Maryland Hospital Patient Safety Program
Annual Report
Fiscal Year 2018

Maryland Department of Health
Office of Health Care Quality

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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 2018 (July 1, 2017 to June 30, 2018). 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 tend to occur in several major categories such as surgical events, which include inadvertently 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. These events are costly for both patients and hospitals. Adverse events, by definition, 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.

Most hospital adverse events are the result of poorly designed policies and long-entrenched cultural and procedural factors. The underlying causes of individual variations in performance are usually multi-factorial and multi-disciplinary. As such, hospital patient safety is not solely the responsibility of the patient safety officer. Optimizing the hospital environment and processes to reach the highest level of safe operation requires a hospital-wide concerted 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 patient safety into medical staff and governing body functions.

This FY18 Hospital Patient Safety Report analyzes, both quantitatively and qualitatively, 224 serious adverse events affecting 259 patients reported to the OHCQ by Maryland hospitals in fiscal year 2018 (FY18). This report compares FY18 with previous reporting years, both in terms of the types of events reported and the outcomes attributable to those events.

Key findings include:

- Seventy-six patients died in FY18 from preventable medical errors.
- Several types of reported events that typically carry high mortality increased in FY18 reporting, as compared with FY17. Reported delays in treatment increased by 38%, reported airway events more than doubled, and reported surgical events also more than doubled.

- The most common causative factors[1] identified in root cause analyses submitted for FY18 Level 1 events were concerns with critical thinking, communication, and assessments.
- There were 8 suicides or serious attempts reported in FY18.

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

1. Hospitals must do more 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, ineffective communication, and poor decision making.

2. The most common types of root causes identified in adverse events are communication, assessments, and critical thinking. Hospitals should use patient data, including early warning, decision support, and predictive systems more effectively and use data derived from these systems to improve communication and drive coordination and oversight of care.

Analysis of the reported events indicates that, prior to FY18, one person died per week in a Maryland hospital of a preventable error. Unfortunately, this number went up in FY18 and should be the focus our attention.

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[1]The use of the terms "causative" or "causal" factors do not connote a proven causal relationship. According to COMAR 10.07.06, causal factors are those event details which significantly contributed to the adverse outcome.

Introduction

Fiscal year 2018 (July 1, 2017 to June 30, 2018) marked the 14th year of the Maryland Hospital Patient Safety Program. As in past years, this report includes comparisons of the current year with previous reporting years. The Office of Health Care Quality (OHCQ) has identified general areas of improvement demonstrated by hospitals, such as decreases in the reported falls and hospital acquired pressure ulcers (HAPUs). This report highlights some successful and creative corrective actions and better practices undertaken by hospital-based teams. Of note, many hospitals continue to struggle with the continuing challenge of implementing effective, lasting interventions with measurable outcomes.

STATE OF THE STATE

Different metrics are employed to capture patient safety on a national and state level. These metrics are based on a variety of patient safety variables and are analyzed utilizing multiple approaches. When considering what can be inferred from these metrics regarding the actual state of hospital patient safety in Maryland, it is important to understand that they are drawn from different data sources and that the rates are calculated using distinct methodologies.

While many safety and quality measuring systems track hospital mortality, it is difficult to link an outcome to an event. Few, if any of these systems, report on root causes. Although the Maryland Hospital Patient Safety Program has a small number of events, this report attempts to link the events to the root causes. Extrapolating from the number of adverse events causing fatalities reported under the Maryland Hospital Patient Safety Program, we know that in FY18, 1.4 persons died in Maryland every week from a preventable adverse event. There were 76 preventable deaths of hospitalized patients reported in FY18.

The Maryland Health Services Cost Review Committee (HSCRC) uses a weighted observed/expected ratio to measure rates of 63 potentially preventable conditions (PPCs)[2] in hospital discharge data. The PPCs are grouped into tiers. Tier 1 are high volume, high cost PPCs, with opportunities for improvement and a national focus. Tier 1 PPCs are weighted at 100%. Tier 2 includes all other PPCs, including obstetric-related events and those PPCs with very low volume that affect fewer hospitals. Tier 2 PPCs are weighted at 50%. In CY15, the last year for which data is available, Maryland hospitals showed a 33% decrease in PPCs from CY13.

[2] https://hscrc.maryland.gov/documents/HSCRC_Initiatives/QualityImprovement/MHAC/RY2018/Rate-Year-2018-Quality-Program-Update-07-29-16.pdf

The Centers for Disease Control and Prevention (CDC) tracks the rates of some hospital-acquired infections[3] (HAIs) using a standardized infection rate (SIR) to compare rates across states. The SIR is derived from the observed/expected ratio of infections. For CY17, the most recent data available, Maryland hospitals reported central line-associated bloodstream infection rates that were 10% lower than the national rate and reported 10% fewer catheter-associated urinary tract infections than the national rate. However, for Methicillin-resistant Staphylococcus aureus (MRSA) infections, 6% of the 35 reporting hospitals in Maryland had an SIR significantly higher (worse) than 0.86, the value of the national SIR. MRSA is an antibiotic-resistant bacteria usually spread by contaminated hands. In a hospital, MRSA can cause serious bloodstream infections in already sick patients.

Because COMAR 10.07.06 requires reporting only death or serious disability associated with a HAI, we receive few reports annually related to HAIs. For FY18, only one report met the criteria. It involved a patient who developed a badly infected chest wound following heart surgery. The root cause analysis (RCA) identified many breaks in infection control in the ICU, including an infestation of flies and an abandoned bird's nest in the ceiling of the ICU that was covered in ants. The staff elevator was adjacent to a loading dock with a non-functional air curtain. The patient had arrived with an oral infection that was not adequately assessed or treated, and an Infectious Disease consult had not occurred until day 20 of the hospitalization.

REPORTED ADVERSE EVENTS

A Level 1 adverse event is defined in COMAR 10.07.06 as any event that causes death or serious disability.[4] Since the enactment of the Maryland Patient Safety Program regulations on March 15, 2004, almost 3,500 Level 1 adverse events have been reported by Maryland hospitals through June 30, 2018. In comparing reporting rates for specific adverse event categories from FY18 to prior years we note:

- Reported delays in treatment have increased both in number and as a percentage of total events reported. This is true not only when comparing FY17 with FY18 data, but also historically when looking at increases from an average of 7.7% of total events reported from FY12 through FY15 to 20% of reported events in FY18. This increase is especially concerning due to the high mortality typically associated with these events. Ninety-two delays in treatment, 28% of the total number, have been reported just in the last two years with an average 86% mortality per year.

[3] https://gis.cdc.gov/grasp/PSA/HAIreport.html
[4] 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.

- Surgery-related adverse events more than doubled this year, from 15, or approximately 7% of total events in FY17 to 33 (15%) in FY18. This number includes ten wrong site/patient/procedures and 19 retained foreign bodies (RFB).
- Falls and Health Care-Acquired Pressure Injuries/Ulcers (HAPU) which accounted for 43% of the Level 1 events reported in FY18 both decreased in number as compared with FY17.
- Suicides and injurious suicide attempts increased from 2 in FY17 to 8 in FY18. Three of the suicides or attempted suicides occurred in hospitals this year, and five reported suicides occurred just after release from inpatient units.
- Staff to patient assaults and restraint/seclusion injuries and deaths have also increased in FY18 and will be discussed later in the report.

CLASSIFICATION OF EVENTS

OHCQ's Patient Safety Program continues to classify the types of Level 1 adverse events in our database using the National Quality Forum's "Serious Reportable Events"[5] taxonomy. This is a nationally known classification schema used by several state reporting systems as their criteria for reporting. Given that the National Quality Forum (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 related to the failure to maintain a patient's airway;
- 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.

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 intra-op or post-op deaths, and all wrong patient/site/consent events (referred to as "wrongs").

