Maryland Hospital Patient Safety Program
Annual Report
Fiscal Year 2017

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 2017 (July 1, 2016 to June 30, 2017). 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. They 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/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 collective 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-wide patient safety activities and integration of patient safety into medical staff and governing body functions.

The FY17 Hospital Patient Safety Report analyzes, both quantitatively and qualitatively, the 207 serious adverse events affecting 244 patients reported by Maryland hospitals to the Office of Health Care Quality in fiscal year 2017 (FY17). This report compares FY17 with previous reporting years, both in terms of the types of events reported and the outcomes attributable to those events.

Key findings include:
- Hospitals with over 300 beds each reported an average of 5.8 events in FY17, up slightly from five reports per hospital in FY1.
- Falls and pressure ulcers accounted for 59% of the reported events. These two types of events accounted for 61% of all reports in FY16.
- The five most common types of events from FY14 through FY17 were falls (27%), pressure ulcers/injuries (30%), delays (13%), surgery-related events (9.5%), and medication errors (4.5%).

- The most common causative factors[1] identified in root cause analyses submitted for FY17 Level 1 events were lack of critical thinking, communication, and assessment.
- Forty of the Level 1 events reported in FY17 affected behavioral health patients.
- Following changes to nationwide event surveillance classification, Maryland is the only state tracking delays in treatment and certain types of surgery-related events.

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

1. Hospital leaders should participate in the root cause analysis process to gain valuable insight into the challenges faced by patients and by front line staff. Leadership participation also reinforces that administration supports the root cause analysis process. Most adverse events require some analysis of latent issues that hospital leadership is in a better position to rectify.
2. To address the most common types of root causes identified in adverse events—communication, assessments, and critical thinking—hospitals should use patient data, including early warning, decision support, and predictive systems more effectively, including using data derived from these systems to improve communication and drive coordination and oversight of care.
3. Maryland hospitals must address the reality of staff to patient assault. These types of events should be reported to OHCQ even if the patient sustains no lasting injury. Hospitals need to improve and extend their training programs to ensure all staff, including non-clinical staff, understand mandated patient rights, hospital obligations, and therapeutic interactions with sick and distressed persons.

Analysis of the reported events indicates that one person dies per week in a Maryland hospital of a preventable error. Unfortunately, this number has remained stable over the past six years. One of the most commonly reported events, delays in treatment, carries a very high mortality. Since 2005, when the first delay was reported, 273 of these events have been reported with 233 fatalities, an 82% mortality. Those numbers should acutely focus our attention.

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

Maryland Hospital Patient Safety Program Analysis

Introduction

Fiscal year 2017 (July 1, 2016 to June 30, 2017) marked the 13th year of the Maryland Hospital Patient Safety Program. As in past years, this report includes comparisons of the current year with previous reporting years. It remains difficult to quantify improvements in quality and safety at a high level of precision. However, the Office of Health Care Quality has been able to identify general areas of improvement demonstrated by hospitals, such as decreases in the reported falls and hospital acquired pressure ulcers (HAPUs). This report includes some creative corrective actions and better practices undertaken by hospital-based teams. Nonetheless, many hospitals continue to struggle with implementing effective, lasting interventions and 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 a myriad of approaches. When trying to determine 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 rates are calculated using distinct methodologies.

On a national level, the Agency for Healthcare Research and Quality (AHRQ) Interim Update on 2015 Hospital-acquired Condition Rate[2] determined that there was an overall 21% decrease in adverse events nationally from 2010 through 2015. Multiple factors contributed to this decrease in adverse events or hospital-acquired conditions (HACs). There are numerous incentives, both positive and negative, spurring a reduction in harm. On the positive side, the Centers for Medicare and Medicaid Services (CMS) has applied incentives designed to reduce HACs including adverse drug events, falls, pressure ulcers, and readmissions. The AHRQ Progress Report indicated that hospitals had achieved 3.1 million fewer harm events over the time period from 2010.

In January 2011, the Maryland Health Services Cost Review Commission (HSCRC) started measuring Maryland hospital-acquired conditions, or MHACs. Modeled on the potentially preventable conditions (PPCs)[3] that the Centers for Medicare and Medicaid Services (CMS) measures as indicators of hospital quality, the MHACs include 52 complications of medical care weighted for severity, frequency, and potential for lost revenue. PPCs are defined as complications that are not present on admission and are unlikely to be a consequence of the natural progression of an underlying illness. MHACs are identified by comparing admission

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[2] http://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html
[3] PPCs are defined as complications that are not present on admission and are unlikely to be a consequence of the natural progression of an underlying illness, and as noted, are counted irrespective of patient outcome.

diagnoses with discharge diagnoses and MHAC rates are benchmarked against State-wide rates. MHAC rates are one indicator of hospital quality, and the MHAC rates affect hospital payments. Because of Maryland's unique rate-setting structure, the State had to get a waiver from CMS to track MHACs, and the HSCRC had to prove to CMS that Maryland's method of tracking PPCs was comparable to the federal mandates. In a November 2015 press release,[4] the HSCRC announced that Maryland hospitals had exceeded performance expectations by decreasing MHACs by 26% and had decreased potentially preventable readmissions more than any other state.

However, none of the extant measuring systems consider the outcome to the patient of these preventable events. Extrapolating from the number of adverse events causing fatalities reported under the Maryland Hospital Patient Safety Program, we know that approximately one person dies in Maryland every week from a preventable adverse event. There were 58 preventable deaths of hospitalized patients reported in FY17.

Hospitals have several other quality and safety reporting mandates. The core measures [5] are disease- or procedure-specific measurements of minimum care standards that cover cardiology, medical oncology, orthopedics, OB-GYN, HIV and Hepatitis C, and some gastrointestinal conditions. The core measures are mandated by CMS and are derived by comparing admission and discharge diagnosis and procedure codes obtained from Medicare charge data.

The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) is a list of 27 questions asked of recently discharged patients about their perceptions of care. Publicly reported HCAHPS results are based on four consecutive quarters of patient surveys.

The CDC collects healthcare-associated infection (HAI) data via the National Healthcare Safety Network (NHSN). These data are also derived from discharge billing disease and procedure codes. The CDC is particularly interested in central-line associated blood stream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), some surgical site infections (SSIs), ventilator-associated pneumonia (VAP), and an intestinal infection called clostridium difficile (C-diff). The CDC also tracks staff immunization rates and staff exposures to communicable diseases. The NHSN uses a patient mix and risk adjusted score (again by discharge codes) called the standardized infection rate (SIR) that compares the expected infection rate to the actual infection rate. The SIR provides a baseline by which to compare hospitals. For instance, a hospital with a C-diff rate of +1 would have 1% more actual C-diff cases than expected for other hospitals with a similar patient mix.

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[4] http://www.hscrc.state.md.us/documents/md-maphs/CMS-and-NEJM-find-successes-in-Year-1-of-Maryland-hospital-system-111215.pdf

[5] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualitymeasures/core-measures.html

CMS publishes participating hospitals' NHSN, Core Measures, and HCAHPS results on the Hospital Compare website[6] four times a year, with the oldest quarter of data rolling off as the most recent quarter rolls on.

REPORTED ADVERSE EVENTS

A Level 1 adverse event is defined in COMAR 10.07.06 as any event that causes death or serious disability.[7] Since the enactment of the Maryland Patient Safety Program regulations on March 15, 2004, over 3,200 Level 1 adverse events have been reported by Maryland hospitals through June 30, 2017. In comparing reporting rates for specific adverse event categories from FY17 to prior years we note:

- The percentage of reported delays in treatment remained at 14% of the total events in FY16 and FY17. This represents a significant, increase from an average of 7.7% of total events reported from FY12 through FY15. Since 2005, when the first delay was reported, 273 of these events have been reported with 233 fatalities, an 82% mortality. Ninety-six delays in treatment, 35% of the total number, have been reported in the last three years with an average 84% mortality per year.

- Surgery-related adverse events dropped this year, from 21, or 14% of total events in FY16 to 18 (8.6%). This number includes seven wrong site/patient/procedures and 11 retained foreign bodies (RFB).

- Nearly 20% of adverse events affected behavioral health patients in FY17.

- Falls and Health Care-Acquired Pressure Ulcers (HAPU) accounted for 58% of the Level 1 events reported in FY17.

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"[8] 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 the 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.

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[6] www.hospitalcompare.hhs.gov
[7] 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.
[8] National Quality Forum. "Serious Reportable Events in Healthcare—2006 Update." Washington DC: 2007

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 related to a healthcare-associated infection;
- unanticipated fetal or neonatal death or injury; and
- misdiagnosis causing death or serious disability.

NQF recently added death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results. This scenario is covered under our delay in treatment category of reportable events, which covers not just failure to follow up on diagnostics but delays in performing diagnostic testing and delays in reacting to changes in patient condition or symptoms.

In 2012, the NQF added deaths in low mortality diagnosis-related groups as a quality indicator.[9] Their assumption is that deaths in patients with diagnoses that typically carry low mortality, for instance birth related diagnoses, is an indicator of substandard care. We track birth events and have various ways of arriving at these data, such as tracking reported delays in treatments, unanticipated complications, and deaths that occur during or just after a typically low mortality invasive procedure.

There is likely to be some under reporting from Maryland hospitals, especially of non-lethal events, as reflected in the wide variability seen in numbers of events reported by hospitals of similar size and acuity. 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—acute general, psychiatric, chronic, children's, and rehabilitation. Acute general hospitals account for 72% of all licensed Maryland hospitals and reported 87% of the Level 1 adverse events in FY17. Statistical analysis of FY17 reports showed no significant difference between the number or type of reports received from teaching- versus non-teaching hospitals. Non-psychiatric specialty hospitals accounted for 4.2% of reports, while psychiatric hospitals accounted for the remaining 8.8%. The percentage of events reported by non-acute hospitals is nearly double the FY16 numbers.

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[9] Qualityforum.org/0347.pdf

Table 1: FY17 Level 1 Adverse Events Reports per Hospital

Number of Licensed Beds	Number of Hospitals	Average Reports per Hospital FY16	Average Reports per Hospital FY17
300 or more beds	11	4.9	5.8
200 – 299 beds	15	5	4.8
100 – 199 beds	17	4.1	2.7
Less than 100 beds	21	0.9	1.1

For FY17, with a few exceptions, the number of reported events is quite consistent with the number reported in FY16 (see Table 2).

