

**Maryland Hospital Patient Safety Program
Annual Report
Fiscal Year 2015**

**Department of Health and Mental Hygiene
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 2015. Adverse events are unexpected outcomes of medical care that result in a patient's death or serious injury. Level 1 adverse events tend to occur in several major classes including delays in treatment, medication errors, falls, etc. These events are costly for both patients and hospitals. Adverse events, by definition, are life- and function-threatening for patients and can result in costly lawsuits for hospitals while negatively affecting the emotional health of a hospital's workforce, leading to suboptimal performance or personnel loss. Since March 15, 2004, Maryland hospitals have been required to report serious adverse events to OHCQ within five days of becoming aware of the event.

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 function of the stand-alone 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 hospital-wide 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 the medical staff and governing body.

The FY15 Hospital Patient Safety Report analyzes, both quantitatively and qualitatively, the 221 serious adverse events affecting 252 patients reported by Maryland hospitals to the Office of Health Care Quality in fiscal year 2015 (July 1, 2014 to June 30, 2015). This report compares FY15 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 4.8 events in FY15, down slightly from the average per hospital of 5.1 events reported in FY14.
- The discrepancy between reports received (221) and patients affected (252) is due to hospitals reporting cohorts of patients affected by the same type of events. This is most commonly seen with pressure ulcer reports, where a hospital may report a cohort of three or four patients who developed pressure ulcers during a quarter.

- Falls and pressure ulcers accounted for 50% of the reported events. These two types of events accounted for 60% of all reports in FY14. Hospitals reported 50 Level 1 falls in FY15, far fewer than the previous average of 84 reports per year.
- The five most common types of events from FY13 through FY15 were falls (31%), delays, (26%), surgery-related events (20%), airway events (5%), and medication errors (4%).
- For FY15, the number of reported delays in treatment and surgery-related events were double the averages for previous years with 36 events being reported for each category in FY15 as compared to the previous average of 18 per annum for each type.
- The most common causative factors¹ identified in root cause analyses submitted for FY15 Level 1 events were critical thinking, communication, and assessment.
- Following changes to nation-wide event surveillance classification, Maryland is the only state tracking delays in treatment and certain types of surgery-related events.

These key findings have informed 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 lets the staff know that administration supports the root cause analysis process. Most adverse events require some analysis of latent issues that hospital leadership is in a better position to rectify.
2. In order 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 may be able to reduce surgery-related events by addressing the causative and contributory factors significantly related with these types of events including complacency and a lack of adherence to hospital policies. The causative factor “policies” was significantly associated with surgery-related events. Analysis of the data suggests that a lack of standardization in hospital processes and policies contributes to the occurrence of a surgical event. For example, in order to reduce the risk of retained foreign bodies, the obstetrical operating suite should have the same policies for counting equipment as the general surgical services.

¹ The use of the term “causative” or “causal” factors does not connote a proven causal relation. According to COMAR 10.07.06, causal factors are those event details which significantly contribute to the adverse outcome.

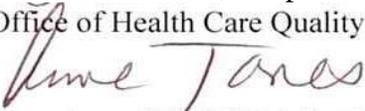
4. One of the strongest causal relationships found was between airway events and training. In preventing airway events hospitals should consider having clinicians with expertise in this area, such as anesthesia providers or other head and neck specialists evaluate the airways of patients with known or suspected difficult airways upon admission, rather than waiting and being unprepared for emergency situations.

Sincere gratitude to Elizabeth Kasameyer, RN, BSN, MSN/MPH, DrPH for her significant technical contributions. As always, we are available for questions or comments.

Sincerely,



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Maryland Hospital Patient Safety Program Analysis

Introduction

Fiscal year 2015 (July 1, 2014 to June 30, 2015) marked the eleventh 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 rates of 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 measureable 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 2013 Hospital-acquired Condition Rate² determined that there was an overall 17% decrease in adverse events nationally from 2010 to 2013. 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, adverse drug events, falls, pressure ulcers, and readmissions. For example, in 2010 CMS created a program called Partnership for Patients (PfP)³ to make care safer and to improve care transitions. One of the project goals was that, by the end of 2014, preventable HACs would decrease by 40% nationwide, thereby resulting in approximately 1.8 million fewer injuries to patients. The AHRQ Progress Report indicated that hospitals had achieved 1.4 million fewer harm events by the end of 2013. The second goal of the PfP project is that errors occurring during transitions in care would decrease by 20%. Achieving this goal would prevent 1.6 million patients from being readmitted within 30 days of discharge from a hospital.

A report issued by HealthGrades in 2011⁴ suggested that Marylanders might not be benefiting from this national trend. According to the HealthGrades report, Maryland was one of

² <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html>

³ <http://partnershipforpatients.cms.gov/>

⁴ HealthGrades Patient Safety In American Hospitals, March 2011

the ten worst states for patient safety outcomes. This ranking was based on the ratio of expected to observed adverse events. A higher number ranking indicated that the observed number of adverse events was greater than or equal to the expected number of events. Maryland's ratio of observed to expected was 1.08, meaning that Maryland hospital patients suffered 8% more adverse events than would have otherwise been expected based on the variables HealthGrades used to calculate their expected event rate. For the Mid-Atlantic States, Delaware was ranked 24th, Virginia was 33rd, Maryland was 48th, and the District was last at 51st. Reading this report one might assume that Maryland had abysmal patient safety outcomes as compared to the rest of the nation. However, it is important to note that HealthGrades only uses 13 safety indicators, nine of which were specific post-operative complications. Additionally, events were included in their analysis irrespective of patient outcome; in contrast to the methods employed by the Maryland Hospital Patient Safety program wherein events are classified not only by type but by outcome as well.

In January 2014, the Maryland Health Services Cost Review Commission (HSCRC) started measuring Maryland hospital-acquired conditions, or MHACs. Modeled on the potentially preventable conditions (PPCs)⁵ 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 diagnoses with discharge diagnoses. 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,⁶ 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 take into account 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.

⁵ 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.