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

The category medication events 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/fetal events include preventable birth injuries and deaths as well as unanticipated fetal and neonatal injuries.

The wide variability seen in numbers of events reported by hospitals of similar size and acuity, especially of non-lethal events, is likely related to underreporting from some Maryland hospitals. At the same time, 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.

HOSPITAL DEMOGRAPHICS

Maryland hospitals are classified into five categories, including acute general, psychiatric, chronic, children's, and rehabilitation. Acute general hospitals account for 72% of all licensed Maryland hospitals and reported 95% of the Level 1 adverse events in FY18. Non-psychiatric specialty hospitals (chronic, children's, and rehabilitation) accounted for 4.2% of reports, while psychiatric hospitals accounted for the remaining 8.8%.

Table 1: FY18, Level 1 Adverse Events Reports per Hospital Bed Size

Number of Licensed Beds	Number of Hospitals	Average Reports per Hospital FY17	Average Reports per Hospital FY18
300 or more beds	11	5.8	6.4
200 – 299 beds	15	4.8	3.8
100 – 199 beds	17	2.7	3.8
Less than 100 beds	21	1.1	1.5

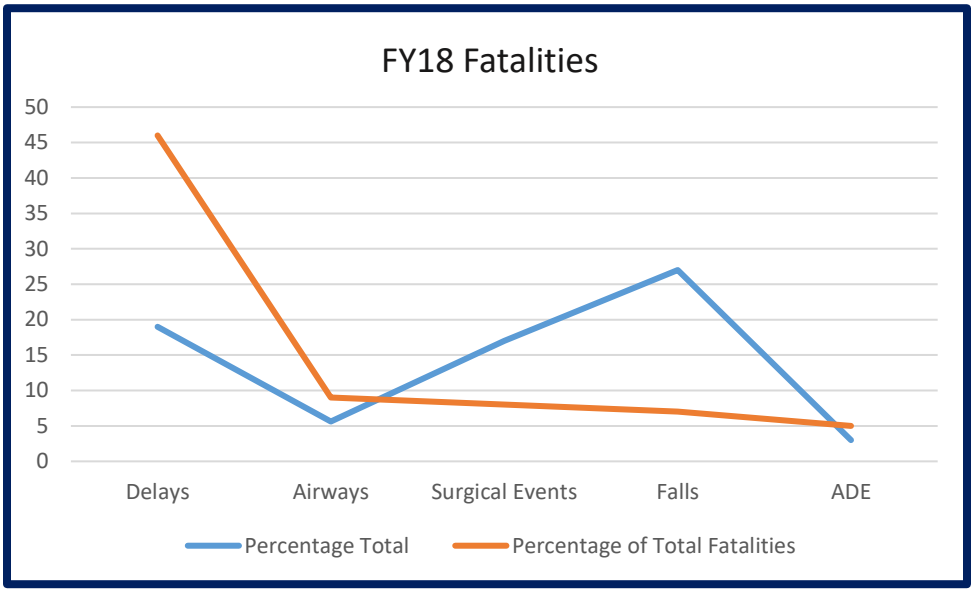
Event Outcomes

FATALITIES

Figure 1 details the most commonly reported fatal Level 1 adverse events from FY18, along with the proportion that were fatal. These five event categories represented 71% of the reported Level 1 events and 75% of the fatalities. As noted, in FY18, more than one person died per week in a Maryland hospital of a preventable error. One of the most commonly reported events, delays in treatment, carries a very high mortality. Since 2005, when the first delay was reported, 283 of these events have been reported with 235 fatalities, an 83% mortality. In FY18,

the number of fatal delays in treatment accounted for more than 45% of the total fatalities while accounting for 20% of reported events.

Figure 1: Events with Associated Fatalities FY18



There were other fatal events reported in FY18, many of which will be discussed in the next section. Since all of the reported delays in treatment, surgical events, medication errors, and airway events are preventable, along with many of the falls, these adverse events represent an unacceptable loss of life.

The 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

Among those over 65, the CDC[6] estimates that 11% of all accidental deaths are caused by adverse events, which includes adverse outcomes related to medical care and to medications. According to the 2015 census, approximately 800,000 Marylanders are aged 65 or older, representing 13% of the total population. Figure 2 details the age of patients at the onset of an adverse event. In FY18, 65.4% of reported Level 1 events occurred to those over 65 almost 10% from FY17.

[6] https://www.cdc.gov/injury

Figure 2: Age at Onset of Adverse Event

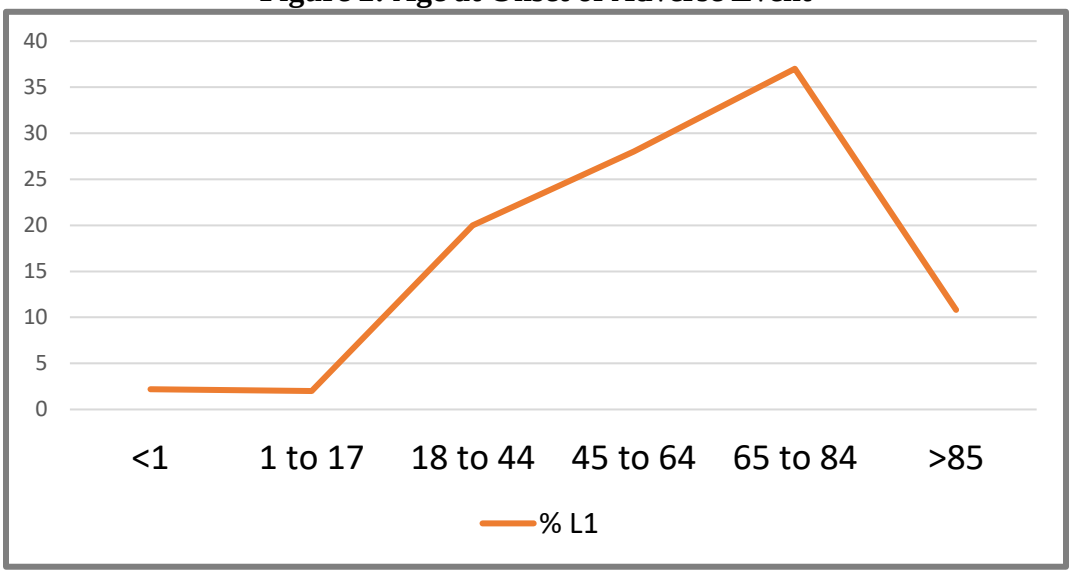


Figure 3 details mortality as a result of adverse events for each age group, with the highest number of events in the 65 to 84 year old range.