Table 2: Multi-year Level 1 Event Reports (the complete list may be found in Appendix B)

Death or serious disability associated with	FY13	FY14	FY 15	FY16	FY17
Suicides or Serious Attempts	7	9	5	5	2
Airway Events	12	11	11	5	6
Maternal/Child	2	2	3	4	2
Medication Errors (ADEs)	10	12	13	6	8
Delays in Treatment	28	19	36	30	30
Surgery-related Events	16	14	36	21	15
Falls	73	72	50	58	65
HAPUs	52	63	76	76	56
Restraint/Seclusion Injuries	0	4	3	1	4

REPORTS OF NON-LEVEL 1 EVENTS

Since March 15, 2004, a total of 617 events that did not meet the criteria for a reportable event[10] under COMAR 10.07.06 were reported to the Maryland Patient Safety Program by hospitals. Sixty-four of these non-Level 1 events were reported to the Office of Health Care Quality in FY17. Some were initially reported as Level 1 events and were downgraded after further review by the hospital or the OHCQ. Additionally, many hospitals have also reported events that they are aware do not meet the criteria for mandatory reporting and are not Level 1

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[10] Under COMAR 10.07.06. 02 B (4) the hospitals are required to report all Level 1 events defined as adverse events which result in death or a serious disability to the patient.

adverse events. These hospitals have reported these events because they realize that serious systemic problems may have caused the errors and could occur again with more significant consequences. Burns that occur in the OR do not usually cause Level 1 injuries, but many hospitals report these uncommon events when they occur even if the injuries are minor. Retained foreign bodies that are removed during the same surgical occurrence and wrong site procedures that do not cause serious harm to patients are also reported by hospitals regardless of the presence of serious disability or death. These types of events are considered "never events" and OHCQ appreciates the willingness of hospitals to go beyond the letter of the law so we can track events that should never happen, even if there is no evidence of injury or if the injury is relatively minor.

The Office of Health Care Quality Patient Safety staff also maintain a separate list of reports that may or may not be Level 1 events. Because the statute calls for reporting events within five days of the hospital's knowledge of the event, a few events are reported prior to ascertaining with certainty that the adverse outcome was caused by a preventable medical error. Sometimes, it is not even known if the patient suffered a serious injury. The hospitals may want to wait for peer review, an autopsy, or more discussion with the clinicians involved before defining the event as a Level 1 error. Twenty-eight reports of these types of reports were received in FY17. The conversion rate of these reports into Level 1 adverse events is less than 1%. Again, the Office of Health Care Quality appreciates the willingness of hospital staff to report unexpected outcomes even if it is initially unknown whether the outcome was due to a preventable medical error.

REPORTING ADVERSE EVENTS

When reporting serious adverse events, please include the following information:

- Patient's age or date of birth;
- Date of admission;
- Date of event;
- Type of event (fall, medication error, etc.);
- Type of injury (death, fractured hip, etc.);
- Anticipated outcome for the patient (surgery, loss of limb, anoxic injury, etc.); and
- Whether disclosure was made to the patient and/or family.

Event Outcomes

FATALITIES

Figure 1 details the most commonly reported fatal Level 1 adverse events from FY13 through FY16, along with the proportion that were fatal. These five event categories represented 86% of the reported Level 1 events and 75% of the fatalities. As noted, one person dies per week in a Maryland hospital of a preventable error. Unfortunately, this number has remained stable

over the past five years. One of the most commonly reported events, delays in treatment, also carries a high mortality. Since 2005, when the first delay was reported, 243 of these events have been reported with 205 fatalities, an 85% mortality.

Figure 1: Events with Associated Fatalities FY17
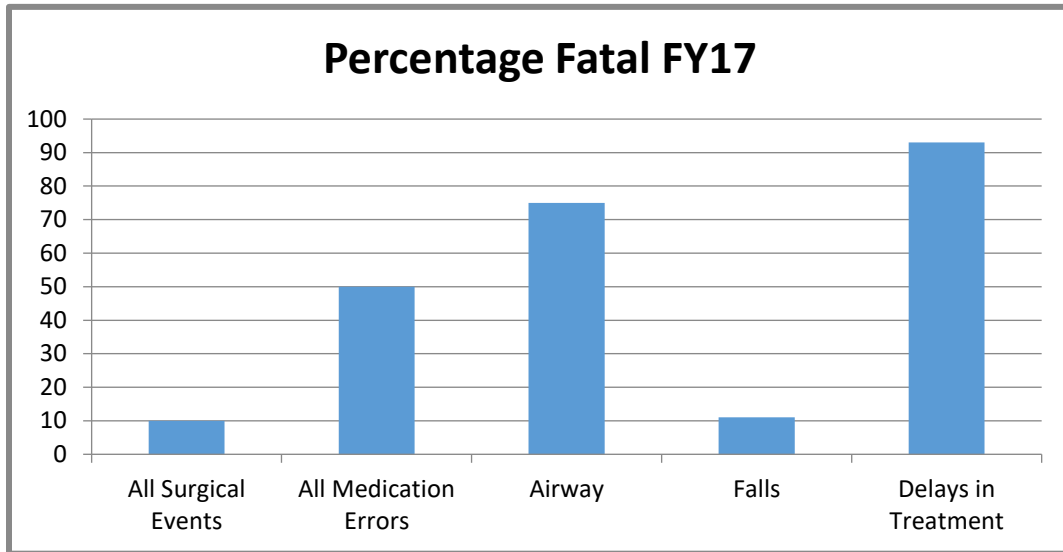
While the formation of hospital-acquired pressure ulcers (HAPUs) is correlated with overall decreased life expectancy, HAPUs are the least likely event to cause inpatient death. Only one HAPU-associated death (due to massive infection) has been reported since 2004. For FY17, airway events only represented 2% of events, but 75% resulted in a fatality. Airway events, delays and medication errors were significantly more likely to result in a fatality. In FY17, these three event types accounted for only 21% of reported events but nearly 60% of all fatalities. Since all 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 of course 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).
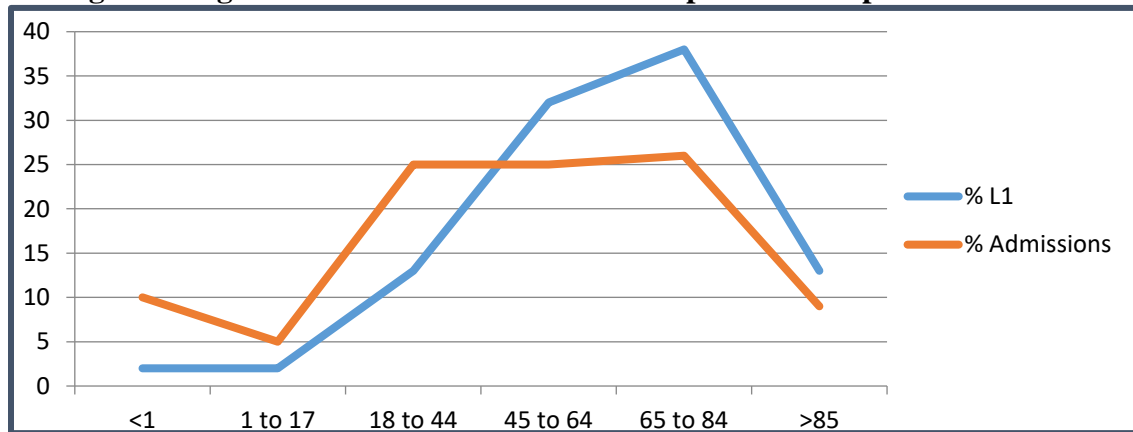
AGE AND ADVERSE EVENTS

According to the Healthcare Cost and Utilization Project (HCUP)[11] from the AHRQ, the percentage of hospital admissions is roughly equal for the age groups encompassing 18 to 84

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[11] https://www.hcup-us.ahrq.gov/

year olds. However, we see a significant spike in adverse events occurring to patients aged 45 to 84. In FY17, 87% of adverse events were reported in those over 45. Excluding trauma, many patients under 45 are admitted for relatively uncomplicated surgeries such as orthopedic procedures and other low mortality procedures. In addition, since childbirth occurs primarily in the under 45 age bracket, it makes sense that the prevalence of adverse events in this age group would also be low. Those under 45 are also less likely to be afflicted with age-related chronic conditions that add complexity to care in later life. According to 2015 HCUP data, the median age at hospital admission in Maryland was 49.

Among those over 65, the CDC[12] estimates that 11% of all accidental deaths are caused by adverse effects, which includes adverse outcomes related to medical care and to medications. According to the 2015 census, the population of Marylanders aged 65 or older is approximately 800,000, or 13% of the total. In FY17, 56% of reported Level 1 events occurred to those over 65.

Figure 2: Age at Onset of Adverse Event Compared to Hospital Admissions

If we look at the mortality as a result of adverse events rates for each age, we arrive at Figure 3.


Figure 3: Adverse Event Death Rates per Age

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[12] https://www.cdc.gov/injury
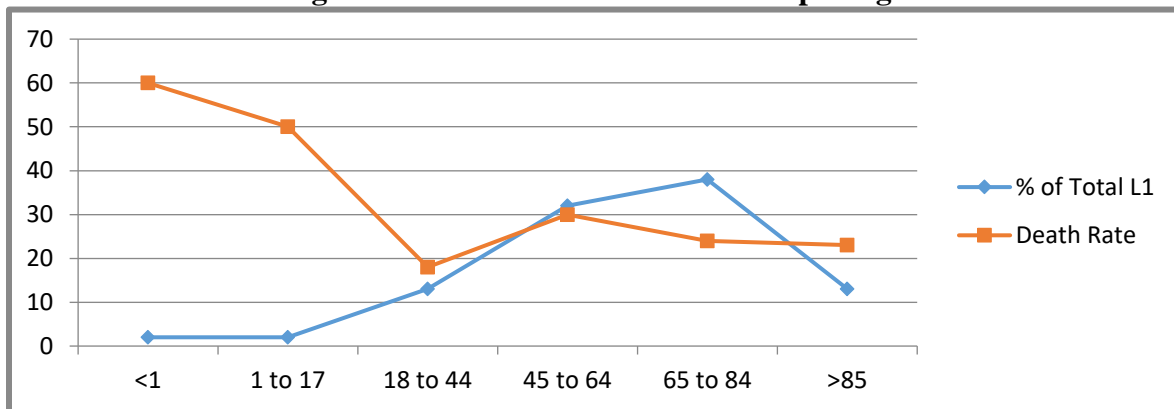
Figure 4 demonstrates the percentage distribution of the most commonly reported adverse events across age groups. One can see that airway events disproportionately affect those over 85 while falls and HAPUs affect those in the 65 to 84 range, and delays in treatment affect those patients aged 45 to 84.

