she should be transferred to the ICU. The intensivist did not talk to the hospitalist who was covering the patient on the telemetry unit, nor did she talk with the patient's attending or write an actual transfer order. After the hospitalist saw the patient later in the day, he wrote an order for the patient to be transferred to the ICU. At change of shift, she was moved to the ICU but did not have a portable monitor in use, only the telemetry. She arrived at the ICU pulseless and not breathing. A code was called but she could not be resuscitated.

The narrative included in the RCA explained what happened, but not why any of this happened. The RCA had an insufficient analysis of human factors. For instance, the RCA mentions that the timing of the physician's order to transport the patient to the ICU occurred just before the 7 PM shift change, but does not explain why the order was written so late since the patient had been quite sick for at least 10 hours with low blood pressure and low oxygen levels. The RCA did not consider the failure to act on the patient's deteriorating condition. Again, the lack of involvement by the charge nurse or nurse manager of the patient's deteriorating situation is not addressed nor is the failure to call the rapid response team. There were no reasons for the lack of communication between the intensivist and the hospitalist. There were many presumably well-trained and skilled staff and MDs providing care to this patient yet they failed to treat this patient in a timely manner.

The RCA also explained that the telemetry technician saw the patient's heart stop on the remote monitor and called the nurse and the telemetry unit several times, but did not explain why no one responded to the phone calls. The RCA also failed to explain why the telemetry tech did not take his concerns to the next level and call a supervisor or activate the chain of command. The hospital must ensure that telemetry techs have the authority and training to call a code for a dire rhythm if they are not getting any response from the unit. There should be a back-up plan for the change of shift when there are barriers to a prompt response. Hospitals should have systems for communicating critical information that needs immediate action.

The RCA mentions that several policies having to do with transporting patients, and responding to critical alarms were not followed, but contains no analysis of why they were not followed, if not following policies is standard on this unit, or how the hospital ensures accountability and compliance with policies and procedures.

Since no causation was established, the root causes identified in the RCA are only first-level, sharp-end causes and the corrective actions included in the RCA were insufficient to eliminate or overcome the risks to other patients. Other patients will remain at risk until the hospital addresses the many system issues in the event such as supervision, chain of command, physician hierarchy, and lack of fault tolerance (fault-tolerant systems are designed to compensate for human error). Until these higher level problems are fixed, the same set of circumstances could affect all areas of the hospital, but patients in acute areas such as ICUs, step-down units, ORs, and procedure areas remain most at risk.

The overwhelming problem with poor RCAs continues to be superficial analyses that fail to uncover anything other than first level or proximate causes for the events. Many of the RCAs reviewed mentioned that "why" questions had been asked, but no answers were given in the RCA and the corrective action did not reflect an in-depth level of analysis. In some RCAs, there is not enough information provided for Office of Health Care Quality reviewers to determine what the adverse event was or what caused the bad outcome. Sometimes, there is not enough information to determine what injury the patient suffered.

Many of the RCAs reviewed by the OHCQ continue to lack measurable outcomes. Outcome measures listed in many RCAs are usually only process measures, in that they measure the completion of the process. While milestones for project completion must be set, the outcome measures must measure the impact of the corrective actions on the root causes. Outcome measures must measure the results of new policies and education. These expectations must be clear and measure compliance or non-compliance. The impact of these new behaviors on patient care and expected patient-centric outcomes and measure for these. Outcomes measures should clearly define the expectations of the corrective actions on patient care. Hospitals must also reconsider its corrective actions if the actions fail to attain the desired impact on patient care.

Most of the RCAs that fail to meet the requirements of COMAR 10.07.06 have failed to consider the latent issues of accountability, supervision, training, and decision support for staff.

