Maryland Department of Health
Office of Health Care Quality

Maryland Hospital Patient Safety Program
Annual Report
Fiscal Year 2019

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Executive Summary

Fiscal year 2019 (July 1, 2018 to June 30, 2019) marked the 15th year of the Maryland Hospital Patient Safety Program. 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 2019 (July 1, 2018 to June 30, 2019).

A Level 1 adverse event is defined in COMAR 10.07.06 as any unexpected outcome of medical care caused by a preventable error that causes death or serious disability. These adverse events tend to occur in several major categories such as delays in treatment, surgical events including inadvertently retained foreign bodies and wrong site surgeries, health care-acquired pressure ulcers/injuries, medication errors, and patient protection events including falls. By definition, adverse events are life- and function-threatening for patients and can result in financial burdens for hospitals while negatively affecting the emotional and physical health of a hospital's workforce, leading to suboptimal performance or personnel loss.

Hospital patient safety is not solely the responsibility of the patient safety officer. The underlying causes of individual variations in performance are usually multi-factorial and multi-disciplinary, and most hospital adverse events are the result of poorly designed policies and entrenched cultural and procedural factors. Optimizing the hospital environment and processes to reach the highest level of safe operation requires engaged leadership and hospital-wide effort. Patient safety only succeeds as a collaborative effort with the involvement and engagement of all staff and with the direction and support of hospital leadership. Both the Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC) require hospital-inclusive patient safety activities and integration of these patient safety activities into quality assessment performance improvement (QAPI), medical staff, and governing body functions.

Key patient safety findings in FY19 include:

- 212 Level 1 adverse events were reported in FY19, affecting 253 patients. While this number is consistent with prior years, the distribution of types of events was different in FY19.
- Forty-five patients died in FY19 from preventable medical errors—the lowest number of fatal events reported in seven years.
- Reported delays in treatment decreased from over 45% of reported events in FY18 to 11% of the total events reported in FY19. The number of reported delays in treatment is the lowest since FY14, but mortality related to these events remained high at 63%.
- The reported number of surgery-related events remained the same in FY19 as in FY18, with 35 Level 1 events reported.

- The number of reported hospital-acquired pressure injuries (HAPI) increased from 47 in FY18 to 52 reports in FY19, affecting 71 patients.

Analysis of these key findings has informed the recommendations contained in this report including:

1. Consider and develop organizational strategies to increase direct engagement and involvement of hospital executive leadership in patient safety systems and activities.

2. Consider and develop strategies to address the causes of delays in treatment. These types of events are multi-disciplinary and multi-factorial 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, hospitals can now go beyond core measures and Maryland hospital-acquired conditions (MHACs) and address delayed or faulty diagnoses, the causative factors of which are at the heart of so many catastrophic outcomes for patients.

3. Consider culture change projects and activities that focus on increasing engagement and oversight of clinical care by more experienced staff to better assist with care delivery by less experienced staff and to catch concerns in care early.

4. Consider effective use of patient data, including early warning, decision support, and predictive systems by using data derived from these systems to improve communication and drive coordination and oversight of care, in order to address the most common types of identified root causes (communication, assessments, and critical thinking).

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Maryland Hospital Patient Safety Program Analysis

Introduction

Fiscal year 2019 (July 1, 2018 to June 30, 2019) marked the 15th year of the Maryland Hospital Patient Safety Program. The FY19 Hospital Patient Safety Report analyzes, both quantitatively and qualitatively, the 212 serious adverse events affecting 253 patients reported by Maryland hospitals to OHCQ in fiscal year 2019 (FY19). This report compares FY19 with previous reporting years, both in terms of the types of events reported and the outcomes attributable to those events.

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 3,700 Level 1 adverse events have been reported by Maryland hospitals through June 30, 2019. In comparison to prior years, FY19 reporting rates for specific adverse event categories indicates:

- Reported delays in treatment decreased both in number and mortality in FY19, from 40 reported delays with 87% mortality in FY18 to 23 reports with 63% mortality in FY19.

- Surgery-related adverse events remained relatively constant with FY18 at 35 reports in FY19. This number included nine wrong site/patient/procedures and 20 retained foreign bodies (RFB).

- The two most commonly reported adverse events, falls and health care-acquired pressure Injuries/Ulcers (HAPI/HAPU), accounted for 43% of the Level 1 events reported in FY18 and 49% of the events reported in FY19.

- Suicides and injurious suicide attempts decreased from eight in FY18 to four reported in FY19. All four occurred in hospitals.

- Hospitals reported 11 airway misadventures with nine fatalities and two permanent anoxic injuries.

[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.

- There were three reported misdiagnoses leading to one unnecessary surgery and two deaths.

- Hospitals reported two confirmed sexual assaults, one of which was a patient-to-patient assault and the other by a stranger who wandered into an Emergency Department (ED).

- Two cases of intentionally unsafe care were reported in FY19, one of which had the potential to affect 10 patients, although no injuries were reported.

- For the first time in five years, no staff-to-patient assaults were reported. However, hospitals reported five restraint-related injuries during FY19.

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. This is a nationally known classification schema used by several state reporting systems as their criteria for reporting. Given that the NQF system is nationally recognized, it 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 related to the use of anticoagulants,
- 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.

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

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, unanticipated

[2] National Quality Forum. "Serious Reportable Events in Healthcare—2006 Update." Washington DC: 2007

intraoperative or postoperative deaths, and all wrong patient/site/consent events (referred to as "wrongs").

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

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

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. Nonetheless, evidence suggests that some under reporting from Maryland hospitals is likely, especially of non-lethal events, as reflected in the wide variability seen in numbers of events reported by hospitals of similar size and acuity.

HOSPITAL DEMOGRAPHICS

Maryland hospitals are classified into five categories—acute general, psychiatric, chronic, children's, and rehabilitation. Acute general hospitals account for 72% of all licensed Maryland hospitals and reported 93% of the Level 1 adverse events in FY19. Children's and rehabilitation hospitals accounted for 2% of reports, while psychiatric and chronic hospitals accounted for 5% each. Five hospitals failed to report any adverse events in FY19. Four of the five non-reporting hospitals had fewer than 100 beds.

Table 1: FY19, Level 1 Adverse Events Reports per Hospital Bed Size

Number of Licensed Beds	Number of Hospitals FY19	Average Reports per Hospital FY18	Average Reports per Hospital FY19
300 or more beds	11	6.4	5.6
200 – 299 beds	11	3.8	5.3
100 – 199 beds	15	3.8	5
Less than 100 beds	16	1.5	1

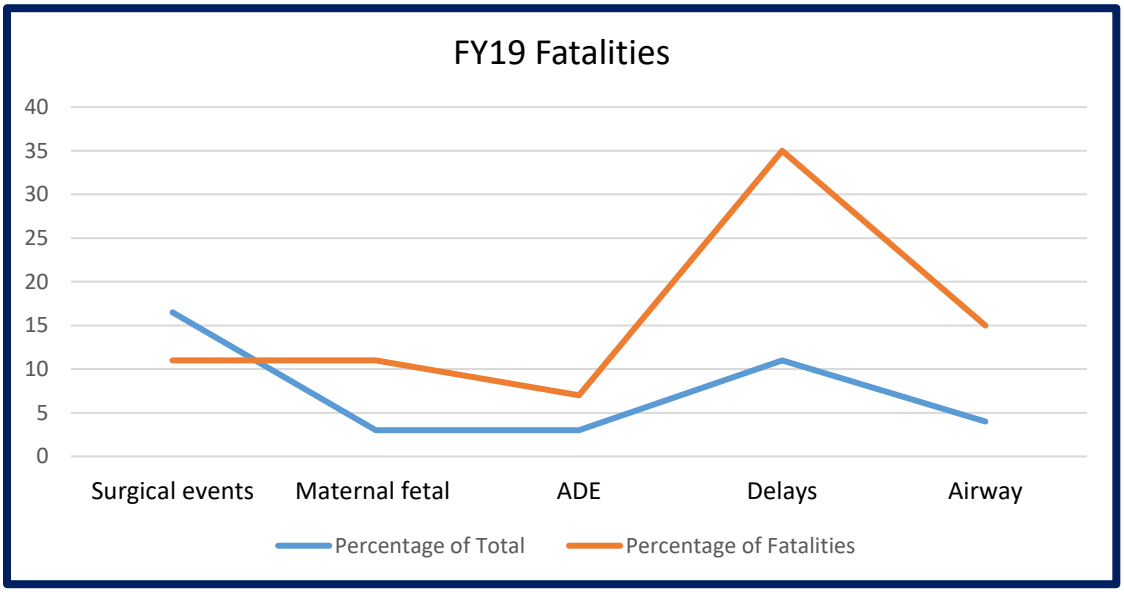
Event Outcomes

FATALITIES

Figure 1 details the event types with the highest percentage of fatalities in FY19. These five event categories represented 37.5% of the reported Level 1 events and 79% of the fatalities. One of the most commonly reported events, delays in treatment, carries a very high mortality. Since 2004, when the first delay was reported, 334 of these events have been reported with 271

fatalities, an 81% mortality rate. In FY19, the number of fatal delays in treatment accounted for more than 35% of the total fatalities while accounting for only 11% of reported events.