Figure 4: Distribution of the most commonly reported adverse events across age groups:
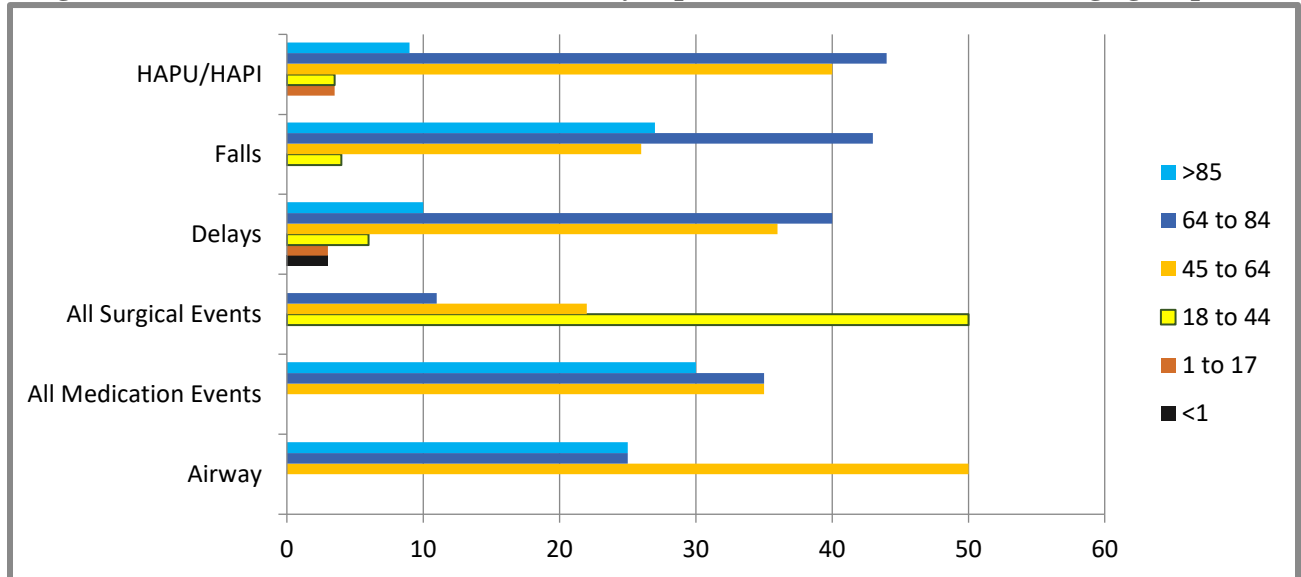
Adverse Events in the Behavioral Health/Psychiatric Population

In FY17, a new trend emerged of at least 40 Level 1 events affecting patients with behavioral health diagnoses were reported by Maryland hospitals. These events represented 20% of the total number of reported Level 1 events. Eighty-three percent of events affecting behavioral health patients were reported by acute general hospitals and included six staff to patient assaults, four elopements of vulnerable adults, and four restraint injuries. Both reported fatalities from untreated hypoglycemia (low blood sugar) occurred in behavioral health patients. One patient had taken an overdose of her parent's antihyperglycemic medication because she liked the way it made her feel. When she presented to the emergency department (ED) after the overdose, the staff were focused on assessing her suicidal ideation and did not ask about the dose or the timing of the medication, and no one checked her blood sugar until the next day after she suffered a fatal cardiac arrest.

As both the general and behavioral health patients are aging, falls are fairly common in the behavioral health population. Many of these are due to patient factors such as confusion, agitation, and overconfidence in one's skills and strength. There were 18 falls reported in this population, none of which were fatal. A few of these patients were geriatric patients who fell

during agitated or combative periods. A couple of the falls were caused by a patient inadvertently getting in the way of someone else's agitated or combative state.

In 2012, Maryland hospitals experienced a sudden spike in the number of in-hospital suicides and serious suicide attempts but over the past couple of years, more of the suicides are occurring outside the hospital, post discharge either from an inpatient unit or the ED. Only two suicides were reported in FY17, and both occurred within the 24-hour post-discharge period and both pointed out the need for vigilant screening of home environments.

There were four elopements of vulnerable adults reported in FY17. Elopements of vulnerable adults or patients who lack capacity should be reported to OHCQ even if the hospital does not know if the patient was injured. One patient who was very confused and hallucinating ran out of the ED and was quickly returned by security staff. This ED had a locked area for psychiatric evaluations, but the patient was placed in a regular ED cubicle. Neither the level of supervision nor other interventions were changed following the first episode of elopement and the ED physician was not notified. The patient ran out again and this time fell over a low wall and fractured his leg. Another patient escaped from a locked psychiatric unit via the laundry chute. The staff had disabled both the lock on the utility room door and the lock on the chute itself because they took too long to unlock. Just because a patient is on an involuntary hold and lacks capacity doesn't mean that he or she cannot recognize an opportunity to elope when it presents itself.

Figure 5 shows the distribution of the most common adverse events reported in the psychiatric population.

Figure 5: Distribution of Events and Fatalities in the Behavioral Health Population, FY17
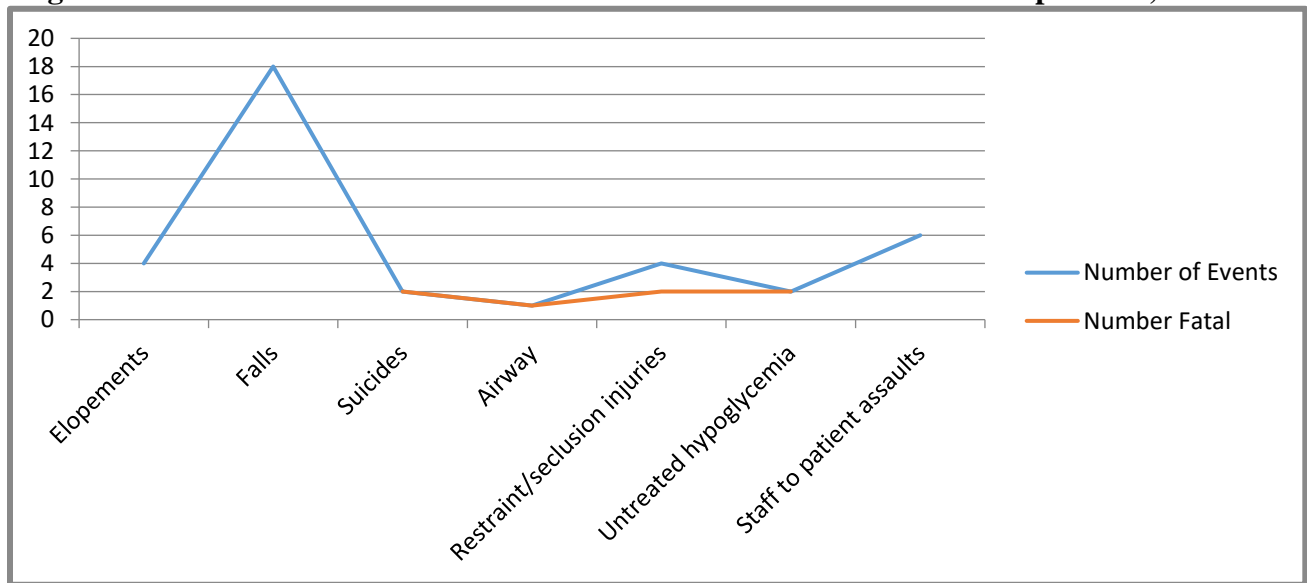
There were the six staff to patient assaults and two of the four fatal restraint episodes for behavioral health patients. One patient died after being restrained face-down on the emergency

department floor by security personnel for approximately 10 minutes. The patient was noted to be yelling that he couldn't breathe and asking the security personnel to get off him. This ED had no seclusion room, but the behavioral health unit was adjacent to the ED and the patient was not moved there. The security personnel had had no training in the safe use of restraints or in dealing with patients with unsafe, combative behaviors so they apparently felt they should hold the patient prone until the local police came. Security also had no CPR training and were unable to identify respiratory distress. The nurses deferred to security and the ED physician was not notified about the patient's behavior until the code blue was called.

There is a myth that as long as someone is able to make noise, that he or she must be breathing. That is not true. The lungs are capable of exhaling approximately 1200 cubic centimeters of air (the expiratory reserve volume) even if the person cannot inhale. This means that when someone is physically prevented from inhaling, that person is capable of speaking even while suffocating. This fact of physiology is worth mentioning while training security personnel or indeed anyone who applies restraints or may ever has the opportunity to put hands on a patient.

Two other patients suffered broken arms during hands-on restraint episodes.

The six reports of staff to patient assaults represent a new high. There was one reported assault in FY16 and two reported in FY15. In one FY17 event, a minor child was kept in a locked door seclusion room overnight, apparently because she was intrusive and needy. Even though there was no physical harm, OHCQ and the hospital's patient safety officer agreed that this act represented such an egregious overuse of seclusion that it should be considered an assault. The child reported to the morning shift that the nurses had been mean to her the night before. When the hall video was reviewed, it showed the non-violent child being placed in the seclusion room.

A patient with an intellectual disability called a patient care technician a derogatory name and the technician punched the patient.

A teenage patient being evaluated in the ED for self-injurious behavior was sexually assaulted by a radiology technician, in view of a nurse. The nurse promptly reported the incident.

One adult patient was given forced medication over a dozen times during his stay in the behavioral health unit. When a nurse reported a concern, the hospital investigated and found that about half of those injections could not be justified by either the documentation or the hall and common area video. Forced medications are allowed in only a couple of very narrow circumstances, the most common of which is to control dangerous behavior in an emergency situation. A patient who is not violent has the right to refuse medications. Members of the medical and nursing staff were disciplined and reported to their respective State boards for violating the patient's rights.

Another patient on a behavioral health unit was assaulted by one member of the security staff while two others watched. The patient had several annoying, but non-violent behaviors like wiping feces on the unit furniture. This unit had 24-7 presence of security personnel and there had been, according to the RCA, some "slippage" of role definition, with the nursing staff too often deferring to security and expecting them to control the behavior of patients. This assault was further complicated by the inaction of the staff. Not only did two security persons watch what happened without stopping it or reporting the other staff's behavior, but the hall video showed what happened and the patient reported the assault to a nurse and a mental health professional. They documented what the patient said but did nothing else. If a hospital has a policy whereby security is a continual presence on behavioral health units, role definitions must be reinforced frequently. Clinical staff must remain in charge during all patient interactions.