Hospitals must address these problem areas or adverse events will continue. For instance, in the telemetry event noted above, the RCA should examine the staffing levels on the unit during that day. The hospital should have a system to support individual accountability and adherence to standards of practice. Unit supervision must be active, not passive. Hospitals should offer the charge and management personnel additional training about effective supervision and intervention. Charge nurses should have the resources (time, staff, and back-up) needed to effectively manage their shifts.
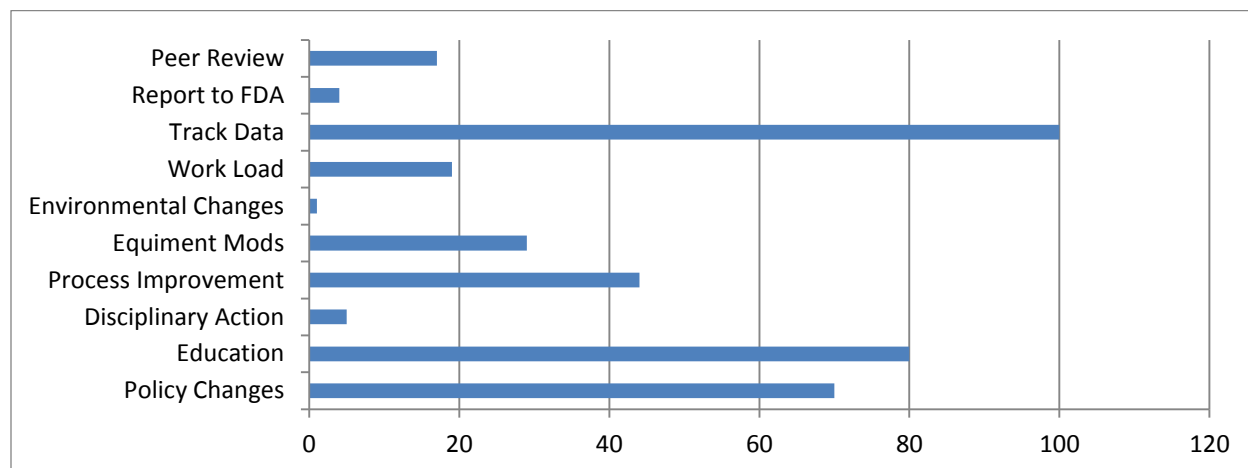
CORRECTIVE ACTIONS

Hospitals continue to struggle with implementing corrective actions that will be long-lasting and effective at controlling or eliminating hazardous conditions. As noted in Table 6, education and policy changes are very popular interventions. In FY13, we also noted some stronger actions. More hospitals are improving problematic processes, usually by streamlining and standardizing, and are making more processes fault-tolerant, which mean that more safeguards are built into the process to compensate for inevitable mistakes. More hospitals are also changing work-loads and staffing in order to provide safer care. This usually does not mean acquiring additional staff, but deploying staff better and with more focus. Examples of changing the workload include:

- Dedicating certain staff to be unit preceptors,
- Deciding that the charge nurse will not have a patient assignment so he can supervise and assist all the nurses, or
- Holding the surgeons accountable for leading the time-out.

Hospitals are getting better at tracking and trending patient safety data and are less focused on formal discipline as a first response to an adverse event.

COMAR 10.07.06 requires the hospital to monitor the results and effectiveness of all action plans derived from the RCA. Hospitals continue to struggle with differentiating between process steps and evaluating how effective a corrective action has been in remediating the set of circumstances that led to the adverse event. Completion of implementation is certainly something the hospital should track, but that is not a measure of effectiveness. Hospitals need to determine what the goal of the corrective action is, how to measure that goal and the impact the action will have on the problematic process. Further considerations include evaluating whether this action eliminates or controls the problem and how the hospital will know if it has worked. Hospitals should establish their expectations of the staff including ways to ensure they are meeting expectations. Even relatively weak actions like policy changes can be made more effective with frequent, random staff observations.

Table 6: Corrective Actions

Horizontal bar chart showing corrective actions:
- Peer Review: ~17
- Report to FDA: ~4
- Track Data: ~100
- Work Load: ~19
- Environmental Changes: ~1
- Equiment Mods: ~29
- Process Improvement: ~44
- Disciplinary Action: ~5
- Education: ~80
- Policy Changes: ~70

Notifying Patients and/or Families

The Maryland Hospital Patient Safety Program and Maryland regulations require a hospital to notify a patient, or if appropriate, a patient's family member, whenever an outcome of care differs significantly from an anticipated outcome. Hospitals continued the trend of the previous six years of reporting that patients and/or the family were notified of an adverse outcome. In FY13, 10% of the adverse events were not reported to the patient/family but the hospitals almost always had a reason, for instance, the patient had no family or specifically requested they not be told. More than a few patients who fall are embarrassed and request that the staff not notify their family members. As in previous years the Department cannot determine the quality of the disclosure, but we can tell that there is improvement in hospital policies regarding the type of disclosure, with most policies specifying that the attending physician is to make the disclosure as he or she already has the relationship with the patient.

Complaints

In addition to receiving the reports of adverse events, the Office of Health Care Quality serves as the state regulatory and licensing agency for hospitals and other health care providers. As the regulatory agency, the OHCQ is the recipient of complaints regarding Maryland hospitals. Regulatory agencies consider complaint investigation to be a valuable tool in the monitoring of quality in licensed facilities. In FY13, the OHCQ received 432 complaints about hospitals from patients, families and other citizens.

Since the Maryland Patient Safety regulations were implemented on March 15, 2004, the OHCQ has received more than 1900 reports of Level 1 Adverse Events. During that same time frame the OHCQ has received 3,122 complaints from citizens. There continues to be little overlap between the self-reported adverse events and the complaints received from the public.