⁶ <http://www.hscrc.state.md.us/documents/md-maphs/CMS-and-NEJM-find-successes-in-Year-1-of-Maryland-hospital-system-111215.pdf>

MANDATORY REPORTING OF ADVERSE EVENTS

A Level 1 adverse event is defined in COMAR 10.07.06 as any event that causes death or serious disability.⁷ Since the enactment of the Maryland Patient Safety Program regulations on March 15, 2004, through June 30, 2015 a total of 2,472 Level 1 adverse events have been reported by Maryland hospitals. In comparing reporting rates for specific adverse event categories from FY15 to prior years, we note:

- The percentage of delays in treatment increased from 9% of total events in FY14 to 14% in FY15.
- Surgery-related adverse events more than doubled in FY15, from 14 in FY14 to 36 in FY15, or 14% of the total reported events. This number includes 13 wrong site/patient/procedures and 23 retained foreign bodies (RFB).
- Airway misadventures accounted for 5% of total reported events in both FY14 and FY15.
- Falls and Health Care Acquired Pressure Ulcers (HAPU) accounted for 60% of the Level 1 events reported in FY14. This percentage dropped in FY15 to 50%, driven by a decrease in the number of Level 1 falls from 72 to 50 reports; and an increase in HAPU reports from 63 in FY14 to 76 in FY15.

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.

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;

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

- 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.

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 categorized as acute general, psychiatric, chronic, children’s, and rehabilitation. Acute general hospitals account for 72% of all the licensed Maryland hospitals. They reported 94% (236) of the Level 1 adverse events in FY15. Statistical analysis of FY15 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 2.5% of reports, while psychiatric hospitals accounted for the remaining 3.5%.

The number of reports received from acute care hospitals is indicative of the acuity of patients served as well as the more invasive and complex services provided in these hospitals and likely reflect the resources and staffing available for adverse event monitoring and reporting. The 22 hospitals with less than 100 beds reported 19 Level 1 adverse events in FY15. Half of the hospitals with less than 100 beds are specialty hospitals serving chronic, psychiatric, rehabilitation, or pediatric populations. These smaller hospitals typically report adverse events at a lower rate than do the larger hospitals. During FY15, 46 of 64 hospitals reported at least one Level 1 Adverse event. An overview of the types and sizes of hospitals licensed in Maryland is provided in Appendix A.

Table 1: FY15, Level 1 Adverse Events Reports per Hospital

| Number of Licensed Beds | Number of Hospitals | Average Reports per Hospital FY14 | Average Reports per Hospital FY15 |
|-------------------------|---------------------|-----------------------------------|-----------------------------------|
| 300 or more beds | 11 | 5.4 | 4.9 |
| 200 – 299 beds | 14 | 4.2 | 6.5 |
| 100 – 199 beds | 17 | 2.8 | 3.7 |
| Less than 100 beds | 22 | 0.7 | 0.9 |

Hospital licensed bed size has been decreasing for the past few years, creating a downward shift in the number of hospitals in the higher categories of bed size. For instance, in FY14, Maryland had 15 hospitals with over 300 beds and 19 with less than 100 beds. In FY15 the number of hospitals with more than 300 beds dropped to 11 and the number with less than 100 increased to 22. We think that, because the hospitals have only changed their bed size, and not their safety cultures or reporting patterns, the downward shift in bed size correlates with a corresponding increase in reports per hospitals bed size category, as seen in Table 1. In other words, a hospital with 298 licensed beds in FY15 will report roughly the same number of events as in FY14, when it had 305 beds. Hospitals with over 300 beds accounted for 24% (61) of the adverse events reported in FY15, while hospitals with 200 to 299 beds reported 40% (105) of the adverse events. Hospitals with 100 to 199 beds reported 28% (71) of the Level 1 events and hospitals with less than 100 beds reported 8% (19) of the total events.

For FY15, with a few exceptions, the number of reported events is quite consistent with the number reported in FY14 (see Table 2). The exceptions are delays in treatment and surgery-related events, each of which doubled from prior averages.

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

| Death or serious disability associated with... | FY12 | FY13 | FY14 | FY 15 |
|---|-------------|-------------|-------------|--------------|
| Staff to Patient Abuse or Sexual Assault | | | | 2 |
| Hyperbilirubinemia | | | | 1 |
| Infrastructure Failure | | 1 | | 1 |
| Assaults | 4 | 2 | 5 | 5 |
| Suicides | 16 | 7 | 9 | 5 |
| Healthcare-associated Infections | 3 | 9 | 5 | 3 |
| Airway Events | 7 | 12 | 11 | 11 |
| Maternal/Child | 6 | 2 | 2 | 3 |
| Medication Errors | 12 | 10 | 12 | 13 |
| Delays in Treatment | 10 | 28 | 19 | 36 |
| Misdiagnosis | 2 | 1 | 2 | 2 |
| Surgery-related Events | 25 | 16 | 14 | 36 |
| Falls | 98 | 73 | 72 | 50 |
| HAPUs | 86 | 52 | 63 | 76 |
| Restraint/Seclusion Injuries | 5 | | 4 | 3 |

REPORTS OF NON-LEVEL 1 EVENTS

Since March 15, 2004, a total of 520 events that did not meet the criteria for a reportable event⁹ under COMAR 10.07.06 were reported to the Maryland Patient Safety Program by hospitals. Forty-one of these non-Level 1 events were reported to the Office of Health Care Quality in FY15. 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 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 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. Over the years, we have also received several reports of alleged sexual assaults occurring in hospitals. While most of these reports have turned out to be unfounded or not proved, it is better for all concerned if the Office of Health Care Quality is informed of these types of allegations by the hospitals, rather than by the media. The OHCQ appreciates the willingness of hospitals to go beyond the letter of the law so we can track events that should never happen, even if there is no evidence of injury or if the injury is relatively minor.