Figure 1: Events with Associated Fatalities FY19



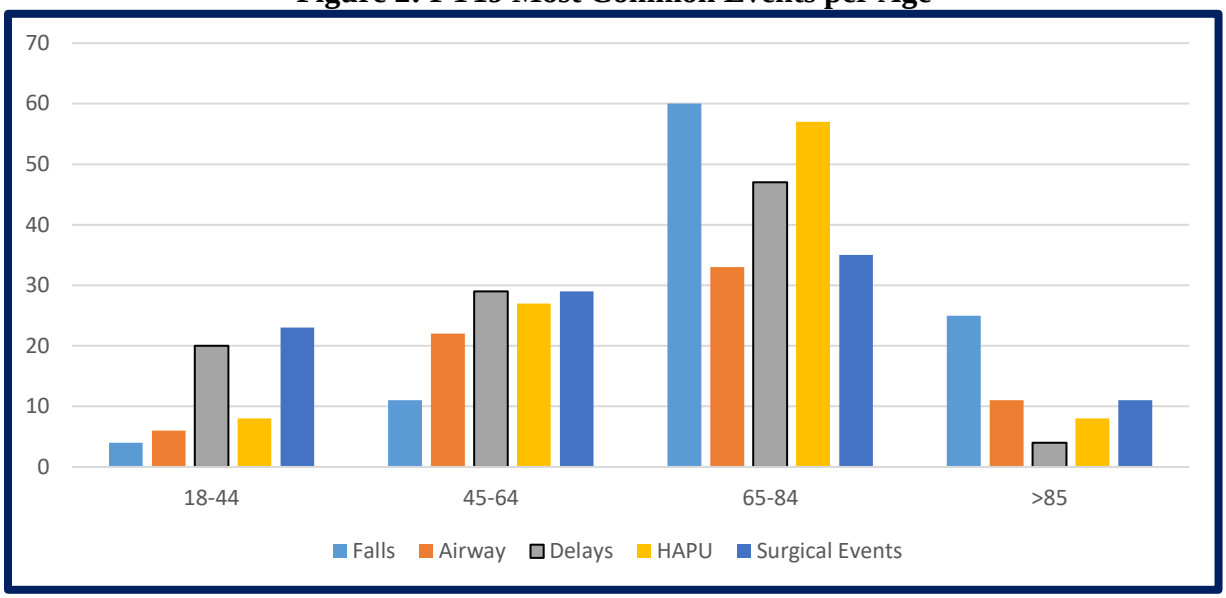
There were other fatal events reported in FY19, many of which will be discussed in the next section. All of the reported delays in treatment, surgical events, medication errors, and airway events were preventable. Along with most of the fatal birth events, these adverse events represent an unacceptable loss of life.

Each 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 and died three months later in a long-term care facility, that adverse event would be categorized as an anoxic injury (brain damage from a lack of oxygen).

AGE AND ADVERSE EVENTS

According to the 2015 census, the population of Marylanders aged 65 or older is approximately 800,000, or 13% of the total population. In FY19, 57% of reported Level 1 events occurred to those over age 65—down slightly from FY18.

Figure 2: FY19 Most Common Events per Age



The reader will note that the percentages do not add up to 100% in all cases, since these five events types do not include all events that may have affected an age cohort. In addition, while airway events affected every age group, the number reported was small, only nine. One-third of the airway events involved people between age 65 and 84, which represents three patients.

Figure 3: FY19 Top Five Reported Events - Distribution of Age Cohorts

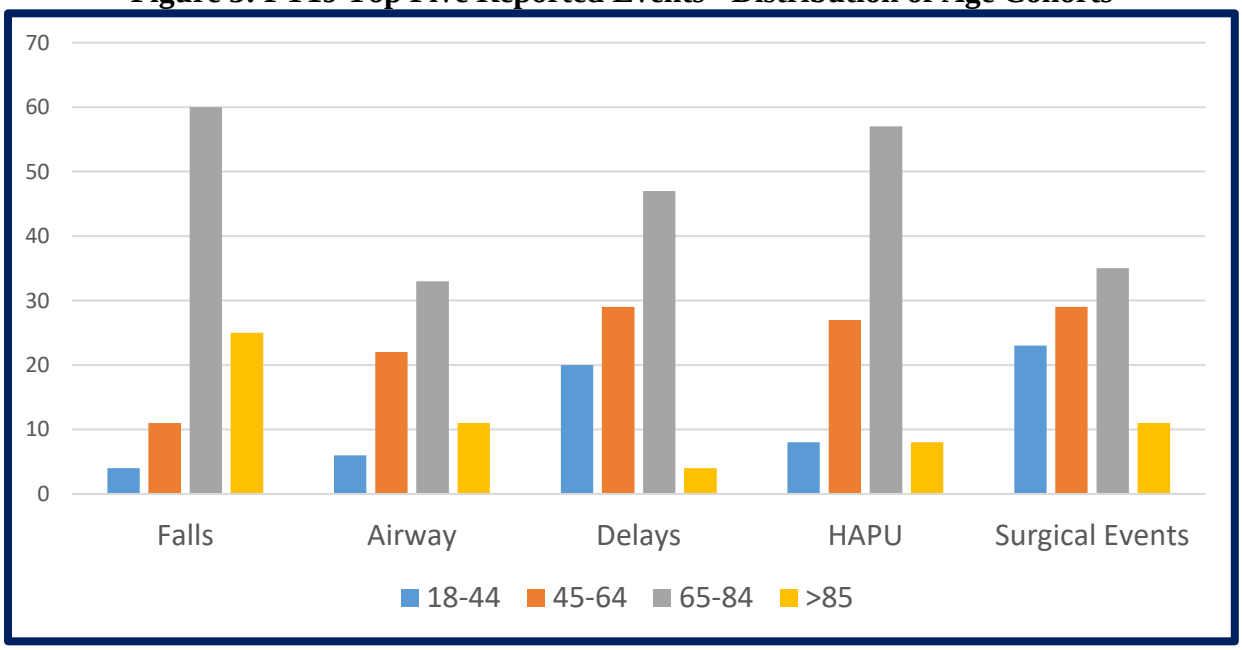


Figure 4: FY 19 Age and Fatality Rate

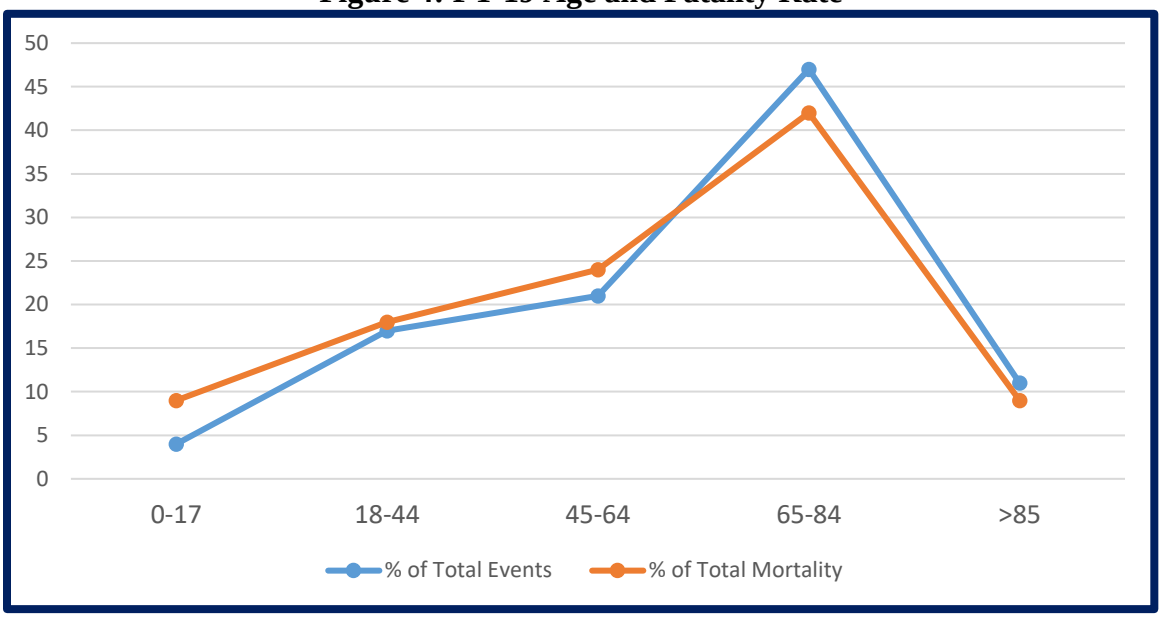


Figure 4 demonstrates that mortality is distributed across all age groups in the same proportion as the events themselves.