Approximately three reports were received through both sources (as a complaint and as a self-reported adverse event) in FY13. Since adverse event reporting became mandatory, only 35 or 1.7% of the adverse events reported by hospitals were also received as a complaint submitted to the OHCQ from other sources. The data obtained from the complaint process has little relevance to the number and type of adverse events occurring in Maryland hospitals. This lack of duplication indicates that the vast majority of patients or families affected by serious adverse events do not file complaints about those events. The mandatory reporting and the review of RCAs provide another tool for the Department to evaluate the quality of care delivered in Maryland hospitals as well as how well hospitals are addressing serious problems.

When a complaint is received by the OHCQ that appears to be a reportable Level 1 Adverse Event, a surveyor is assigned to investigate the complaint in accordance with the complaint investigation processes. If the findings indicate that the complaint was an adverse event and the event was not reported by the hospital, additional review may be warranted to examine the hospital's patient safety program. Evidence that the hospital failed to have a program or failed to report may result in deficiencies and possible sanctions.

The Patient Safety Program regulations COMAR 10.07.06 require patient safety engagement throughout all levels of the hospital organization, including the governing body. The Department staff continues to be concerned that some hospitals may not have internal reporting systems capable of capturing all adverse events. Heading onto our tenth year, we have received reports from all acute general hospitals and from all but one specialty hospital. We assume that hospitals with robust reporting systems are actually safer than hospitals that underreport. It is unclear why two hospitals with catchment areas of similar population densities and with nearly identical bed capacity should have reporting rates that differ by 50-75%. When there is a suspicion that a hospital lacks a well-integrated patient safety program, or a complaint is verified regarding an event that should have been reported to the Department, an on-site survey of the hospital's compliance with COMAR 10.07.06 can be performed. These enforcement actions do not focus on the adverse event itself, but, as we ask hospitals to do in their RCAs, focuses on the systems, culture, reporting and analysis, and policies and procedures needed for a robust patient safety program.

Since 2011, the Office of Health Care Quality has sent out annual report cards to hospital patient safety officers. The report cards provide a way to double check the events reported, reconcile the hospital's files with the Department's, and ensure there are no outstanding RCAs. The report cards also provide a way for us to monitor reporting rates of individual hospitals on a longitudinal basis.

Leadership Involvement

The Maryland Patient Safety Program regulations require that hospitals designate a staff person to function as the patient safety coordinator. The OHCQ has noted significant change in not only reporting rates but interest and engagement in the patient safety process when a hospital loses or changes its patient safety coordinator. Patient safety cannot function in a silo under the

direction of one person. Keeping patients safe is not just a nursing function. It must be a hospital-wide effort with the direction and involvement of hospital leadership. In addition, both CMS and TJC require hospital-wide patient safety activities and integration of patient safety into the quality improvement, medical staff, and governing body.

For that reason, it is critical that a hospital's leadership is committed and involved in patient safety. Leadership involvement continues to be a key element in a hospital's patient safety program. Hospital-wide and departmental leadership can increase its involvement and commitment to patient safety through:

- Providing resources for additional training of charge nurses and supervisors focused on effective patient management, leadership, and interpersonal skills.
- Regularly scheduling meetings between risk management, quality improvement, infection control, patient safety, and medical staff leaders to discuss events and to determine how the events should be addressed by the hospital.
- Reviewing actual RCAs, not merely data related to the numbers of events per patient days.
- Actively participating in a root cause analyses. Participation by leadership can provide valuable insight into the challenges faced by patients and by front line staff. Leadership participation also lets the staff know that administration supports the RCA process.
- Providing regular reports regarding adverse events to the Board and other executive level committees. Tell the patient's story by describing what happened or failed to happen that resulted in harm.
- Celebrating successes and adverse events avoided.
- Establishing and participating in administrative rounds that focus on patient safety.
- Attending the training on patient safety provided by the hospital or by the Maryland Patient Safety Center.
- Educating new department heads and nurse managers about the hospital's patient safety program and how their department is expected to interface with the patient safety staff and program.
- Establishing patient safety goals and monitoring the hospital's performance for those goals.
- Consideration of having a leadership representative on RCA teams during the development of corrective actions. Front line staff are focused on front line solutions, and most adverse events require some part of the focus be on latent issues that hospital leadership is in a better position to rectify.

Clinical Alerts

Based on the information obtained from the review of the events and the root cause analyses, the OHCQ has developed and distributed hospital Clinical Alerts. It is hoped that the experience of a hospital or several hospitals disseminated through the Clinical Alerts will prevent the recurrence of the event in another hospital and will enable the office to share "Best Practices." In FY13, *Falls in Maryland Hospitals Revisited* and *Automatic External Defibrillators* were published.

