MARYLAND DEPARTMENT OF HEALTH
Office of Health Care Quality

Maryland Department of Health
Office of Health Care Quality

Maryland Hospital Patient Safety Program
Annual Report
Fiscal Year 2020

Larry Hogan, Governor
Boyd Rutherford, Lt. Governor
Robert Neall, Secretary
Jinlene Chan, MD, MPH, FAAP, Acting Deputy Secretary for Public Health Services
Patricia Tomsko Nay, MD, CHCQM, FAAFP, FABQAURP, FAAHPM, Executive Director

Table of Contents

Executive Summary

On behalf of the Office of Health Care Quality (OHCQ), we are pleased to present the Maryland Hospital Patient Safety Program's Annual Report, State Fiscal Year 2020. During this year, the emergence of the COVID-19 pandemic challenged the health care system with new adverse events not previously encountered. Adverse events are life- and function-threatening for patients and negatively affect the emotional and physical health of a hospital's workforce contributing to suboptimal performance. In addition to the human toll, these events are costly for both patients and hospitals.

COMAR 10.07.06 defines a Level 1 adverse event as any unexpected outcome of medical care caused by a preventable error that causes death or serious disability. These events are organized into categories, such as surgical events, including retained foreign bodies and wrong site surgeries, and patient protection events, including falls, health care-acquired pressure ulcers and injuries, delays in treatment, and medication errors.

Most hospital adverse events are the result of poorly designed processes, policies, and long-entrenched cultural and procedural factors. The underlying causes of individual variations in performance are usually multifactorial and multidisciplinary. As such, hospital patient safety is not solely the responsibility of the patient safety officer. Patient safety is the responsibility of everyone in the hospital environment. Optimizing the culture, hospital environment, and processes to reach the highest level of safe operation requires broad engagement and hospital-wide commitment. Patient safety only succeeds as a collaborative effort with hospital leadership and all staff across the care continuum. Both the Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC) require hospital-inclusive patient safety activities and integration of patient safety into medical staff and governing body functions.

Fiscal year 2020 (July 1, 2019 to June 30, 2020) marked the 16th year of the Maryland Hospital Patient Safety Program. The analysis of the adverse events reported in FY20 includes the following findings:

- 264 of the 310 reported adverse events were Level 1 adverse events in FY20, affecting 286 patients. While this number was an increase from the previous year, there is not an upward trend in this metric.
- Forty-six patients died in FY20 from preventable medical errors - one more than the lowest number in seven years reported in FY19.
- Delays in treatment were the third most reported event and represented 11% of FY20 events. The number of reported delays in treatment was the lowest since FY14.
- The number of surgery-related events decreased from 35 reported events in FY19 to only 19 in FY20.

- The number of reported hospital-acquired pressure injuries (HAPI) increased from 52 in FY19 to 63 reports in FY20.

These key findings have led to the recommendations contained in this report:

1. Hospitals must do more to address the causes of delays in treatment. These types of events are multidisciplinary and multifactorial, but there are interventions that can change the outcomes for patients caught in the spiral of inadequate assessments, poor communication, and poor decision making. With a new public focus on diagnostic errors by the Agency for Healthcare Research and Quality (AHRQ) and the Academy of Medicine, addressing causal factors in treatment delays could minimize the associated catastrophic outcomes and improve patient care.
2. To address the most common identified root causes (communication, assessments, and critical thinking), hospitals should utilize patient data from early warning, decision support, and predictive systems more effectively to improve communication and to drive coordination and oversight of care.

Tennile Ramsay MS, RN, CNL
Nursing Program Consultant
Office of Health Care Quality

Patricia Tomsko Nay, MD, CHCQM, FAAFP, FABQUAURP, FAAHPM
Executive Director
Office of Health Care Quality

Maryland Hospital Patient Safety Program Analysis

The fiscal year 2020 (FY20) Hospital Patient Safety Report quantitatively and qualitatively analyzes 264 Level 1 adverse events affecting 286 patients reported by Maryland hospitals to the Office of Health Care Quality (OHCQ) in FY20. This report compares FY20 event types and outcomes with previous reporting years.

Reported 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, more than 4,000 Level 1 adverse events have been reported by Maryland hospitals through June 30, 2020. There has been an average of 235 events reported each year. Figure 1 compares reporting rates for adverse events from 2004 through 2019.

Figure 1: Hospital Reporting of Adverse Events from FY05 to FY20


Maryland Hospitals Adverse Event Reporting

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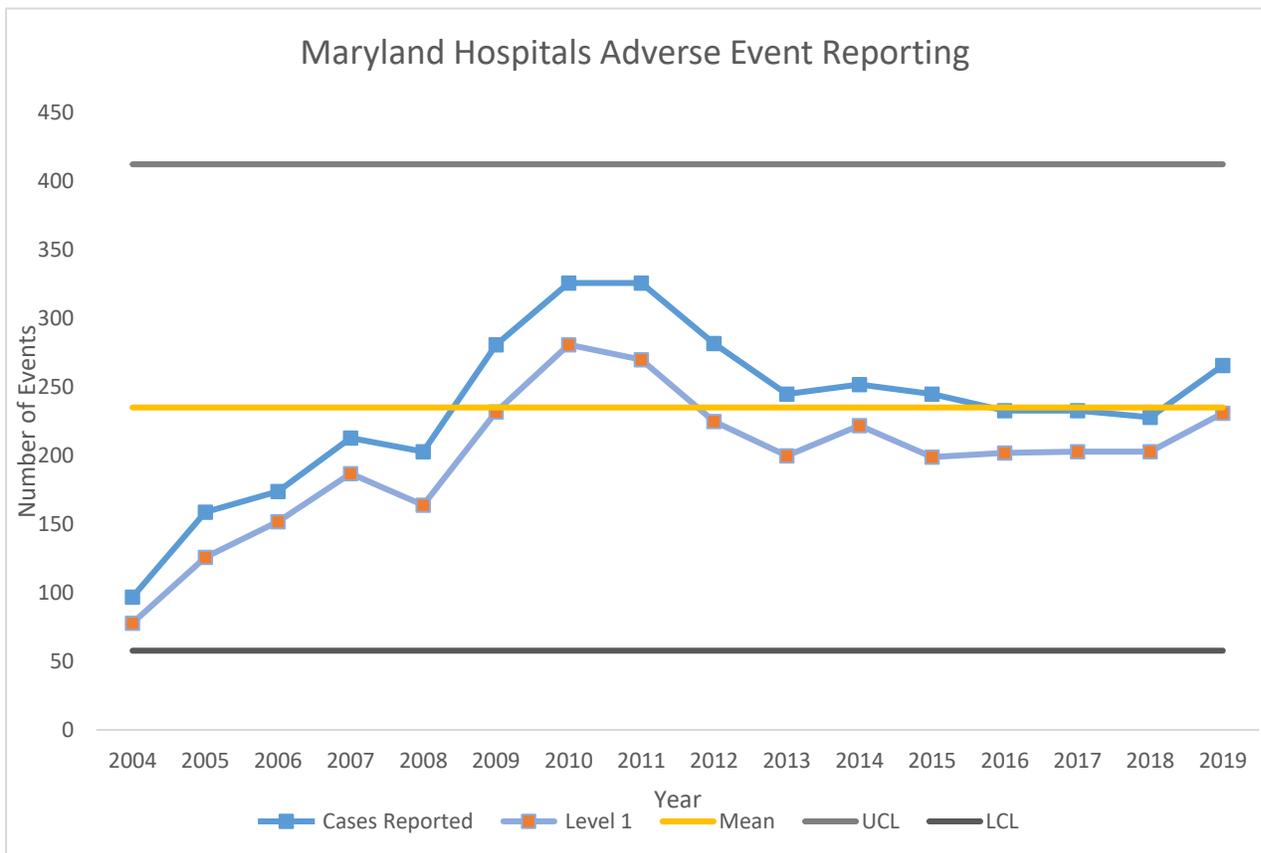
[1] Serious disability is defined in COMAR 10.07.06.02B(11) as a physical or mental impairment that substantially limits one or more major life activities of an individual lasting more than seven days or is present at the time of discharge.

In comparing reporting rates for specific adverse event categories from FY20 to FY19, it is noted:

- The two most commonly reported adverse events, falls and health care-acquired pressure injuries or ulcers (HAPI or HAPU) accounted for 52% of the Level 1 events reported in FY20.

- Fall events were the most reported level 1 event in FY20, increasing from 53 in FY19 to 74 events in FY20. Although there is an increase from the previous year, overall, there has been a downward trend since 2012.

- Health care-acquired pressure injuries or ulcers (HAPI or HAPU) increased from 53 in FY19 to 63 in FY20.

- Delays in treatment have historically been associated with high mortality. In FY20, 40 percent of reported delays in treatment events were fatal, compared with 63% in FY19.

- In FY20, there were 13 maternal or fetal events reported, an increase from 7 reported in FY19. In FY20, 46% of the reported maternal or fetal level 1events were fatal.

- Surgery-related adverse events decreased from 27 in FY19 to 18 events in FY20. Of the surgical events reported, 84% (16) were retained foreign objects (RFO).

- Suicides and suicide attempts with injuries increased from 4 in FY19 to 5 in FY20. All 5 events occurred post discharge.

- There were eight airway events reported in FY20, one less event compared to 9 in FY19. One of these events that occurred in Radiology is reviewed later in this report.

- Nine misdiagnosis events were reported in FY20 compared to 3 in FY19. The contributing factors, including bias, omitted diagnostics, and communication, are discussed in a later section.

- There were five physical assaults and three sexual assaults in FY20. One physical assault was a fatal patient-to-patient assault by a behavioral health patient. One sexual assault was an unanticipated, intentional act committed by a hospital team member.

- Three events reported involving restraint and seclusion in FY20, including one fatal event involving a patient in a seclusion room.

- One fatal event highlighted the need to assess organization readiness, equipment, and the physical environment to ensure safety during the COVID-19 pandemic.

Figure 2 compares the various categories of reported adverse events in FY19 and FY20.

Figure 2: Comparison of FY20 and FY19 Adverse Events
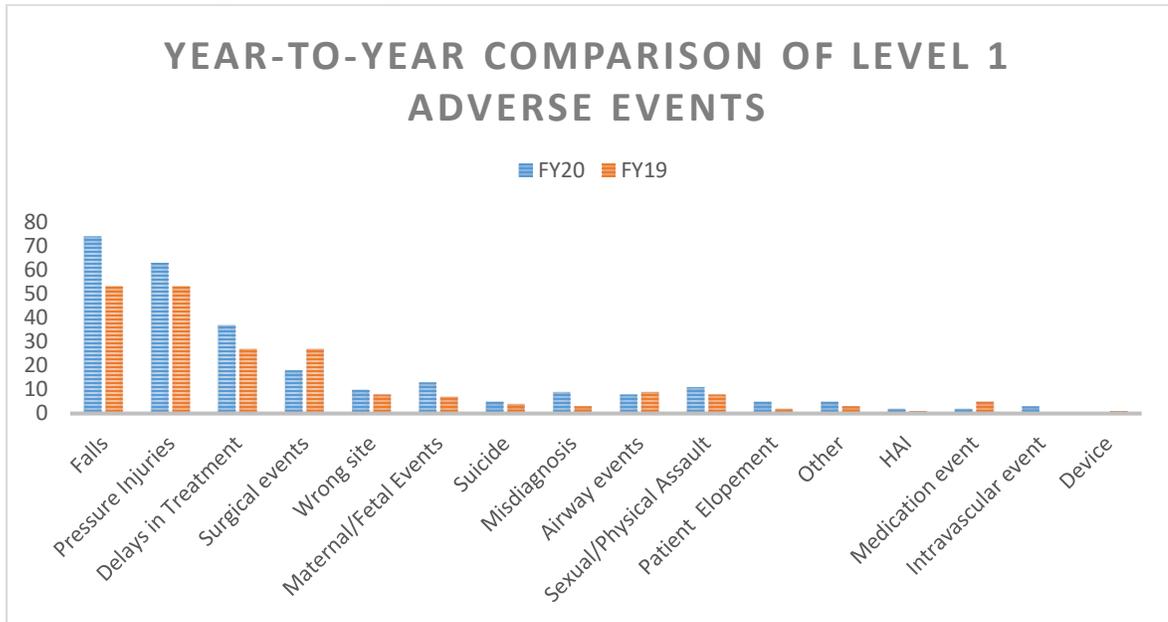
Classification of Events

OHCQ's Patient Safety Program continues to classify the types of Level 1 adverse events in our database using the National Quality Forum's (NQF) "Serious Reportable Events"[2] taxonomy.   Using this nationally recognized classification system enables OHCQ to compare its data with other state reporting systems. Because the Maryland Patient Safety Program is focused on patient outcomes and 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 resulting from an unanticipated complication,
- death or serious disability related to a delay in treatment,
- death or serious disability associated with airway management,
- death or serious disability related to a healthcare-associated infection,
- unanticipated fetal or neonatal death or injury, and
- misdiagnosis causing death or serious disability.