Figure 3: Reported Adverse Event Death Rates per Age

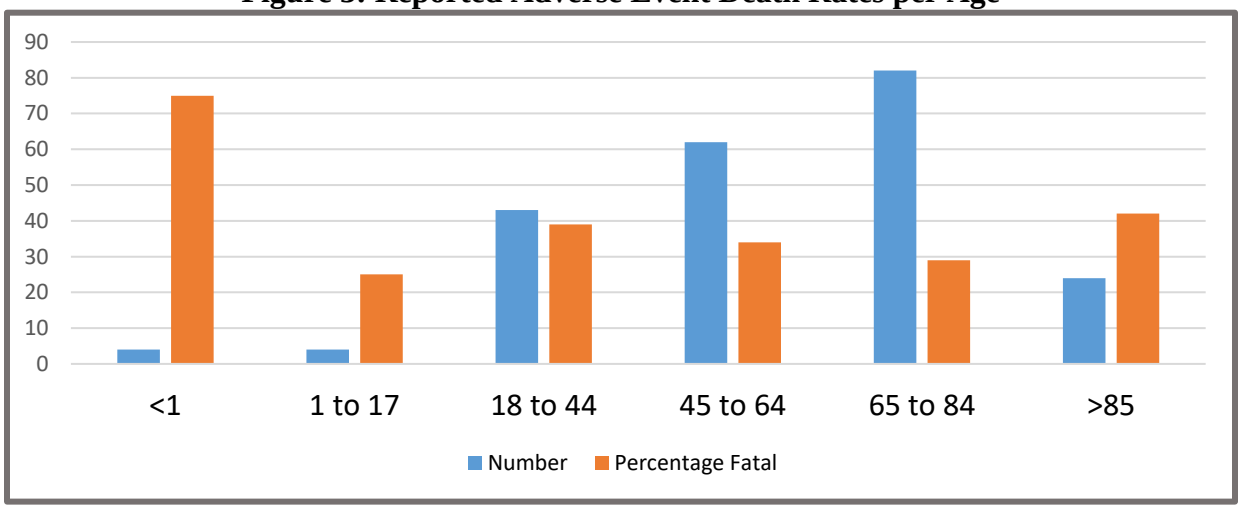
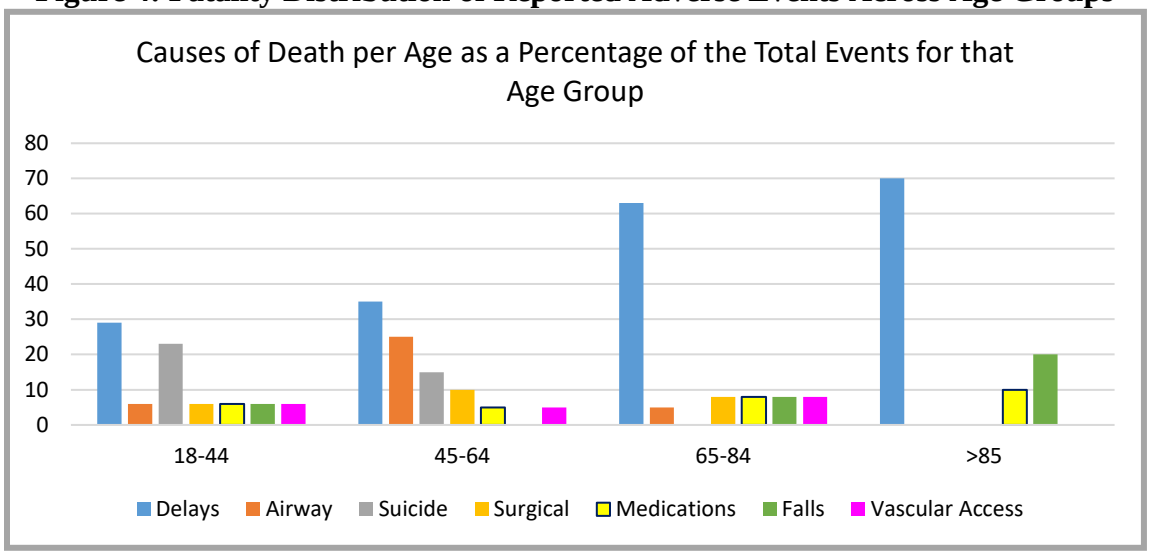


Figure 4 demonstrates the fatality distribution of the most commonly reported adverse events across age groups for FY18. The death rate from delays in treatment rises with age, accounting for 70% of the fatalities in those over 85 years old.

Figure 4: Fatality Distribution of Reported Adverse Events Across Age Groups



Adverse Events in the Behavioral Health and Psychiatric Population

As noted, 13% of the reported adverse events occurred in the behavioral health population, including multiple patient to patient assaults, multiple staff to patient assaults, one confirmed criminal sexual assault, and a death caused by improper restraint techniques. Most of these events occurred in the EDs or behavioral health units (BHU) of acute general hospitals.

There were several events reported where BHU staff were complicit in aggressive behavior or failed to react to prevent patient to patient assaults. For instance, one unit had a very delusional and intrusive patient (patient 1). Staff had used yellow tape to define a “do not approach” section on the floor in front of the nurse’s station. The patient could not comply with this warning and as he repeatedly approached the station, a staff person sprayed him with air freshener, causing the patient to become violent. He was injured in the subsequent restraint episode.

Patient 2 suffered a fractured skull and other fractures after he was beaten by a peer for urinating on the floor. The peer had told staff that the other patient had urinated on his floor and what he was planning to do, but staff failed to intervene. The RCA identified a concern with judgement among the staff.

Patient 3 was struggling with staff who wanted him to go to his room. He spit on a nurse’s aide who walked away, but then came back and spit on the patient.

Patient 4 became upset at the wait time and was loud and disruptive in the ED waiting room. The security staff tried to talk to him. The patient apparently called the staff person a name and the staff person punched the patient.

Patient 5 reported to a day shift nurse that she had been assaulted by the night staff. Review of hall video showed a staff person grabbing patient 5's arms on at least three occasions to get her back to her room as she was yelling and throwing furniture. No other staff intervened to help manage the patient using non-violent techniques.

Patient 6 was on an acute unit and evidenced some difficult, but non-violent behaviors such as smearing feces on the furniture. Review of video after his complaint of assault showed the patient sitting reading when a security person came up and hit him in the back of the head with his radio. According to the RCA, this unit had 24-7 security presence and there had been some "slippage" of roles. On the night the patient was assaulted, the nurse had asked the security staff to "watch him."

Patient 7 was a newly admitted patient on an inpatient behavioral health unit (BHU) when he stabbed himself with a pen and required surgery. Patient 7 had stabbed himself in the same place several years previous. The nurse had no reason to suspect self-injurious behavior because this information was not in his record. While a nurse was passing medications on the unit, patient 7 was hovering and was able to grab a pen.

Patient 8 was a young person who was able to hang herself over a supposedly ligature resistant door hinge. Patient 8 suffered a permanent anoxic injury.

Patient 9 came to the ED with both mental health and physical complaints. He was evaluated by the psychiatrist for suicidal ideation and agreed to a voluntary admission to the BHU, but this information did not get to the ED physician. Patient 9 was admitted to a med-surg bed in error. The staff on the floor had limited training in suicide precautions. The room was not cleared of hazards and the patient had a sitter who was not familiar with suicide precautions. Patient 9 was able to commit suicide in the room.

Patient 10 was a very large man with a history of schizophrenia and bipolar disorder. He was brought to the ED one night on an Emergency Petition (EP) for threatening a family member. An EP is a court order for a psychiatric exam to determine if the patient needs hospitalization. Patient 10 was placed in a room on a locked section of the ED specifically for psychiatric evaluations.

Patient 10 refused to have blood drawn. While it is preferable to draw blood on patients awaiting psychiatric review, there is nothing in the court-ordered EP that requires blood testing. Several people tried to talk patient 10 into complying, and he refused. Instead of letting him rest until morning and revisiting the subject, security was called. One security staff person went into the room and talked to the patient with a clinical person present. When patient 10 continued to refuse to have blood drawn, the other 4-5 security personnel entered the room. The patient was

pepper sprayed or pepper foamed, dragged to the floor face down with one arm twisted up, and held in place by one security person.

Review of the hall video showed several staff entering and leaving the room over the next 10 minutes, all coughing, retching, and showing signs of pepper spray exposure. Two staff had to be helped to the main ED for treatment.

After 10 minutes, a code blue was called as patient 10 was noted to have stopped breathing. Video showed several people, including a physician, nurses, and a respiratory therapist with a ventilator enter the room. After several more minutes trying to resuscitate patient 10 in a room full of pepper spray, he was placed on a bed to be taken to the main ED, but did not survive.

It is not true that as long as someone is able to make noise that he or she must be breathing. The lungs are capable of exhaling approximately 1200 cubic centimeters of air, the end expiratory reserve volume, even if the person cannot inhale. This means that when someone is physically prevented from inhaling, for instance by prone positioning with a foot pressing on his back, that person is capable of speaking even while suffocating. Understanding the physiology of suffocation is important to include when training security personnel or anyone who applies restraints or puts their hands on a patient.