The Office of Health Care Quality Patient Safety staff also keep 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. Several of these types of reports were received in FY15. 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

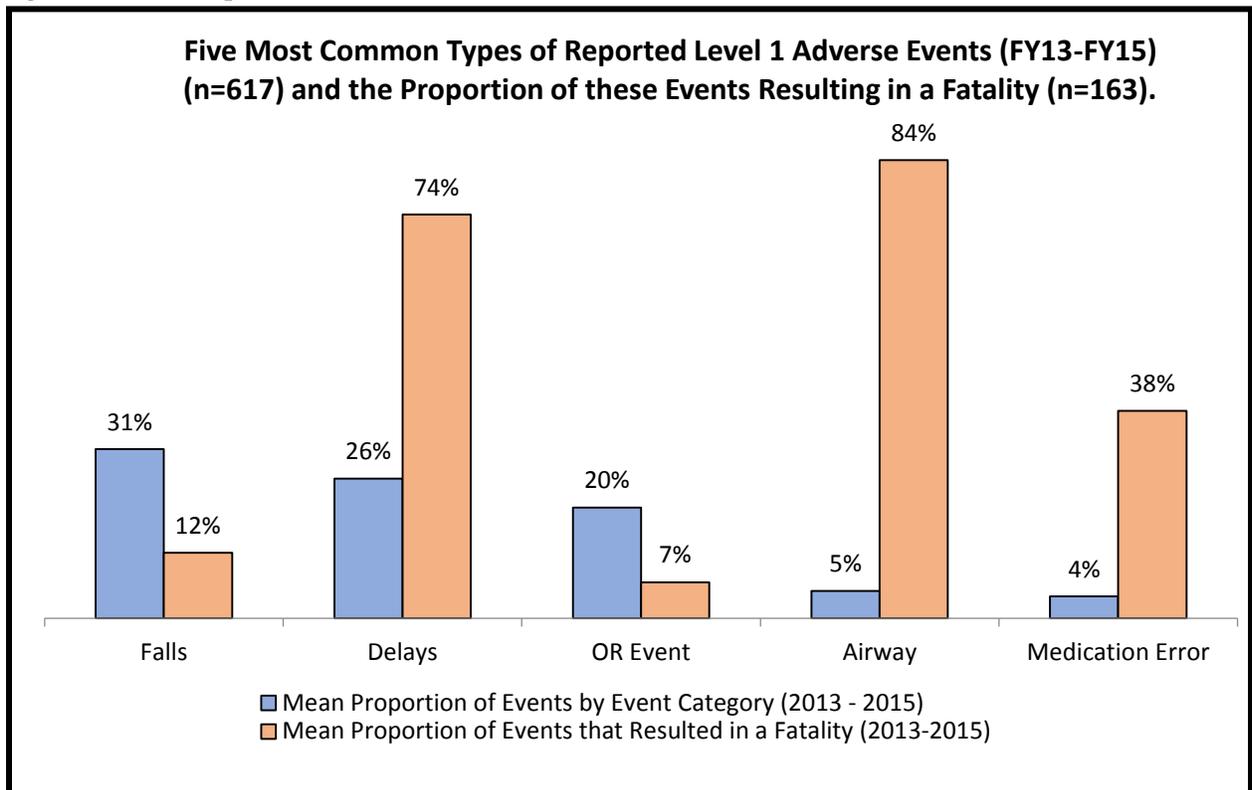
⁹ Under COMAR 10.07.06. 02 B (4) the hospitals are required to report all Level 1 events defined as adverse events which result in death or a serious disability to the patient.

- 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.)
- Whether disclosure was made to the patient and/or family.

Event Details

Figure 1 details the most commonly reported Level 1 adverse events from FY13 through FY15, along with the proportion that were fatal. These five event categories represented 85% of the reported Level 1 events and 72% of the fatalities, respectively. Although falls were the most common type of event, they were the second least likely type of event to result in a fatality.

Figure 1: Mean Proportion of Events with Associated Fatalities



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. Airway events only represented 5% of events, but on average 84% of airway events resulted in a fatality. Airway events, delays and medication errors were significantly more likely to result in a fatality (chi-squared test for homogeneity, $p < 0.0001$) than other types of events. Since all of the delays in treatment, surgical events, medication errors, and airway events are preventable, along with most of the falls, these adverse events represent an unacceptable loss of life.

The next section of this document discusses four of these event types in detail: delays in treatment, airway events, surgery-related events, and adverse drug events.

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 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.

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, although the early iterations of the National Database of Nursing Quality Indicators (NDNQI)¹⁰ 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.”¹¹ The AHRQ and HealthGrades now classify failure to rescue as “deaths among surgical inpatients with treatable, serious complications.”^{12 13} 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.

There were 36 level 1 delays in treatment reported in FY15, with 28 fatalities (78%). Thirty-six delays is double the previous average frequency per year. Of the non-fatal events, three patients, two of whom were children, suffered permanent, severe brain injuries. Two patients had to be transferred to higher levels of care for multiple surgical procedures. One patient was put into permanent renal failure because of delayed lab work. One patient was left a quadriplegic when staff failed to react to evolving symptoms of spinal cord impingement, and one patient spent over a month in the hospital undergoing multiple surgical procedures.

Most patients who deteriorate do so over hours. Even patients who have an acute cardiac arrest usually show deteriorating vital signs for hours prior to the actual event. For instance, a patient was admitted with a blood clot in the femoral artery (the main artery feeding the leg). On

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

¹¹ http://psnet.ahrq.gov/popup_glossary.aspx?name=failuretorescue

¹² HealthGrades Patient Safety in American Hospitals Study, March 2011

¹³ www.qualityindicators.ahrq.gov

the day after admission, the patient had low blood pressure all day, and vomited a small amount of blood in the evening. In the middle of the night, the patient started vomiting larger amounts of blood, but did not have blood work done until 1 PM, more than 24 hours after symptoms started. The patient's blood count was dangerously low. An hour after the blood was drawn, the patient started having bright red bloody stools. The gastroenterologist finally saw the patient at 4 PM and the patient was moved to the ICU. A blood transfusion was started two hours later but the patient arrested and died within one half hour. There were numerous opportunities to intervene over the 36 hours that this patient's condition gradually deteriorated; all were missed.