---

[2] http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx#sre4

The full list of Classification of Events used by OHCQ's Patient Safety Program is found in Appendix A.

In this report, all surgical-related adverse events are grouped under surgical events. This category includes inadvertently retained foreign objects, deaths in ASA-1 patients, and unanticipated intra-op or post-op deaths. While traditionally OHCQ has included all wrong patient, site, consent events (referred to as "wrongs") with surgical-related adverse events, these are now reported as a separate category. This allows the program to account for wrong patient events in other areas of the hospital.

The category medication or adverse drug events (ADEs) includes events involving untreated hypoglycemia and events involving anticoagulation, as well as all other medication events leading to death or serious disability.

Maternal or fetal events include preventable birth injuries and deaths as well as unanticipated fetal and neonatal injuries.

Sexual or physical assaults include injuries to patient or staff resulting from physical assault occurring within or on the grounds of a facility.

Figure 3 shows the distribution of reported adverse events in FY20.

Figure 3: Distribution of FY20 Events by Classification
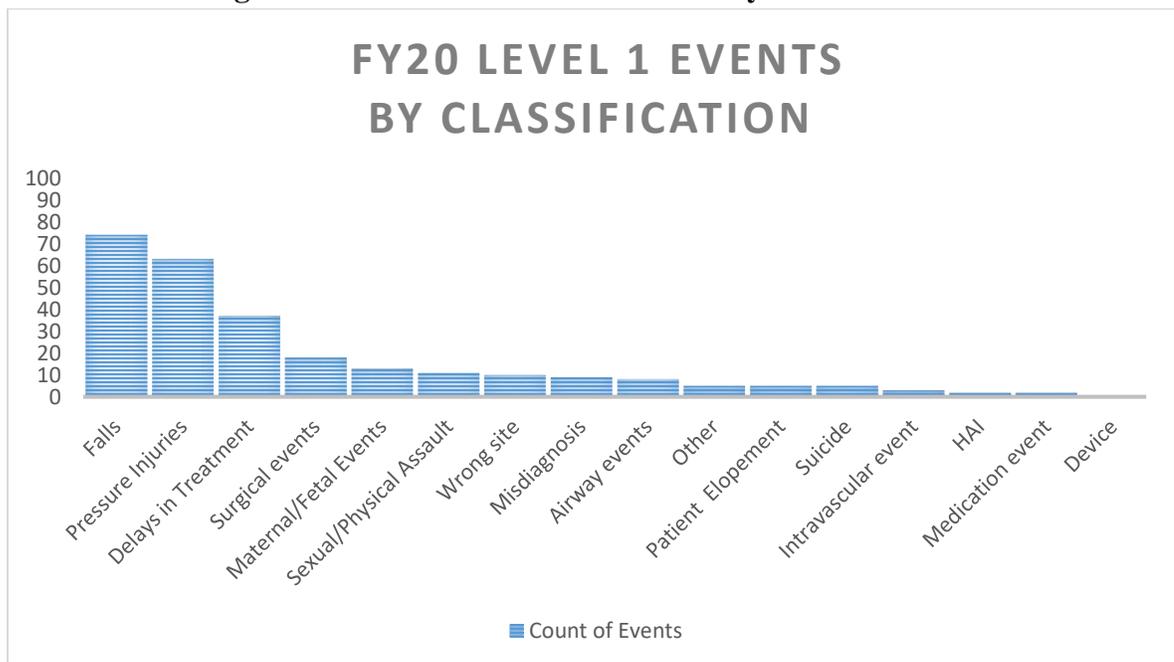
Hospital Demographics and Reporting

Maryland hospitals are classified into five categories - acute general, psychiatric, chronic, children's, and rehabilitation. Table 1 shows the number of hospitals with 300 or more beds, 200 – 299 beds, 100 – 199 beds, and less than 100 beds. Acute general hospitals account for 73% of all licensed Maryland hospitals and reported 93% of the Level 1 adverse events in FY20. Children's and rehabilitation hospitals accounted for 2% of reports, while psychiatric and chronic hospitals accounted for 5%. Eight hospitals failed to report any adverse events in FY20. Five of the eight non-reporters had fewer than 100 beds. Fifty percent of the non-reporting group were psychiatric hospitals.

Table 1: Number of Hospitals within Specified Licensed Bed Ranges

| Number of Licensed Beds	Number of Hospitals
300 or more beds	11
200 – 299 beds	15
100 – 199 beds	14
Less than 100 beds	22
Number of Maryland hospitals	62

Event under-reporting is likely, especially of non-lethal events, as reflected in wide reporting variability between hospitals of similar size and acuity. This may reflect gaps in safety culture or an opportunity to highlight best practices. There is heightened awareness among the general public and other Maryland and federal governmental and private sector payor organizations about the importance of identifying and addressing safety issues. Given the focus on quality and high reliability in healthcare, it is important to validate hospital reporting to the Maryland Patient Safety Program. Future validation of reporting and safety practices will be conducted after the COVID-19 public health emergency.

Event Outcomes: Fatalities

Patient outcome is determined from adverse event reports and represents the most severe outcome that occurred while the patient was in the hospital following the adverse event. For instance, if a patient suffered a delay in treatment and died four days later, that outcome would be classified as a fatality. If another patient suffered an airway mishap with anoxic injury (brain damage from a lack of oxygen) and died three months later in a long-term care facility, that adverse event would be categorized as an anoxic injury because the death did not occur contemporaneous to the hospital stay.

Figure 4 details the top 5 event categories and associated fatalities for FY20. These five event categories represented 77% of the reported Level 1 events. Delays in treatment have the highest number of fatalities at 19 deaths representing 40% of the reported events in this category. The highest percentage of fatal cases are seen in maternal or fetal events. While the number of maternal and fetal events are low compared to the other four categories, 46% (6) of the events were fatal.

Figure 4: Top 5 Level 1 Events Associated with Fatalities in FY20

FATALITIES IN TOP 5 ADVERSE EVENT CATEGORIES

Number of Fatal Level 1 Events
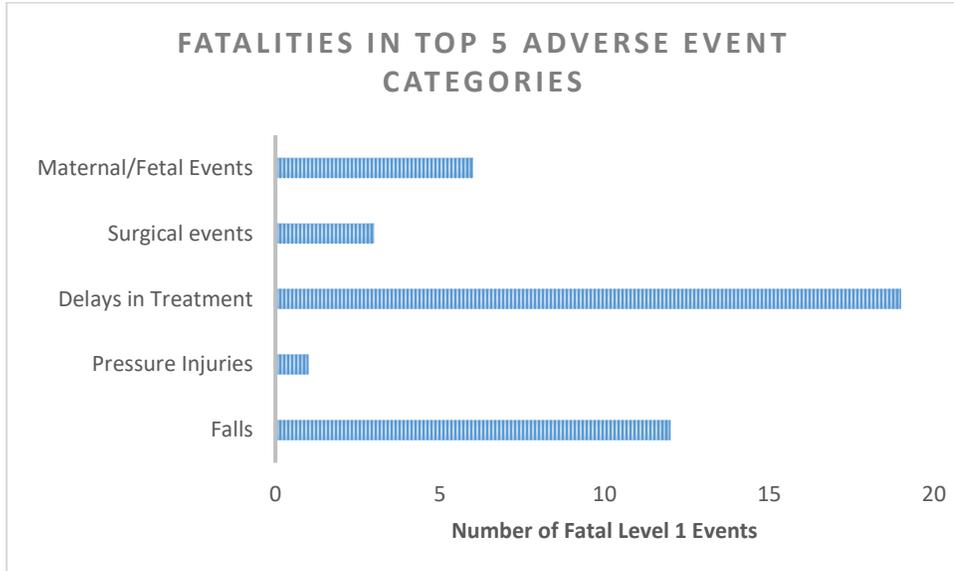
Most of these reported delays in treatment, surgical events, medication errors, airway events, and fatal birth events were preventable.

Age and Adverse Events

Figure 5 breaks down the Level 1 events by age of the patients involved. The majority of the events occur in the 65 to 84 year old group. Figure 6 shows the distribution of certain events by age group, including falls, pressure injuries, delays in treatment, surgical events, maternal or fetal events, and sexual or physical assaults.

Figure 5: Level 1 Events by Age Ranges in FY20

AGE OF PATIENTS WITH
LEVEL 1 EVENTS
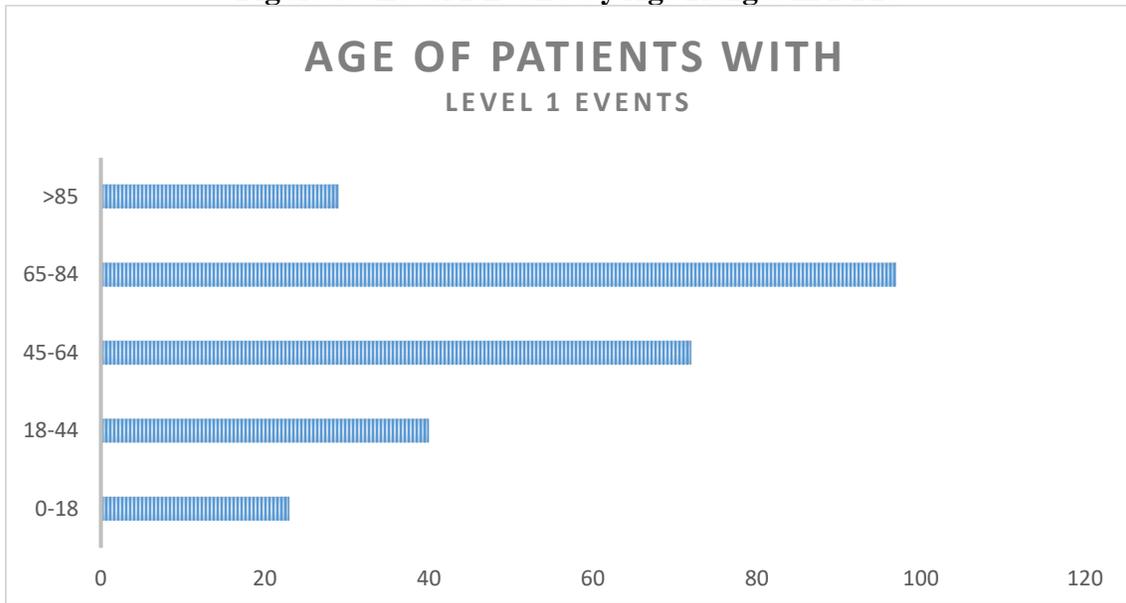
Figure 6: Top 5 Level 1 Events by Age Ranges in FY20