All personnel who apply restraints should receive the same training in, at a minimum, the safe use of restraints and in recognizing signs of distress. Many training programs in hospitals rightly focus on verbal de-escalation techniques with the hands-on or restraint techniques used as a last resort. To be effective, these programs should be part of the training of all personnel who are part of security or other protective services. Many hospitals have hired off-duty law enforcement officers to provide security in their emergency departments. These officers may not be accustomed to dealing with a sick and sometimes mentally ill population and may not be used to dealing with people in a therapeutic environment. It may prove beneficial to provide training to these employees about the rights of patients in the emergency department or hospital and about the need to maintain clinical control over patient-staff interactions, even those involving angry or seemingly out of control patients. In addition, the CMS Patient Rights Condition of Participation requires that all personnel involved in applying restraints must have current CPR certification.[7] This requirement includes any full- or part-time security personnel or off-duty law enforcement employed by the hospital who may have occasion to assist with applying restraints.

Because most of the reported staff to patient assaults did not cause serious injury to patients, we believe that other patients may be subjected to assault or abuse that is not reported to OHCQ. According to the CMS Patient Rights hospital Condition of Participation regulations,

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

hospitals must have policies, training, and supervision sufficient to identify all instances of abuse, including abuse that occurs in the hospital. Hospitals may need to revise their policies and training programs to address this issue. This type of training may be best accomplished through the use of drills, role-playing, and simulations. It's hard to tell how someone will react when another person is calling him or her names or tries to strike or spit at them. Most abuse policies reviewed by OHCQ hospital surveyors address identifying and reacting to abuse that occurs outside the hospital, prior to admission, or to identifying possible abuse cases seen in the ED. The four assaults by staff reported this year are problematic. In addition, the consequences for standing by and not reporting patient assault at the hands of a staff person must be made unambiguous to all employees.

Potentially Preventable Patient Deaths

The death rate from adverse events increased in FY18 from a five-year average of 54 per year to 76. It may be instructive to review the circumstances and analyses of some of these deaths.

Patient A was a middle-aged patient who arrived at the emergency department (ED) by car along with his wife and complained of severe chest pain. He was triaged, and lab work and an EKG were done. An ED physician reviewed the EKG and the patient was sent to the ED waiting room to await an available bed. The patient was not started on oxygen nor was he attached to a cardiac monitor. Approximately two hours later, the ED physician went to the lobby and brought the patient to the intake area to do a medical exam. At this time, a second EKG was completed, and the patient was given medication to ease his chest pain and increase the circulation to his heart. The patient was taken to a room in the ED and placed on a stretcher.

Approximately one hour after the medical exam, the patient was assisted to the bathroom where he again complained of severe chest pain. The nurse repeated the EKG. Seeing changes in the patient's rhythm, the nurse took the EKG to a physician. The patient was left sitting on the side of the bed as he refused to lay back due to the pain and anxiety. He became unresponsive and fell to the floor, striking his head. After successfully reviving him, it became apparent that he had suffered a particular type of heart attack called an ST-elevated myocardial infarction (STEMI) so staff called in the STEMI team. The patient was taken to the cardiac catheterization lab for intervention, but died a few hours later in the critical care unit. Of note, there was a secondary failure when there was a lengthy delay in staff reporting this event to the hospital patient safety officer.

There were numerous multidisciplinary proximal and latent errors with this patient's care. Even though the patient was in a high-risk situation and was having severe chest pain and other subjective and objective symptoms of a heart attack, he was triaged as only a moderate risk based on the initial EKG that showed a non-ST-elevated myocardial infarction (non-STEMI).

Both STEMI and non-STEMI are types of heart attacks, but this hospital had a special protocol and focus on patients suffering from STEMIs. The triage nurse started the chest pain protocol but did not complete it when the ED physician was not concerned about the EKG, even after being told the patient was having severe chest pain. Initially, the ED physician was focused on identifying a STEMI for early intervention and missed the fact that the patient was suffering a non-STEMI acute heart attack. As a result, the triage RN did not start the patient on oxygen or give him aspirin or another standard medication for chest pain. The patient was not placed on continuous cardiac monitoring as called for by the chest pain protocol and the triage nurse did not notify the ED charge nurse that there was a patient waiting who was having a heart attack. When the patient was finally taken to a room, he was left unattended, sitting on the side of the stretcher with no oxygen or cardiac monitoring.

The hospital's RCA determined that the latent errors included the fact that nurse staffing level was low because a new ED nurse manager had alienated some staff, although none of the nurse executives had addressed this known concern. The ED also did not have enough telemetry packs that would have allowed for remote cardiac monitoring of patients in the waiting room. Many of the quality oversight processes had failed over the previous year. For instance, the STEMI committee only reviewed the timing of getting patients to the cardiac catheterization lab, not the quality and timing of the entire spectrum of care. In addition, no one was performing quality reviews of cardiac arrests that occurred in the ED, and no one was reviewing the care non-STEMI heart attack patients were getting.

Patient B arrived at the ED minimally responsive and with a high heart rate and very low blood pressure. Because the patient was elderly, staff assumed she was at her baseline, even though the patient's family told them she was not normally like this. She was triaged as a lower level than her presenting symptoms warranted, resulting in a longer wait to be assessed by the physician. This ED had no standardized way of handing off a patient from triage to the main ED. The ED relied on the triage nurse entering information in the electronic medical record (EMR) and the nurse assigned to the patient accessing and reading the triage notes and vital signs. The patient was placed in a bed, but the assigned nurse later said they didn't know the patient was in the room for 90 minutes because there was no verbal hand-off. This ED also had a manual process for performing the sepsis screen. In this case, the screening was not done because of the staff's assumptions about the patient's baseline condition. After being in the room for 90 minutes, someone walking by the room told the RN that the patient "looked bad." When the patient was finally assessed, she had vomited a large amount of fecal matter and was non-responsive. A code blue was called, but the patient could not be resuscitated.

One fetal demise *in utero* was classified as a delay in treatment rather than a fetal death or injury related to the birth process because it involved both the ED and the obstetrics (OB) unit and occurred due to a cascade of poor decisions and erroneous assumptions by several clinicians.

Patient C, a woman of advanced maternal age, presented to the ED one morning complaining of dizziness, difficulty breathing, and spotting. Her blood pressure was dangerously high, over 200/150. She stated she may be pregnant but was not sure and had received no prenatal care to date. After giving the patient medication to bring her blood pressure down and receiving a positive urine pregnancy test result, the ED physician contacted the obstetrician on call who requested an ultrasound to determine the age of the fetus. This was completed approximately three hours after arrival and verified a viable fetus of 27 weeks.

According to the RCA, the attending nurse in the ED was a new nurse and a new hire, although she was no longer on orientation. The nurse apparently did not realize that the patient was an obstetric emergency as she continued to monitor the patient's vital signs. She had no sense of urgency to transport the patient to the OB unit. Meanwhile, the OB staff called the ED several times for updates on the patient's condition but neither the OB nurses nor the on-call obstetrician went to the ED to see the patient. OB staff finally went to the ED to get the patient two hours after the ultrasound had been done, five hours after arrival at the hospital. Upon arrival on the OB unit, an ultrasound was repeated and no fetal activity or heart rate was detected.

All information necessary to care for this patient was readily available to the clinical team, but due to assumptions, ineffective communication, inexperience, and a lack of guidelines and supervision of a new staff member, the information was not effectively communicated by the clinicians. During triage, the date of the patient's last menstrual period was not recorded in the record. In addition, the obstetrician did not come to the ED because she was waiting for the ultrasound and she assumed the patient was not as far along in her pregnancy as she was. Furthermore, the OB staff did not communicate the urgency of performing the ultrasound or of transporting the patient because they assumed the ED staff understood. Each time the OB staff called to inquire about the patient's condition, they were told the patient was ready for transport, yet no staff on either unit arranged for transport.