Adverse Events in the Behavioral Health and Psychiatric Population

In FY19, 9% of all events involved behavioral health patients. The events were generally evenly divided between behavioral health units (BHUs), emergency departments (EDs), and medical/surgical units.

One completed and three attempted suicides were reported in FY19, including a patient who suffered a fatal anoxic episode after shoving a wad of paper towels down her throat.

Another patient was able to asphyxiate herself using a sheet tied over a supposedly ligature-resistant paper towel dispenser. The patient was rescued in time and was placed on oxygen for a few hours. This patient was ordered to be on one-to-one supervision but was not, even after the first asphyxiation attempt. When she was left alone again, she tried to asphyxiate herself with the oxygen tubing.

A third patient was admitted after a suicide attempt using a razor. At one point, she was given her journal. Staff didn't notice there was a pencil in the journal. The patient went to her room and stabbed herself repeatedly. She also was rescued quickly by an alert staff person who noticed her door was shut while everyone else was at lunch. The patient required multiple transfusions and a lengthy hospital stay to treat her wounds.

The fourth potential suicide attempt took place in the waiting room of an ED. The patient had two ED visits in 24 hours after drinking hand sanitizer at his residence. On both occasions, he was allowed to sober up, and was then discharged. After the second visit, he was placed in the

waiting room to wait for transportation. He locked himself in a bathroom and drank all the available hand sanitizer, eventually consuming approximately 10 ounces of isopropyl alcohol. After several hours, he was noted to be unresponsive in the waiting room and had to be intubated and admitted to the ICU.

Staff interactions with behavioral health patients was noted to be a significant contributing factor in many events. For instance, one of the restraint injuries occurred when a delusional, confused patient in a part of the ED designated for behavioral health patients became combative after a staff person yelled back at her during a loud outburst. The staff that yelled was on a non-patient care related errand in that area and did not normally work with delusional patients. The staff began arguing with the patient to de-escalate her behavior. The yelling made the patient start to fight with the staff. She was injured when security tried to escort her to her room. This area for behavioral health patients was new for the ED and staff had not been adequately trained. Security staff had not received training on de-escalating behavior. There was an experienced nurse at the nurse's station who did not intervene either in the argument or in the restraint episode.

Another patient with delusions and exhibiting hypersexual behaviors attempted to sexually assault another patient on a BHU. A psychotic and delusional female patient with hypersexual behaviors was assigned a male staff to perform one-to-one observations. The staff person became uncomfortable when the patient repeatedly tried to disrobe in her room and went to the nurse's station to seek help. The nurse at the station was watching the closed circuit video monitoring of the halls and group areas and refused to help. While they waited for a staff person to come to the station, the female patient went unclothed into another patient's room and attempted to engage in sexual contact. While neither patient was injured, neither was legally capable of consenting to sexual acts due to their mental illnesses.

Three patients, each lacking decision-making capacity following traumatic brain injuries, eloped from medical-surgical units. One was found unhurt. The fates of the other two patients were not known at the time of the RCAs.

Five patients were injured during restraint episodes. One elderly patient was tackled onto the floor with an unapproved method. He was then taken down the hall to a seclusion room screaming that his leg was broken. In fact, he sustained a fractured hip and elbow during the restraint.

One of the airway deaths occurred on a BHU. A patient with a history of throwing herself on the floor choked on her lunch in the dining room. She tried to get the attention of the nearby staff for several moments before pitching face forward onto the floor. Staff ignored her for two minutes, apparently believing she was doing this on purpose. One staff person, without trying to rouse the patient, eventually went to get a nurse. Resuscitation efforts failed and the patient died.

A homeless patient suffered two broken arms when she was forcibly undressed for decontamination after arriving in the ED infested with pests. The patient was also struggling and fighting staff, who did not know she had muscle contractures of both arms.

Two other patients suffered broken arms while being restrained by security personnel.

The Patient Rights Condition of Participation[3] for CMS has clear requirements for training and clinical oversight of all restraint episodes in the therapeutic environment. The regulatory language is here:

- **§482.13(e)** Standard: Restraint or seclusion. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.
- **§482.13(e)(3)** - The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.
- **§482.13(e)(4)(ii)** - implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.
- All of the training requirements under **§482.13(f)(2)(i to viii)** must be met.

In reference to weapon use by hospital staff or contracted services, CMS interpretive guidelines state:

- "CMS does not consider **the use of weapons** in the application of restraint or seclusion as a safe, appropriate health care intervention. For the purposes of this regulation, the term "weapon" includes, but is not limited to, pepper spray, mace, nightsticks, tazers, cattle prods, stun guns, and pistols. Security staff may carry weapons as allowed by hospital policy, and State and Federal law. However, the use of weapons by security staff is considered a law enforcement action, not a health care intervention. CMS does not support the use of weapons by any hospital staff as a means of subduing a patient in order to place that patient in restraint or seclusion. If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, or visitor) to protect people or hospital property from harm, we would expect the situation to be handled as a criminal activity and the perpetrator be placed in the custody of local law enforcement.
- The use of handcuffs, manacles, shackles, other chain-type restraint devices, or other restrictive devices applied by non-hospital employed or contracted law enforcement

[3] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

officials for custody, detention, and public safety reasons are not governed by this rule. **The use of such devices is considered law enforcement restraint devices and would not be considered safe, appropriate health care restraint interventions for use by hospital staff to restrain patients.** The law enforcement officers who maintain custody and direct supervision of their prisoner (the hospital's patient) are responsible for the use, application, and monitoring of these restrictive devices in accordance with Federal and State law. However, the hospital is still responsible for an appropriate patient assessment and the provision of safe, appropriate care to its patient (the law enforcement officer's prisoner)."

CMS has additional requirements:

"The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

§482.13(f)(2)(vii) – The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification."

All staff who are involved in application of restraints must have current CPR certification. Even staff peripherally assisting in the restraint process must have CPR certification and training in how to identify a patient in distress.

Diagnostic Errors and Delays in Treatment

Diagnostic errors were identified as the top patient safety concern for FY19 by the ECRI Institute.[4] The Agency for Healthcare Research and Quality (AHRQ) stated that diagnostic errors account for 17% of adverse events. A systematic review of 40 years of autopsy reports identified that 9% of patients died from an undiagnosed condition.[5] A 2019 Society for Diagnosis in Medicine (SIDM) study, also published by AHRQ, estimated that one in three malpractice cases involving serious harm were due to diagnostic error. Much of the available research is focused on errors made by individual clinicians.

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. OHCQ has found that, like most adverse events, diagnostic errors are multi-disciplinary and multifactorial. It is rare that a single provider arrives at a diagnosis with no input from information in the electronic medical record, consultants, nursing, laboratory personnel, and/or radiology. For that reason, diagnostic errors should not be blamed on a single provider. By solely

[4] www.ecri.org/patientsafetytop10
[5] https://psnet.ahrq.gov/primers/primer/12

focusing on the actions of physicians and licensed independent practitioners (LIPs), much valuable information and opportunities for intervention may be lost.

In the Maryland Patient Safety Program, diagnostic errors are captured in our categories of misdiagnosis and delays in treatment. Three misdiagnosis events were reported in FY19 and each caused serious harm.