DISTRIBUTION OF EVENTS BY AGE FY20
LEVEL 1 EVENTS
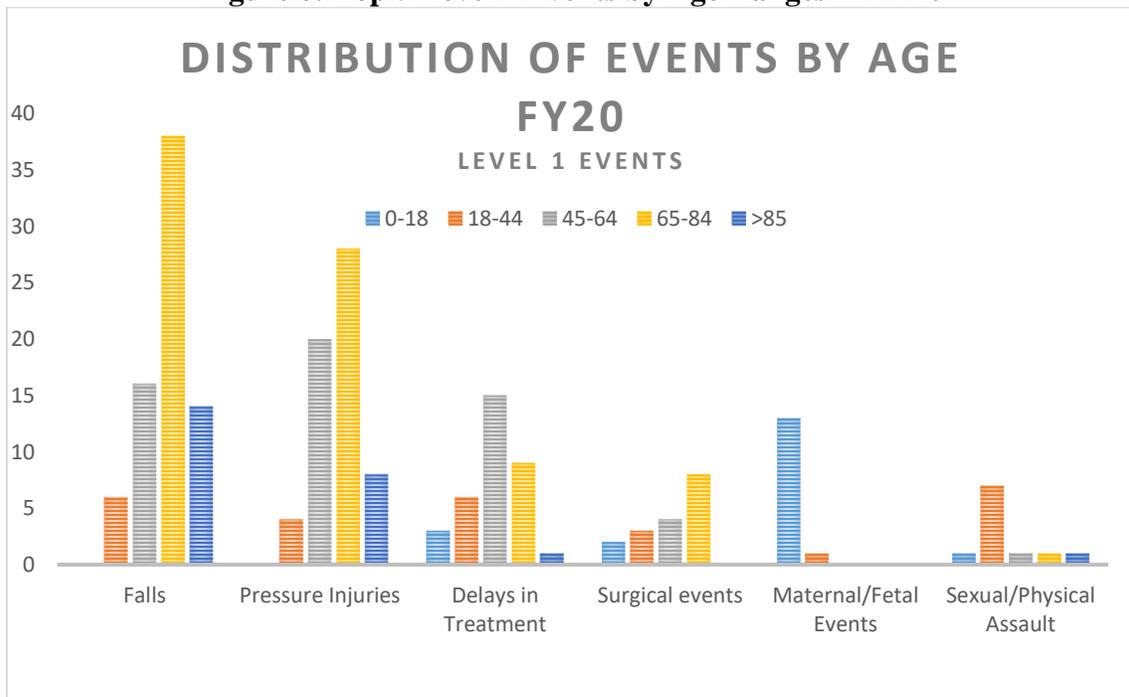
When looking at the top 5 categories of Level 1 events, ages 65 to 84 experienced more falls, pressure injuries, and surgical events than any other population.

Figure 7: Age Ranges Associated with Fatal FY20 Level I Events

AGE AND FATALITY OF LEVEL 1 EVENTS

■ 0-18 ■ 18-44 ■ 45-64 ■ 65-84 ■ >85

7%
11%
12%
31%
39%
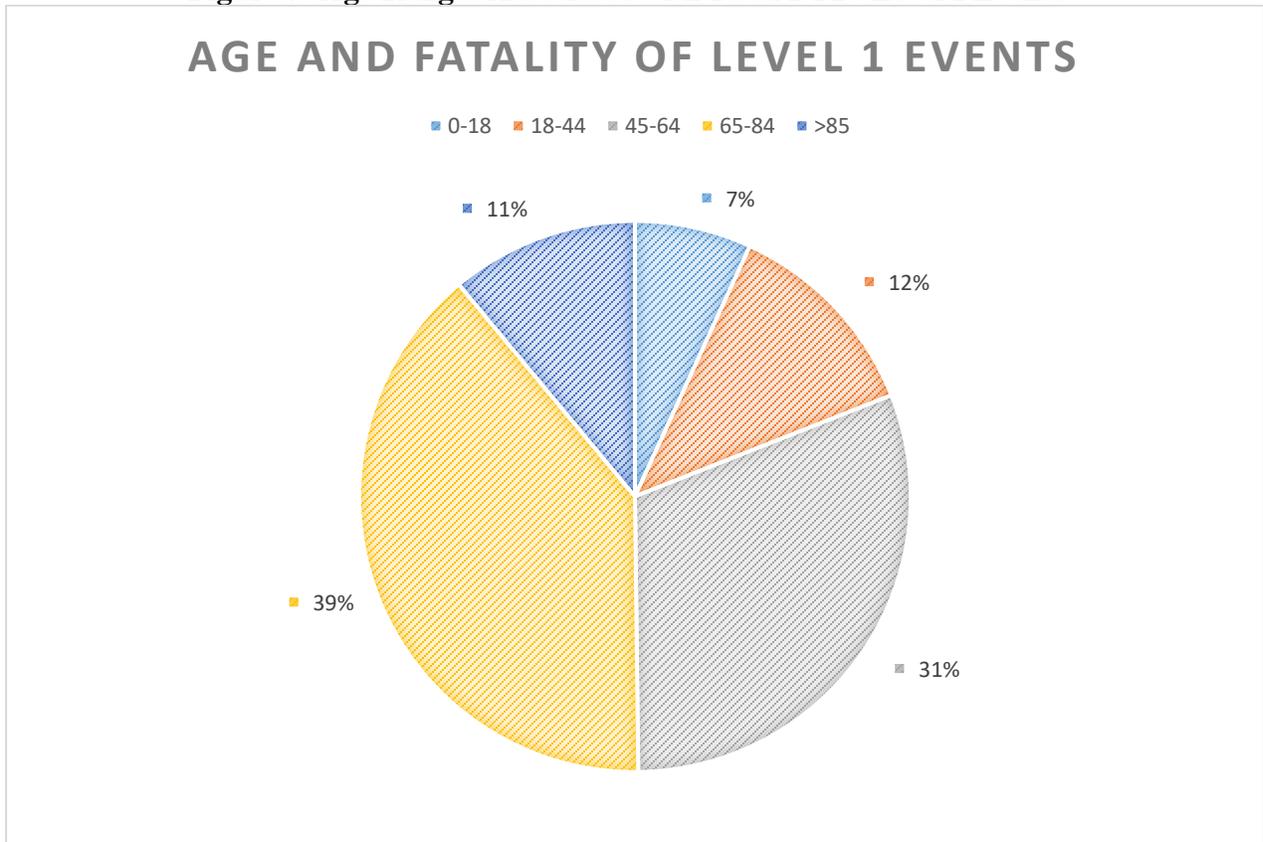
Falls

According to the Agency for Healthcare Research and Quality (AHRQ) more than one-third of hospital falls result in injury, including serious injuries such as fractures and head trauma. The Centers for Medicare and Medicaid Services do not reimburse hospitals for the associated additional costs resulting from falls in the hospital. Fall prevention in hospitals requires striking a balance between managing a patient's underlying fall risk factors (e.g., problems with walking and transfers, medication side effects, confusion, frequent toileting needs) while also assessing and respecting patient choice and autonomy.

Hospitals have reported Level 1 events involving falls since the inception of the Hospital Patient Safety Program in 2004. There is an average of 65 falls reported annually. Since 2011 there has been a decrease in the number of falls reported and a decrease in Level 1 fall events.

Figure 8: Reported Falls from FY05 to FY20
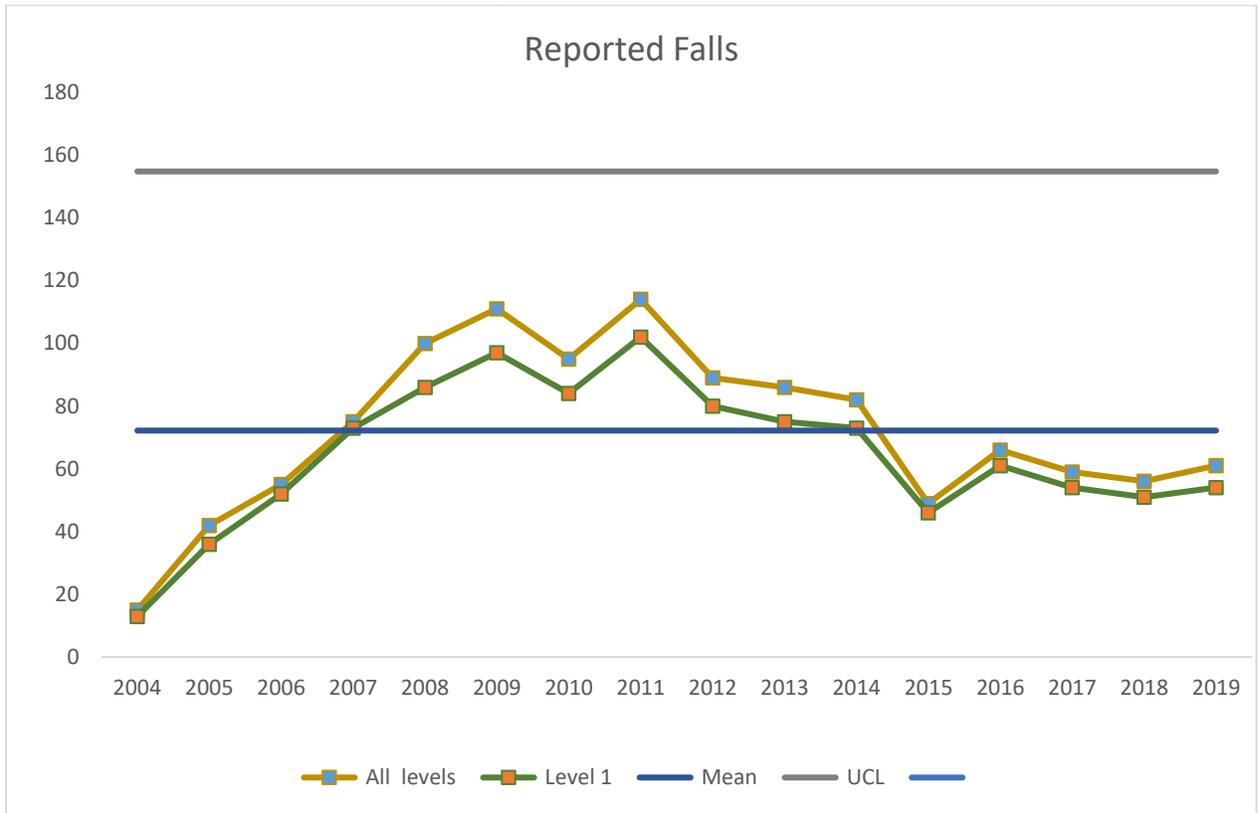
In FY20, falls were the most reported event with 71% in medical-surgical areas and 19% in emergency departments. Falls occurred in other care areas, including the intensive care unit, rehabilitation, psychiatry, and radiology. In 15% of the events, the fall resulted in death.

Figure 9: Outcomes of Reported Falls in FY20
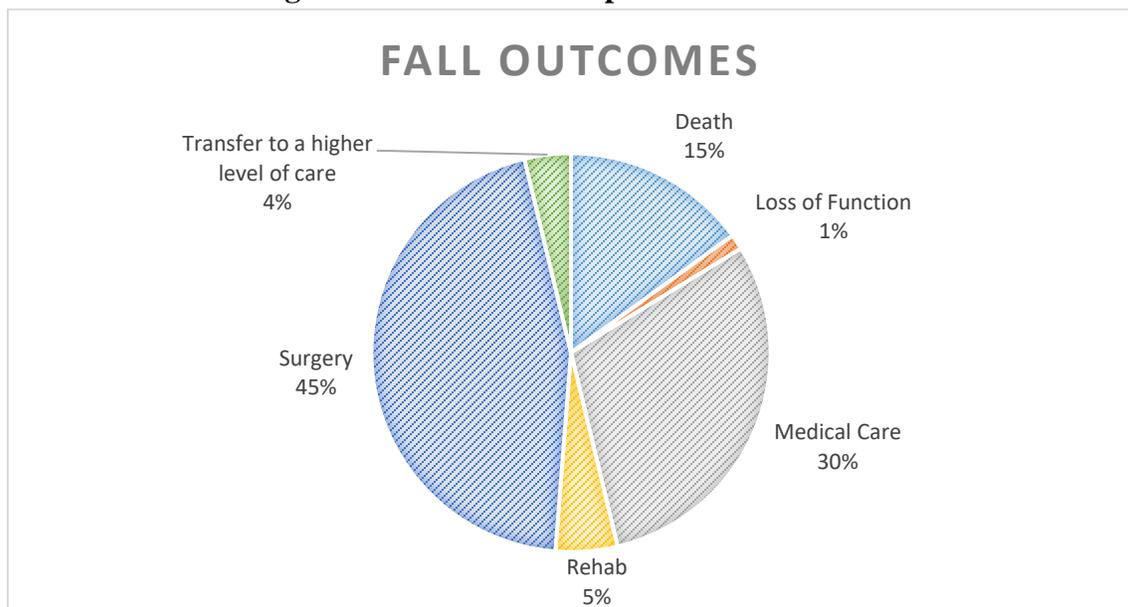
Falls occur due to a variety of physical, cognitive, and systemic factors. Submitted hospital analyses have shown that falls are multifactorial, but often occur as a result of deficits in assessment of patient risk, tailored interventions, communications, or human factors such as staff forgetting to implement or re-engage interventions.