There were several deaths reported in FY18 associated with diagnostic errors. In one instance, patient C arrived at the ED complaining of shortness of breath. The chest x-ray was read by the ED physician as pneumonia and the patient was started on antibiotics and admitted. The radiologist read the x-ray the following day and discovered patient C had a collapsed lung. The radiologist called the attending physician, but the patient had just died of respiratory failure.

Patient D was a young woman in her 30th week of pregnancy when she was involved in a motor vehicle accident. She had multiple injuries and was sent to the general OR for an emergency C-section and a repair of other injuries. The patient had an ultrasound in the ED to confirm gestational age and viability. The ultrasonographer identified an abruptio placenta, meaning the placenta has slipped into or over the birth canal. An abruptio requires immediate C-section because the lives of the mother and baby are at risk from hemorrhage. As an abruptio was

not considered a critical finding for an ED ultrasound, the ultrasound technician did not report this information. The OB had evaluated the patient, but left the ED when the decision was made to take the patient to the OR. The fetal heart rate monitor was removed at that time. There was then a 90-minute delay while OR staff tried to get OB equipment in the OR. When the patient was finally on her way to the OR with ED staff, no one had told them about a broken elevator. This led to a further delay as they tried to find an alternative route into the OR. The mother survived, but the infant did not.

Six patients died of unnoticed hemorrhage following relatively minor procedures. Two of these patients died following liver biopsies, three died after laparoscopic gall bladder removal, and one died following a hernia repair.

Patient E had a liver biopsy and was delivered to the med-surg floor by a clinician who did not give a verbal report to the patient's nurse, as the nurse was temporarily unavailable. The clinician told the patient care tech that the patient was in his room. When the nurse saw patient E an hour later, he noted the patient time of arrival as that time, not the correct time of arrival. No vital signs were taken for several hours. This patient had a previous spinal cord injury and decreased sensation in his abdomen, so the only way to identify the massive bleeding in his abdomen would be through physical assessments and vital signs, neither of which were done until the patient's heart stopped. Patient E could not be resuscitated.

Patient F had a laparoscopic gall bladder removal. During the surgery, patient F suffered a liver laceration which was cauterized. While in the post-anesthesia recovery unit, she started complaining of chest pain and an EKG was done which was abnormal. The surgical PA-C did not come to examine her for three hours. It was another three hours before she was taken back to the operating room (OR). Because this patient was young and remained alert and oriented even with chest pain and shortness of breath, there was little urgency to provide definitive treatment. Once in the OR, her abdomen was found to be full of blood from pulsatile liver bleeding which could not be stopped. Patient F died.

Patient G also had a laparoscopic gall bladder removal with an infected, gangrenous gall bladder. When he fainted in the post-anesthesia care unit (PACU) and had a very low blood pressure and rapid heart rate, clinical staff assumed he had a massive infection (sepsis). There was a couple hour delay in getting him back to the OR as they tried to treat the presumed sepsis with fluids, antibiotics, and vasoconstricting medications to raise his blood pressure. The hospitalist was at the bedside, but the surgeon was not notified of the patient's condition for several hours. When the patient continued to deteriorate, the anesthesiologist deferred to the hospitalist. During the patient's cardiac arrest, the anesthesiologist apparently thought the hospitalist was in charge, while the hospitalist thought the anesthesiologist should be directing

the resuscitation efforts. The subsequent miscommunication, lack of role definition, and assumptions about the cause of the patient's symptoms led to the death of patient G.

Two patients died following minor procedures to insert access for hemodialysis. Patient H had missed two dialysis sessions because the access was clotted off and the metabolic derangements resulting from missing dialysis were not addressed or corrected. These electrolyte imbalances caused patient H's heart to stop.

Patient I had a serious cardiac history even though he was only in his 30s and arrived with a history and physical exam that simply said "cardiac optimized." This patient had no pre-op EKG or other cardiac work-up even though anesthesia noted that he had a severe, but non-life threatening, systemic disease. Patient I suffered a fatal heart attack following surgery.

Other post-surgical deaths include patient J, who had known obstructive sleep apnea for which he used a CPAP at home. He died following neck spinal surgery for which a frontal approach was used. Patient J's oxygenation was not monitored the first night after surgery nor was he placed on a CPAP.

Patient K suffered an unnoticed fatal bowel obstruction with necrosis following routine hip surgery. Because his complaints of pain were centered on the side of his abdomen near the surgical site, clinical staff assumed the pain was surgical in nature. Assessments were not done until it was too late to surgically resect the dead tissue.

Several patients died related to lab or diagnostic values that were not acted upon timely. Patient L came to the emergency department with suicidal ideation. She told the staff that she had taken a parent's hypoglycemic medication (to lower blood sugar in diabetics) to get high. The staff focused on assessing her suicidal thoughts and she was admitted. She was found in cardiac arrest the following morning and testing during resuscitation efforts identified a blood sugar so low it was incompatible with life. No one had checked a blood sugar or asked her when she had taken the medication or how much she had taken.

Patient M was on an anticoagulant. While admitted for unrelated symptoms, her coagulation studies were extremely elevated over three days. No one acted on these results because the lab and the clinicians assumed they were in error. Patient M was discharged with the elevated coagulation studies, but returned to the ED within a few hours with a severe and fatal brain hemorrhage.

Patient N arrived with a very elevated potassium level which was retested and assumed to be inaccurate over her three-day admission. In addition, she was discharged on a potassium-sparing blood pressure medication that she'd been on previously and was undoubtedly one of the

causes of her elevated potassium. The abnormal potassium level was not fully addressed. She was brought back to the ED within a few hours of discharge and subsequently died of a heart attack.

Patient O came to the ED with nausea and vomiting leading to dehydration. The ED nurse wanted to make sure patient O received the entire liter of IV fluid before leaving the ED, so the nurse administered it through a pressure bag, which delivers IV fluid very quickly using pressure outside the IV bag. Shortly after starting the infusion, patient O started complaining of a severe headache and had a mental status change. Patient O was taken for a head CT, which showed free air in the skull, a dire finding requiring immediate intervention. However, because the finding of free air on a head CT was not on the hospital's list of diagnostic findings requiring immediate clinician intervention, the ED physician was not notified. It was only after the patient arrested and died that anyone was made aware of the air embolus, likely caused by using a pressure bag to deliver IV fluid.

FY18 saw an uptick in reported deaths associated with vascular access devices. These are typically large catheters inserted into central veins and used to perform dialysis or used in diagnostic testing such as cardiac catheterizations.

Patient P was an elderly, confused patient who was receiving dialysis in the hospital's dialysis unit through a large-bore temporary IV access. She was sitting in a reclining chair bundled up in blankets. The tubing was draped over her abdomen because of the placement of the dialysis machine. The tubing became disconnected and she exsanguinated. By the time staff noticed the blood, it was too late. Patient P died.

Patient Q had been very sick and had a large-bore catheter inserted in his groin for temporary dialysis. This catheter was inadvertently left in after he improved and was transferred to a step-down unit. One night he pulled the catheter out and bled to death. The nurse assigned to him that night was not even aware that he retained this catheter because that information was not included in report, nor was it readily apparent on his medical record. The hospital's RCA found that only 40% of the RNs on the step-down unit had had any training in central line management.

Patient R was on a med-surg floor following a cardiac catheterization through a large vein in his groin. Part of the catheter was removed by the clinician on the floor. There is a protocol for these patients involving holding pressure on the area and assessing for excessive bruising or other signs of bleeding. The protocol was not followed by the technician who removed the catheter or by the nursing staff. The nurse caring for patient R overnight attributed his confusion, and complaints of severe back pain and shortness of breath to his age and documented that he was at baseline. Patient R's heart stopped in the morning and he died. It was

determined that his blood count was extremely low and had been bleeding into his abdomen all night.