In the first reported event, an elderly woman was brought to the ED via EMS after a car accident. The patient arrived in a hard cervical collar. A CT scan of her neck was completed and read as negative for fracture so the hard collar was removed. She complained of weakness and severe neck pain as she was getting dressed to go home, so the patient was admitted. Upon arrival to the floor, she was given a moderate dose of a narcotic to relieve her pain. She immediately stopped breathing and was revived with naloxone (Narcan). The patient was transferred to the ICU and had another apneic episode, requiring the use of a breathing tube and ventilator.

The intensive care physician repeated all imaging and the second set of neck films showed a dislocated C6-7 fracture. The patient was immediately transferred to a tertiary care center for neurosurgery. As of the time of the RCA, the patient's prognosis was grave with vent-dependence and no resumption of motor function below the neck.

However, when reread, the original films showed a non-dislocated fracture. This hospital was not a trauma center and had no protocols for dealing with potential spinal trauma. The fractures were missed on the original CT, then the collar was removed despite the patient's complaints of increasing pain. The physician's assistant (PA-C) in the ED who was managing the care did not consult a trauma surgeon or the ED physician before making the decision to remove the collar. Despite signs of neurologic deficits, the patient was admitted to an observation unit rather than the ICU. The admitting physician did not write an order for periodic neurologic function testing that nurses can do, so no neurological assessments were completed. While in the ICU, the second CT scan was not ordered STAT (immediately). The CT scan was not done for eight hours, by which time the patient was non-responsive and paralyzed.

Another patient was admitted with signs of a massive infection. Several cultures were taken, including a needle aspiration of an inflamed knee. This patient underwent unnecessary knee surgery when the lab technician who read the results picked the wrong result from the pull-down menu in the electronic medical record (EMR) and reported an infection where no infection was actually present. No one on the surgical team noted that the reported infectious agent is rarely, if ever, found in an enclosed joint with no broken skin allowing infectious exposure.

In another case, a patient was sent from her residential setting to the hospital with shortness of breath. This patient had metastatic cancer and was not to be resuscitated, but her family wanted her to have some symptom relief. A chest x-ray was done and read by the ED provider as pneumonia, so the patient was admitted for oxygen and breathing treatments. The

following day, a radiologist read the chest x-ray and determined the patient had a completely collapsed lung, a potentially treatable condition. The radiologist immediately reported the findings, but the patient had already died.

There were several diagnostic errors leading to delays in care and treatment, including the following:

An elderly patient had spent months on a hospital's subacute rehab unit (SAR) recovering from a stroke before being discharged home. A few hours after discharge, she became unresponsive and was brought back to hospital by EMS. The patient was not worked up for stroke despite being unresponsive with weakness and a facial droop. Staff seemed to assume that she was at her baseline, despite being told by the family that this was not normal. ED staff did not use any standardized assessment or protocol to assess her symptoms. The MRI was not done until the following day and showed a massive ischemic stroke for which she should have received a clot-busting drug. The patient was placed on palliative care by her family and died.

A middle-aged patient was admitted with suspected colitis. He had abdominal surgery and a couple of days later started to have difficulty breathing. He was emergently intubated in the early afternoon and transferred to the ICU. This patient did not wake up from the sedation used during intubation. The assessments were poor and his neurologic deterioration was missed. Around midnight, his pupils changed to a dire sign of brain damage. This new finding was reported to the physician, but the physician did not see him for three hours. The physician ordered a routine head CT, not STAT, which was not done until 8:00 a.m. The CT showed massive bleeding in the skull that led to a not-survivable condition where the brain was pushed down the spine by the pressure of the blood in the head. His family elected to withdraw care and the patient died. Peer review, done at the same time as the RCA, determined that surgical intervention might have changed the outcome if he would have had the CT scan when his neurologic decline was first noted.

Another middle-aged patient, well known to ED staff, was brought into the ED by EMS with vague abdominal complaints. He was triaged and left on the stretcher in the hall against the wall. After a few hours, EMS staff moved him to a hospital stretcher and left him in the hall. At that time, EMS staff tried various methods to elicit a response, but they got none. They failed to report this finding to anyone. Staff in the ED assumed the patient was drug-seeking and ignored him as he had several seizures. The back of his stretcher was raised and pointed away from staff at the nurse’s station. Other patients were placed behind him for brief periods of time, but no one reassessed this patient for several hours, until he was taken to a room by a staff person who pulled the stretcher backwards without looking at the patient. Immediately after arriving in the room, the patient was noted to be apneic and not-responsive. A code was called, but the patient could not be resuscitated. The cause of death was a fatal drug-to-drug interaction with his prescription medications.

In another case, a patient lost his sight after being admitted with a severe infection in his sinus and eyes. The infectious disease specialist saw the patient on day one and recommended an ophthalmology consult. When that didn't happen, the consultant wrote another note in the record, this time in ALL CAPS. At no time did anyone call the attending physician to advocate for the patient. The patient complained to the nurses of gradually diminishing sight, but this information was not passed on to anyone. By the time the attending called the ophthalmologist, and the patient had surgery, he had lost the sight in both eyes.

Of special mention is one of the delays in treatment associated with cardiac monitor alarms. A patient with many nuisance alarms dropped his heart rate precipitously during change of shift one morning. When the monitor technician could not get anyone to answer the phone on the unit, he or she silenced the alarm permanently instead of suspending it. The patient died before anyone responded to the room. As part of the hospital's plan of correction, the clinical engineering department eliminated the ability to permanently silence the alarms. Three days later, another monitor technician was able to go to the manufacturer's web site and download a code that allowed him or her to override the engineering modification and permanently silence the alarms again.

Additional Events

As noted, the FY19 distribution of events was different than prior years. This included hospitals reporting two instances of deliberately unsafe care.

One nurse, newly out of school and having just completed orientation, took an insulin pen from a discharged patient and used it over the next week or so to give insulin to as many as 10 patients. Along the way, the insulin doses had been double-checked by other nurses, as per policy, but not until the last time did a staff question the new nurse. The nurse thought he or she was practicing within guidelines and being efficient because the other nurses had complained about how slow the pharmacy was to fill orders. While this deliberate practice deviation continued, where were the other nurses? Why did the preceptor or charge nurse not check in periodically to ensure the new nurse was practicing within acceptable standards?

The other deliberately unsafe care arose from drug diversion. A nurse contracted to work in the ICU was diverting narcotics from a patient's patient-controlled analgesia (PCA) pump. The patient stopped breathing twice in one night because the nurse was priming the pump with additional narcotics so he or she could then withdraw the medication from the pump. This left enough extra in the pump to overdose the patient the next time he pushed the button. The patient, who was alert and oriented despite having a tracheostomy, told staff after the second resuscitation that he thought the nurse had done it. The patient reported to staff that the nurse would pull the outside curtain and sleep in the chair in the room.

In another event, a man wandered into a busy hospital ED during the night and attempted to sexually assault a patient sleeping in an ED cubicle. According to the RCA, ADA-compliant

doors between the waiting room and the main ED had just enough of a delay that the man was able to come in behind staff. Because the ED was so busy, no one thought anything was amiss with someone walking around the ED.

There were two failure-to-rescue events reported in FY19. Failure-to-rescue applies to events where there is a clear duty to perform CPR or attempt resuscitation and for whatever reason, staff do not.

In one event, an elderly patient came to the hospital and was found to have metastatic cancer. He originally had an order to not resuscitate (DNR), but the patient changed his mind on day 2 of the hospitalization and a full code order was written. The EMR retained both the original and the new order. When the patient's heart stopped a few days later, the nurse checked the EMR and only saw the original DNR order, so resuscitation was not attempted. The patient had the right to change his mind about his code status and wanted to be resuscitated. The EMR should have the most recent resuscitation orders front and center, so patient wishes are accurately maintained.

AIRWAY EVENTS

In 2019, hospitals reported nine adverse airway events with seven fatalities. Five of these events occurred after inadvertent dislocation of either a tracheostomy or an oral endotracheal tube (ETT). In most of these events, there was insufficient equipment at the bedside with which to establish a patent airway. In one case, the respiratory therapist and the nurse at the bedside tried to provide oxygen to the patient by applying the ambu bag to the tracheostomy stoma, rather than occluding the trach stoma and trying to bag per mouth as would normally be done. This was a patient who had an ETT for quite a while before the tracheostomy was inserted. Delivering air under pressure to the tracheostomy stoma using the ambu bag caused an excessive amount of air to enter the tissues of the chest wall, effectively preventing the patient's lungs to expand.