In another event categorized as a case of abuse, a nurse, responding to a call about an unresponsive patient, slapped the patient across the face and hyper-extended the patient's finger. This patient had a history of frequent periods of unresponsiveness related to his underlying mental illness, and the nurse was apparently trying to "wake him up." The hospital did not become aware of this event for nearly a month, when a nurse overheard two other staff people discussing the event and reported to nursing leadership.
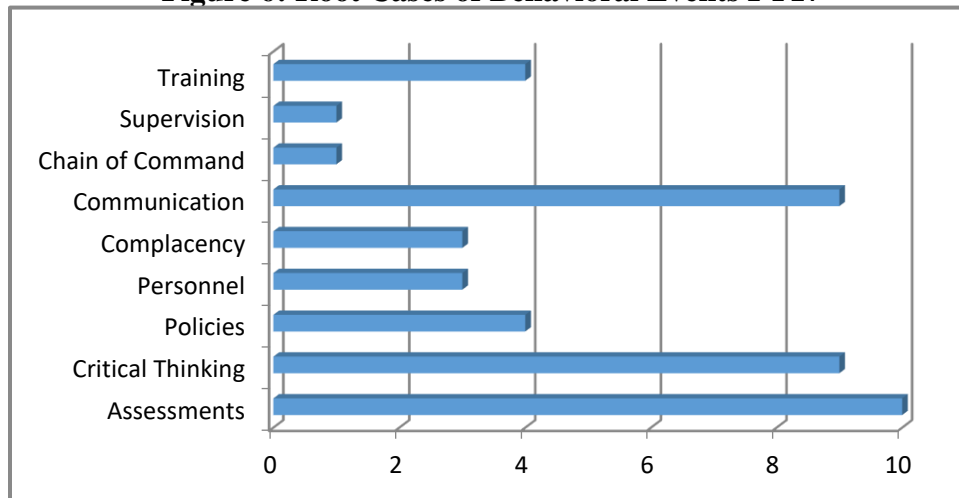
ROOT CAUSES OF BEHAVIORAL EVENTS

According to the submitted RCAs, training was identified as a causative factor in 10% of the adverse events that affected the behavioral health population. Training is usually a factor in the restraint and assault episodes. 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 a hospital 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 have the skills to deal with a sick and sometimes mentally ill population and may not be used to dealing with people in a therapeutic environment. Hospitals may find it beneficial to provide some 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.

Under the Federal anti-dumping statute, the Emergency Medical Treatment and Active Labor Act (EMTALA), hospital staff whether clinical or non-clinical, should not impede, refuse entry, or otherwise dissuade a person seeking treatment in the emergency department, even if the patient is acting out, under the influence, or disruptive. Qualified medical personnel have an obligation to perform a medical screening examination on everyone who presents to the hospital to determine if the patient has an emergency medical or psychiatric condition. If the medical screening examination determines that the patient does not have an emergency medical

condition, he or she may be removed from the ED. However, the hospital must arrange a safe discharge for all patients.

According to the Patient Rights Hospital Condition of Participation regulations from CMS, hospitals must have policies, training, and supervision sufficient to identify all instances of abuse, even if that abuse happens in the hospital.[13] Many hospitals may need to revise their policies and training programs to address this issue. This type of training may be best accomplished through 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 hit the staff. Most abuse policies reviewed by our 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. With six assaults reported this year, and probable under-reporting, there is likely a problem. 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.

Figure 6: Root Cases of Behavioral Events FY17

There are more than 40 root causes or probable causative factors because as with other event types, behavioral health events are multi-faceted. Assessments and critical thinking are well-represented as causative factors. These two factors apply most often to the events that do not constitute abuse or assault. For instance, in the two deaths from untreated hypoglycemia, one patient told the staff she had deliberately taken an unknown quantity of medication that lowers the blood sugar even though she was not a diabetic. In the other case, the patient was a diabetic and had had frequent visits to the ED in the past for low blood sugar. Both patients died when staff failed to assess their glucose levels and failed to separate symptoms of critically low blood sugar from underlying behavioral health symptoms.

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

Two of the falls that occurred on behavioral health units noted critical thinking as root causes. In the first, direct care staff thought that touching an unsteady patient while assisting him or her down the hall was the same as a hands-on restraint. The patient fell and fractured a hip. This event also required staff education.

The other patient fell because he used a bariatric wheelchair and the door to the bathroom was too narrow for the wheelchair. Two staff tried to assist him, but one was in front and one was behind as they went through the door. The patient fell against the door, which had a heavy self-closing mechanism and slammed shut, knocking him to the ground.

Another patient fell during a nursing change of shift because two or more of the direct care staff were on breaks, thus reducing available staff to a critical level. This practice was contrary to hospital policy.

OHCQ shares de-identified information with Disability Rights Maryland (DRM)[14]. Among many other activities, DRM monitors psychiatric facilities and advocates to prevent and address abuse, neglect, coercive practices, and barriers to discharge in adult mental health facilities.

DELAYS IN TREATMENT

The Office of Health Care Quality defines delays in treatment as untimely assessments of evolving symptoms or changes in a patient's condition, and/or a delay in reacting to diagnostic testing results or in providing definitive treatment. Because these types of events have such a high mortality, and usually involve many caregivers and hospital systems, we consider delays in treatment to be the most serious type of reported events. In FY17, there were 30 level 1 delays in treatment reported, with 93% being fatal. Since 2005, when the first delay was reported, 273 of these events have been reported with 233 fatalities, an overall 82% mortality. Ninety-six delays in treatment, 35% of the total number, have been reported just in the last three years with an average 84% mortality per year

Maryland is the only state that tracks delays in treatment. The NQF has never had delays in treatment or failure to rescue on its list of serious reportable events. The early iterations of the National Database of Nursing Quality Indicators (NDNQI)[15] started by the NQF contained failure to rescue as an indicator of nurse-driven quality. Failure to rescue was defined as "errors of omission in which clinicians fail to prevent a clinically significant and often devastating complication of a patient's underlying condition or of his or her medical care."[16] The AHRQ and HealthGrades now classify failure to rescue as "deaths among surgical inpatients with treatable,

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[14] https://disabilityrightsmd.org/mental-health/
[15] https://www.qualityforum.org/Publications/2004/10/National_Voluntary_Consensus_Standards_for_Nursing-Sensitive_Care__An_Initial_Performance_Measure_Set.aspx
[16] http://psnet.ahrq.gov/popup_glossary.aspx?name=failuretorescue

serious complications."[17], [18] This narrow definition misses the many catastrophic events that occur to patients who have not had surgery or who suffer devastating delays while still in the emergency department (ED). We prefer the term delay in treatment because the reports and subsequent root cause analyses (RCAs) overwhelmingly implicate more disciplines than nursing in the patient outcome. For instance, delays in treatment caused by failing to provide diagnostic testing, or failing to follow up on abnormal results, usually involve multiple departments and disciplines.

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 such as 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. These data should be included in the shift report 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 the shift report or on rounds. Incorporating vital signs trends into the process of rounding can alert managers about nurses who may be getting in over their heads 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.

EVENTS

Seven of the delays in treatment reported in FY17 involved patients with sepsis, an overwhelming, life-threating response to the presence of one or more infections. Most emergency departments use evidence-based protocols for assessing and treating patients who may have sepsis. Effectively treating sepsis requires a timely multi-disciplinary approach that, for several reasons, does not always happen.

One patient was treated by an ED physician who was not familiar with the sepsis protocol. The nurse had to prompt the physician for an order for the appropriate testing. When the patient's assessment score (based on lab results, vital signs, and symptoms) indicated the strong probability of sepsis, the physician was reluctant to order some of the standard interventions, such as intravenous fluids to raise the blood pressure. When the MD neglected to order the fluids, none of the rest of the protocol was implemented. The patient was admitted to a regular nursing unit without oxygen or a large-bore IV. By the next day, she was showing signs of poor oxygenation and had a very low blood pressure. Even though other physicians were

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[17] HealthGrades Patient Safety in American Hospitals Study, March 2011
[18] www.qualityindicators.ahrq.gov

involved in the patient's care, they were focused on the patient's respiratory status and not the positive sepsis screen that was the likely cause of the shortness of breath, low blood pressure, and low oxygen levels. Because the sepsis interventions were not in the ED, the other physicians assumed the patient had screened out for sepsis and had something else. Critical blood test results were so bad that they were assumed to be incorrect and not reported to the physician, and there was a delay in establishing central line access, a critical delay in establishing an effective airway, and a delay in transferring the patient to a higher level of care. There were also a number of late or inadequate communications between providers and staff. All of which led to the patient's death.

Another patient arrived at the ED barely responsive 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 informed the hospital staff that she was not normally like this. She was triaged as a lower level than her presenting symptoms should have warranted, meaning she had to wait to be assessed by the physician for a longer period of time. This ED had no standardized way of handing off a patient from triage to the main ED and relied on the triage nurse entering information in the electronic medical record (EMR). The nurse assigned to the patient was accessing and reading the triage notes and vital signs. The patient was placed in a bed, but the nurse later said he or she was unaware that the patient was in the room for 90 minutes because there was no verbal hand-off between staff. This ED also had a manual process for performing the sepsis screen. In this case the sepsis screen was not done because of the assumptions by the staff about the patient's baseline condition. After being in the room for 90 minutes, another staff 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.

A fairly healthy middle-aged patient had a low-mortality gastrointestinal procedure in a hospital same-day surgery center. The procedure was more complicated than the surgeon anticipated so the patient was admitted to the hospital rather than going home following surgery. The patient had severe pain and bloating for the first two or three days after surgery which was attributed to the complexity of the procedure rather than the development of sepsis. On post-operative day three, the patient developed a rapid heart rate, fever, and low blood pressure. The patient was moved to the ICU under the care of the intensivist. When the surgeon did not come see the patient for more than 10 hours, the staff called the on-call surgeon. The on-call surgeon evaluated the patient and conferred with the primary surgeon who was at another hospital. The primary surgeon was delayed and did not get to the hospital for several hours. The patient was taken to surgery immediately where it was found that he or she had suffered a perforated intestine. The patient died the following day.

During the RCA, all participants agreed that ineffective and untimely communication was the primary cause of the delay in getting the patient to the operating room. The intensivist should have gotten the surgeon involved sooner, the primary surgeon should have told the on-call

surgeon how late he or she was going to be, and the on-call surgeon should have communicated the delay to the intensivist. In addition, there were abnormal lab results from the first two post-op days that should have resulted in more in-depth assessments of the patient.