A patient came to the ED with rather vague complaints of abdominal pain. Because the patient was an alcoholic, the assumption was made that he was suffering from an inflammation of the pancreas. The physician ordered a routine abdominal CT scan without contrast and the patient was admitted to an observation unit. The CT was done that evening, and the nursing staff called the physician the next day to report that the CT had not been read yet, but no one called the radiology department. The patient had very high blood pressure, which was not investigated because the assumption was that he had pancreatitis. The patient continued to deteriorate and then suffered a cardiac arrest and died. An autopsy showed that the patient had a ruptured aneurysm of his abdominal aorta (the large vessel that carries oxygenated blood from the heart). Two days prior to this last admission, the patient had been discharged from another two-day stay on the same observation unit with the same abdominal pain and very high blood pressure, also ignored.

Failing to provide timely blood transfusions led to the deaths of five severely anemic patients in FY15. All five were post-operative patients; two were actively bleeding and, for two patients, the prescribers wanted to wait to infuse the blood products until each patient's next dialysis session. One elderly patient had a surgical repair of a fractured hip. The post-operative blood count was very low and blood was ordered at 7 AM. The blood was ready to be infused at 8 AM, but the staff on the patient's unit were unable to reach the family for consent to give the blood. The patient suffered a cardiac arrest six hours later while the staff were still trying to get consent. The transfusion was started then, but the patient had had a massive heart attack and died the following day. After the cardiac arrest, staff realized the patient had a blood consent in the medical record that had been signed prior to surgery.

Monitoring patients for changes in vital signs, changes in oxygen saturation, and changes in mental status are basic assessments that should trigger some action when abnormalities are found. However, we find that it is often the failure to perform these simple assessments and then act on assessment findings that leads to delays in treatment. Delays in treatment, perhaps more than other type of adverse events, involve a cascade of poor decisions made by multiple caregivers. Ineffective communication, erroneous role assumptions, knowledge deficits,

cognitive biases, complacency, inexperience, and passive supervision all contribute to the serious delays in treatment reported to this office.

Nearly every delay in treatment occurs because one or more caregivers failed to understand, or act on, the seriousness of a patient's symptoms. For instance, a patient was taken to surgery following a car accident to repair a compound fracture of his leg, meaning that the bone was broken in more than one place. The repair took several hours longer than normal due to the patient's heavily muscled physique. Lab work had been sent halfway through the surgery and returned very abnormal results. The surgeon and staff in the OR assumed that the abnormal results were an artifact of the blood cells rupturing in the test tube, but did not retest the patient. Throughout the eight hour surgery the patient had low blood pressure and low urine output.

When the patient finally had a head-to-toe assessment in the post-anesthesia care unit (PACU), he was found to have severely compromised circulation of the leg that had not been operated on and he was suffering from a life-threatening breakdown of muscle tissue where muscle fibers try to circulate through the bloodstream, which can lead to multi-organ failure. Before the patient could be taken back to surgery, he suffered a cardiac arrest and could not be resuscitated. Several systems failed in this case; communication was very poor among team members in the OR, assumptions were made about the causes of his abnormal blood work, and assessment findings were not acted upon. While no one appreciated the seriousness of this patient's condition, they also failed to appreciate the increased risk the patient had for just these conditions to develop.

In FY14, we identified several delays caused by failing to act on symptoms, warnings, and findings mediated by monitors or other hemodynamic measurements. The failure to follow up on dire signs because the patient was awake and talking remained a problem in FY15. For instance, a patient came to an emergency department (ED) complaining of several days of constipation with abdominal pain. The patient was triaged and a nurse-directed protocol was initiated for abdominal x-rays and blood work. However, no vital signs were taken because the patient arrived at change of shift and the off-going ED technician was reportedly angry at the on-coming tech and had not reported that no vital signs had been measured for this patient. When the patient's blood pressure (B/P) was finally taken after one and a half hours it was catastrophically low at 30/15 (B/P for an adult should be above 90/60). The patient also had a high respiratory rate and low temperature. The technician told the nurse, who did not believe the reading was accurate because the patient was communicative. When the nurse re-checked the B/P, it was not registering. Because the patient was still awake and communicative, the nurse did not believe the evidence in front of her, and went out to get another nurse for a second opinion. They arrived back at the room just as the patient suffered a cardiac arrest, from which he ultimately died. The ED physician had not been informed of any of the patient's symptoms or diagnostic results until the patient arrested.

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 modified early warning systems (MEWS) as part of the electronic medical record in order to track patients' vital signs and other physiologic markers, and to alert 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 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 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 ICU patients who may be well enough to go to a step-down unit. For this information to be effective, the expectation has to be that trends indicating patient deterioration will be acted upon.

A young patient who suffered a delay in assessments arrived at the ED with fairly minor injuries following a collision. Diagnostics revealed a broken rib and a collection of blood in the abdomen. Unfortunately, the patient suffered a massive allergic reaction to a medication given in the ED and spent the next two days sedated, with a breathing tube and ventilator. The patient was noted to be very restless and agitated, even while sedated and attached to a ventilator. When, after two days, the patient's breathing tube was removed, she complained of severe abdominal pain and was found to have air in her abdomen and a bowel perforation. The patient was extremely sick and required multiple surgeries over the next few weeks to repair the damage.

Hospitals reported six delays in treatment associated with failing to respond to monitor alarms. Three of these events involved patients who had between 30 minutes and one hour of dangerous heart rhythms prior to being found and prior to a cardiac arrest being identified. The dysrhythmias were not noted until a post-arrest review of the patient's monitor history was completed. During the review of one event that involved a patient who went into a respiratory arrest, the hospital discovered that their newly integrated peripheral oxygen sensor system had been set to warning alarm, not to a higher level danger alarm. This alarm, which no one noted in the din of a busy unit, sounded a warning whether the patient's oxygen saturation was 90% or 40%. Normal oxygen saturation is over 90%; a reading of 40% is a dire sign.