One hospital had not upgraded their communication equipment for some time and were still using a pager system to contact in-house providers. After weaning an ICU patient from the ventilator, the breathing tube was removed in a planned extubation. The patient immediately began having airway occlusion from swelling. While rescue medications were given by the intensivist at the bedside, other staff tried to page an anesthesiologist to insert another breathing tube. There was no way to track who got paged when, and when no one responded immediately, the intensivist was not notified. It took several minutes to reach someone and then the ICU staff did not tell the anesthesiologist this patient had a difficult airway, so the anesthesiologist arrived at the bedside with no additional equipment. The patient died before a viable airway could be established.

In another case, a patient drowned in tube feeding after having a feeding tube re-inserted by a nurse after the patient pulled her first tube out. The nurse inserted a large-diameter tube

normally used for suction instead of a smaller-diameter tube considered safer for tube feedings. The nurse didn't tell anyone he or she had replaced the tube and x-rays were not taken before tube feedings were resumed. Copious tube feedings were suctioned from the lungs during the resuscitation attempt. The patient could not be resuscitated and died.

Another patient came to the ED one day having an allergic reaction to something he had ingested. He told the staff that he had a hereditary condition that caused his airway to swell in response to allergens and that he'd had two cardiac arrests and been intubated over 20 times. He had been unable to take his preventive medication for two months because he could not afford the cost. His initial examination was benign. He was given rescue medications for the allergic reaction, but not treated for his condition. He was admitted for observation. During the night he became very upset, demanding his treatment (blood products) and saying he felt like he was choking and would need to be intubated soon. The physician came to the bedside and found that the patient's throat was not visibly swollen or inflamed and the patient was maintaining his oxygen saturation. An hour later, the patient stopped breathing. Even though it was known that he would be a difficult patient to get an airway in, no additional equipment was at the bedside. The patient's lower airway, not visible on an oral exam, was so swollen, staff could not get an airway established. Despite multiple intubation efforts and resuscitation, this patient died.

ADVERSE DRUG EVENTS

The number of reported ADEs is typically low because most medication events do not cause death or serious disability. In FY19, six ADEs were reported and two of those were mediated by workarounds from nationwide drug shortages. In one event, the shortage in single dose vials of a benzodiazepine led a nurse to draw up 10 times the ordered dose from a multi-dose vial without checking the concentration, assuming the concentration was the same as the single dose vial. This patient survived because the nurse administered the drug slowly enough that he or she could stop it when the patient became suddenly somnolent.

In the other event, the shortage of a medication widely used in resuscitation led a nurse from the automated medication dispenser to the refrigerator for the pre-mixed bags prepared by the pharmacy. Unfortunately, the bins in the refrigerator were out of order, so in haste, the nurse grabbed an antibiotic that was in the bin that the dispenser directed her to. She passed the bag off to another nurse who also didn't check the label and gave the medication at a very fast IV rate.

Two fatal events were reported involving anticoagulation. In the first, a patient was transferred from an outside hospital with symptoms of a stroke. He arrived on an anticoagulant IV drip and was immediately admitted to the ICU. The nurse turned off the anticoagulant to change it to a concentration used in the hospital. The patient required an emergency brain scan, so another nurse took him. The bedside nurse did not tell the transporting nurse that the anticoagulant had been off only a few minutes. When the results of the scan showed an occlusive stroke, the patient received a time-sensitive clot-busting drug. The dose of that medication added to the anticoagulant and caused a massive intracranial hemorrhage.

An elderly patient was brought to the ED with facial numbness and weakness. She had had a stroke in the past and was currently on an anticoagulant for an irregular heart rhythm. Labs were sent by the ED nurse including a test of her anticoagulation status. The result was approximately double the therapeutic range, meaning that she was very anticoagulated and at high risk of bleeding. However, the lab considered this result to be an artifact and did not report the results to the ED. The patient was diagnosed with a bladder infection and discharged. Later that same day, the patient was brought back to the ED having vomited blood and was found to be in the midst of a hemorrhagic stroke and did not survive.

The RCA determined that the anticoagulant testing was a triage nurse-driven protocol for all patients on anticoagulation, although the ED physician said he or she would never look for a lab result that he or she did not directly order. The laboratory technician assumed that the specimen was contaminated and asked for a new specimen without reporting the original result. The second result remained at double the therapeutic level, so the lab tech called the ED 20 minutes prior to the patient's discharge, but the hospital could not determine who spoke to lab about the abnormal lab result. The lab policy allowed for unilateral decision making by a lab tech as to quality of a specimen and the validity of the results. The final problem was that the lab information system did not interact with the hospital's EMR, so results had to be pushed out or delivered to the ordering clinician manually.

SURGICAL EVENTS

For each of the past two years, hospitals have reported 35 surgical events. The category of surgical events includes all wrong site/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. For FY19, only four of these events were reportedly fatal, all were unanticipated intra-operative or immediately post-operative deaths. One of these shows the dangers of not considering contingencies when moving practitioners out of their expected environment.

A patient was having an emergency vascular procedure to restore circulation to his leg. Normally, these procedures would be done in the interventional radiology (IR) suite, but this case was done in the OR because the IR was being remodeled. Two IR nurses were assisting the vascular surgeon, one as scrub and the other circulating. The surgeon tried to access the patient's vasculature via a large arm artery, but the patient's circulation was so poor that this just occluded the circulation to the patient's arm. This condition is extraordinarily painful if only one limb is affected. The patient was in so much pain that he fainted and stopped breathing. The nurses tried delivering oxygen under pressure using an ambu bag and called the OR desk for help. An anesthesiologist arrived in the room, but the surgeon told him that he was almost done and everything was fine, so the anesthesiologist left the room. The surgeon finished up and the

patient was transported to the ICU, still non-responsive. He had had a massive heart attack and did not survive.

The RCA identified many problems and staff performed peer review coincident with the RCA. The surgeon had not done any pre-op work-up to determine this patient's suitability for moderate sedation. The surgeon did not write a pre-op note about the patient's condition or the likelihood of surviving the procedure. The nurses stated that if they'd been in IR, they would not have hesitated to call a code blue, but since they weren't sure of the process in the OR, they just called the desk for help. They both said they felt ignored by the regular OR staff and by the surgeon and anesthesiologist. Since the anesthesiologist had never seen the patient before and the anesthesiology department had not been consulted about the sedation plan, he didn't feel comfortable stepping in when the surgeon sent him away.

By far, the most common surgical event reported to OHCQ is retained foreign objects (RFOs). In FY19, 20 of these events were reported by Maryland hospitals. Most of these events involved surgical teams who closed a patient's incisions prior to confirming the count or checking the x-rays whenever the count is wrong. In several events, the surgeon didn't take part in or confirm the accuracy of the count before leaving the OR. Some events are caused by policies that don't require counting every object that goes into a patient or into any body cavity.

Among these was a patient who had pelvic surgery and walked around for two weeks with a fist-sized ball of sponges wrapped in a surgical glove that had been left in her vagina. Another patient carried a retained part of a drain for five years following knee surgery. A patient who had a colon resection retained a piece of the stapler used during the case in his colon for a year before it was found on a colonoscopy. Four patients retained parts of catheters used during vascular procedures. One of these patients had these foreign bodies for more than two years before it was found on a routine chest x-ray.

One patient incurred a bladder injury during pelvic surgery. A urologist came to assist, and the scrub tech opened a stent and placed it on the surgical field. After the surgery was over, the stent could not be found but the urologist was adamant that he had not used it. The GYN surgeon ordered a pelvis x-ray the following day to check on the bladder injury and the x-ray identified the stent. The urologist performed a "bedside cystoscopy" to remove the stent during change of shift with no consent and no anesthesia on a patient with very limited English proficiency.

This patient was at high risk for an RFO due to the emergency need for another surgical team during the case. In addition, being a teaching hospital, the OR was crowded with surgeons and students, but only one scrub tech and one circulating nurse. When the GYN team changed to urology halfway through the case, no count was done.

Ten of the reported surgical events were wrong site/wrong patient/wrong procedures including one patient who had the wrong procedure done to the wrong body part when he

misheard his name in the pre-op area and answered to someone else's name. No one checked his identification. In this area of the hospital, providers came to get patients from the lobby. The patient may or may not have registered yet. In this instance, this patient did not have an arm band.