In one event, an elderly patient was transferred from the intensive care unit to a medical floor. The patient had a specialty low air loss bed with no bed exit alarm. The family informed the care team the patient often tries to climb out of bed at night and requested virtual monitoring and mittens. The nurse informed the charge nurse, but all monitoring units were in use. The charge nurse checked if any of those units could be discontinued and identified a unit for the patient. The nurse was unaware the patient's family had already left and other interventions, such as the available telemonitor, had not been implemented. The patient died shortly after the fall.

In another hospital, an elderly patient presented to the emergency department to be evaluated for a possible stroke. A full fall assessment was not completed, and appropriate fall prevention interventions were not instituted. While in the emergency department, the patient was found on the floor beside the stretcher. The patient was noted to be alert and oriented by nursing after the fall assessment. A provider assessed the patient and noted no injuries. No diagnostics were ordered. The patient was admitted to the inpatient unit and was experiencing post-stroke aphasia. Staff documented pain assessments using the behavioral pain scale with intermittent ratings of discomfort noted over the next four days. When the patient's speech began to return, the patient reported hip pain. An x-ray revealed a left displaced femoral neck fracture. The patient underwent a left hip hemiarthroplasty and was subsequently transferred to subacute rehab.

In another event, a moderate fall risk patient was transferred from the ICU to the telemetry unit after admission for respiratory failure with subsequent intubation. The patient was requesting the door be kept closed, but had demonstrated the ability to use the call bell system. Telemetry technicians were monitoring the patient's cardiac status on a system where the default was to monitor only one lead at a time unless the setting was changed. Nursing and monitor techs received advisory messages when leads were off, but there was no audible alert. In this case, the patient's leads failed, but the one lead monitored by the techs remained connected and the patient was not checked. There was a 24 minute delay in assessing the resident after an unwitnessed fall. The patient was found in ventricular fibrillation and could not be resuscitated.

In various cases, staffing or case load has been identified as a contributing factor in falls. In one such event, a new agency nurse was caring for a patient with a complex history. During her first shift, she was assigned three patients with no Patient Care Tech (PCT) on a unit with a

usual two-patient to one staff assignment ratio. With the heavy workload, the patient assessment was inadequate and potential interventions were not instituted prior to a serious fall.

Hospital-Acquired Pressure Injuries

The criteria for reportable HAPIs under the Hospital Patient Safety Program is based on the National Quality Forum (NQF) definition of **"**Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting." Hospitals must report all HAPIs except (1) injuries that progress from wounds acquired pre-admission as long as they were recognized at admission; (2) deep tissue injuries (DTIs) unless these evolve into or are debrided into Stage III or IV open wounds; and (3) Kennedy ulcers that arise due to hypoperfusion in the 24 to 48 hours prior to death.

Figure 10: Hospital Acquired Pressure Injuries from FY05 to FY20
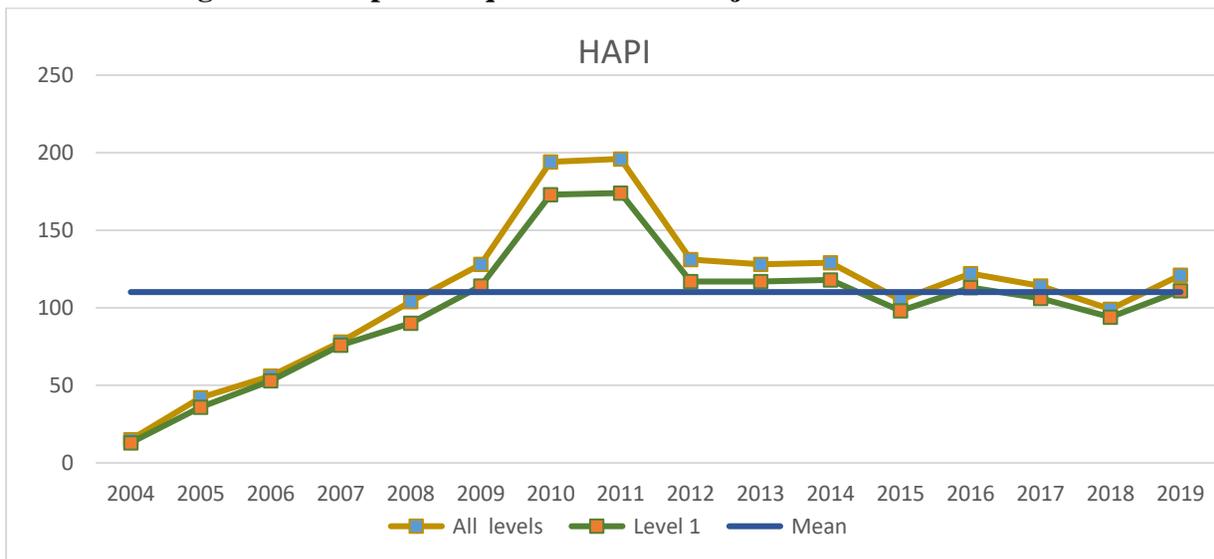
The COVID-19 pandemic has impacted pressure injury prevention in acute care hospitals. The National Pressure Injury Advisory Panel (NPIAP) [4] published a position paper discussing unavoidable pressure injuries during COVID-19. Patients with COVID-19 experience hypercoagulopathy and corresponding skin changes where the skin appears purpuric and quickly becomes necrotic. These skin wounds mimic the appearance of deep tissue pressure injury (DTPI), especially when they occur over tissue exposed to pressure and/or shear stress, such as the sacrum or heels, or under medical devices. If the vessels are severely or fully occluded, then adequate reperfusion is not achievable even with reasonable repositioning and turning of the patient and the use of appropriate support surfaces. In addition, NPIAP reports of true pressure injuries that rapidly deteriorate from microvascular thrombosis caused by COVID-19.

With this in mind, during FY20, OHCQ reviewed event details and root cause analysis (RCA) findings to appropriately classify HAPI events involving COVID-19 patients. In some cases, this resulted in reclassifying events to non-reportable. However, COVID-19 diagnosis alone is not an exclusion of a reportable HAPI event.

Identified root causes in HAPI events reviewed in FY20 included inadequate assessments, failure to comply with care processes, modified processes to minimize exposure to COVID-19, and/or direct impact of various devices.

A patient in his 40s was admitted for subdural hematoma and T12 fracture after a serious fall. The patient arrived on the inpatient unit with a Thoracic Lumbar Sacral Orthosis (TLSO) brace in place. After two weeks, a deep tissue injury was noted on the patient's medial back, which then evolved to necrotic tissue and full thickness pressure injury. Upon identification of the pressure ulcer, the wound nurse implemented recommendations to prevent the wound from progressing further. Root Causes identified included that unit nurses and physicians were unfamiliar with the brace and with skin care needs related to it. As staff did not ask for training, and the wound care nurse assumed staff was competent. The RCA also identified that there was no policy for care related to the brace in use.

In another event, an elderly COVID-19 patient had a tracheotomy placed and a device related pressure ulcer developed. The causal analysis found multiple systems failed. First, the trach itself was sutured too tightly. Second, the patient experienced prolonged immobility due to intubation. Last, limiting staff entering the room due to COVID-19 precautions contributed to staff failing to keep the area dry and failing to sufficiently assess and reposition the patient with the needed frequency.

Another device-related HAPI occurred in a premature newborn. After a short intubation period, the infant was placed on a certain type of nasal cannula for oxygen for 22 days. The baby developed an avoidable stage 4 HAPI on the nasal septum. Multiple root causes included that a skin barrier system obstructed viewing the skin for assessment, the cannula was not correctly positioned, and the cannula was not the correct size. Per the manufacturer, "improper selection of size, improper positioning or improper use may result in septal trauma or necrosis."

Diagnostic Errors and Delays in Treatment

Missed and delayed diagnoses were identified as the number one patient safety concern by the ECRI for 2020.[3] The Agency for Healthcare Research and Quality (AHRQ) states that diagnostic errors account for 17% of adverse events. A 2019 Society for Diagnosis in Medicine (SIDM) study, also published by AHRQ, estimated that one in three malpractice cases involving

---

[3] https://assets.ecri.org/PDF/White-Papers-and-Reports/2019-Top10-Patient-Safety-Concerns-Exec-Summary.pdf

serious harm was due to diagnostic error. According to Sarah Creswell, MSN, RN, CPHQ, patient safety analyst, ECRI, "When a diagnosis is missed or delayed, the patient might not get the treatment they need when they need it. When this happens, "we've missed a critical window."

Rather than individual error, diagnostic errors or omissions occur from a variety of cognitive and systemic factors and are influenced by communication, access to pertinent information, and decision support systems. Focusing on the actions of physicians and licensed independent practitioners may result in the loss of valuable information and opportunities for effective interventions.

In the Maryland Patient Safety Program, diagnostic errors and delays in treatments are captured in the categories of misdiagnosis, delays in treatment, and staff member's failure to act. In FY20, misdiagnosis events increased to nine events from three events in FY19. Each misdiagnosis in FY20 resulted in serious harm. Delays in treatment increased from 27 in FY19 to 37 in FY20.

In one fatal case, a patient on a medical floor sustained an aspiration event. A nasal-gastric tube for feeding had been placed and was x-rayed to confirm accurate placement. After staff provided tube-feeding the patient developed rapid breathing, required increased oxygen, became completely obtunded, and was transferred to a unit with a higher level of care. The RCA found the x-ray report narrative was not clear. While the radiology narrative described the position of the tube, it did not include a clear statement indicating whether it was in place or needed to be corrected by advancement. Staff failed to recognize it as a critical concern and did not follow up with the physician or seek clarification.

In another event a man in his 20s presented to the emergency department with altered mental status and approximately one week of coughing, sore throat, nausea, and vomiting. Labs indicated elevated glucose and severe acidosis. The patient was diagnosed with diabetic ketoacidosis (DKA), treatment was initiated per protocol, and the patient was admitted to the Medical Intensive Care Unit (MICU). A head CT obtained in route to the MICU revealed no gross intracranial abnormality, but the radiologist noted that the imaging quality was limited by motion artifact from the patient's agitation and recommended a repeat CT if there was high clinical concern. On admission to the MICU, the patient's neurological exam revealed a Glasgow Coma Scale (GCS) of 9, nonsensical answers to questions, and spontaneous movement with periods of intermittent agitation and lethargy.

Two hours after admission to MICU, the patient's neurological exam showed the GCS had declined to 3, the patient had no motor response, and changes to eye pupils indicated serious clinical decline with the right pupil larger than the left. The patient was intubated, and a stat

head CT was ordered. The head CT obtained indicated "no acute intracranial abnormality" on the senior radiology resident's initial read. The radiology attending performed the final CT read five hours after the senior radiology resident called critical results to the MICU team, which was positive for "moderate diffuse brain edema." Hypertonic saline therapy was initiated and the MICU continued treatment for DKA and sepsis, but the patient progressed to brain death. The root cause in this event was the delay in recognition and timely treatment of cerebral edema due to:

1. Failure to recognize continued decline in neurologic status despite effective DKA treatment.
2. Failure to recognize possible meningoencephalitis as cause of DKA and altered mental status.

It was noted that as part of standard DKA treatment, patient received hypotonic fluids for an extended period of time, potentially exacerbating cerebral edema and increasing likelihood for cerebral herniation. Additionally, neither the resident nor the nurse recognized the need to escalate concerns regarding patient's continued decline to the overnight MICU fellow or attending.