Another patient fatally affected by monitor complacency was a patient who was on a remotely-monitored telemetry unit. This patient had had several runs of ventricular tachycardia (V-tach, a concerning rhythm irregularity that, if sustained for more than a few beats, can lead to cessation of cardiac function and death). Overnight, there were three RNs for more than a dozen

patients, 11 of whom were being remotely monitored. Only the charge nurse was certified in caring for telemetry patients, meaning that the charge RN had additional training and experience in interpreting heart rhythms. The charge nurse had not told the house supervisor that she needed to have a telemetry-certified float pool nurse. She assumed all nurses knew something about rhythms. This patient's nurse was new on the unit and had not yet been certified. The technician performing remote monitoring for all telemetry patients in the hospital identified several long runs of V-tach and called the patient's unit and spoke to the unit clerk, thinking the clerk was the patient's nurse. During the RCA, the clerk stated he told the nurse but the nurse did not remember the conversation. Over the next hour, the telemetry clerk called the unit three times. The nurse eventually went in the room and found the patient having trouble breathing. The patient suffered a cardiac/respiratory arrest prior to the resuscitation team getting to the room and, despite sustained effort, could not be resuscitated.

During the RCA, the hospital found that someone had repeatedly silenced the patient's monitor alarms from the nurse's station but were unable to identify the responsible party. The telemetry policy required the monitor technician to go up the chain of command after making three calls about any patient, but this did not happen. The staffing policy for the unit called for telemetry certification, but there were no time limits by which new staff had to become certified. Neither the nursing supervisor who placed a medical/surgical nurse on a telemetry unit nor the charge nurse were aware of this requirement. The shift charge nurse reported feeling "overwhelmed" but did not tell the supervisor or ask for help. The RCA identified that the unit manager was unaware of her responsibility to have an available cell phone dedicated to calls from the monitor techs. Because this unit was the only unit in the hospital without a dedicated telemetry cell phone, it seems highly unlikely that this particular event was the first time this problem had arisen. It also seems unlikely that the nurse manager was personally responsible for purchasing and programming the phone. Furthermore, there was no extant hospital policy covering the use of the dedicated phone. Irrespective of the RCA's focus on personal responsibility, this patient and these staff were set up by hospital systems that behaved exactly as designed.

Three patients suffered delays in treatment that were complicated by either limited English proficiency or communication deficits. One patient in the ED for a non-cardiac problem suddenly started showing a heart rhythm disturbance. The patient was back in a normal rhythm at the time of discharge and was given the contact information for a cardiologist and told to make an appointment as soon as possible. However, the urgency of the need for this consult was either not well communicated or not well received by this patient for whom English was not the primary language. The patient was brought back to the ED in a full cardiac arrest two months later, the day before the appointment with the cardiologist.

Another patient suffering from gastrointestinal bleeding was seen in an ED one day. The patient's hemoglobin and hematocrit (a measure of the amount of oxygen-carrying proteins in the red blood cells and the ratio of red blood cells to blood volume) was critically low at 3.5 and 11.5 (normal should be at least 12/34.9). Blood was sent to the blood bank to start the blood typing process prior to releasing blood for transfusion. Three hours later the blood bank technician called the ED physician to say that it would take longer than usual to find compatible blood because the patient had antibodies to some substances in normal blood and the blood transfused would have to match the patient's antibodies. The patient was seen by a hematologist (a specialist in blood and blood-borne diseases) who recommended that the patient be given the least incompatible blood. By the time that order was written, the patient had stopped actively bleeding so she was transferred to the ICU. The patient continued to deteriorate with low blood pressure over the next few hours and died during hour 10, without ever receiving the transfusion.

The RCA found many personnel and systemic problems. The blood bank technician who had been working on the blood all this time was fairly new and inexperienced and was known to not handle stress well. There was a lead technician on call, who was at home, and knew nothing about the problems in the blood bank until very late in the day and then assumed that the technician at the hospital had checked the blood supply for the least incompatible units before starting the arduous and time-consuming process of typing all of the antibodies. When the hematologist called with the directive to give the least incompatible blood, the blood bank technician did not understand what that meant and did not clarify with the physician. There was no policy to cover giving the least incompatible blood in an emergency and the tech was unfamiliar with that process. There was a policy for emergency release of blood, but the technician assumed that the physician wanted to wait for compatible blood. The technician did not communicate what was delaying the process and how long it would take, nor did the nurses and physicians ask how much longer getting blood would take, and no one used the chain of command.

As is the case with so many delays in treatment, the culture in this hospital encouraged passive supervision and there was no obligation for the on-call blood bank technician to call at any certain interval to check the status of the work being done in the blood bank. As is true at many hospitals, the least experienced and confident practitioners end up on evening or night shifts, making the need for close supervision especially imperative yet reducing the likelihood of receiving close supervision.

There are many mind-sets that people find themselves in that may contribute to delays in accepting the evidence in front of us and acting on those findings. Delays in treatment are usually errors of omission, in that they occur because of steps not taken. The steps not taken are much harder to find while one is in the midst of providing care and are often expressed later as unwarranted assumptions. In the case above, many people made assumptions and failed to ask or

communicate critical information. In the pancreatitis vs. aneurysm rupture event discussed earlier, the clinicians suffered from attentional lock-up, in that the assumption that the patient had pancreatitis made the clinicians look only for confirmatory evidence of pancreatitis and unconsciously exclude non-confirmatory evidence, such as the patient's high blood pressure.

Much research has been done in the past few years on the cognitive biases that affect how clinicians process information and make decisions. For instance, the AHRQ released a patient safety primer on diagnostic errors¹⁴ that speaks to the contributing factors for delays in treatment. Although the study findings were specific to physicians, the same shortcuts and erroneous assumptions (heuristics) are made by the multi-disciplinary contributors to delays in treatment. The following chart from AHRQ represents a few of the most common cognitive biases, with examples taken from the FY15 reports.