Several of the wrong sites were facilitated by surgeons who did not call for x-rays or imaging to be present in the OR, or did not check the available images. In one case, a patient underwent wrong-site brain surgery because it was an emergency posting to the OR schedule and the OR gave the surgeon an arbitrary end time. The surgeon felt rushed and so did not call up the imaging to determine which side was affected. Even when not rushed, the surgeon admitted that his or her usual process is to rely on memory since the consent for brain surgery did not require laterality under hospital policy.

Another surgeon performed a kidney procedure on the incorrect side after he or she did not use the available imaging to determine the correct side. This was the second wrong site surgery for this surgeon with the same root cause of failing to use all available information

Another patient had surgery to his left lung. Once in the ICU, a chest x-ray was completed. During this portable x-ray, the labels were switched, so the left side was labeled as right. The surgeon argued with the intensivist that there could not possibly be a small collapsed lung on the non-operative side, but the intensivist had the x-ray and apparently did not notice that the x-ray also showed the patient's heart on the wrong side. So, the intensivist inserted a needle in the right side of the chest to re-expand the small lung collapse seen on the x-ray. The patient had an unnecessary procedure, and then had to have the procedure repeated on the correct side, once the error was identified.

After falling at home, another patient presented to the hospital needing a hip repair. This patient had very severe kyphosis preventing spinal anesthesia, so the anesthesiologist performed a block on the wrong side. In this case, no pre-op anesthesia assessment had been completed so anesthesia did not realize the planned spinal anesthesia would not be possible. The patient had been positioned lying on her operative side for the spinal and when the plan was changed, the anesthesiologist just performed a block on the uppermost hip.

There was one very serious burn caused by an OR cautery device reported in FY19. The assisting surgeon used the cautery wand and laid it on the drapes in the sterile field. The holster for this device had been placed on the surgeon's left side and he or she was right handed so the device was propped up on the drapes. The cord for this wand was stiff and caused the wand to flip over, making contact with the patient's upper arm. No one noticed the patient getting burned until blood started dripping on the floor. The burn was so bad that the patient required a vascular repair to stop the bleeding.

HOSPITAL-ACQUIRED PRESSURE INJURIES

In FY 19, 71 patients acquired pressure injuries in the hospital. This is 20 more than the number of patients affected by HAPI in FY18. In comparing the number and type of reports per hospital, it became apparent that this uptick in reports was attributable to two hospitals assigning wound nurse specialists to their patient safety teams. The rate of HAPI reported per hospital remained consistent other than those two hospitals.

The criteria for reportable HAPIs is to report all HAPI except progression from wounds acquired pre-admission as long as they were recognized at admission. It excludes deep tissue injuries (DTIs) unless these evolve into or are debrided into Stage III or IV open wounds. It also excludes Kennedy ulcers that arise during hypoperfusion in the 24 to 48 hours prior to death.

Causative Factors

As discussed, most adverse events have more than one cause. In most events, the listing of causes and contributing factors are the hospital's best guess as to why an adverse event occurred. Asking "why" questions during the RCA process is the best way of arriving at the underlying causes of events and gaining an understanding of individual deviations of practice. This "why" questioning eventually leads to illuminating latent issues in the hospital's practices. Latent issues are much more difficult to fix because solutions require resources, culture change, and consistent leadership. Hospitals cannot fix what they are not aware of or do not identify as a concern.

Figure 5: FY19 RCA-derived Causative Factors

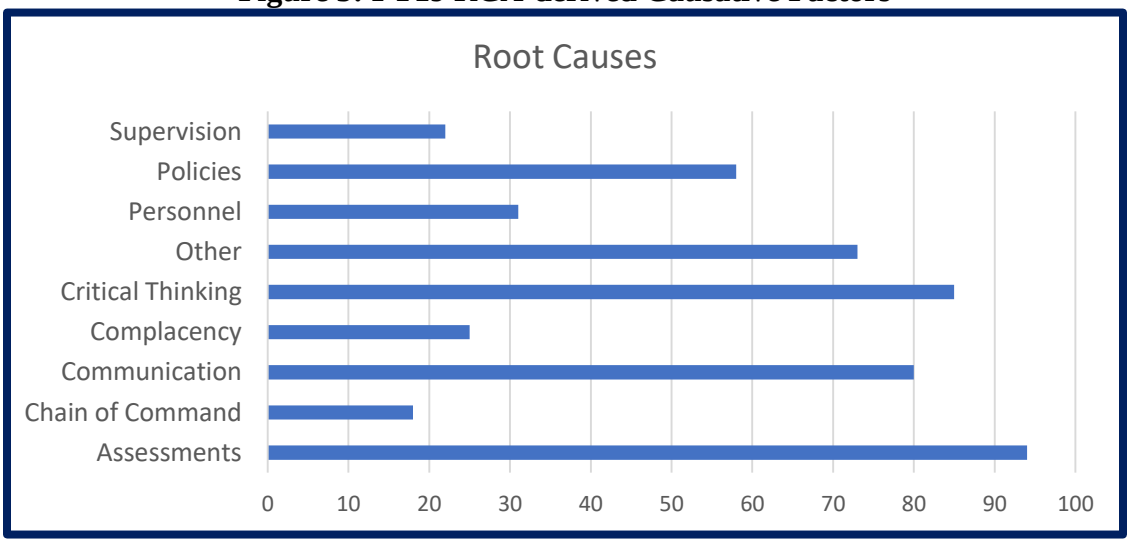


Figure 5 details the percentage of causative factors identified in RCAs submitted in FY19 for all events. Please note that slightly more than 20% of the RCAs note supervision and 18% cite chain of command factors. Timely intervention by a more experienced clinician and more

effective communication between clinical team members about the plan of care could prevent many delays in treatment. Therefore, a hospital can increase the likelihood of a timely intervention by ensuring that supervisors are actively engaged in assessing the well-being and the care being provided to all patients on the unit. Ensuring that more experienced staff are actively involved provides advantages to less experienced staff by increasing access to advanced critical thinking skills. Engaged supervisors may be more effective at communicating and at activating the chain of command.

People—especially those who are trying to prove their competency in a new environment—may not know when they are in trouble. Nurses are usually placed in the charge nurse and preceptor roles based on clinical experience, but they may have little or no experience in managing other nurses. Hospitals need to fill in these gaps in knowledge, especially since most new nurses start on off-shifts when other clinical support is usually not as available as on the day shift.

Practitioners are trained and socialized to act independently. A corrective action that might save lives is a culture change that puts the emphasis on cooperation, communication, and active supervision. Charge nurses and house supervisors need to make rounds, ask probing questions, and look at patients. If a hospital uses PA-Cs and hospitalists working overnight, the expectation must be that they will communicate with each other effectively. Many hospitals still have no formalized process for hand-offs at shift change between physicians. In addition, the physician must take the lead in ensuring that patient problems are addressed in a timely and effective manner. Everyone should know how to use the chain of command if their concerns are not being addressed.

CORRECTIVE ACTIONS

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 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 at-risk behavior, in which a staff person willfully deviated from policy or procedure? Or was the error the result of risky 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 causes of individual variations in performance must be investigated. Very few of the adverse events reported to OHCQ since 2004 can be attributed to just one clinician. Clearly, people who willfully deviate from standards by, for instance, diverting narcotics, require disciplinary action. This activity should take place in parallel with the root cause analysis of the error itself.

Hospitals are advised to teach their supervisory staff how to engage in active supervision. Supervisors must look for clinicians who need assistance, regardless of what the staffing

numbers say about the acuity of units. Supervisors need to actively look for concerns and effectively intervene. As discussed previously, mid-levels, hospitalists, and intensivists should make rounds using the MEWS scores and other objective data. Simply asking a bedside nurse or other clinician if there are any problems with his or her patients will not routinely detect issues with patients who are subtly deteriorating. The bedside clinician must understand his or her patient's condition before being able to effectively communicate. Since critical thinking is one of the most often cited causes for delays, the hospital's responsibility is to design decision support systems to compensate for lapses in clinical knowledge and judgment. Hospitals must hold staff accountable for answering their emergency phones and systems and to ensure periodic training of monitoring technicians.