Root cause analyses for five of the reported delays in treatment implicated lack of use of the chain of command as a strongly causative factor. In these events, the nurses involved stated that they were afraid to use the chain of command because they did not want to jeopardize their working relationships with the physicians involved. For instance, one younger patient died of sepsis when his severely low blood pressure and abnormal labs were ignored for more than 15 hours. During the RCA, the nurses reported being pressured by the resident physicians to not call rapid response teams (RRT) for changes in patient condition. A RRT usually includes a respiratory therapist, an experienced nurse from the intensive care unit, and often, a specialist in critical care medicine. The purpose of the RRT is to assess the patient, offer resources, and intervene early, before the patient condition reaches the point of no return. In this case, and in others, the nurses reported push-back from the RRT on calls.

In at least two reported events, there was one physician who acted as an impediment to transferring the patient to a higher level of care or to providing definitive treatment. In each RCA, the nurses reported a cultural power gradient in the hospitals that strongly discouraged going up the chain of command beyond the attending physician.

One patient who was critically ill and deteriorating with low oxygen levels, high heart rate and low blood pressure was kept on a medical/surgical (med-surg) unit with a five patients to one nurse ratio for over 24 hours because the hospitalist refused to transfer the patient to the ICU. Neither the nurses nor the nurse manager activated the chain of command to go over his head. The nurses asked repeatedly for a transfer and the physician refused. This physician also asked the nurses not to call a RRT. Eventually, the patient had a lateral transfer to a unit with the same nurse patient ratio and the same level of care, but the unit had a different name. The physicians apparently thought that the level of care on this unit was higher than the first med-surg unit. This is clearly a time when a more experienced clinician could have intervened long before the patient could no longer compensate, lost his heart rate, and died. A member of nursing leadership usually must approve or facilitate transfers of this type.

One delay in treatment occurred because the hospital had a policy that all transfers within the hospital for patients needing a higher level of care had to be affected by the sending physician and the receiving physician. This is a good policy in theory, but only effective if the physicians cooperate with each other. Hospitals should consider developing a fallback method by which the nurses, or nursing leadership, can facilitate the transfer process if it is in the best interest of the patient.

In another delay in treatment, a patient who was on an anticoagulant was admitted through the ED from a rehabilitation facility. He was alert and oriented and told the ED staff that the staff at the rehabilitation facility had used a gait belt to help him walk and he was having

severe abdominal pain. A gait belt is a thick stiff webbed belt that is placed around a patient's abdomen to provide a handle of sorts that the staff can hold to help a patient ambulate. Imaging showed a massive amount of blood behind his abdominal cavity that was compressing the main vein feeding his heart and was squeezing one of his kidneys. The following details the sequence of events:

- A general surgeon was consulted and decided that the bleeding would stop on its own and the patient did not need surgery.
- The ED physician tried to transfer the patient to a higher level of care for a vascular surgery consult but the one hospital she tried had no beds.
- The patient was admitted under the care of a hospitalist but remained in the ED overnight waiting for a bed.
- The hospitalist wrote orders for a blood transfusion without realizing the ED staff could not read inpatient orders because the electronic medical records (EMR) did not talk to each other.
- The blood bank's policy was that they would not call the nursing unit to tell them when the blood was ready. It was up to the patient's nurse to frequently check the EMR to see when blood products were ready to be picked up. Because the ED nurse didn't know about the blood orders, there was no reason for him to check.
- Because he was considered a boarder in the ED, the patient's vital signs were taken rarely over that night. In addition, no interim blood tests were taken that would have identified the continued bleeding and his dropping blood count.
- When he was finally admitted to the intensive care step-down unit, he was in hypovolemic shock due to the continued bleeding, which had further compressed the blood vessels around his heart. Even though his vital signs were very unstable at that point, no consideration was given to transferring him to the ICU. Shortly after arriving on the step-down unit, his heart and breathing stopped and he could not be resuscitated.

This event points out the interrelatedness of causation in delays in treatment. From the initial surgeon's consult, who felt that the patient's bleeding would stop on its own, to the night shift ED physician and nurses who, once they had handed care over to the hospitalist, rarely looked at the patient, to the ED physician who requested a transfer to only one hospital, to the hospitalist who didn't realize how sick the patient was and didn't seek any information that would have told him or her just how close to death the patient was, to the nursing supervisors who did not to expedite the admission to the ICU or a transfer to a higher level of care. Of note were the two EMRs that weren't compatible and the blood bank's policy of making people check if the blood is ready contributed to the outcome.

Four of the reported delays in treatment involved patients with cardiac monitoring. In one event, the button that permanently silenced all alarms was directly below the suspend alarm button that silences the alarms for a few minutes. The alarms were inadvertently shut off. Even though there was only a few minute delay in recognizing the life-threatening rhythm on the monitor, the patient could not be resuscitated.

In another monitor event, a patient was found sitting up in a chair, but pulseless and unresponsive. He could not be resuscitated. Review of the telemetry history showed his leads had come off about a half-hour prior to being found. There were a couple problems identified in the RCA. The unit had no set time to change and replace the leads on patients, so the leads of several patients a day fell off, causing many nuisance alarms. Then, a fairly inexperienced nurse had been floated to the telemetry monitoring room because the hospital was short of telemetry monitoring technicians. The nurse had certification in recognizing adverse rhythms but had not had orientation regarding the telemetry expectations for monitoring and communicating with patient's nurses. So, when the patient's leads fell off, the nurse did not notify anyone.

CAUSATIVE FACTORS:

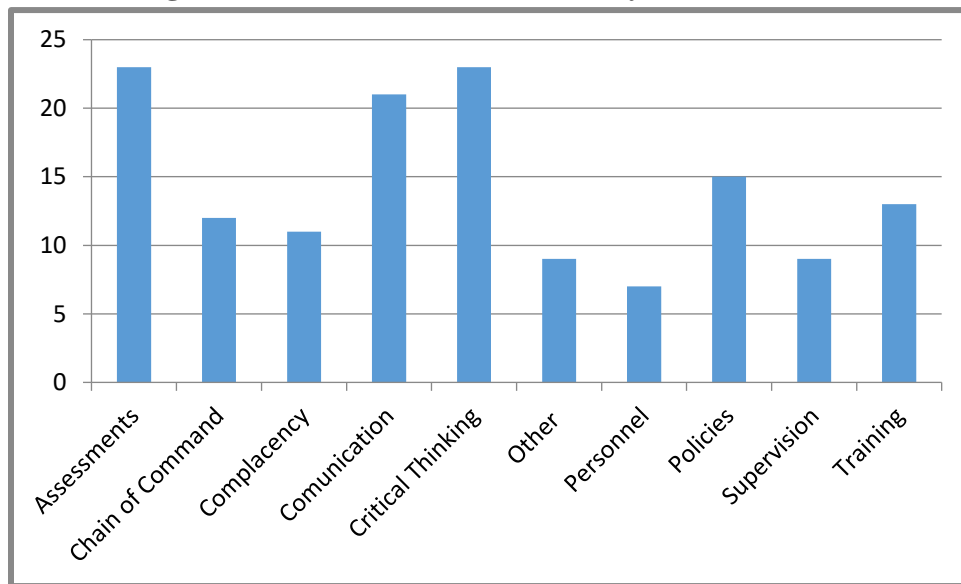**Figure 7: FY17 Root Causes of Delays in Treatment**

Figure 7 details the raw number of causative factors identified in RCAs submitted in FY17 for delay in treatment events. Since most events are multi-factorial, the total number of factors adds up to more than the number of events.

Since 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, one way hospitals can increase the likelihood of a timely intervention is to ensure 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 likely to, and be more effective at, communicating with the rest of the care team, and at activating the chain of command.

For instance, a new nurse one day off orientation was caring for a patient with a specialized piece of equipment inserted through her skull to monitor the fluid pressure in her head. The monitor had a stopcock that was to be opened every hour to check the pressure. For the entire 12-hour shift, the nurse documented the same pressure. The charge nurse and the nurse's former preceptor asked him frequently if he needed any help, but he always responded that things were fine. When the day-shift nurse came on, he found the patient's neurological status indicated severe brain damage and the pressure reading was extraordinarily high. Immediate actions were taken to try to rescue the patient, but she died.

The RCA determined that the new nurse had had the stopcock turned the wrong way all night. A simple look at the documentation, which would have shown the same readings, or a request to demonstrate his technique in using the monitor by the preceptor or the charge nurse would have avoided the fatal outcome. People 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 not have 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, it seems that the only 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 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.

SURGERY-RELATED EVENTS

In FY17, there were fifteen reported Level 1 adverse events associated with retained foreign bodies (RFB) or wrong site/wrong procedure/wrong patient surgeries or procedures. (For the purposes of this report, wrong site/wrong procedure/wrong patient will be referred to as wrong procedures). Although HealthGrades, the AHRQ HACs, HSCRC MHACs, and the NDNQI no longer track wrong procedures,[19] NQF continues to have wrong procedures on their list of serious reportable events. The reader will note that the patient outcomes for surgical events are not usually severe. However, because these are events that are 100% preventable, we expect hospitals to report them even if the outcome is not life-threatening or function-limiting.

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[19]https://www.qualityforum.org/Publications/2004/10/National_Voluntary_Consensus_Standards_for_Nursing-Sensitive_Care__An_Initial_Performance_Measure_Set.aspx

[19] http://psnet.ahrq.gov/popup_glossary.aspx?name=failuretorescue

[19] HealthGrades Patient Safety in American Hospitals Study, March 2011

[19] www.qualityindicators.ahrq.gov

In one of the eleven RFB events, a patient had a cardiac defibrillator implanted in a lab at the hospital. A few days later, she returned to the ED with a wound infection, for which she was prescribed antibiotics. Several days after starting the antibiotics, she returned to the ED because the infection had gotten so bad that the device was protruding through her skin. Imaging studies identified a retained sponge. She required removal of the device and several plastic surgery procedures to clean and close the wound.

The RCA determined that, partly because of being located in a fairly isolated part of the hospital, the staff in the lab had developed some habits not consistent with the surgical services operations. The physicians had trained the radiology technicians to suture and the technicians frequently closed the incisions while the surgeon was out of the room. Suturing incisions is outside the allowable scope of practice for radiology technicians. No one performed the standard counting protocol that should be done before, during, and after all invasive procedures, during which all sponges, equipment, needles, and anything that went into the patient is accounted for. The radiology technicians were also taking and reading the post-procedure x-rays, which is also outside their scope of practice.