Clinical Alerts may be obtained at: http://dhmh.maryland.gov/ohcq/HOS/SitePages/Alerts.aspx

The Office of Health Care Quality also sent out several patient safety notices through the Maryland Patient Safety Center's patient safety manager listserv on various topics of immediate interest.

The Maryland Patient Safety Center

The Maryland Patient Safety Center[9] (MPSC) brings patient safety professionals together to study the causes of unsafe practices and put practical improvements in place to prevent errors. Designated in 2004 by the Maryland Health Care Commission, the Center's vision is to make Maryland hospitals the safest in the nation.

The Department continues to support the efforts of the Maryland Patient Safety Center by:

- Regular contribution to training workshops sponsored by MPSC;
- Speaking at various events including the annual Maryland Patient Safety Conference, MedSafe, and the Falls Collaborative Update conference;
- Attendance and updates when requested at the MPSC Patient Safety Directors' meetings; and
- Attendance and assistance when requested with special projects.

Future Plans and Conclusions

As previously noted, we recognize that there is turnover in patient safety coordinators at the hospitals. In order to assist patient safety staff, the OHCQ has consolidated its patient safety tools into a folder and made it available for training or as a refresher for hospital staff. The OHCQ would like to compile this information to develop a Patient Safety Tool Kit and make it available on the OHCQ website. We ask that hospitals provide contact information, including email addresses, for new patient safety coordinators to our office.

---

[9] Maryland Patient Safety Center www.marylandpatientsafety.org

Integral to the success of the Maryland Patient Safety Program is the sharing of information between hospitals and in forums such as the Annual Report. Information sharing provides patient safety officers and others the opportunity to review their own systems and procedures and make proactive changes to prevent an adverse event that occurred elsewhere from happening in their hospitals. The Department will continue to review events and RCAs to develop Clinical Alerts to disseminate information to hospitals and other healthcare providers. The OHCQ staff continues to be available to provide training to interested groups and organizations.

The OHCQ also takes advantage of opportunities to interact and share with other state patient safety programs. Beginning in FY10, the staff of the OHCQ has actively participated in the National Quality Forums /Agency for Healthcare Research and Quality sponsored *Improving Patient Safety through State Based Reporting in Healthcare* initiative. Meetings and periodic conference calls provide a forum for staff of state based reporting programs to exchange ideas, discuss best practices and share the challenges faced in operating reporting programs.

Additional plans for the dissemination of information continue to include:

- Research and publish best practices for commonly occurring Level 1 Adverse Events;
- Support for the collaboratives sponsored by the Maryland Patient Safety Center;
- Identification of hospital-specific trends and patterns and assisting hospital to develop methodologies to address repeated similar events;
- Identification of trends and patterns of poor RCAs submitted by specific hospitals; and
- Participation in the educational offerings provided by Maryland Patient Safety Center.

In conclusion, the Department is pleased to see that most hospitals are engaged in patient safety activities through the increased reporting of events, the continued improvement of the quality of root cause analyses submitted, and the continued reported disclosure of adverse outcomes to patients and families. The Department will continue to engage hospitals in the process through our participation in opportunities for outreach and training. We will continue to develop Clinical Alerts as a means to communicate patterns and trends identified through the receipt of events and the review of root cause analyses.

APPENDICES

APPENDIX A: MARYLAND HOSPITAL DEMOGRAPHICS

Maryland regulation classifies hospitals in two groups. The majority (46) are licensed as acute general hospitals ranging in bed capacity from nine to 1000 beds. All but one of these has an Emergency Department. Certain hospitals also provide specialized services such as trauma, burn and stroke care. However, not all hospitals offer certain other services, such as pediatrics, labor and delivery and/or behavioral health. Several acute general hospitals also operate separate units that are dually licensed as Special Hospitals, either Chronic or Rehabilitation types.

The licensed bed capacity of each acute care hospital is adjusted annually at the beginning of the fiscal year based on Health General Article §19-307.2 and is based on 140% of the hospital's average daily census. The number of beds the hospital is allowed to operate therefore changes on an annual basis. This statute does not apply to special hospitals.

1. Twenty two hospitals are licensed as special hospitals. There are four types: rehabilitation, chronic, children's, or psychiatric. Special hospitals do not have operating rooms, emergency departments or intensive care units where patients would undergo more invasive and complicated procedures.

   a. The 11 Special Hospitals-Psychiatric range in size from 15 licensed beds to 639 beds.
   b. Five of these hospitals are State operated.
   c. Two psychiatric hospitals serve only specific populations (children, forensics).

2. All four Special Hospitals—Chronic serve patients who are ventilator-dependent or who have chronic respiratory problems. These hospitals range in size from 60 to 180 beds. Two are operated by the State of Maryland. While all provide some rehabilitation services, two of the hospitals are dually licensed as rehabilitation hospitals.