Table 3: Common Cognitive Biases

| Cognitive Bias | Definition | Example |
|---|--|---|
| Availability heuristic | Diagnosis of current patient biased by experience with past cases | An alcoholic was incorrectly treated for pancreatitis, despite indications that an aortic dissection was present. Extremely high B/P was ignored. |
| Anchoring heuristic (premature closure) | Relying on initial diagnostic impression, despite subsequent information to the contrary | Elevated intra-operative potassium level dismissed as hemolyzed. |
| Framing effects | Diagnostic decision-making unduly biased by subtle cues and collateral information | A heroin-addicted patient with abdominal pain was treated for opiate withdrawal, but later found to have a bowel perforation. |
| Blind obedience | Placing undue reliance on test results or "expert" opinion | Waiting for the blood bank to finish analyzing blood without questioning the delay. |

Many of these cognitive biases may be overcome with better communication among team members, more supervisory support, and better decision support systems, such as modified early warning systems (MEWS) that analyze trends in patient vital signs and other parameters to score the risk of likely deterioration. As noted, the findings from these systems are routinely ignored in favor of intuition. Intuition is itself an anchoring heuristic and a framing effect.

¹⁴ <https://psnet.ahrq.gov/primers/primer/12/diagnostic-errors>

In two studies of the decision making processes of 240 acute and primary care nurses done in 2004 and 2005,¹⁵ researchers found that the nurses used external information or consultation in only a tiny fragment of decisions made over hours of practice. This means that nurses are relying on their own experience and shared peer experiences to make care decisions, often to the exclusion of other decision supports. The problem with this approach is that not all nurses are experts, and a lot of what is intuited as factual is contradicted by research. Nurses are, of course, not the only clinicians to fall prey to logical fallacies and cognitive biases.

The ten causative factors identified by submitted RCAs include: Assessments, Critical Thinking, Chain of Command, Communication, Complacency, Policy Adherence, Personnel, Supervision, Training, and an “Other” category that covers patient factors and health information technology. Critical thinking and communication are the most frequently cited root causes identified in the RCAs submitted in FY15 for delay in treatment adverse events, with assessments coming in third (see Figure 2). Only eight of the RCAs cited supervision as a causative factor, but delays in treatment, perhaps more than any other event type could be prevented with timely intervention by a clinician with more knowledge and experience than the bedside clinician who may be over his or her head.

Figure 2: FY15 Root Causes of Delays in Treatment

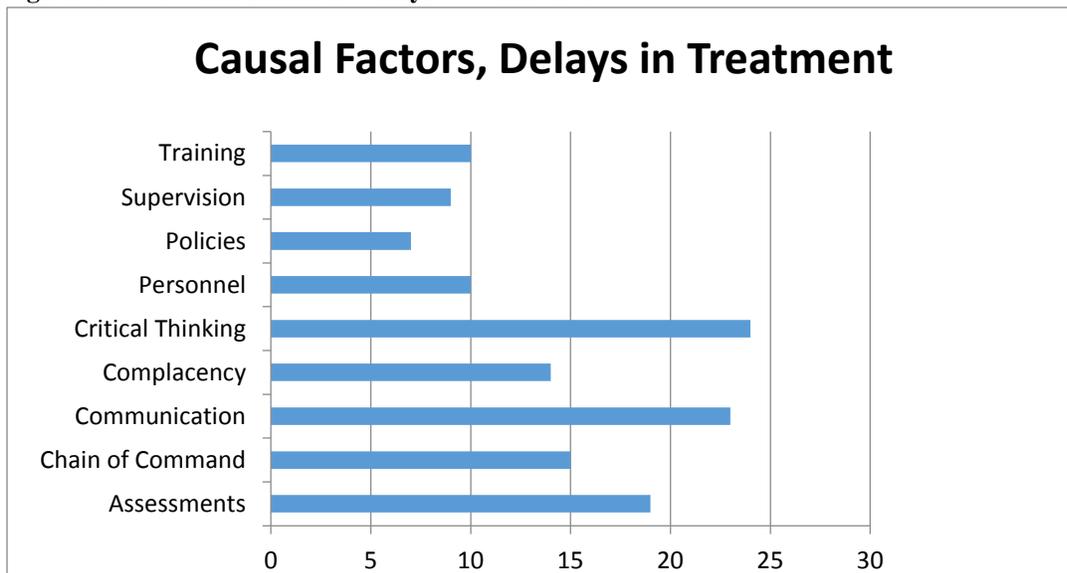


Figure 2 details the raw number of causative factors identified in RCAs submitted in FY15 for delay in treatment events. Since most events are multi-factorial, the total number of factors adds up to more than the number of events.

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 trouble and look for ways

¹⁵ Thompson and Yang, Health Care Quarterly, vol. 12. Special Issue, 2009

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, and since critical thinking is the most often cited cause for delays, the hospital's responsibility is to design decision support systems to compensate for lapses in clinical judgment.

According to a statistical analysis of level 1 delays in treatment reported from FY12 through FY15, delays are five times more likely to be associated with problems using the chain of command, 2.1 times more likely to be associated with a communication failure, and 1.9 times more likely to be associated with critical thinking among staff. Delays were significantly less likely to be associated with health IT (information technology) or patient-specific factors (those related to the patient's underlying disease). Fully one third of reported events shared the same tripartite causative cluster: critical thinking, communication, and chain of command. Please see the section on causative factors, beginning on page 28, for more information.

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 manner in which 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.

Given that practitioners are trained and socialized to act independently, it seems that the only mitigating practice 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 and ask probing questions. If a hospital has a certified physician's assistant (PA-C) and a hospitalist working overnight, the expectation needs to be that they will communicate with each other frequently. In addition, the physician must take the lead in ensuring that problems are addressed in a timely and effective manner.

SURGERY-RELATED EVENTS

In FY14, there were five reported Level 1 adverse events associated with 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). The number of wrong procedures more than doubled during FY15 to 13. The number of reported retained foreign bodies also doubled, from 10 in FY14 to 23 in FY15. Although HealthGrades, the AHRQ

HACs, HSCRC MHACs, and the NDNQI no longer track wrong procedures,¹⁶ 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.

Many of the wrong procedure adverse events reported in FY15 were caused by errors in posting or errors in marking. Two patients who had surgery to remove skin lesions had the wrong lesions removed. Each patient had been referred from a dermatology office with a written description of the location of the lesions. These types of referrals call for more than just a written report. Many patients with skin lesions have multiple areas that may or may not require removal and biopsy. Surgeons need to start requiring at least a body map with the lesions clearly marked, or a photograph of the lesions and the locations. Hospitals should not post procedures without very clear identification of the site.