ADVERSE MEDICATION EVENTS

One elderly patient suffered a fatal medication error when he was erroneously prescribed and given methadone. He had called an ambulance from his assisted living facility and arrived at the hospital determined to never go back. He did not have capacity to make decisions and had no known family. Because he had no acute care needs, he was admitted on observation status and followed by case management as the hospital went through the process of getting a guardian appointed by the state. The hospitalist saw the patient every day on the observation unit. On the twentieth day, the EMR automatically discharged the patient. The hospitalist service, apparently assuming someone else had reported this problem with the EMR, re-wrote the orders daily. After several days of this, one of the physicians wrote an order for methadone on this patient's medical record in error. The physician recognized the error immediately and discontinued the order. Because the order was discontinued and not cancelled, it still showed up on the EMR. Even though the patient had been in the hospital for more than three weeks and had not previously been prescribed opioids, the pharmacy filled the order. Because the patient had been discharged, the nurse could not "see" the previous medication administration records and assumed the patient had been on methadone for the duration, so the nurse gave the medication. And, since the nurse was not familiar with the patient, she assumed that the patient's drowsiness and somnolence was her baseline mental status and did not call a RRT until the patient stopped breathing.

In the aftermath of this event, the hospital had their EMR modified to not automatically discharge patients. They also made the process of reporting EMR problems to the IT department easier and more transparent. And they made it mandatory that any physician ordering methadone document that the dose was verified by the patient's community methadone clinic by including the name and phone number of the person at the clinic in the order.

Two patients fatally overdosed on opioids brought in from outside the hospital. One patient brought his own drugs into the hospital and the other patient had drugs brought in by a family member. While little can be done about visitors, in the face of the growing opioid crisis, hospitals may need to confer with their legal counsel to determine when and how they may search patients and their belongings.

A very elderly patient was admitted to the hospital one evening accompanied by her daughter, who told staff she was a physician's assistant (PA-C). The daughter refused to let staff take vital signs and took them herself, reporting the results to the staff. She also asked for, and was given, the patient's nighttime and morning antihypertensives and a dose of a cardiac medication that also lowers the blood pressure. The nurse, who was not very experienced, asked the charge nurse for help with this situation and the charge nurse told her to call the PA-C that was covering the unit that night. The PA-C and the new nurse tried to manage this very difficult family situation all night without calling a nursing supervisor, an in-house physician, or the patient's attending physician. Early in the morning, the patient's blood pressure had become so dangerously low that the daughter had no choice but to tell the staff. A code was called but the daughter asked that resuscitation efforts be stopped after a few minutes.

PA-Cs are not considered independent providers by either federal law or Maryland's practice act. A physician must be responsible for the care of every patient. Reporting and communication expectations must be made clear to all clinical staff.

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, some would say, a moral obligation to hold staff accountable for following established, evidence-based processes and procedures. The intent of the staff member who makes an error must be considered. Was the error the result of 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 the Office of Health Care Quality since 2004 can be laid at the feet of one clinician. Clearly, staff who willfully deviate from standards by, for instance, assaulting a patient must be held accountable for their actions. This activity should take place in parallel with the root cause analysis of the event as there may be systems that contributed to the event.

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

numbers say about the acuity of units. Supervisors need to go look for potential problems and look for ways to 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 judgment. The 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.
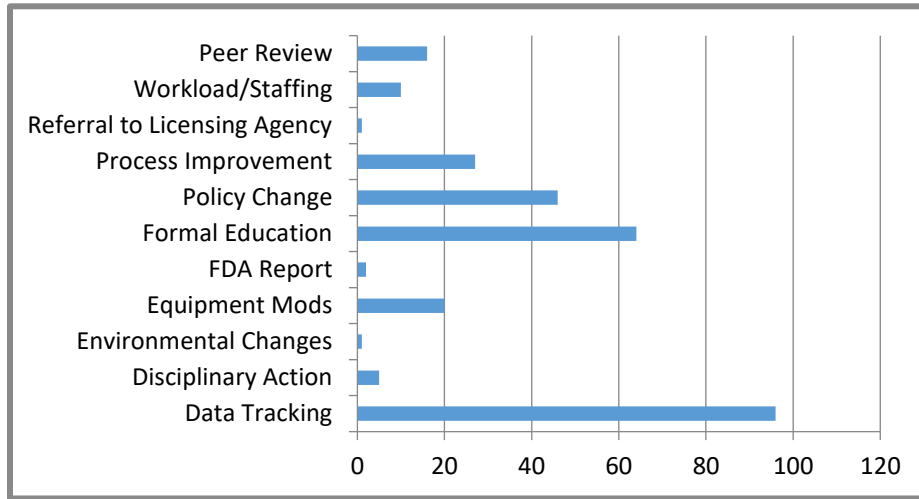
Hospitals continue to struggle with implementing corrective actions that will be long-lasting and effective at eliminating or controlling hazardous conditions. Policy changes and training remain perennial favorites when implementing corrective actions. Although each is considered a weak intervention on its own, both are likely to be part of the overall corrective action plan. Even weak interventions like education and policy changes can be made stronger with frequent, random observations of staff behavior. Staff are unlikely to continue a short cut or policy deviation if they are observed doing so and receive on the spot correction once or twice.

More hospitals are improving problematic processes, usually by streamlining and standardizing, and are making more processes fault-tolerant, which 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 rather 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 decrease the volume on monitor alarms; data tracking and trending refers to either mid-term or long-term tracking of performance improvement measures; the other corrective actions should need no explanation.

Figure 8: Percentage of Corrective Actions, All Events, FY17

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 a patient-focused outcome.

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 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 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 that decisions can be made about the value and evidence-based nature of activities hospital staff takes 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, 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 team work 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.[20]

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.

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 the COMAR 10.07.06 as the basic or contributory causal factors that underlie variations in performance.[21] Root causes are generic, in that the causative factors for a given error may occur almost anywhere in patient care areas and may lead to the same or similar outcomes if not fixed. Root cause analyses should focus primarily on systems and processes. The hospital staff must also identify risks and contributing factors for recurrence and determine what improvements in systems or processes are needed to prevent recurrence.

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

1. 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;

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

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 assume that hospitals with robust reporting systems are safer than hospitals that under report. 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 do not focus on the adverse event itself, but as we ask hospitals to do in their RCAs, 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, the Office of Health Care Quality has sent out annual report cards to hospital patient safety officers. The report cards provide a way to double check the events reported, reconcile the hospital's files with the Department's, and ensure there are no outstanding RCAs. The report cards also provide a way for us to monitor reporting rates of individual hospitals on a longitudinal basis. 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.

Recent changes to the federal survey process for hospitals calls for more attention to be paid to patient safety activities. During surveys for compliance with quality assurance, performance improvement (QAPI) surveyors must now look at incident reports, at the incident reporting process, and at RCAs and failure mode 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 a few reportable events through the new survey process that had not been reported to the hospital patient safety or quality manager.

To strengthen the confidentiality firewall between the Patient Safety Program and hospital surveying activities, the Patient Safety Program was moved under the supervision of the Office's Quality Improvement department in January 2015.

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 activities and integration of patient safety into the quality improvement, medical staff, and governing body.

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

- Providing resources for additional training of charge nurses and supervisors focused on effective patient management, leadership, and interpersonal skills;
- Regularly scheduling meetings between risk management, quality improvement, infection control, patient safety, and medical staff leaders to discuss events and to determine how the events should be addressed by the hospital;
- Reviewing actual RCAs, not merely data related to the numbers of events per patient days;
- Actively participating in a root cause 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 has a new website:

https://health.maryland.gov/ohcq/Pages/Patient-Safety.aspx/

This page on the Office of Health Care Quality'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.

Many hospitals report quality data to the Maryland Health Care Commission. Their web site is a good source for comparison data on quality in several health care settings:

https://healthcarequality.mhcc.maryland.gov/

The Maryland Patient Safety Center[22] (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.[23] 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.

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[22] www.marylandpatientsafety.org
[23] http://www.marylandpatientsafety.org/MPSCPSO.aspx

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

- Speaking at various events including the annual Maryland Patient Safety Conference,
- Attending and offering updates when requested at the MPSC Patient Safety Officers' meetings;
- Providing an update on new hospital regulations and a patient safety update annually for the past five years;
- Holding a restraint and seclusion seminar with input from regional and Nationally-known experts and local hospital representatives annually for the past three years in conjunction with the Maryland Hospital Educational Institute.[24]

Future Plans

Integral to the success of the Maryland Patient Safety Program is the sharing of information between hospitals and in forums such as this report. Information sharing provides patient safety officers and others the opportunity to review their own systems and procedures and make proactive changes to prevent an adverse event that occurred elsewhere from happening in their hospitals. The Department will continue to review events and RCAs to disseminate information to hospitals and other healthcare providers. The OHCQ staff continues to be available to provide training to interested groups and organizations. As noted, additional on-site surveys will be performed to identify hospitals that may not be complying with the COMAR requirements for adverse event reporting.

Conclusion

In conclusion, the Department is pleased to see that most hospitals are fully engaged in patient safety activities as evidenced by the increased reporting of events, the continued improvement of the quality of root cause analyses submitted, and the continued willingness to discuss events that may not need to be formally reported.

Our hospitals have done an enormous amount of work in reducing the harm from preventable medical errors, especially healthcare-associated infections. They have taken proactive steps to go beyond the bedside and expand patient safety practices to outpatient and community settings. The OHCQ will continue to support that work and engage hospitals in the process through our participation in opportunities for outreach and training and in discussions with individual patient safety officers. We will continue to develop educational offerings to communicate patterns and trends identified through the receipt of events and the review of root cause analyses.

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[24] http://www.mhei.org/

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 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.