3. There are two Special Hospitals-Rehabilitation and two Special Hospitals-Children. The latter are also dually licensed as rehabilitation hospitals. The children's and rehabilitation hospitals have less than 102 beds each and all offer outpatient services.

APPENDIX B: TYPES OF EVENTS

Type of Event	FY11	FY12	FY13	Total (since 2004)
Death or serious disability - fall	93	98	73	663
Hospital acquired Stage III or IV pressure ulcers	144	86	52	240
Death or serious disability - delay in treatment	17	10	28	158
Death or serious disability - airway management	10	7	12	88
Death or serious disability - medication error	10	10	10	78
Post-surgical retention of foreign body	17	13	11	75
Suicide or attempted suicide	5	16	7	74
Death or serious injury of patient – HAI	8	3	9	55
Unanticipated complication of treatment	7	4	1	50
Unanticipated fetal death or injury	8	5	2	48
Surgical Procedure not consistent with consent/ wrong patient/ wrong body part	2	8	3	36
Misdiagnosis	1	2	1	30
Death or serious disability - anticoagulants	2	1	1	26
Other	3	1	2	26
Unanticipated intra-op or immediate post-op death	2	0	1	25
Malfunctioning device	1	1	0	24
Death or serious disability - failure to act	6	1	1	21
Death or serious disability - vascular access device	3	0	0	20
Death or serious disability - restraints seclusion, or side rails	0	5	4	17
Death or serious injury - physical/sexual assault occurring within or on hospitals grounds	4	4	2	16
Maternal death or serious disability associated with Labor & Delivery	4	1	0	13
Death or serious disability – hypoglycemia	4	1	1	13
Death or serious disability - burn	1	2	0	9
Death or serious disability - intravascular air embolism	0	3	0	9
Intra-op or post-op death in ASA 1 patient	1	2	1	8
Death or serious disability - contaminated drug, device or biologic	0	2	0	3
Infrastructure failure	0	0	1	2
Intentionally unsafe care	0	0	0	1

APPENDIX C: COMPARISON OF FATALITY RATES
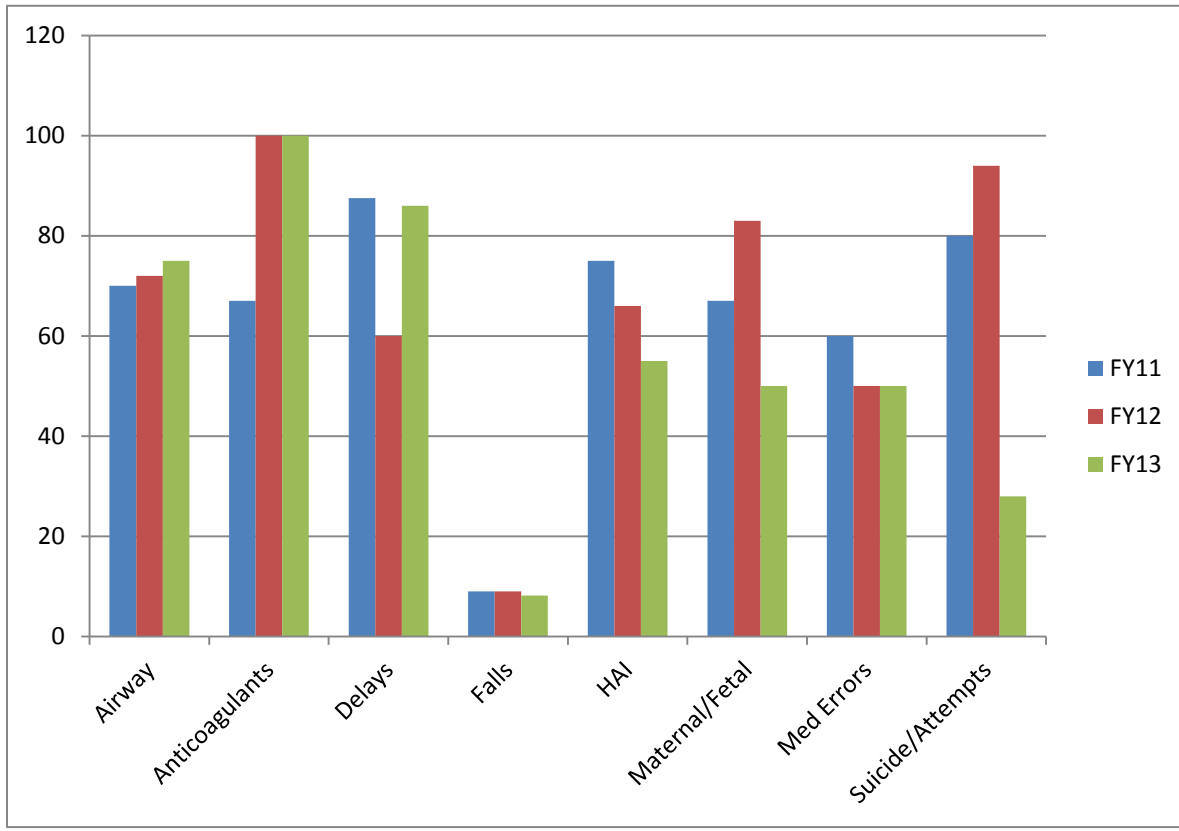
For some events, like falls, the number of events per year is large, but the fatality rate over the past eight years is low. Many other event types have consistent fatality rates, but occur less often. For instance, in FY12 and FY13, anticoagulant events had 100 percent mortality, but only one event was reported each year.