Failure to follow-up on with a patient's primary care provider contributed to another event. A middle-aged woman with a history of smoking presented to emergency department for double vision, loss of peripheral vision, dizziness, and frontal head pressure while working. A CT of the head was initially found to be unremarkable, but the following day, an addendum was placed at the end of the report noting an incidental finding of a right upper lobe lung mass. This additional finding was not called to a provider and was not included in the patient discharge summary. Over the next four months, the patient had multiple follow-ups with her primary care physician and an ENT for persistent cough, weight loss, and eventually voice hoarseness, severe temporomandibular joint pain, and parotid gland swelling. Ultrasound and a CT of the neck and chest revealed a concern for lung carcinoma with possible metastasis to the left mandible and other locations. Ultimately, the patient was diagnosed with metastatic small cell carcinoma, four months after the lung mass had first been identified.

Inexperienced nursing staff contributed to the death of a patient in another reported event. A patient presented to the emergency department with five days of gastrointestinal and upper respiratory symptoms. He was admitted for observation and an order was placed for continuous cardiac monitoring, but telemetry was not initiated. The patient was found in cardiac arrest and he could not be resuscitated. In their root cause analysis, the hospital noted that the telemetry order was acknowledged by a novice RN with a complex case load on a very busy unit. The staffing mix on the unit included four novice RNs and a tenured nurse who was charge. The unit had also been newly converted into a COVID-19 unit and the organization had recently

implemented a new electronic health record system with new workflows and screens. The primary RN did not verbalize she needed help and the charge nurse did not recognize that she needed help.

In another event, after surgery an elderly patient was transported from a post-anesthesia unit to a medical-surgical unit post-surgery. A few hours later, the patient was found without pulse and CPR was initiated, but staff were not able to resuscitate the patient. An autopsy was performed and referenced a probable acute cardiac event. In review of the patient's care, it was discovered that the patient had vital sign changes while still in the post-anesthesia surgical unit that were not responded to by the RN nor the patient care tech. The primary nurse on that unit was a new graduate with less than six months experience but was allowed to float to the post aesthesia unit on occasion. The primary nurse was provided with a "tip sheet" that outlined the unit standards for post-op vital signs, PCA monitoring, unit resource phone numbers, and assistance to locate critical unit resources.

The RCA investigation revealed the vital signs required on the unit were structured and clear, but the assigned post-anesthesia nurse was uncertain of the required vital sign frequency for a post-op patient. In addition, the patient had a patient controlled analgesic (PCA) pump which required one-hour assessments and four-hour vital signs. The unit used a bedside vital sign monitor that was not electronically linked to the electronic health record system, so all vital signs had to be entered into the EMR manually. In addition, the monitor did not collect temperatures or respiratory rates, which were also assessed manually. Nonetheless, in addition to the identified systems concerns, the RN had delegated the vital signs collection to the primary PCT who did not record the vital signs in real time and the assigned nurse lacked awareness of the vitals. These variances in following unit guidelines were identified as gaps in practice.

Surgical Events

Hospitals reported 35 surgical events during FY20, the same number as reported in FY19. The category of surgical events includes all patient procedure events along with retained foreign objects (RFO), intraoperative death in healthy individuals having low risk procedures, and unanticipated intra-operative or immediately post-operative deaths. Surgical events typically have low lethality compared to other event categories, but unexpected deaths do occur intraoperatively and post-operatively.

In one adverse event, an elderly patient with a history of gastric bypass, gastroesophageal reflux disease, and obesity presented to the emergency department with one-hour of chest pain with gradual onset, dyspnea, and diaphoresis. The patient was diagnosed with likely acute cholecystitis (gall bladder inflammation). Surgery was consulted and antibiotics were initiated. He was admitted to the surgical service and a scan confirmed the diagnosis. The patient

underwent an uneventful gall bladder surgery with 100 mL blood loss and episodes of hypertension controlled with medication (hydralazine) intraoperatively. Post-operatively, the patient had reduced urine production with episodes of clamminess and weakness. Intravenous fluids were administered, and bladder scans were performed. On post-operative day two, the patient had a cardiac arrest. Cardiopulmonary resuscitation was initiated, but he was unable to be resuscitated. An autopsy revealed approximately 2 liters of blood in the abdomen with clotted blood also noted at the gallbladder fossa.

The root cause analysis revealed that post-operatively the attending physician was very ill and could not be on site. There was no other attending physician coverage. A physician assistant (PA) was on site daily and the attending was looking at labs and placing orders from home. There was insufficient coordination of care between the PA and the attending. The patient's post-surgical complications and oliguria were not effectively managed, and the staff did not escalate the coverage or care concerns to the surgical attending.

By far, the most common surgical event reported to OHCQ is retained foreign objects (RFO). In FY20, 16 of these events were reported by Maryland hospitals compared to 20 events in FY19. Retained objects are often discovered when the patient has poor healing or complications post-procedure. Most RFO events involve surgical teams who closed a patient's incisions prior to confirming the count and prior to checking the x-ray results when the count is wrong. In several events, the surgeon did not take part in the count or confirm the accuracy of the count before leaving the operating room. Some hospitals also lacked policies requiring counting every object that goes into a patient or into any body cavity.

In one case, a patient presented after a motor vehicle accident with a large liver laceration that required a massive transfusion protocol with multiple abdominal surgeries for bleeding. After the first surgery, the patient abdomen was left open and packed because of the need for future surgeries. At end of the third surgery, an x-ray noted a potential retained foreign object, but the object was not recognized as anything that had been used in the surgery. The RFO was found on a CT three months after the initial hospitalization. This was found to be a quick-clot product that had apparently been left in during the first surgery.

A second reported event also involved a quick-clot product that was retained. A woman in her 50's with an extensive cardiac surgery history had a procedure where a dual chamber Automated Implanted Cardioverter-Defibrillator was placed. Two months later, during a planned procedure to insert a left ventricular (cardiac) lead, a foreign object was identified. A quick clot gauze was used during the procedure, but as it was not routinely used in the electrophysiology lab, it was not consistently counted. During the procedure, there were changes in the staff. Some staff were not familiar with the product and thought it was dissolvable; therefore, a dissolvable product would not be included in the counts. The routine x-ray taken

post procedure missed the RFO because it was very difficult to detect. On later review of the x-ray, the gauze was evident.

In another event, an elderly man with decreased vision due to a right dislocated intraocular lens presented for surgery to replace the intraocular lens. He was intubated, general anesthesia was administered, and the procedure was performed without difficulty. Following the procedure, the patient complained of a sore throat and a sensation of mucous in his throat. He denied shortness of breath and his oxygen saturation was normal. He was able to swallow water and used the incentive spirometer without difficulty. The team presumed that the throat symptoms were due to the recent intubation. At his scheduled post-op visit the following day, the patient reported significant coughing overnight with vomiting of cotton material, which he brought to the visit. This item was determined to be a bite block composed of wrapped and taped gauze. The intraocular lens was no longer in place and the patient had to undergo the surgical procedure a second time. The RCA team noted that taped gauze is a makeshift bite block and is not manufactured for this purpose. The RCA noted that in this case, the CRNA did not follow her customary practice of taping the bite block to the endotracheal tube. The CRNA also lost situational awareness as to the location of the bite block, believing it had been removed.

A pediatric patient with a history of dual cuff peritoneal dialysis catheter insertion by a general pediatric surgeon successfully underwent kidney transplantation. A peritoneal catheter was inserted and ultimately removed by the transplant surgeon. The patient developed erythema and abdominal pain postoperatively that was diagnosed as cellulitis and treated with antibiotics, but the patient's condition did not improve. Upon catheter site exploration by the general pediatric surgeon, one of the two catheter cuffs were found to have been retained. The child recovered well postoperatively. The root cause analysis found there was lack of clear documentation in the electronic medical record identifying the product type on insertion of the catheter during the procedure. Providers changed between insertion and removal, and the second provider did not have a clear and accurate record of what was placed to know what should be removed. The device design was such that a cuff could detach in a patient when removing the catheter. The design complication was reported to the FDA.

Miscounting remains one of the most common root causes in RFO events. There is evidence to support the use of sponge counters which are more accurate and reduce the likelihood of a retained sponge. In one event, an operating room nurse used a kick bucket instead of the available sponge counter. An elderly patient had a T10-L2 laminectomy orthopedic procedure. Two OR nurses determined the counts were accurate at final and closing. The patient had multiple wound care visits for a non-healing surgical wound. The patient was readmitted for a post-op infection and found to have a retained sponge. When an x-ray was done after the original procedure, the radiologist identified a possible RFO on the x-ray and recommended correlation with the clinical course. The radiologist did not call the attending

physician due to past challenges when contacting providers in the past. The object remained retained until the issues with poor wound healing resulted in follow-up.

In another event, a middle-aged woman was admitted for bilateral total mastectomies for breast carcinoma. The closing sponge count did not match the initial sponge count. An x-ray of the abdomen was ordered. The sponge was in the left axilla and was out of the range of the abdominal x-ray that was taken. The surgeon reported he did not visualize any retained foreign object.

Instrument failures or defective devices can be sources of retained foreign objects as well. A woman underwent a total laparoscopic hysterectomy. Per the operative report, a monopolar hook was used to create a colpotomy ring. During this process, the monopolar ring was noted to detach from its probe base after becoming affixed to the vaginal cuff. An x-ray should have been done as soon as possible after the equipment breakage and the skin should have not been closed until there was confirmation of no retained foreign objects.

One hospital reported , a patient with left lower extremity surgery was brought back to the operating room due to poor blood flow. The vascular surgeon removed a retained foreign body, which was most likely the balloon. Adequate blood flow was restored to the limb. During the initial surgery, the balloon had detached from the shaft (a rare occurrence). Of note, a defective balloon had been recognized a few weeks prior to this case and was reported to the manufacturer. Careful inspection of devices should be done before and after each device use.

Despite universal protocols and time outs being an accepted best practice, wrong site, wrong patient, and other "wrongs" still occur. These may occur as a result of distraction, noncompliance with universal protocols, human error, or gaps in a process and procedure. A middle-aged man consented for a left thoracentesis procedure. When patient got back to the floor, RN charted dressing on his right back but did not notice that this was not the same side as the consent. The hospitalist noticed the dressing was on the right side, which was inconsistent with the consented procedure and called the interventional radiologist. The root cause analysis found the patient image on CT was inverted so the physician thought he was performing the procedure on the left side when he was actually on the right.

In another event, the patient presented to the hospital for a right upper extremity venogram in the Cardiac and Vascular Interventional Laboratory. The patient consented for a right upper extremity venogram. The left upper extremity was prepped for procedural access and a time out was performed, identifying the right upper extremity as the intended procedure site. A left upper extremity venogram and angioplasty were performed. The attending exited the procedure room and then realized that the right upper extremity was the intended procedural site. The right upper extremity was prepped and the planned right upper extremity venogram and

angioplasty were performed. The root cause analysis revealed that the posting sheet and the consent do not differentiate between the target treatment site and the procedural access site for procedures where ipsilateral upper extremity access is required. Miscommunication between the nurse and the vascular surgery fellow led to procedural access site prep on the incorrect upper extremity. Additionally, the pre-procedure verification process along with the final verification process time-out were not conducted in accordance with hospital policy.

Occasionally events occur in the initial ordering process. In one event, an elderly man was scheduled for robot-assisted ureterectomy for recently diagnosed urothelial cancer. A urologist performed a cystoscopy, bladder biopsy, bilateral retrograde pyelogram, and "left" ureteroscopy with resection of ureteral tumor at another facility. The pathology report inaccurately indicated urothelial carcinoma of "right" distal ureter. The patient signed a consent form for a right distal ureterectomy, and the site was marked by the urologist. A time out was conducted per protocol and the patient underwent a right ureterectomy with stent placement. The pathology report for the "right" ureterectomy was negative for tumor, which prompted the urologist to review the medical record. The patient then underwent surgery to remove the right ureteral stent and biopsy the left ureter. The pathology report confirmed a high grade papillary urothelial carcinoma of the left ureter.

A woman presented for left breast mastectomy for ductal carcinoma in situ with sentinel node biopsy followed by plastic surgery. The patient consented to general anesthesia and a left chest regional nerve block. The Regional Block Service (RBS) was to place the nerve block pre-procedure. The RBS anesthesia resident used ultrasound guidance to locate the appropriate site for the pectoral block. Due to challenges with the patient's anatomy, the RBS attending decided to place the block. The breast surgeon and plastic surgeon had marked their initials on the left side. However, per routine, the plastic surgeon had also placed multiple anatomical markings bilaterally on the patient's chest to ensure symmetry. The anesthesia attending placed both right and left blocks. The error was realized when the surgeon noted bilateral puncture marks at skin prep. The RBS attending and resident acknowledged that a block time out did not occur, citing distraction and production pressure. Further, there was uncertainty as to who should initiate the time out.