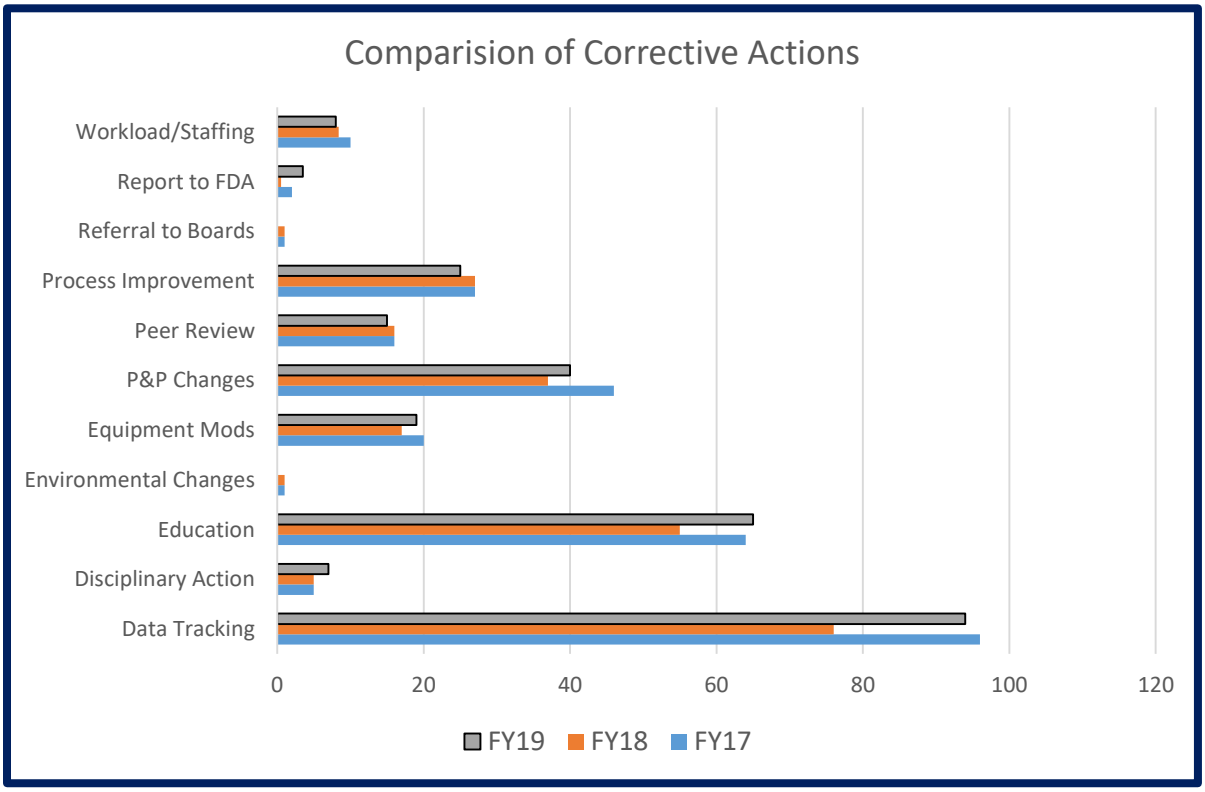
Hospitals continue to struggle with implementing corrective actions that will be long-lasting and effective at eliminating or controlling hazardous conditions. Policy changes and training remain perennial favorites when implementing corrective actions. Although each is considered a weak intervention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

More hospitals are improving problematic processes, usually by streamlining and standardizing, and are making more processes fault-tolerant. Safeguards are built into 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 assist all the nurses; and
- Holding the surgeons accountable for leading the time out.

Environmental changes refer to structural changes. Discipline refers to individual counseling or performance improvement plans. Changes in workload generally refers to changes in staff tasks, responsibilities, or deployment. Equipment modifications refers to changing the function or configuration of equipment; for instance, eliminating the ability to lower the volume on monitor alarms. Data tracking and trending refers to either mid-term or long-term tracking of performance improvement measures.

Figure 6: Percentage of Corrective Actions for All Events, FY17, FY18, and FY19



COMAR 10.07.06.03C requires hospitals to monitor the results and effectiveness of all action plans derived from the RCAs. Hospitals continue to 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). Completion of implementation is certainly something the hospital should track, but this alone is not a measure of effectiveness. Hospitals need to determine the goals of the corrective action and how to measure goal attainment. Each corrective action should, if at all possible, have a patient-focused outcome goal.

Hospitals need to ensure the corrective action is aimed at the correct cause. For instance, changing the way nurses verify that the right patient is getting the correct procedure is not going to fix the problem of posting patients for the wrong surgical procedure. It may help catch some incorrect postings, but the solution needs to be aimed more directly at the problem of inaccurate postings.

Many of the submitted RCAs aim all or nearly all corrective actions at bedside providers. This fact is probably due to multiple factors. Hospitals may have only, or predominantly, bedside providers on the RCA team. This type of team would naturally look at the proximal causes of events and at proximal solutions. RCA teams made up chiefly of nurses are likely to only look at nursing solutions because they may believe, rightly or wrongly, that they are powerless to affect

change in other disciplines. In many of the RCAs, the corrective actions may be multidisciplinary, but the implementation and continued monitoring are assigned to nurses. Although most nurses are willing to do almost anything to improve patient outcomes, they are often powerless in holding administration and other disciplines accountable.

It is these entrenched administrative systems that are considered latent causative factors. Latent causes are generic, in that they affect the entire hospital. If an RCA teams look hard enough, and asks enough "why" questions during the RCA, they will find latent failures that contributed to every event.

Just as the latent causative factors are generic, the corrective actions must have a facility-wide focus. Clearly, hospitals will want to fix the local problem first, but attention must also be paid to expanding a successful solution to all affected areas. If a hospital has a problem with the reluctance of nurses on one unit to call an RRT, it is likely that other units have the same problem. If there are problems with hand-offs on one unit, hand-offs are likely to be problematic throughout the hospital. If the hospitalist did not examine a patient who fell, it is likely a habit affecting multiple hospitalists on multiple units and shifts. Piloting a solution on one or two units is a good way to start, but successful solutions will likely require wider deployment. If latent causative factors are not fixed, adverse events will recur.

Several national initiatives are underway to reduce the number of adverse events. Comprehensive unit-based safety programs (CUSP), originally developed to combat central-line associated blood stream infections, are increasingly being used to target medication errors and other types of preventable events. CUSP processes seek to combine best clinical practices with safety science principles. The safety principles underlying CUSP are:

1. Standardize as much as possible: Standardization brings processes under examination so decisions can be made about the value and evidence-based nature of activities that hospital staff take for granted. For instance, several adverse events have been reported involving surgeon preference cards used to set up for surgeries and procedures. If, for instance, all but one eye surgeon uses a certain sequence of drops in the eye during surgery, but one uses a different set of drops at different times, an error in the set-up of those medications is almost inevitable. Standardizing the eye drops regimen eliminates the variability between individual surgeons, simplifies staff training, and makes patients safer.
2. Create independent checks: Independent double checks of information being used to make decisions can catch cognitive errors. To do this effectively, the person confirming the information should not be the person seeking confirmation. In other words, one person should be blind to the expected finding. Systems should be fault-tolerant with

sufficient safeguards built into them to make errors visible and contain them before they reach the patient.

3. Learn from mistakes: Learning from errors is a task that can be facilitated by thorough investigation into the root causes of the errors, and by sharing the results throughout the organization.

CUSP and TeamSTEPPS, another teamwork tool which has been around for several years, are trying to change the way clinicians interact and share information. Both CUSP and TeamSTEPPS are available through the AHRQ.[6]

AHRQ has also published several decision support tools to address diagnostic errors.[7] These tools may be a valuable resource for hospital attempting to reduce the number of errors and delays in diagnoses.

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; 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 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 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.

[6] http://www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/index.html
[7] https://psnet.ahrq.gov/primers/primer/12/Diagnostic-Errors
[8] COMAR 10.07.06.02 (B)(10)

If a 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 noted during FY19 among poor-quality RCAs:

1. A few misidentified the level of event;
2. Several RCAs focused on what happened rather than on why, yet often lacked sufficient description of the adverse event to even determine what happened;
3. The poor quality RCAs lacked defined root causes and the information given was insufficient to establish causality;
4. In part because causality had not been determined, the interventions lacked specificity;
5. The listed outcome measures were inadequate to determine if the corrective actions would have any effect on the problematic process(es); and
6. Hospitals continued to focus on bedside, sharp end, corrective actions for adverse events.

Enforcement Activities

The Hospital 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. We have not uncovered the reason that two hospitals, with catchment areas of similar population densities and with nearly identical bed capacity, have reporting rates that differ by 50-75%, but we suspect that at least part of the discrepancy is attributable to varying levels of engagement and commitment among staff and leadership.