**Appendix D: Identified Causation per Event Type, FY13**
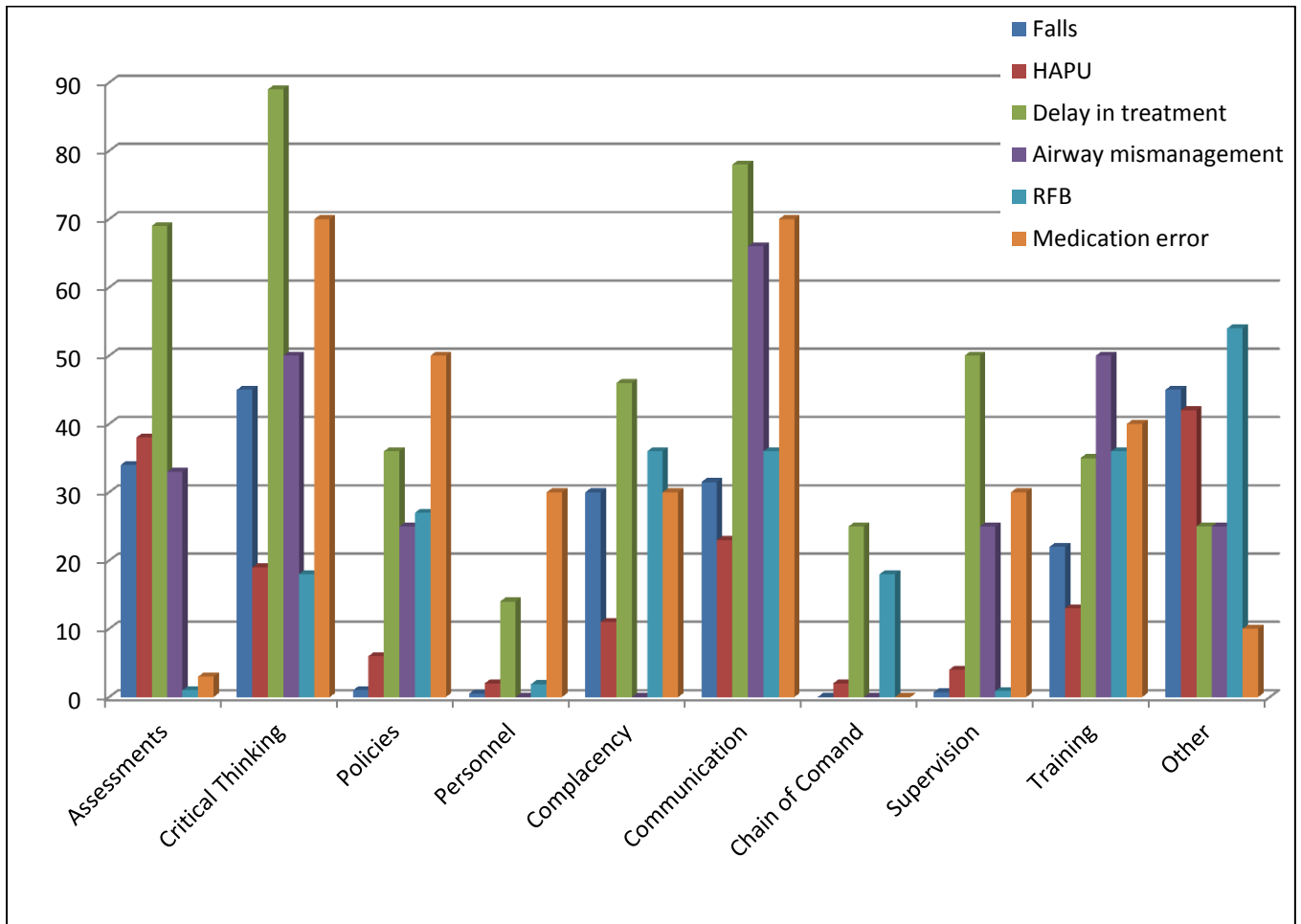
APPENDIX E: OUTCOMES FOR FY13 LEVEL 1 EVENTS