Maternal or Fetal Events

Maternal health was identified as the number two patient safety concern by the ECRI Institute for 2020.[4] Centers for Disease Control and Prevention show more than 700 women die each year from childbirth-related complications in the United States and more than half of these deaths are preventable. The United States has the highest maternal death rate among the world's developed nations, and it is rising further, even as it falls throughout most of the rest of the

---

[4] https://www.ecri.org/landing-top-10-patient-safety-concerns-2020

world, explains Carlye Hendershot, MSN, RN, CPPS, CPHRM, senior patient safety analyst and consultant at ECRI. There were 13 maternal or fetal events reported in FY20, an increase compared to the 7 reported events in FY19. Although the number of events is low compared to other categories, 46% of the reported maternal or fetal Level 1 events were fatal in FY20.

Figure 11: Maternal or Fetal Events Reported from FY05 to FY20
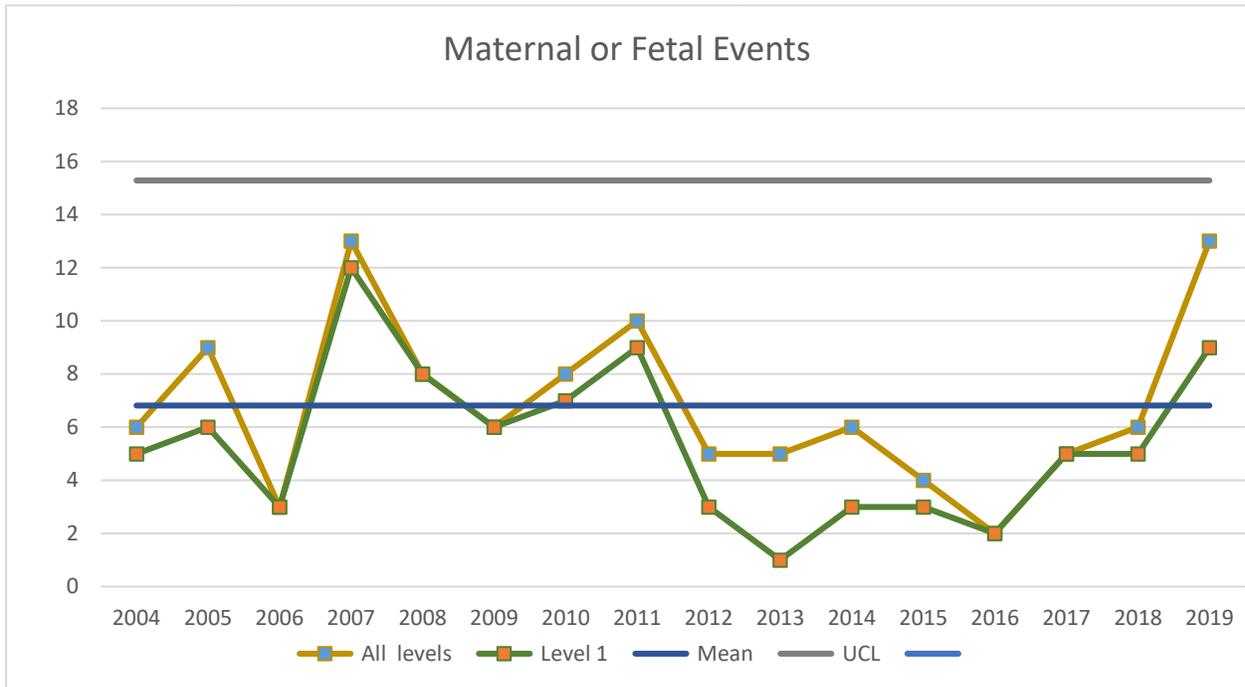
A male infant was born by vaginal delivery at 40.5 weeks. The delivery was complicated with prolonged second stage of labor resulting in fetal tachycardia, with variable and late decelerations. The infant developed a subgaleal hematoma, causing anemia, and requiring a blood transfusion. While in the NICU the infant was noted to have seizure activity and was transferred to another facility. The day shift nurse assessed and reported that the mother was 100% effaced and ready to start pushing, but was not confident in her assessment and did not ask for help. The night nurse had the mother start to push before doing an assessment. The root cause analysis discussed Fetal Heart Rate (FHR) tracing and the need for more immediate intervention. The fetus had a change in condition that was not acted upon timely, and the delivery plan was not altered. The physician expected a long labor and did not put the historical strips together to get an accurate picture of labor.

In another event, a woman presented for decreased fetal movement at noon of the prior day. Fetal monitoring demonstrated minimal variability, which progressed to terminal bradycardia. The resident sought confirmation from the attending before a stat C-section was performed. Nursing personnel recognized clinical deterioration and relied upon the resident to decide. An emergent C-section was performed with delivery of the infant, who lacked heart rate

or respiratory effort. Immediate resuscitation resulted in the return of spontaneous circulation at 21 minutes. The infant was transferred to another facility and withdrawal of care was requested by the parents. The RCA noted that additional training regarding communication and action upon recognition of an emergency was warranted for both nursing and medical personnel. The team also determined that the resident was not clear on his authority to start an emergency C-section without the attending.

Failure of the emergency department physician to consult with the patient's obstetrician was determined to have contributed to one fetal demise case. A pregnant woman presented to the emergency department with six days of cold-like symptom, sore throat, and chest tightness. She expressed concern for decreased fetal movement. There was a fetal heart rate of 140 bpm in triage. She was evaluated for cold symptoms and offered a nebulizer, steroids, and a chest x-ray, but she declined. She was discharged with prescription for antibiotics and instructed to follow-up with her primary care physician. The patient presented to her obstetrician's office one week later stating the baby had not moved all week. Her obstetrician sent her to the birthing center for evaluation. Fetal heart tones showed minimal to absent variability, fetal heart rate of 148, and elevated maternal blood pressure. IV fluids and lab studies were ordered. Fetal heart tones were not improved after fluids and positioning. Prolonged decelerations were experienced, and an emergent C-section was initiated. The infant was intubated and resuscitation attempted, but was not successful. The RCA team found that the mother had an elevated blood pressure and had complained of 6/10 pain during the emergency department visit, which should have prompted staff to contact the obstetrician and transfer the patient to the birthing center for further evaluation.

At 39 weeks pregnant, a woman was admitted for scheduled elective cesarean section. Her pregnancy was uncomplicated, except for noted anemia. Pre-operative tracing of baby was unremarkable. The patient was brought to the operating room for spinal anesthesia placed by the Certified Registered Nurse Anesthesiologist (CRNA). The patient was then laid supine and experienced nausea. The CRNA treated the patient with approximately 1.5 liters of intravenous fluids and multiple doses of ephedrine and phenylephrine post-spinal anesthesia hypotension over 15 minutes.

The time from incision to delivery was 13 minutes. The obstetrician reported a large gush of blood after placenta was delivered without a noted clot, which was concerning for acute placental abruption. A baby girl was born limp with no respiratory effort and no heart rate and large amounts of bloody secretions were aspirated from baby's oropharynx. The baby girl required resuscitation and ultimately required intubation with transfer to another hospital for a higher level of care. Analysis of the event found poor communication of the mother's post-spinal anesthesia hypotension between the anesthesia (CRNA) and the obstetric team. Other personnel (e.g., surgeons, nurses, techs) in the operating room could not visualize the vital sign monitor. At the time of this event, no policy existed addressing neuraxial anesthesia induced hypotension.

Restraint and Seclusion Events

The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) promotes alternatives to restraint and seclusion[5]. They cite an estimated 50 to 150 individuals die each year as a result of seclusion and restraint practices in facilities, and countless others are injured or traumatized. There was one death associated with a seclusion reported in FY20.

A middle-aged man was transported to the emergency department via EMS and police for psychiatric evaluation. Staff documented suspicion for alcohol withdrawal, and that the patient reported depression and suicidal ideation. Basic labs were obtained, including a toxicology screen, which tested positive for cocaine. The patient became increasingly agitated in the emergency department and required chemical sedation with Benadryl, Ativan, and Haldol. Following sedation, the patient calmed down and was admitted to the behavioral health unit (BHU). After arrival to the BHU, the patient's behavior escalated. He began banging his head on the wall and running throughout the unit. The patient was placed in seclusion. He was found unresponsive on the floor in the seclusion room and a code was called, but the patient died. The RCA noted both a time discrepancy in the monitoring documentation and that there was no clear view of the patient in the seclusion room.

Physical or Sexual Assaults

Sexual assaults of any patient on the grounds of a hospital facility are reportable events. There was one unanticipated, intentional sexual assault committed by a team member reported by a hospital. The event involved a young adult female who presented to the emergency department via EMS for medication overdose. She was assessed by the psychiatric team and placed in the emergency department psychiatric holding area pending inpatient psychiatric placement. While in the holding area, the patient was sexually assaulted by a security officer. The police were notified and an investigation substantiated the allegations. The security officer admitted that he was in the patient's room when the patient became sexually assertive. The security officer was terminated and subsequently arrested by police.

In another event, a male patient in his thirties presented to the emergency department with anxiety. The patient was promptly triaged and taken to the main emergency department, where he proceeded to call the police department six times. The police contacted the hospital's security department, who notified the medical team. Hospital security and the medical staff decided to remove the phone. An emergency department physician determined that the patient was having an acute psychotic event. The physician attempted to see the patient twice after this occurred but was called away to a code blue.

---

[5] https://www.samhsa.gov/sites/default/files/topics/trauma_and_violence/seclusion-restraints-4.pdf

Staff determined that the patient should be placed in the emergency department's Behavioral Health Unit (BHU). Due to the patient's escalating behavior, the team decided to move the patient to the BHU without exercising the hospital's usual safety precautions. While escorting the patient to the BHU, he eloped from the security officer and ran into another patient's room. He pulled a 5-inch blade out of his pocket and began swinging the knife. Three officers were injured, including one who was flown to Shock Trauma for treatment. The healthcare team did not know the patient's psychiatric and violent history. There had been violent episodes with the patient in the past that had been captured in the security database but were not in the incident report database. Security does not have access to the EMR or patient history.

Another hospital reported that an adolescent patient with a psychiatric history was admitted with physical injuries after attempting suicide by being struck as a pedestrian. Psychiatric placement proved difficult given his medical injuries and clinical complexity. He remained on a medical unit with a 24-hour sitter. While the sitter was present, the adolescent suddenly ran out of the room and into another patient's room. The sitter and other staff immediately followed the adolescent. The adolescent grabbed a pen, removed the cap, and repeatedly stabbed an elderly woman in the face. Staff responded to the bedside, activated the panic alarm, and called security. Security staff eventually subdued the adolescent patient and contacted the local police. The elderly woman had multiple facial lacerations and presumably sustained a penetrating traumatic brain injury from the assault.

The root cause analysis noted that the care and placement of acute psychiatric patients is challenging, because psychiatric beds for adolescents with medical conditions are limited and adolescents cannot be cared for on adult psychiatric units. The sitter had been with a supplemental staffing organization for several years and was hired before new training requirements were implemented that included intensive de-escalation and behavioral health training. There was also a lack of integrated behavioral monitoring, assessment, and intervention for psychiatric patients in this medical setting.

Adverse Drug Events

While the number of reported adverse drug events (ADE) is typically low, two medication events were reported in FY20. This was the lowest number of events reported since 2004.