In addition to Patient R, two other patients died when their mental status changes were mistaken for their baseline. Patient S required an emergency intubation for respiratory distress and never woke up from the sedation used during the intubation. Several hours later, the nurse noted that the patient's pupils were fixed and dilated (a dire sign), but the PA-C did not come examine him for another 8 hours and a routine CT was not done for 12 hours. The CT showed a massive intracranial bleed with herniation meaning there was so much blood in the head that the brain was being pushed down the spinal cord. The RN had not acted on her concerns, didn't go up the chain of command, and did not conduct an appropriate neurological exam. The corrective actions for this event included training the PA-Cs and ICU RNs on neuro exams—skills that critical care staff should already possess.

Patient T was brought to the ED by his family after he fell at home. Patient T was on anticoagulants which can increase the risk of intracranial bleeding following injury. Even though the family told the RN and ED physician that patient T was not at his mental baseline and was more confused and drowsier, staff documented that he was at his baseline. The first head CT was negative, so patient T was placed on observation status. Patient T continued to deteriorate over the next 24 hours and died of an undiagnosed intracranial bleed.

FY18 had some notable reports of airway misadventures, including the following:

Patient U came to the ED with a severe throat abscess after a course of antibiotics at home failed to improve his symptoms. Patient U was placed on observation status in anticipation of surgery the following day. Patient U was young and remained alert and oriented even as his airway was swelling shut and he complained of difficulty breathing and swallowing. His complaints were discounted until he suffered a respiratory arrest. Despite multiple attempts at intubation because of the abscess and airway inflammation, patient U died.

Patient V was a patient known to have a difficult airway, meaning intubation would be difficult and would likely require additional equipment or techniques to establish an airway. Patient V was admitted to the intensive care unit following heart surgery. He arrived with a breathing tube in place. The intensivist decided to remove the breathing tube and wanted to get it done before the next surgical patient was due to arrive in 20 minutes. The ICU lacked the specialized equipment that anesthesia had used to intubate patient V in the OR. Patient V could not be reintubated and died.

There were 12 deaths of patients in FY18 associated with delayed responses to monitor alarms. Similarities in these events include:

- Ineffective communication between telemetry and nursing staff, including unclear pathways and protocols for notification,
- A lack of urgency in responding to alarms,
- A lack of or delayed assessments of changes to patients despite reports from other staff,
- Lack of empowerment of telemetry techs and nurse's aides to go up the chain of command, and/or
- Equipment challenges.

When patient W dropped her heart rate to 50 beats per minute and over the next hour to 40, the telemetry tech did not call the RN. When patient W's heart rate was 35, the tech called the RN, but got no answer. The tech did not call the nurse back for another 20 minutes, by which time patient W had died.

On another telemetry unit, patient X had been in and out of V-tach (a dire rhythm requiring intervention) for four hours until, the RN suspended the alarms without assessing the patient. Another nurse went in the room an hour later to draw blood and found the patient deceased and the alarms suspended.

Patient Y died when he had 20 minutes of bradycardia (very slow heart rate) followed by 8 minutes of no heart rate. The charge nurse told the patient's nurse, but neither did anything.

Patient Z, had been admitted in respiratory failure but had improved to the point that he was on room air. One morning the patient care technician (PCT) reported to the RN that the patient's blood pressure was low at 80 over 40. The RN told her to take it again and the PCT reported she couldn't because the patient was flailing around. The RN did not assess the patient then or when the telemetry tech called the unit clerk 20 minutes later to report asystole. Forty minutes later, the dietary aide delivered the food tray and found the patient deceased.

In reported adverse drug events, Patient AA suffered a fatal drug-drug interaction after taking a peer's medication. The RCA found that, even though patient AA was on a unit for substance abusers, the RNs were not in the habit of confirming medication ingestion and many of the patients were swapping pills.

Patient BB was an elderly patient newly prescribed an anticoagulant for an irregular heart rate. Patient BB was then given a sleep aid one evening with no additional fall precautions in place related to the now higher likelihood of falling and the increased risk of injury if he did fall. Patient BB fell. Because he told staff he had not hit his head, no diagnostics were completed,

even though the anticoagulant made it more likely he would have a head injury. The next morning, patient BB was found to have suffered a fatal intracranial bleed.

Patient CC was brought to the ED by family after falling at home. She was found to have had a stroke. Patient CC was admitted to an unmonitored bed on a med-surg floor. Overnight her mental status and vital signs continued to deteriorate. At one point, the nurse caring for her called for additional resources from the rapid response team (RRT) and also called the hospitalist. The hospitalist cancelled the RRT before seeing the patient. A few hours later, when the patient became unresponsive and stopped breathing, the resuscitation team found that she had suffered a heart attack as well as a large intracranial bleed.

Patient DD was a patient in his 60s who was being transported in a wheelchair van when the van driver had to slam on the breaks to avoid an accident. The patient fell out of his wheelchair and became wedged under the driver's seat. Instead of stopping and calling for help, the driver drove to the nearest ED, where staff, also instead of calling the fire department for extraction help, got patient DD out from under the seat and back into his wheelchair. This extraction took 30 minutes. He was seen in the ED, but the ED charge nurse, who had helped extract him, documented only that he had fallen, not that he had been wedged for some unknown period of time and then suffered a 30-minute extraction. The ED physician didn't see him for over two hours. Patient DD was found to have a fractured hip and was admitted for surgery the following day. The surgeon saw him in the night and when the surgeon heard the story from the patient, none of which was documented, she tried to get him transferred to a trauma center for a trauma work-up. Before the transfer could be affected, patient DD arrested several times and could not be resuscitated. No one in the ED had asked the driver about the mechanism of injury, or the length of time the patient had been wedged under the seat. Patient DD suffered an undiagnosed ruptured spleen and other internal injuries.

As noted, failure to recognize the risks or to understand the seriousness of a patient's changing condition is evident in nearly all delays in treatment. Many hospitals have implemented decision support software like modified early warning systems (MEWS) as part of the electronic medical record. MEWS tracks patients' vital signs and other physiologic markers, and alerts staff and physicians when a downward trend is occurring. If the trends are displayed on a dashboard-type report, clinicians such as hospitalists who are responsible for many patients can get real-time data on the entire hospital for a high-level view. Then they can drill down to each service, each provider or attending, each unit, and finally to each patient. This data should be included in shift reports and can also help nursing supervisors and unit managers supervise more effectively, allowing a more detailed look at each patient than just the information gathered during shift reports or on rounds. Incorporating vital sign trends into the process of rounding can alert managers about nurses who may need assistance without realizing it or cue intensivists about medical-surgical patients who may be deteriorating or identify ICU patients who may be well

enough to go to a step-down unit. For this information to be effective, the expectation must be that trends indicating patient deterioration will be acted upon.

One hospital's novel way of addressing these very serious events was to institute a Guardian Program whereby experienced ICU nurses monitor 15 parameters of all hospitalized adults twice a day. The parameters include markers for sepsis, including lactate level and white blood cell counts, as well as vital signs, antibiotic use, and early warning system scores.

After the first year of the program, sepsis deaths decreased by 30% while diagnosed cases of sepsis rose nearly 50%. The program was a huge satisfier for staff and patients and the cost savings from early intervention made the case to hospital leadership that the nurses should be hired full-time for this work.