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 but was not, an on-site survey of the hospital's compliance with COMAR 10.07.06 may be performed. These enforcement actions focus on the systems, culture, reporting and analysis, and 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 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 means 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) hospital regulations and CMS Conditions of Participation to the federal survey process for hospitals calls for more attention to be paid to patient safety activities during complaint and validation surveys. OHCQ surveyors must now look at incident reports, at the incident reporting process, and at RCAs and failure modes and effects analyses (FMEAs). This process provides a double check on a hospital's patient safety program. While there has been very little overlap between patient and family complaints and the reported adverse events, hospital surveyors have found several reportable events through the new survey process that had not been reported to the hospital patient safety or quality manager, and thus not reported to OHCQ.

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, the 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 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. 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.

Besides being the right thing to do, leadership involvement and direction for the patient safety program is a regulatory and accreditation requirement.

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 mailbox through which hospitals may report events and submit RCAs. Please send reports and RCAs using an encryption method to:

hospital.selfreport@maryland.gov

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

[9] www.marylandpatientsafety.org

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.

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

APPENDICES

Appendix A: Maryland Hospital Demographics

Maryland regulation classifies hospitals in two groups. The majority (44) are licensed as acute general hospitals ranging in bed capacity from three to over 1000 beds. All but one of these has an Emergency Department. Some hospitals also provide specialized services such as trauma, burn, or stroke care. However, not all hospitals offer other services, such as pediatrics, labor and delivery, or behavioral health. Several acute general hospitals also operate separate units that are dually licensed as Special Hospitals, either Chronic or Rehabilitation types.

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

Of the five Special Hospitals-Psychiatric, the licensed bed size ranges from 15 licensed beds to 639 beds. Three of these hospitals are State operated.

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. The licensed bed capacity is based on 140% of the hospital's average daily census. Therefore, the number of beds the hospital is licensed to operate changes on an annual basis.

Appendix B: Types of Events

Death or serious disability associated with:	FY15	FY16	FY17	FY18	FY19
1A, 1B, 1C, 1D, 1E, 1F. Surgical Events	36	21	15	35	35
2A. Contaminated drug, device, or biologic					
2B. Malfunctioning device			2	1	1
2C. Intravascular air embolism				1	
2D. Infrastructure failure					
2E. Vascular access device			2	3	
3A. Infant discharged to wrong person					
3B. Patient elopement			4	1	3
3C. Suicide or attempted suicide resulting in serious disability	5	5	2	8	4
4A, 4D, 4I. ADEs	13	8	8	8	6
4B. Hemolytic blood reaction due to administration of ABO-incompatible blood or blood products					
4C, 4M. Maternal/fetal death or serious injury associated with labor and delivery	3	4	2	4	7
4E. Failure to diagnose or treat hyperbilirubinemia in neonate		1			
4F. Stage 3 or 4 pressure ulcers acquired after admission	76	76	56	47	52
4G. Death or serious disability associated with spinal manipulative treatment (Chiropractic)					
4H. A staff member's failure to act					2
4J. Misdiagnosis				1	3
4K. Delay in treatment	36	30	30	40	24
4L. Associated with airway management	11	5	4	9	9
4N. Unanticipated complication of treatment			3	1	1
4O. Hospital-acquired infection			2	1	1
5A. Electric shock					
5B. Delivery of wrong or contaminated inhaled gas to patient					
5C. Burn that occurred in a healthcare facility			2	1	1
5D. Falls	50	58	67	48	52
5E. Restraints, seclusion, or side rails	3	1	4	4	5
6A. Care ordered by or provided by someone impersonating a physician, nurse or other licensed provider					
6B. Patient abduction					
6C, 6D. Sexual or non-sexual assault of a patient			2	9	3

6E. Intentionally unsafe care				1	2
6F. Abuse or neglect					
6G. Other			4	1	1

*Note that the data for all years and all event types is not available.

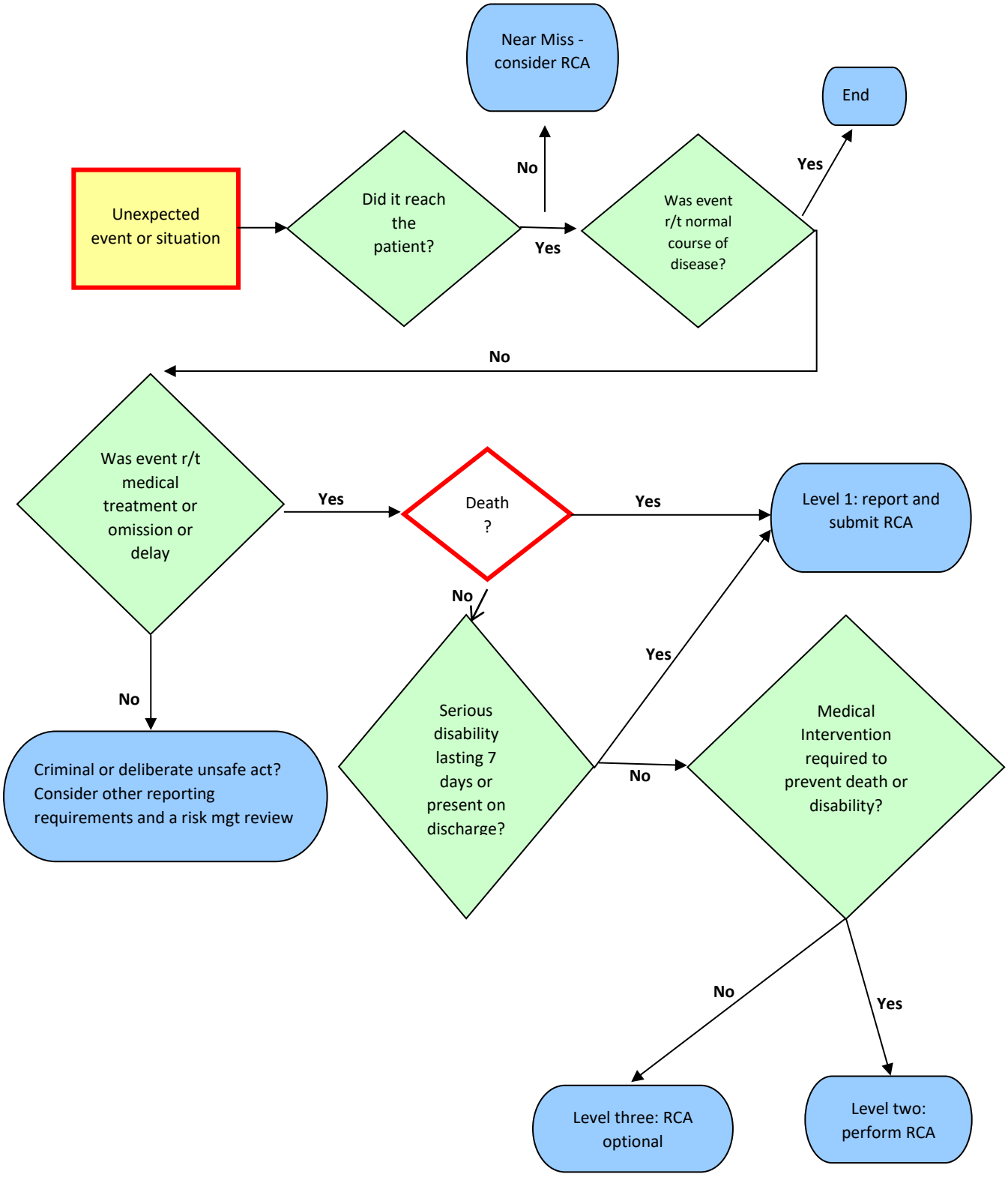
Appendix C: Classification of Events

Please note that this list is not meant to limit the types of reports, but it is how OHCQ categorizes the received reports.

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 the grounds of a facility
6E. Intentionally unsafe care
6F. Abuse or neglect
6G. Other

Appendix D: Patient Safety Decision Tree



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 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. However, it is a reportable Level 1 event if the patient has a hemolytic transfusion reaction because of incorrect typing and goes into DIC and dies. Another example of a reportable Level 1 event is if a patient falls and develops a subdural hematoma (SDH) in his brain and dies--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 reportable event is the fall, not the development of the SDH.