Figure12: Medications Events Reported from FY05 to FY20
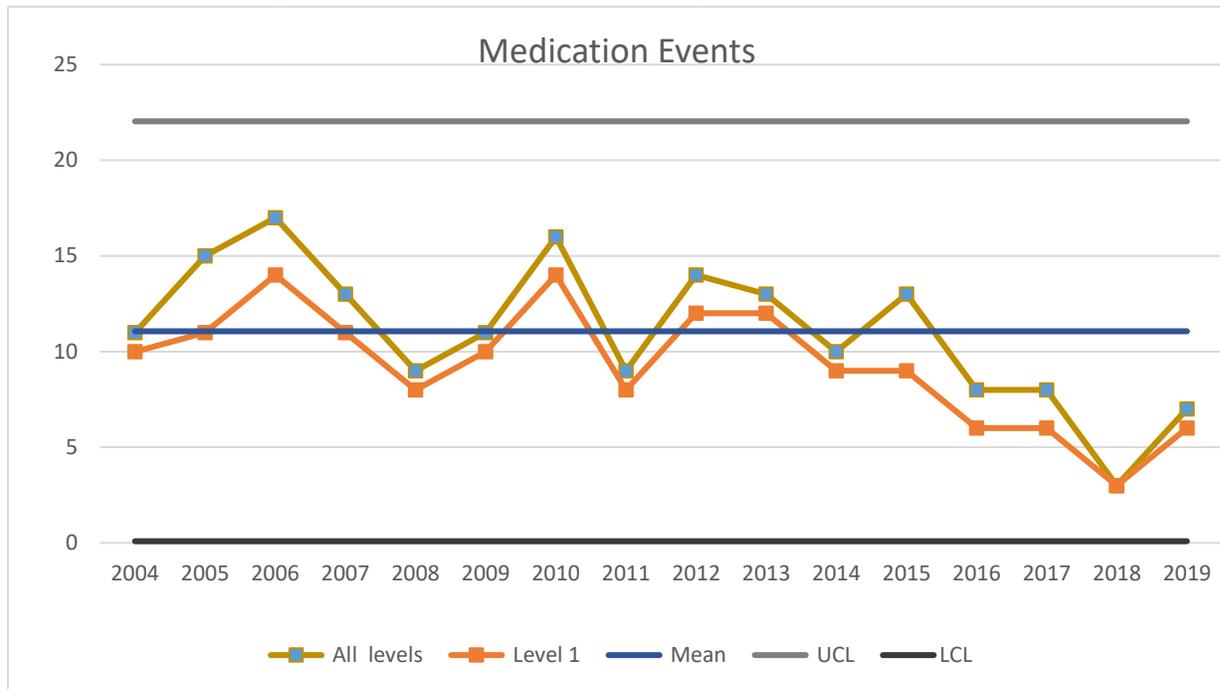
An elderly woman was admitted to the ICU and intubated for airway protection following a left basal ganglia stroke and moderate encephalopathy. During rounds, a neurologist communicated to a physician's assistant (PA) to start a second antiepileptic with a loading dose. The indirect verbal order through the PA included no read-back. Pharmacy had no documentation of order clarification when the order was filled, and when the medication was then administered, the dosing was still not clarified. After administration, the patient had pulseless electrical activity arrest, but was resuscitated.

In the second medication event, drug shortage and failed communication were contributing factors. An elderly man was brought to the emergency department after he was found minimally responsive at home with family. EMS reported systolic blood pressures in the 60s and signs of shock. The emergency department provider requested the nurse prepare epinephrine for "push-dose epi" in case he decided to administer for pressure support in the setting of possible shock. The nurse believed the emergency department provider was giving a verbal order for 1 ml. of epinephrine intravenous push. The nurse administered 1 mg. of epinephrine and within 4 minutes the patient went into cardiac arrest. Upon initiation of CPR, the provider discovered 1 mg. epinephrine was administered and he had instead intended for 10 mcg. epinephrine to have been prepared. The patient received CPR and life-saving measures for 70 minutes until the family asked to stop and the patient expired. The causal analysis team found that the intended timing and dosing of the order were both unclear and having vials with different concentrations of the same medication was confusing.

28

Airway Events

An elderly ventilated patient was admitted with acute encephalopathy that was improving but had right upper extremity weakness. A CT scan was negative, but an MRI was ordered to rule out a stroke or posterior reversible encephalopathy syndrome. She was taken to MRI for a head scan. She appeared anxious and would not keep her head still, so 2 mg. of Ativan was administered. The patient was placed on the MRI compatible ventilator and her blood pressure was monitored throughout the exam. The MRI compatible EKG and oxygen saturation monitor were available but had intermittent reception. At one point her blood pressure was not detected, so the MRI technician stopped the scan to allow for patient evaluation. Upon entering the room, the technician found that the ventilator oxygen hose was not completely connected and was not delivering breaths. The respiratory therapist removed the Y-connector and plugged the oxygen directly into the outlet and the ventilator started delivering breaths. The patient had a faint pulse and was removed from the MRI room and the travel monitor revealed no rhythm. CPR was started and a code blue was called. The patient ultimately died.

COVID-19 Pandemic

During the COVID-19 pandemic, measures were needed to accommodate the surge and complexity of COVID-19 patients presenting to hospitals. Throughout the pandemic, the Hospital Patient Safety Program was fully operational.

In FY20, some of the reported events were related to COVID-19. In one event, a middle-aged bariatric female presented to emergency department after a recent diagnosis of Influenza A and B with worsening cough, chest pain and shortness of breath. Testing revealed that she was COVID-19 positive. She was transferred to a newly converted COVID-19 bio-mode ICU and her condition progressively deteriorated. She required intubation and prone positioning. During repositioning to prevent pressure injury, the endotracheal tube became malpositioned. The patient deteriorated and a code was called with anesthesia support requested. Repositioning the patient to a supine position was attempted and CPR was initiated, but resuscitation efforts were not successful.

The root cause analysis revealed that while the patient was critically ill due to COVID-19, there was a delayed recognition of her deteriorating condition, compounded by a delayed emergency response when the endotracheal tube became dislodged while repositioning the patient during routine scheduled care. It was identified that the patient was frequently turned and repositioned without the use of a bariatric assist device, which required at least five staff members to participate in the turning of the patient on a non-bariatric bed. The patient was not on a bariatric bed because one was not ordered prior to her transfer to the COVID-19 bio-mode ICU. In addition, there was the belief that the type of room the patient was assigned to may have been too small to accommodate this type of specialty bed.

The lack of a coordinated effort and the assist device likely contributed to the dislodgement of the endotracheal tube. Further complicating the emergency response, the code bell did not alarm. When responders were finally contacted, the locked doors created delays in emergency responders arriving to assist the patient. This was an unintended consequence of the recent activation of the transition to Bio Mode. Additionally, there was no ambu bag or Kelly clamp available in the patient's room. The powered air purifying respirators (PAPRs) worn by staff limited their ability to hear sounds, including bell alarms and commands during a resuscitation response. It also limited their ability to identify code team members' roles and responsibilities during a resuscitation attempt.

This event created patient safety concerns related to COVID-19 that apply to all hospital settings, including those not confined within the physical hospital structure that had been adapted to function as bio containment units dedicated to the treatment of COVID-19 patients. These concerns include process, staffing, environment, equipment, and communication.

- Process: Prone positioning[6] of COVID-19 or Acute Respiratory Distress Syndrome (ARDS) patients leads to improved oxygenation and can decrease mortality. However, there are associated risks including pressure ulcers and endotracheal tube obstruction or decannulation. The prone position may also limit the ability of staff to recognize patient deterioration.
- Staffing: The incidence of adverse events is significantly reduced in the presence of trained and experienced staff. This is especially important in making prone positioning maneuvers safe when performed in adapted areas mixed with staff that may not be used to this practice. Additionally, the maneuver often requires at least five staff members to safely position the patient.
- Environment: When surgical beds and units are converted to dedicated Bio Containment Units (BCU), intensive care units or temporary medical, be sure the room can accommodate additional specialty equipment and beds. This includes equipment needed for bariatric patients. Additionally, many BCUs are locked units. It is important to ensure emergency response teams can enter the unit timely and safely to prevent a delay in care.
- Equipment: Given the complexity and acuity of COVID-19 patients, it is important to anticipate and be prepared to respond to deteriorating patients. This includes ensuring emergency equipment such as ambu bags, suction equipment, clamps, and lifting

---

[6] Drahnak, D., & Custer, N. (2015). Prone Positioning of Patients with Acute Respiratory Distress Syndrome. Critical Care Nurse, 32(6): 29-37.
Guerin C, Reignier J, Richard J et al. Prone positioning in severe acute respiratory distress syndrome. NEJM (2013); 368(23): 2159-2168.
Vollman, K, Dickinson, S, & Powers, J. (2017). Pronation Therapy. AACN Procedure Manual for Critical Care 7th ed. Elsevier Sanders, St Louis, Missouri pp. 142-163.

equipment is readily available in the room or easily accessible. When converting non-clinical areas to BCU or other inpatient units, it is important to ensure that systems such as the call bell and code blue alert systems are operational and transmitting to all intended responders.

▪ Communication: Personal protective equipment, such as PAPRs, are essential to protecting staff and patients; however, they may create unintended communication barriers during emergency responses and resuscitation. Staff may also have limited sight due to PPE to clearly identify staff carrying out various roles in the resuscitation team.

Based on lessons learned from this reported event and others, recommendations for hospitals include:

1. Ensure clinical staff are educated on the risks associated with prone maneuvers, such as pressure ulcers and decannulation. Implement pressure ulcer prevention measures and engage Wound, Ostomy, and Continence Nurses (WOCNs) per hospital protocol and policy. Use of assistive devices such as lifts or specialty equipment for populations such as bariatrics is recommended for the safety of the patient and staff.
2. Assess clinical areas for safety. Ensure all alarms and access to locked units function to maintain safety while preventing delays in care.
3. Provide necessary materials, equipment, and trainings to optimize routine and emergent care of COVID-19 patients. Consider monitoring equipment that allows the team to timely identify deterioration and allows for effective therapeutic response.
4. Ensure protocols and policies are in place and accessible to the team. Ensure staff have been educated and trained.
5. Consider visual cues to clarify roles during resuscitation.
6. Encourage staff to continue to report adverse and near miss events to promote a culture of safety.
7. Provide ongoing support to staff to decrease caregiver fatigue.

From Cause to Action

The causal and contributing factors of events are often complex and multifactorial. 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; and
 (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 cause analysis is defined by COMAR 10.07.06 as a medical review committee process for identifying the basic or contributory causal factors that underlie variations in performance associated with adverse events or near-misses.[7] Root causes are generic, in that the causative factors for a given error may occur almost anywhere in patient care 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 10.07.06, OHCQ 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 poor-quality RCAs:

1. Misidentification of event level;
2. Focus on underlinewhat happened rather than on why, some lacked sufficient description of the adverse event to even determine what happened;
3. Failure to identify root causes, and the information given was insufficient to establish causality;
4. Interventions that lacked specificity;
5. Outcome measures poorly aligned or inadequate to determine if the corrective actions would have any effect on the problematic process(es); and
6. Additional focus on bedside and active corrective actions for adverse events, instead of deeper level learning and latent actions to address systems.

The science of safety continues to evolve. However, we continue to see events with many similar causes. This is why the quality and safety industry is shifting to a focus on high reliability. Hospitals must move from a best guess approach as to why an adverse event occurred to a more effective approach of trying to determine "why" did this adverse event occur and "how" do we design the system to prevent this adverse event from happening again. The Institute for Healthcare Improvement (IHI) published RCA squared (RCA2)[8] to guide hospitals in a systematic approach to identifying root causes and contributing factors and to develop robust process improvement. Hospitals must additionally address the cultural components that often

---

[7] COMAR 10.07.06.02B(10)
[8] http://www.ihi.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analyses-and-Actions-to-Prevent-Harm.aspx

have the strongest effect on safety. This requires executive sponsorship to address and provide the resources necessary for a culture of safety.

Strong sustainable solutions are needed to keep patients safe. Hospitals continue to struggle with implementing corrective actions that will be long-lasting and effective at eliminating or controlling hazardous conditions. Policy changes and training remain perennial favorites when implementing corrective actions. Although each is considered a weak intervention on its own, both are likely to be part of the overall corrective action plan. Even weak interventions like education and policy changes can be made stronger with frequent, random observations of staff behavior. Staff are unlikely to continue a short cut or policy deviation if they are observed doing so and receive on the spot correction once or twice.