Event	Death	Anoxic injury or PVS	Surgery	Increased Length of Stay	Transfer to Higher Level of Care	Loss of Function	Loss of Limb or Organ
Air embolism							
Airway	9	2	1				
Burns							
Contaminated device							
Delay	24	1				1	
Fail to act	1						
Falls	5		51	4	5	13	
Fetal Death or injury	4	1					
Healthcare acquired infections	4			1	2		2
Healthcare acquired pressure ulcers				2	50		
Infrastructure Failure	1						
Malfunctioning device							
Medication Error	6	1			2	2	
Misdiagnosis						1	
Other						2	
Physical Assault			1				1
Restraints			3		1		
Retained foreign bodies			10	1			
Sexual Assault							
Suicide	2	1	1		2	1	
Surgical events	1		2				1
Unanticipated Complication							1

APPENDIX F: CORRECTIVE ACTIONS IDENTIFIED IN RCAS, FY13
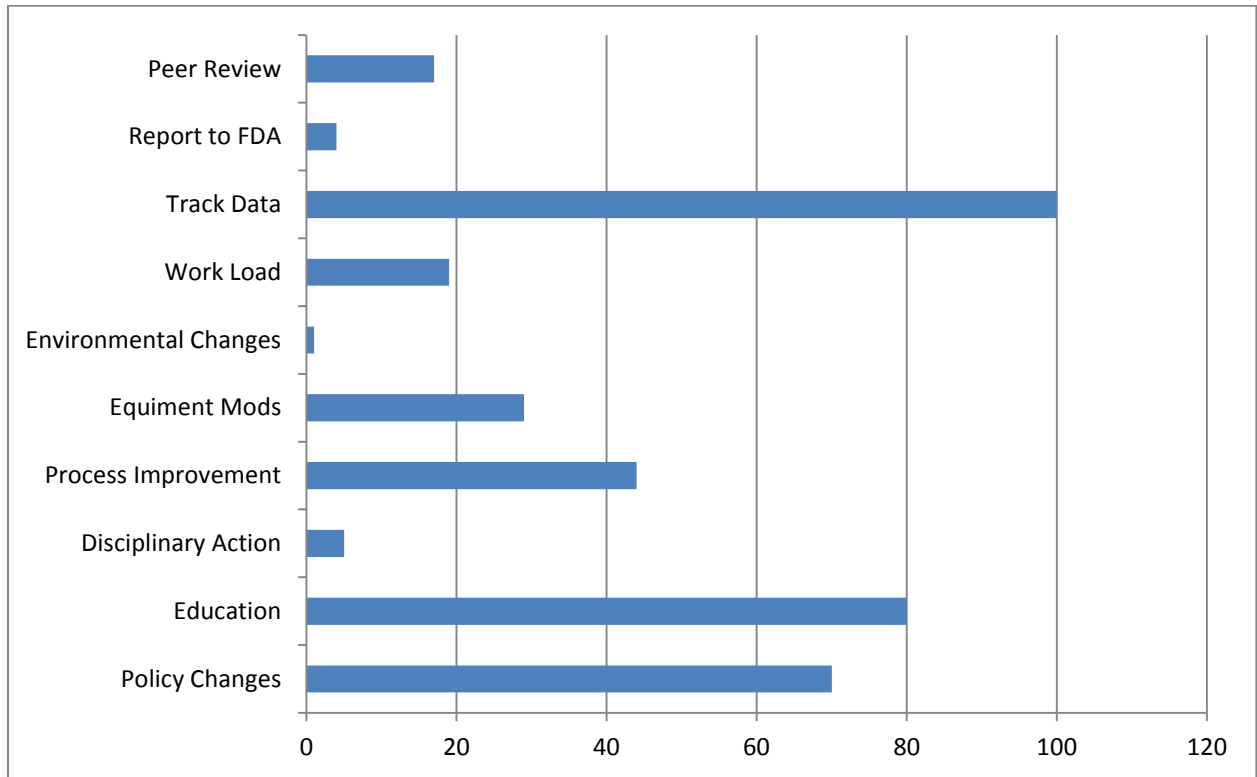
APPENDIX G: PATIENT SAFETY DECISION TREE
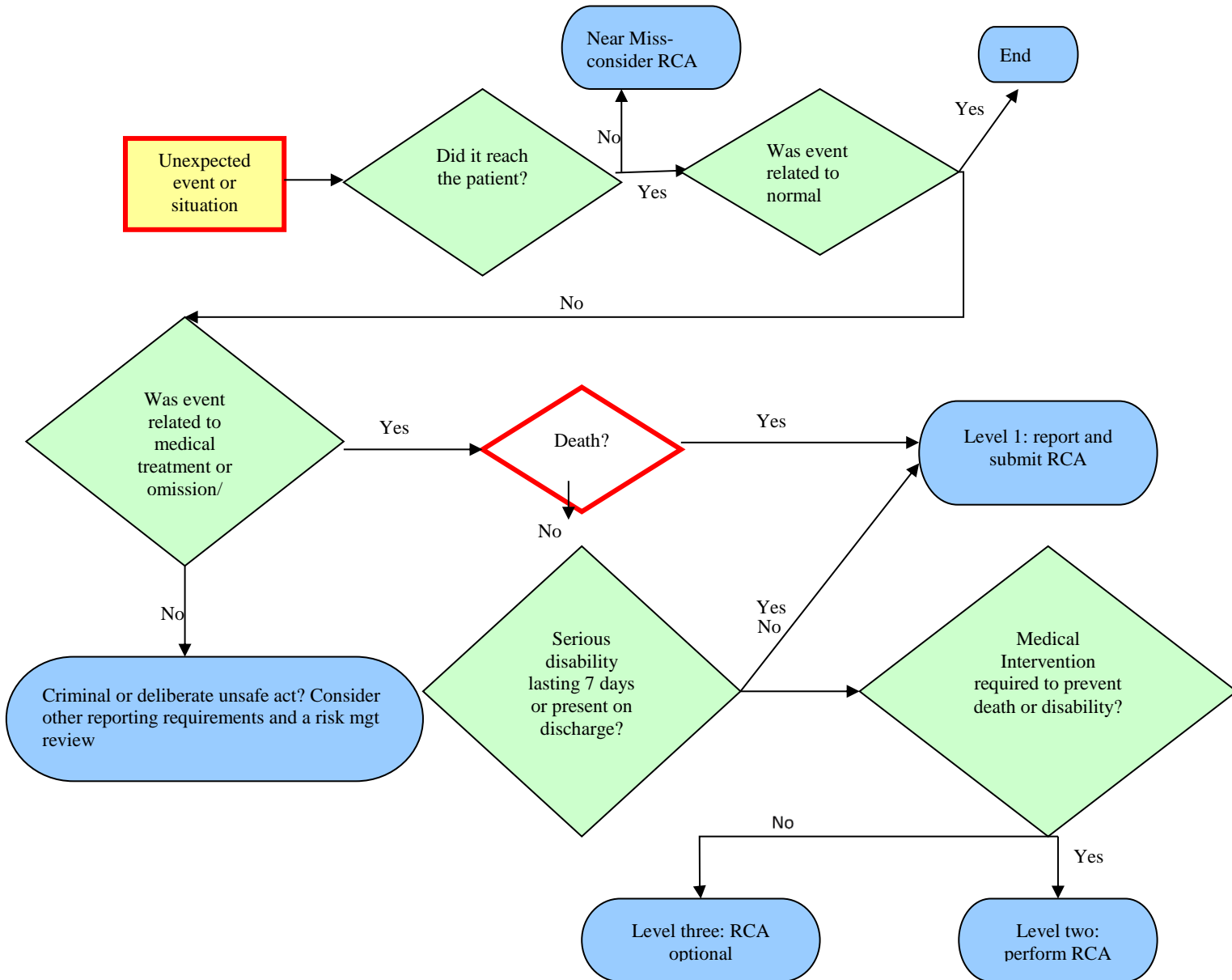
When in doubt about whether to do a RCA for Level 3 and near misses, remember that a lot of valuable information can be gained in the process. Asking these questions may help you decide if a RCA is needed:

1. Does this event or hazard represent a substantial risk to patient safety?
2. Is the event due to faulty processes or system failures that are likely to cause a similar, perhaps more harmful event if not corrected?
3. If the hazardous condition is not corrected, is there a high probability that a sentinel or adverse event will occur?

4. Will the organization receive significant negative publicity if the cause of the event is not corrected?
5. Will failure to conduct a RCA result in deterioration of staff or physician morale and/or trust in the leadership's commitment to patient safety?

An event would be considered to be part of a patient's normal disease course if the untoward event arose from the patient's intrinsic condition, rather than from the exogenous medical treatment. For instance, a patient goes into disseminated intravascular coagulation and dies. If the patient has an underlying coagulopathy or sepsis, or any other condition that caused the DIC, this would not be considered a reportable event. However, if the patient has a hemolytic transfusion reaction because of incorrect typing and goes into DIC and dies, that is a reportable Level 1 event. Another example is if a patient falls and develops a subdural hematoma and dies, this is a reportable Level 1 event, even if the development of the SDH was the result of an underlying coagulopathy. The patient would not have developed the SDH that killed him had he not fallen. The event is the fall, not the development of the SDH. Serious disability is defined in 10.07.06 as a physical or mental impairment that substantially limits one or more major life activities of an individual lasting more than seven days or still present at the time of discharge.