Six of the 13 wrong procedures involved mistakes in laterality. Several of these events implicated the surgeon's non-compliance with the requirement to be an active participant in the time-out process. During the time-out, all staff in the OR, including anesthesia, nursing, surgeons, and surgical technicians, are to pause to verify the patient's identity, the procedure to be performed, the site if necessary, and any special requirements such as the presence of x-rays or scans, or a patient's allergies. In one reported adverse event, a patient was to have surgery to the right leg. She was placed on her stomach so the anesthesiologist could perform a local block of the leg, then flipped on her back for the administration of general anesthesia, and then placed back on her stomach for surgery. The surgeon, who had not been in the room for the administration of anesthesia, came in and made an incision on the incorrect leg. The correct leg had been clearly marked before anesthesia was given, so the patient took part in the verification process. The circulating nurse informed the surgeon that the incision was on the incorrect leg. That incision was closed and surgery proceeded on the correct leg.

A patient came in for a hernia repair in the groin. The surgeon marked the correct side on patient's thigh instead of the abdomen and performed surgery on the incorrect side. Even though the documentation and the consent clearly stated which side was to be repaired, the patient had some pronounced scar tissue on the other side of the abdomen that led everyone to think that was the side on which to operate. Additionally, the site markings were obscured by the drapes.

¹⁶ 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

¹⁶ HealthGrades Patient Safety in American Hospitals Study, March 2011

¹⁶ www.qualityindicators.ahrq.gov

Six of the 23 (26%) reported retained foreign bodies (RFB) involved guide wires that were not removed following insertion of central lines. The guide wire makes the catheter stiff enough to insert through the skin and into a large blood vessel, but must be removed after the central line is in place. Because these catheters are usually inserted into large central blood vessels in the chest and neck, leaving the guide wire in risks blood vessel damage or life-threatening perforation. Even though none of these patients suffered blood vessel damage, several had to undergo invasive procedures to remove the guide wires. Hospitals should check their central line insertion checklists to ensure that removal of the guide wire is a listed task.

Vaginal RFBs accounted for 35% (8 of 23) of the reported RFBs. These included objects inserted into the vagina during abdominal surgery to preserve pneumoperitoneum during laparoscopic procedures. In abdominal and pelvic laparoscopic surgery, an inert gas (usually CO₂) is insufflated into the abdominal cavity to increase the surgeon's work space and visibility. During gynecological procedures in particular, the gas must be blocked from escaping prematurely through the vagina. The choice of object with which to accomplish this is at the discretion of the surgeon. One reported event involved an inflated surgical glove wrapped in a towel. Other items used included the bulbs from the end of syringes. Given that these objects are not counted as instruments, there is no double check to ensure they have been removed. One surgeon, during the second case of the day, realized that the bulb top of a syringe had been left in the first patient done that day. The RFB was removed while the patient was in the post-anesthesia care unit. Although the outcomes of these events are not usually life threatening, the outcomes of many of the event reports in FY15 have noted more severe outcomes than prior years, including vaginal and bladder infections requiring antibiotics, and erosions requiring corrective surgery.

Two of the vaginal RFBs occurred to women who had given birth in hospital-based birthing suites. Because of the family-friendly atmosphere of these units, the staff is encouraged to clear away any bloody sponges and drapes very quickly after the delivery. Unfortunately, this clean up sometimes occurs before the counts have been completed.

Many of the RFBs occurred during surgeries that are known to be very high risk for RFBs. Emergency abdominal surgery, laparoscopic procedures that have to be converted to open abdominal surgeries, very obese patients, and surgeries that involve multiple staff or surgical team changes all carry known risks for RFBs, yet it seems that these events are precisely the events in which policies are circumvented, communication is inadequate, and established protocols are not followed. The higher the risk, the greater the need for policy and procedural compliance and clear communication, especially when the risks are so well known. Figure 3 details the causative factors for surgical events derived from the submitted RCAs.

Figure 3: FY15 Percentage Root Causes for Retained Foreign Bodies and Wrong Procedures

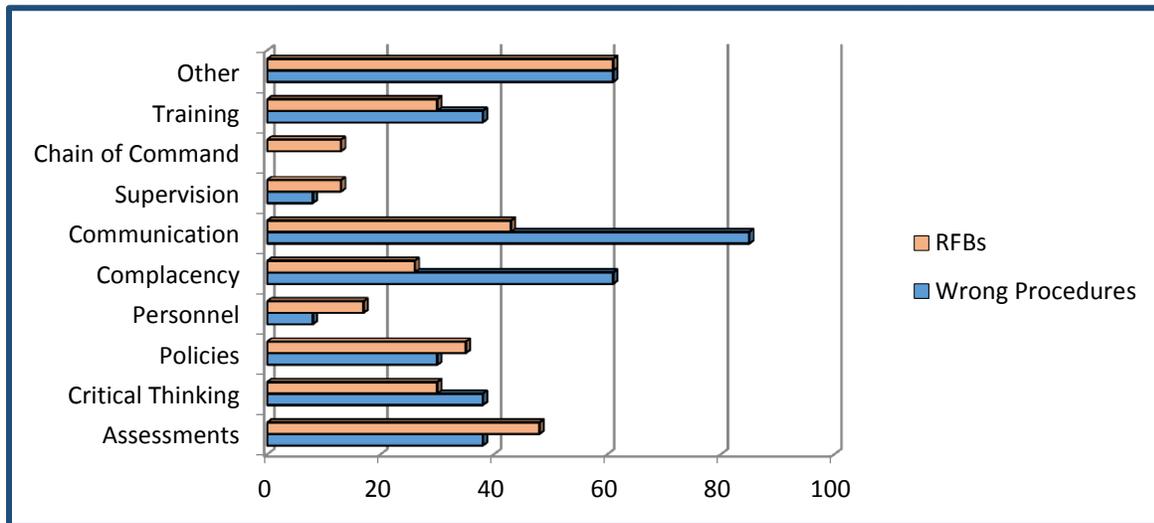


Figure 3 details the raw number of causative factors identified in RCAs submitted in FY15 for surgery-related events. Since most events are multi-factorial, the total number of factors adds up to more than the number of events. The “Other” factor references patient factors or problems associated with Health IT.