CAUSATIVE FACTORS:

Figure 7: FY18 RCA-derived Causative Factors

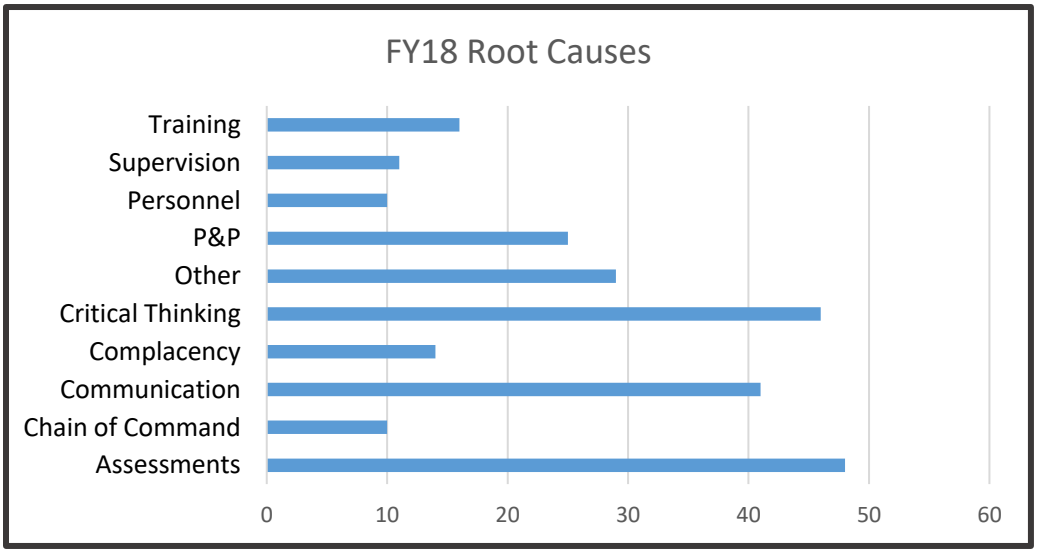


Figure 7 details the raw number of causative factors identified in RCAs submitted in FY18 for all events. Since most events are multi-factorial, the total number of factors adds up to more than the number of events.

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, hospitals can increase the likelihood of a timely intervention by ensuring 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 likely to, and be more effective at, communicating with the rest of the care team, and at activating the chain of command.

People, especially new employees trying to prove their competency, may not recognize when they are in trouble. Nurses are usually placed in the charge nurse and preceptor roles based on clinical experience, but they may have 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 less than that available during day shift.

Given that practitioners are trained and socialized to act independently, perhaps the only corrective action that might save lives is a culture change that puts the emphasis on cooperation, communication, and active supervision. During rounds, charge nurses and house supervisors need to 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 frequently and 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 problems are addressed in a timely and effective manner.

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 deviates 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 laid at the feet of one clinician. Clearly, people who willfully deviate from standards, such as assaulting a patient, require disciplinary action. This activity should take place in parallel with the root cause analysis of the error itself.

For instance, one of the adverse events reported in FY18 involved a nurse in an ED, newly out of school and newly off orientation. The nurse had taken the insulin pen of a patient and used it over the course of several days to give insulin to other patients with orders. This activity was discovered when someone noted the pen in the nurse’s pocket. Over one dozen patients were affected. When questioned, the nurse did not see that he or she had done anything wrong and thought this practice saved time since the pharmacy was perceived to be slow to fill orders at times.

Hospitals are advised to teach their supervisory staff how to engage in active supervision. Supervisors must look for clinicians who may need assistance, regardless of what the staffing numbers say about the acuity of units. 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 judgment. Hospitals must also have systems of accountability to hold staff responsible for carrying (and answering) their emergency phones and systems to ensure periodic updates and training of monitoring technicians.

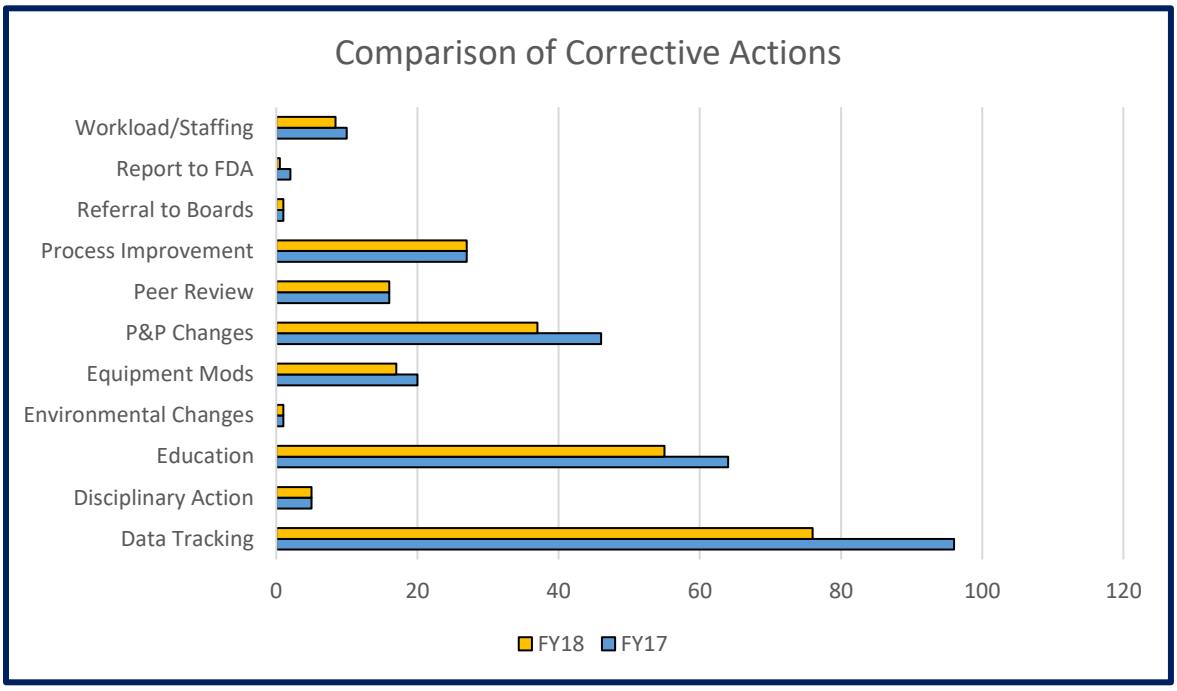
Hospitals continue to struggle with implementing corrective actions that will be long-lasting and effective at eliminating or controlling hazardous conditions. Policy changes and training remain perennial favorites when implementing corrective actions. Although each is considered a weak intervention on its own, both are likely to be part of the overall corrective action plan. Even weak interventions such as 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.

More hospitals are improving problematic processes, usually by streamlining and standardizing. Making more processes fault-tolerant means that 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 refer 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. The remaining corrective actions are self-evident.

Figure 8: Percentage of Corrective Actions, All Events, FY18 Compared to FY17



In comparing corrective actions from FY17 to FY18, there is remarkable consistency. However, since the outcomes were worse for more people in FY18, it is time to rethink these action items.

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, in and of itself, 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 patient-focused outcomes.

Hospitals need to ensure the corrective action is aimed at the correct cause. For instance, changing the way nurses verify that the correct 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 at the surgeons and their offices as the originators of the problem. 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 against administrative systems that abdicate their own roles in holding 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 RCA teams look hard enough and ask 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 a Rapid Response Team (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 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 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, makes staff training much easier, and makes patients safer. Surgical preference cards should be periodically reviewed for compliance with evidence-based standards.

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 built to be fault-tolerant, in that there are 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 Agency for Healthcare Research and Quality (AHRQ).[8]

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 accordance 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.[9] 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.