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 hospitals, 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

Death or serious disability associated with	FY13	FY14	FY 15	FY16	FY17
Staff to Patient Abuse or Sexual Assault	0	0	2	1	6
Suicides or Serious Attempts	7	9	5	5	2
Airway Events	12	11	11	5	6
Maternal/Child	2	2	3	4	2
Medication Errors	10	12	13	8	8
Delays in Treatment	28	19	36	30	30
Misdiagnosis	1	2	2	1	0
Surgery-related Events	16	14	36	21	15
Falls	73	72	50	58	65
HAPUs	52	63	76	76	56
Restraint/Seclusion Injuries	0	4	3	1	4

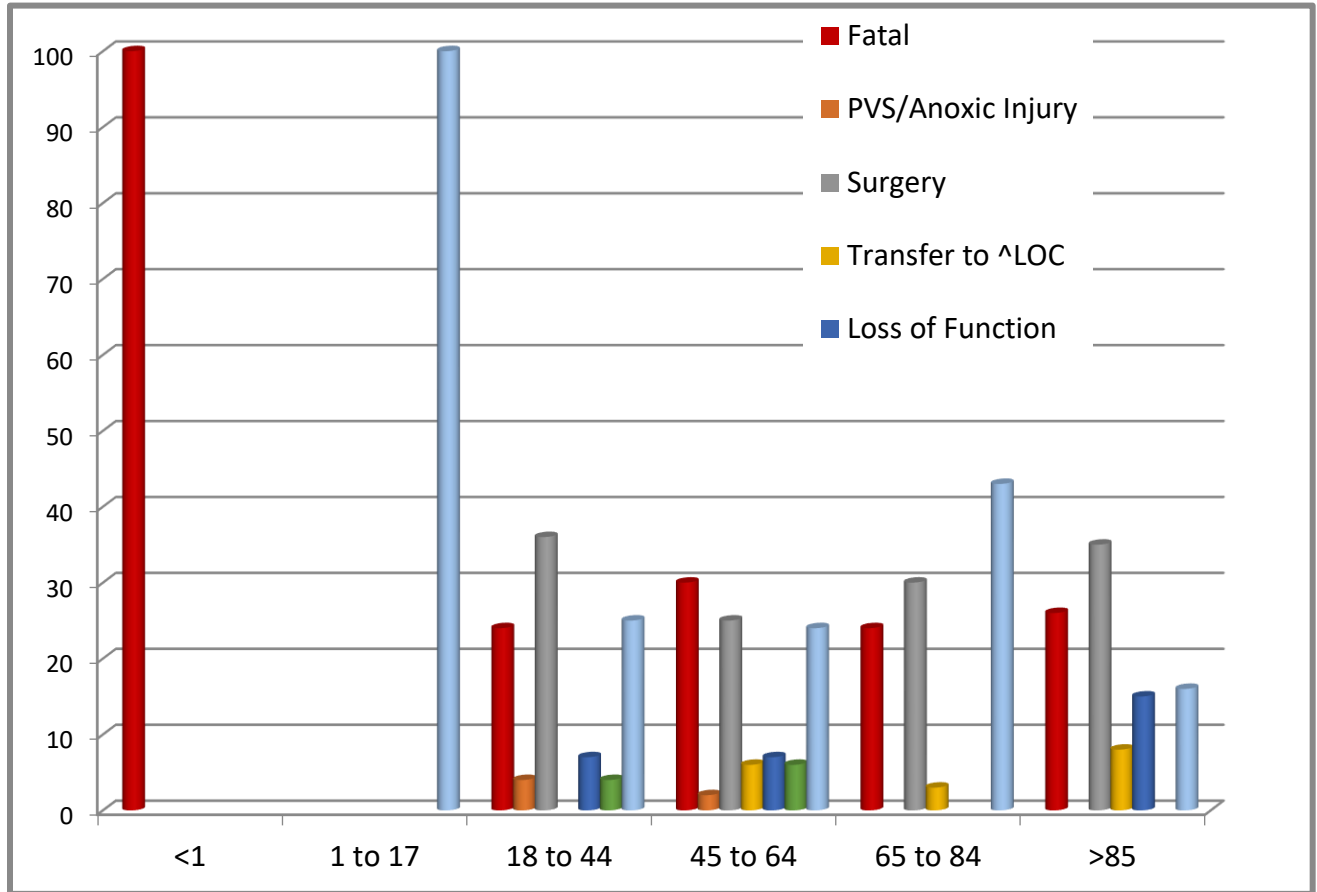## Appendix C: Comparison of Fatality Rates FY17
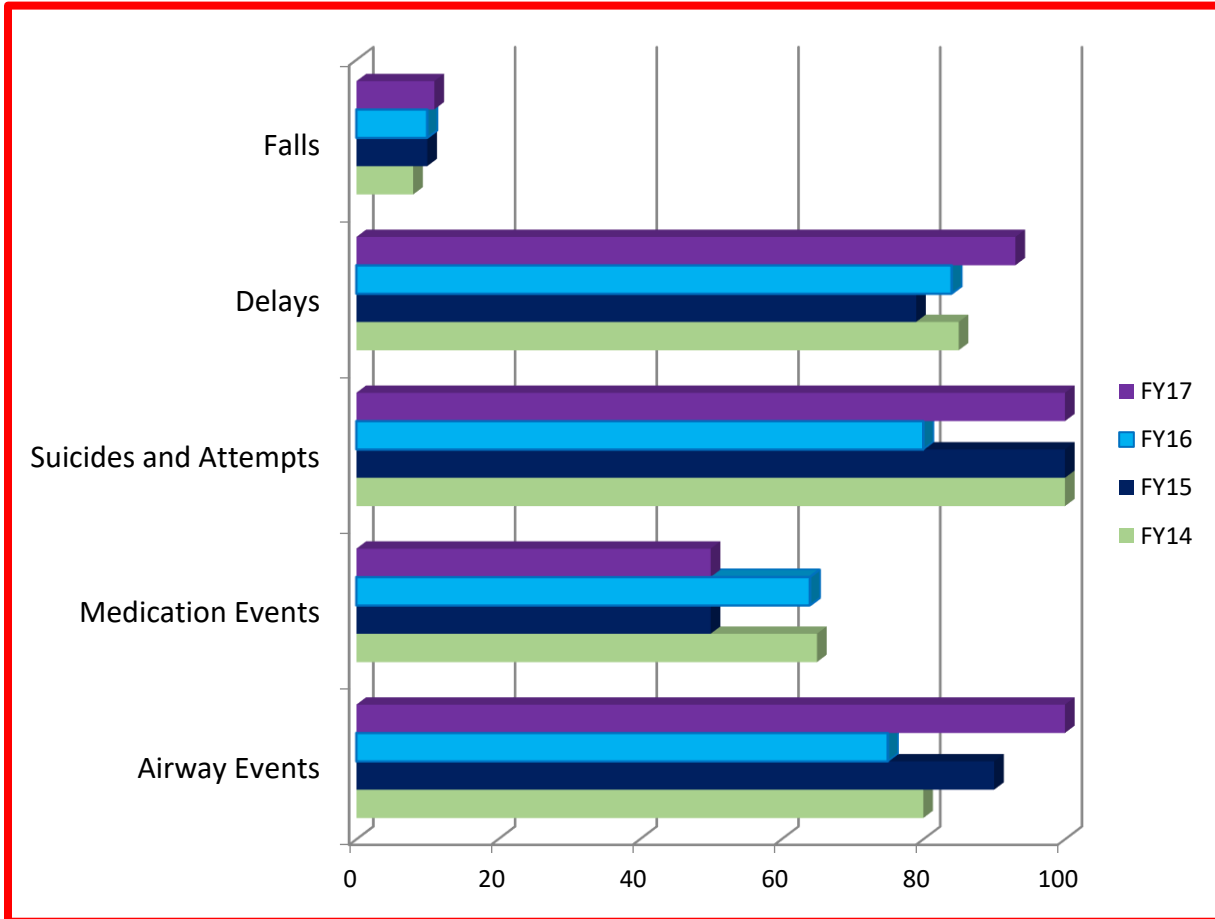
Appendix D: Age at Onset of Adverse Event, FY17 percentages

Legend:
- <1
- 1 to 17
- 18 to 44
- 45 to 64
- 65 to 84
- >85
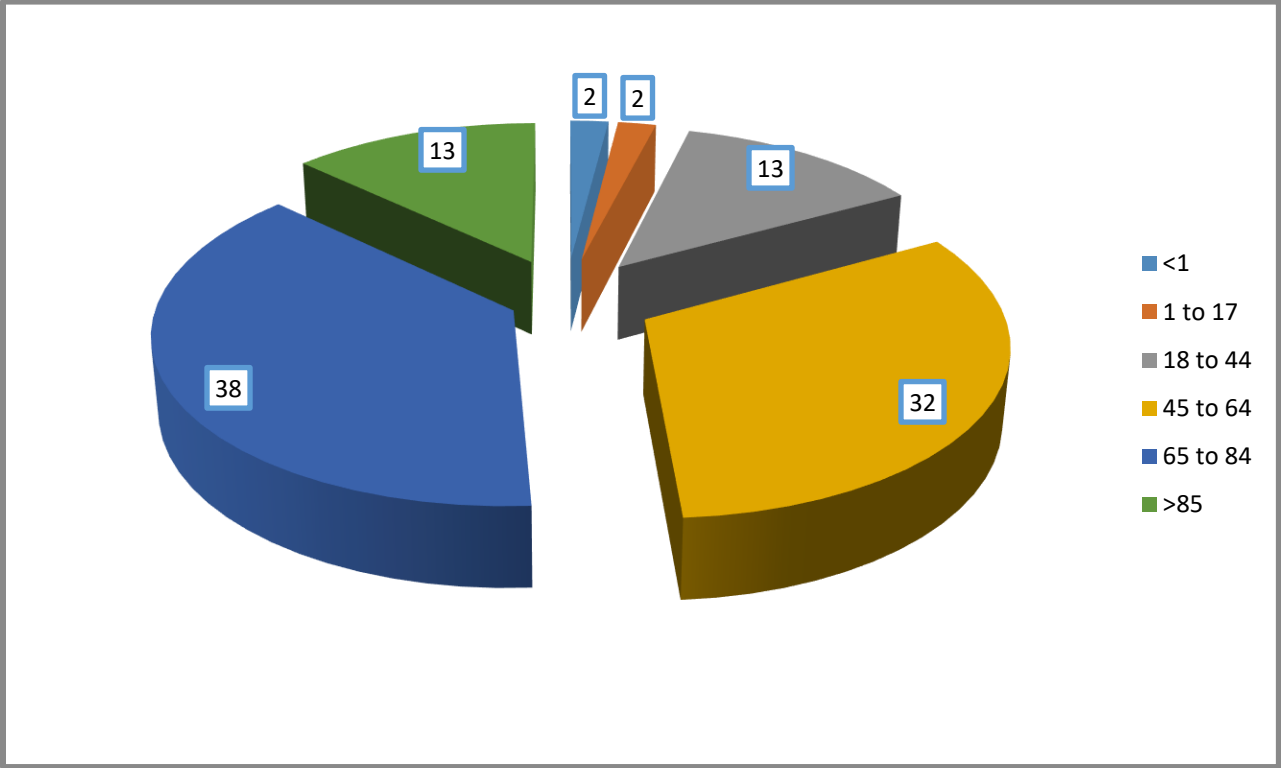
Appendix E: Outcomes of Adverse Events per Age, FY17

This table represents the percentage of known outcomes for all affected patients by age group. There were four adverse events in children younger than one. All were fatal and two were associated with the birth process.