More hospitals are improving problematic processes using Lean, Six Sigma, and process engineering to streamline and standardize processes to make them more fault-tolerant, which means that safeguards are built into these processes *a priori* to compensate for inevitable mistakes. More hospitals are also changing workloads and staffing in order to provide safer care. This usually does not mean acquiring additional staff but deploying staff with more focus on patient outcomes. 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 or she can supervise and be a resource to all nurses.
- Holding the staff accountable for key tasks.

Hospitals are improving tracking and trending patient safety data and are less focused on formal discipline as a first response to an adverse event. The notion of a just culture in service of patient safety does not preclude instances of individual discipline. Hospitals have a regulatory and, some would say, a moral obligation to hold staff accountable for following established, evidence-based processes and procedures. The intent of the staff member who makes an error must be considered. Was the error the result of reckless behavior, in which a staff person willfully deviated from policy or procedure? Or was the error the result of at-risk behavior, that is, was the staff person impaired or otherwise incapable of complying with policy and procedure? If the answer to these questions is no, then the underlying human factors must be investigated and process improvement initiated. Process improvement is vital in that it improves on the assumption that a similar person of equal experience and training in the same circumstance could make the same error. Very few of the adverse events reported to OHCQ since 2004 can be attributed to one clinician. Clearly, disciplinary action is required when people willfully deviate from standards, for instance, by diverting narcotics. This activity should take place in parallel with the root cause analysis of the error itself.

In FY20 education was most often part of the corrective actions taken by hospitals post event. The second highest action was process improvement and third highest data tracking. While education is a weak solution, hospitals are often conducting audits and other measurements which attempt to strengthen the education component. Process improvement historically not been in the top three actions taken by hospitals. This is encouraging considering changes in policies and procedures have typically been in the top three. This demonstrates there is beginning to be a shift in Maryland hospitals to look at events more systematically and improve processes accordingly.

Figure 13 categorizes the corrective actions of hospitals in response to reported events. Environmental changes refer to structural changes; disciplinary action refers to individual counseling or performance improvement plans; changes in workload generally refers to changes in staff tasks, responsibilities, or deployment; equipment modification refers to changing the function or configuration of equipment, for instance, eliminating the ability to decrease the volume on monitor alarms; data tracking and trending refers to either mid-term or long-term tracking of performance improvement measures; and the other corrective actions should need no explanation.

Figure 13: Corrective Actions of Hospitals FY20

FY 20 CORRECTIVE ACTIONS
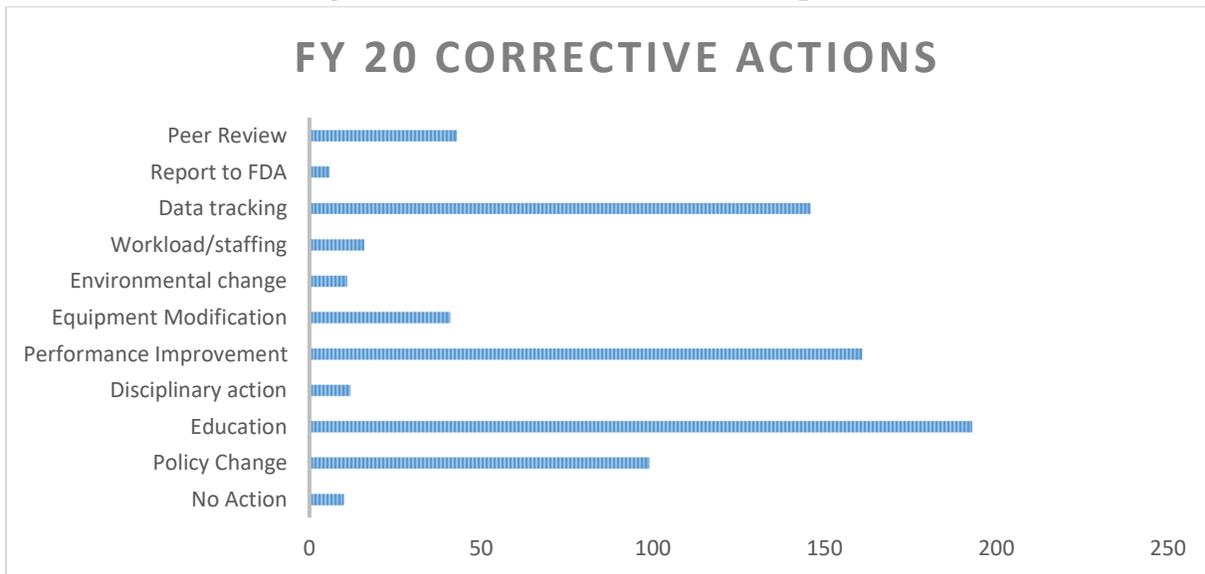
COMAR 10.07.06.03B requires hospitals to monitor the results and effectiveness of all action plans derived from the RCAs. Hospitals sometimes struggle with differentiating between process steps (process measures) and evaluating how effective a corrective action has been in remediating the set of circumstances that led to the adverse event (outcome measures). Each corrective action should, if at all possible, have a patient-focused outcome.

Enforcement Activities

The Hospital Patient Safety Program regulations in COMAR 10.07.06 require patient safety engagement throughout all levels of the hospital organization, including the governing body. Some hospitals may not have internal reporting systems capable of capturing all adverse events. Hospitals with robust reporting systems are likely safer than hospitals that under-report events. It is unknown why two hospitals, with similar populations and bed capacity have reporting rates that differ by 50-75%. This variation may be attributable to the hospital's surveillance systems and possibly the culture.

If it is suspected that a hospital may lack a well-integrated patient safety program or a complaint is verified regarding an event that should have been reported to the program was not reported, then an on-site survey of the hospital's compliance with COMAR 10.07.06 may be performed. These enforcement actions do not focus on the adverse event itself, but as we ask hospitals to do in their RCAs, these enforcement actions focus on the systems, culture, reporting, analysis, policies, and procedures needed for a robust patient safety program. The regulations provide the option of assessing monetary penalties for not reporting events.

Since 2011, OHCQ has issued an annual report card 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. Feedback received from several hospitals indicates that the patient safety officers and quality personnel use the report cards to ensure they are not missing any opportunities to review adverse events.

The Quality Assurance and Performance Improvement (QAPI) regulations of the hospital CMS Conditions of Participation call for more attention to be paid to patient safety activities during complaint and validation surveys. In hospitals with transplant programs, the transplant program quality and safety efforts must align and coordinate with the broader hospital quality assessment performance improvement program. In all hospitals, surveyors are required to look at incident reports, at the incident reporting process, and at RCAs and failure mode and effects analyses (FMEAs). This process provides an additional check on a hospital's patient safety program.

Hospital Leadership Involvement

The Maryland Patient Safety Program regulations require that hospitals designate a staff person to function as the patient safety coordinator. When a hospital loses or changes its patient safety coordinator, OHCQ has noted significant changes in not only reporting rates, but interest and engagement in the patient safety process. Patient safety cannot function in a silo under the direction of one person. Keeping patients safe is not just a nursing function. There must be a

hospital-wide effort with the coordination, direction, and involvement of hospital leadership. In addition, both CMS and The Joint Commission (TJC) require hospital-wide patient safety and quality activities with integration of patient safety into the medical staff and governing body. For all these reasons, 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;
- Reviewing actual RCAs, not merely data related to the numbers of events per patient days;
- Actively participating in a root cause analysis. 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 general oversight to the corrective action implementation process;
- Providing regular reports regarding adverse events to the Board and other executive level committees. Telling 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;
- Educating new department heads and nurse managers about the hospital's patient safety program and how their departments are expected to interface with the patient safety staff and program;
- Establishing patient safety goals and monitoring the hospital's performance towards those goals; and
- Appointing a leadership representative on RCA teams during development of corrective actions. Front line caregivers are focused on front line solutions and most adverse events require some part of the focus to be on latent issues that hospital leadership is in a better position to rectify.

Leadership involvement and direction for the patient safety program is a regulatory and accreditation requirement, but equally important, it is the right thing to do.

Resources

The Maryland Hospital Patient Safety Program can be found at: https://health.maryland.gov/ohcq/Pages/Patient-Safety.aspx. This page on OHCQ's website includes links to the Clinical Alerts and Annual Reports, as well as a section containing many of the patient safety forms and tools hospitals may want to use. The tools section contains the short

forms for falls and HAPU, a form for the initial report of an event, and an example of our RCA evaluation tool with a sample non-compliant RCA. The use of these forms is entirely voluntary.

OHCQ has a new secure email address through which hospitals may report events and submit RCAs. It is hospital.selfreport@maryland.gov. Please send reports and RCAs using an encryption method.

The web site of the Maryland Health Care Commission is a good source for comparison data on quality in several health care settings:
https://healthcarequality.mhcc.maryland.gov/

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. The Center's vision is to make Maryland hospitals and nursing homes the safest in the nation. In 2008, MPSC was federally listed as a Patient Safety Organization (PSO) and created a new entity called the Mid-Atlantic PSO.[10] The purpose of regional PSOs is to collect and analyze data on patient events to achieve the goal of improving the quality and safety of healthcare delivery.

---

[9] www.marylandpatientsafety.org
[10] http://www.marylandpatientsafety.org/MPSCPSO.aspx

Appendix A: Classification of Events

1A. Body part not consistent with consent
1B. Wrong patient
1C. Surgical procedure not consistent with consent
1D. Post-surgical retention of foreign body
1E. Intra-op or post-op death in ASA 1 patient
1F. Unanticipated intra-op or immediate post-op death
2A. Contaminated drug, device, or biologic
2B. Malfunctioning device
2C. Intravascular air embolism
2D. Infrastructure failure
2E. Death or serious disability associated with the use of a vascular access device
3A. Infant discharged to wrong person
3B. Patient elopement
3C. Suicide or attempted suicide resulting in serious disability
4A. Death or serious disability associated with medication error
4B. Hemolytic blood reaction due to administration of ABO-incompatible blood or blood products
4C. Maternal death or serious injury associated with labor or delivery
4D. Death or serious disability associated with hypoglycemia
4E. Death or serious disability associated with failure to diagnose or treat hyperbilirubinemia in neonate
4F. Stage 3 or 4 pressure ulcers acquired after admission
4G. Death or serious disability associated with spinal manipulative treatment
4H. Death or serious disability associated with a staff member's failure to act
4I. Death or serious disability associated with the use of anticoagulants
4J. Misdiagnosis
4K. Death or serious disability associated with a delay in treatment
4L. Death or serious disability associated with airway management
4M. Unanticipated fetal death or injury
4N. Unanticipated complication of treatment
4O. Death or serious disability associated with hospital-acquired infection
5A. Death or serious disability associated with electric shock
5B. Delivery of wrong or contaminated inhaled gas to patient
5C. Death or serious disability associated with a burn that occurred in a healthcare facility
5D. Death or serious disability associated with a fall
5E. Death or serious disability associated with the use of restraints, seclusion, or side rails
6A. Care ordered by or provided by someone impersonating a physician, nurse, or other licensed provider.
6B. Patient abduction
6C. Sexual assault of a patient within or on the grounds of a facility
6D. Death or serious injury of patient or staff resulting from physical assault occurring within or on facility grounds
6E. Intentionally unsafe care
6F. Abuse or Neglect
6G. Other

Appendix B: Patient Safety Decision Tree

Unexpected event or situation → **Did it reach the patient?**

- No → **Near Miss - consider RCA**
- Yes → **Was event r/t normal course of disease?**
  - Yes → **End**
  - No → **Was event r/t medical treatment or omission or delay**
    - Yes → **Death?**
      - Yes → **Level 1: report and submit RCA**
      - No → **Serious disability lasting 7 days or present on discharge?**
        - Yes → **Level 1: report and submit RCA**
        - No → **Medical Intervention required to prevent death or disability?**
          - No → **Level 3: RCA optional**
          - Yes → **Level 2: perform RCA**
    - No → **Criminal or deliberate unsafe act? Consider other reporting requirements and a risk mgt review**

When in doubt about whether to do an 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 an 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 an 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 develops disseminated intravascular coagulation (DIC) 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. 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 (SDH) in his brain and dies, that is a reportable Level 1 event even if the development of the SDH was the result of an underlying derangement in the patient's coagulation system. 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.