[8] http://www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/index.html
[9] COMAR 10.07.06.02 (B)(10)

If an RCA fails to meet one or all of the requirements of 10.07.06, OHCQ may issue a statement of deficiencies or may send the hospital an extended review of the RCA. The extended review identifies which elements of COMAR were not met and provides direction on resources to use to improve the quality of future RCAs. There were several commonalities among poor-quality RCAs:

1. Misidentified the level of event;
2. Lacked sufficient details to determine what happened;
3. Focused on what happened rather than on why it occurred;
4. Defined root causes and the information given was insufficient to establish causality;
5. Failed to determine causality, so the interventions lacked specificity;
6. Failed to develop outcome measures that would determine if the corrective actions would have any effect on the problematic process(es); and
7. Focused 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. OHCQ continues to be concerned that some hospitals may not have internal reporting systems capable of capturing all adverse events. Hospitals with robust reporting systems are actually safer than hospitals that underreport. 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 OHCQ but was not, 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, focus on the systems, culture, reporting, 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 OHCQ's, and ensure there are no outstanding RCAs. The report cards also provide a way for OHCQ 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 for hospitals require more attention on 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. 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, our 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.

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.

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

- Providing resources for additional training of charge nurses and supervisors focused on effective patient management, leadership, and interpersonal skills;
- Regularly scheduling meetings between risk management, quality improvement, infection control, patient safety, and medical staff leaders to discuss events and to determine how the events should be addressed by the hospital;
- Reviewing actual RCAs, not merely data related to the numbers of events per patient days;
- Actively participating in a root cause 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 department is expected to interface with the patient safety staff and program;
- Establishing patient safety goals and monitoring the hospital's performance for those goals; 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.

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[10] (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.[11] The purpose of regional PSOs is to collect

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

and analyze data on patient events to achieve the goal of improving the quality and safety of healthcare delivery.

APPENDICES

Appendix A: Maryland Hospital Demographics

Maryland regulation classifies hospitals in two groups. The majority (47) are licensed as acute general hospitals ranging in bed capacity from four to over 1,000 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.

Seventeen 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 ten Special Hospitals-Psychiatric , the licensed bed size ranges from 15 licensed beds to 639 beds. Five of these hospitals are State operated, and two psychiatric hospitals serve only specific populations (children, forensics).

All four Special Hospitals-Chronic serve patients with chronic illness and/or disease-related disabilities who are ventilator-dependent or who have long-term respiratory problems. Two of these are hospital-based units and two are free-standing and operated by the State of Maryland. All provide some rehabilitation services and two of the hospitals are dually licensed as rehabilitation hospitals.

There are two Special Hospitals-Rehabilitation and two Special Hospitals-Children. The latter are also dually licensed as rehabilitation hospitals. The children's and rehabilitation hospitals have less than 100 beds each and offer limited outpatient services.

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 (Data for all years and all event types not available)

Death or serious disability associated with:	FY14	FY15	FY16	FY17	FY18
1A, 1B, 1C, 1D, 1E, 1F. Surgical Events	14	36	21	15	35
2A. Contaminated drug, device, or biologic					
2B. Malfunctioning device				2	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
3C. Suicide or attempted suicide resulting in serious disability	9	5	5	2	8
4A, 4D, 4I. ADEs	12	13	8	8	8
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	2	3	4	2	4
4E. Failure to diagnose or treat hyperbilirubinemia in neonate			1		
4F. Stage 3 or 4 pressure ulcers acquired after admission	63	76	76	56	47
4G. Death or serious disability associated with spinal manipulative treatment (Chiropractic)					
4H. A staff member's failure to act					
4J. Misdiagnosis					1
4K. Delay in treatment	19	36	30	30	40
4L. Associated with airway management	11	11	5	4	9
4N. Unanticipated complication of treatment				3	1
4O. Hospital-acquired infection				2	1
5A. Electric shock					
5B. Delivery of wrong or contaminated inhaled gas to patient					
5C. Burn that occurred in a healthcare facility				2	1
5D. Falls	72	50	58	67	48
5E. Restraints, seclusion, or side rails	4	3	1	4	4
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
6E. Intentionally unsafe care					1
6F. Abuse or Neglect					
6G. Other				4	1

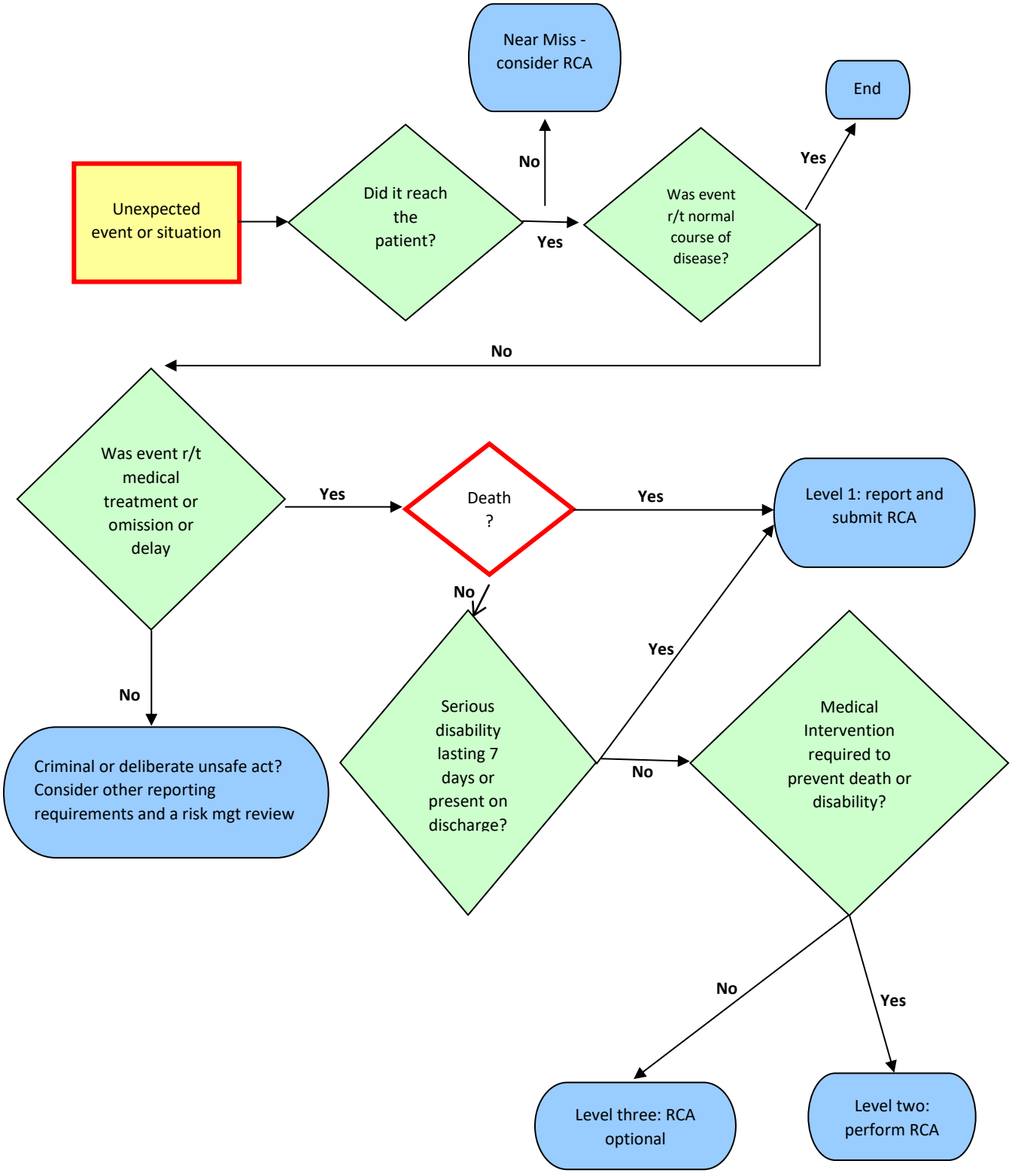
Appendix C: Classification of Events

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

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, 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.