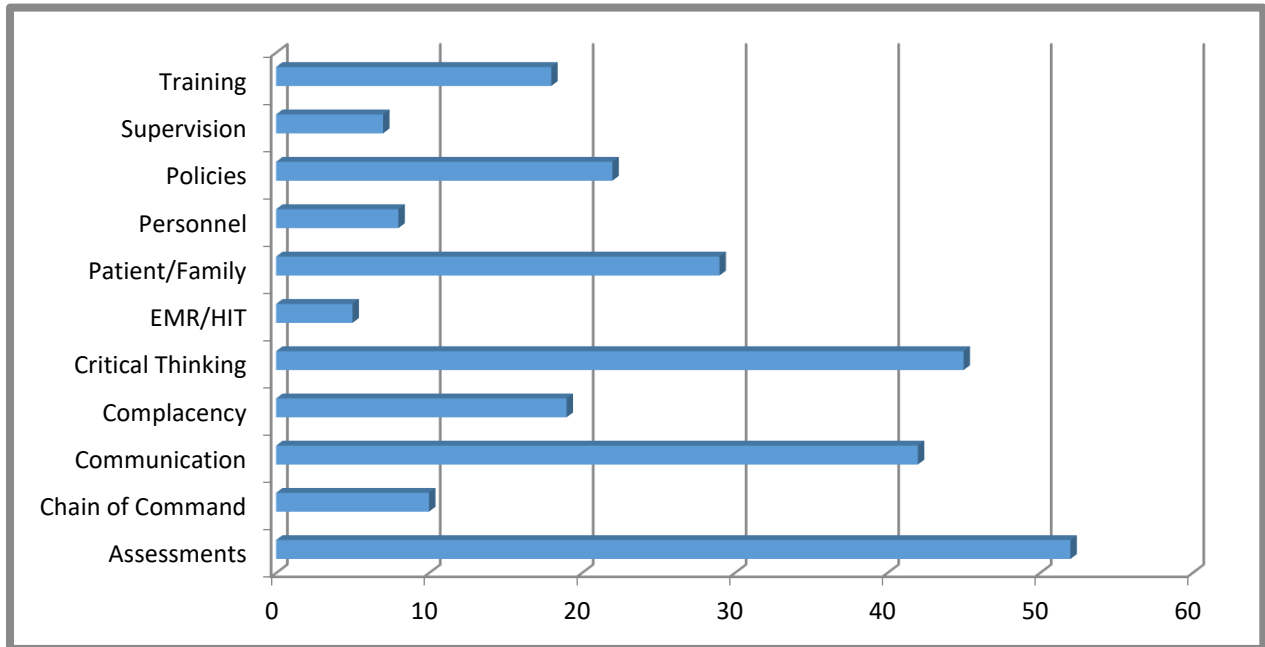## Appendix F: Root Cases and Corrective Actions, all Event Types FY17
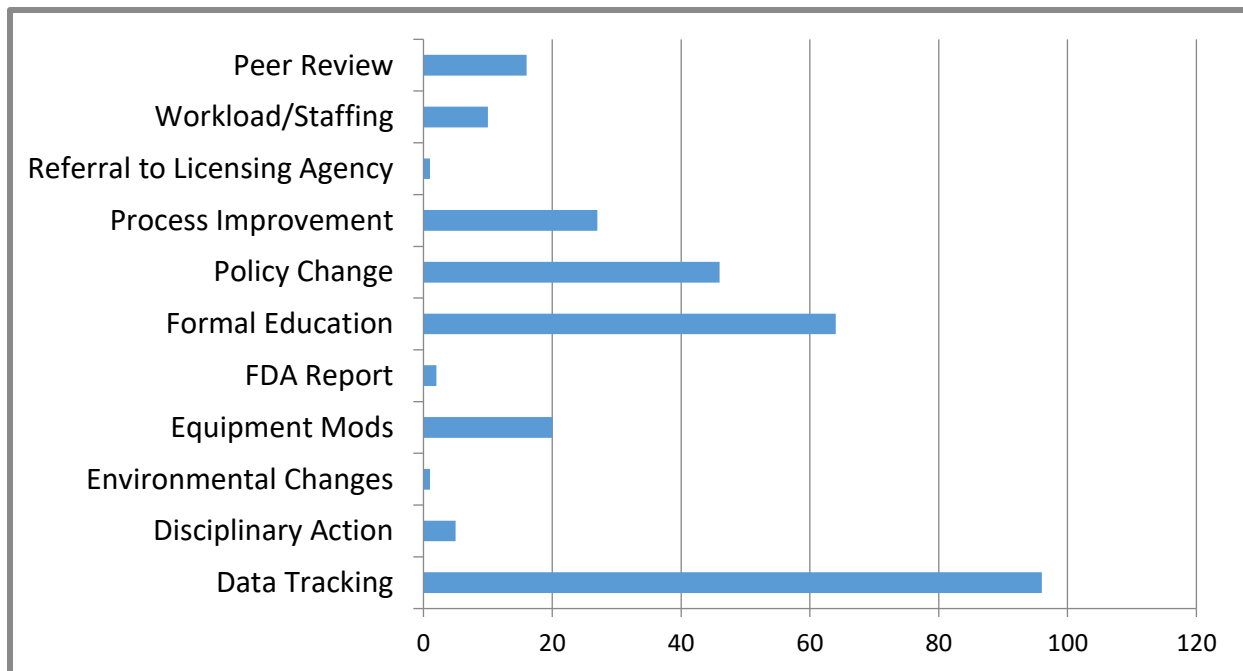

Figure F1 shows the identified root causes for all reported events, identified by RCAs, in percentage. Figure F2, below, shows the corrective action identified in the RCAs, by percentage. The reader may note that even though training is only identified as causative in 18% of events, 64% of corrective action plans include training.

Appendix G: Patient Safety Decision Tree
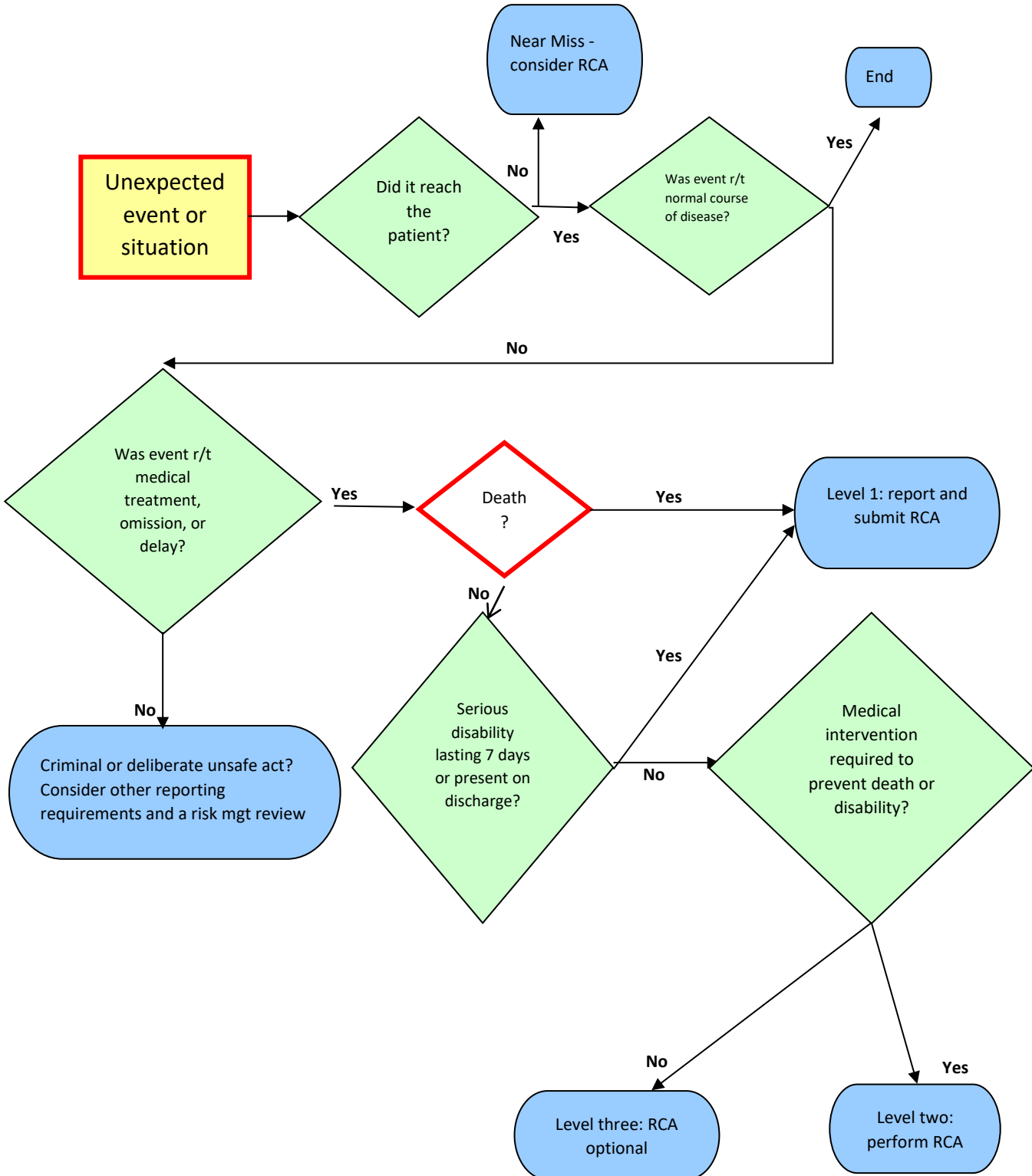
When in doubt about whether to do a RCA for Level 3 and near misses, remember that a lot of valuable information can be gained in the process. Asking these questions may help you decide if a RCA is needed:

1. Does this event or hazard represent a substantial risk to patient safety?
2. Is the event due to faulty processes or system failures that are likely to cause a similar, perhaps more harmful, event if not corrected?
3. If the hazardous condition is not corrected, is there a high probability that a sentinel or adverse event will occur?
4. Will the organization receive significant negative publicity if the cause of the event is not corrected?
5. Will failure to conduct a RCA result in deterioration of staff or physician morale and/or trust in the leadership's commitment to patient safety?

An event would be considered to be part of a patient's normal disease course if the untoward event arose from the patient's intrinsic condition, rather than from the exogenous medical treatment. For instance, a patient 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.