According to causative factors identified in the submitted RCAs, communication and complacency are more problematic for wrong procedures than for RFBs. As noted above, the risk profile of the procedure does not always translate into heightened awareness of the risks among the participants. Many of the communication problems occur because the surgeon is not in the room during, or not actively participating in, the time out process. Some RCAs note communication problems between persons of actual or perceived status differences, although this issue seems to be diminishing over time. The more likely reported scenario is that everyone is busy with his or her own tasks and not paying adequate attention to what anyone else is doing. In the first wrong procedure noted above, no one noticed that the surgeon had applied a tourniquet to the incorrect limb and then made an incision. The surgeon was not in the room for the time out and did not announce his or her intention to start the procedure or verbally confirm the procedure and laterality with those present.

In a statistical analysis of all OR events reported from FY12 through FY15¹⁷, complacency, policy compliance, and training were significantly associated with surgery-related events. Complacency is often manifested as an over-confidence in one’s abilities and a failure to grasp risks and dangers even as they are evolving. For surgery-related events, this means that staff are less sensitive to the risk factors inherent in the procedure, even when these risk factors are well known. Training and policy compliance are two ways to compensate for complacency. By standardizing the steps in the process with the time out checklist and standardized counting procedures, the number of wrong procedures and RFBs can be reduced. The continuing problem, reflected in the RCAs submitted for these events, is formalizing the expectation that every step

¹⁷ See Appendix G

will be followed with every patient during every procedure in every part of the hospital performing invasive procedures. When one or more members of the surgical team opt out from following processes designed to protect both patients and staff, errors occur and often recur. Critical thinking and assessments were significantly less likely to be associated with surgery-related events, perhaps reflecting the rote nature of many procedures associated with surgery and perioperative care.

AIRWAY EVENTS

The number of airway misadventures remained constant in FY15 with 11 reported. Ten of these were fatal and the other patient had to be emergently transferred for advanced care. Four patients aspirated vomitus or tube feeding associated with misplaced feeding tubes, including one patient who had a small diameter feeding tube inserted via the nose while he had a pre-existing larger feeding tube inserted via the mouth. Radiology was not notified of the presence of the two feeding tubes, so an x-ray taken to verify placement reported on the original feeding tube. The x-ray technician had to take the x-ray while the patient was in bed and somewhat rotated to the side, cutting off the top part of the lungs and upper airways. No one noted the small feeding tube coiled in the patient's lung. The patient aspirated and died after two liters of tube feeding had been infused. Another patient aspirated vomitus and died with a sitter next to the bed.

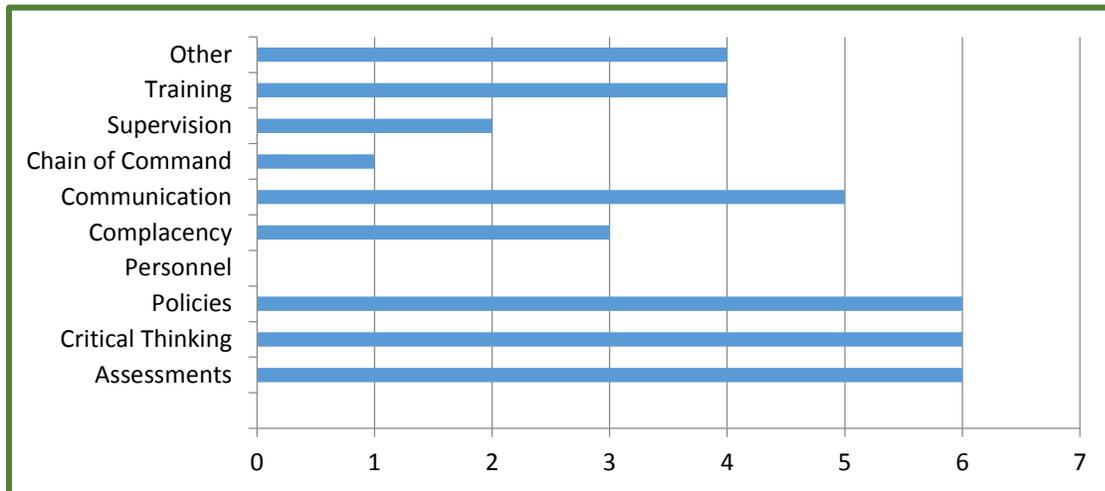
Three patients died after pulling their tracheotomy breathing tubes out. The staff had known the oxygen saturation monitor on one patient had been malfunctioning for two days without anyone swapping it out or getting it fixed, so it did not alarm when the patient pulled her breathing tube out. One patient who had a history of pulling out her breathing tube was alone in her room when she pulled it out for the terminal time. Because the patient was thought to be stable, there were no spare airways or other equipment at the bedside despite the known risk of self-extubation.

Three of the airway fatalities occurred in the OR. One patient needed emergency surgery during the night when there was only one anesthesiologist in the hospital. The patient was in a great deal of pain and received a dose of narcotics in the OR prior to anesthesia. The patient, naive to the effects of narcotics, then became overly sleepy and demonstrated loud, labored breathing. Even though the patient had been assessed as having a restricted airway while still in the ED, there was no difficult airway equipment in the OR. When the anesthesiologist could not insert a breathing tube, the surgeon was asked to perform an emergency tracheostomy. A combination of inexperience and poor communication among team members led to the patient's death.

One patient had a very tenuous oral airway in place and was taken to the OR for a tracheostomy. Someone removed the oral breathing tube before the room had been set up for

surgery, turning a planned and controlled procedure into an emergency. Other than the equipment on the code cart in the OR, there was no equipment with which to resuscitate the patient and an airway could not be re-established. Figure 4 details the raw number of causative factors identified in RCAs submitted in FY15 for airway events. Since most events are multi-factorial, the total number of factors adds up to more than the number of events. The “Other” factor references patient factors or problems associated with Health IT.

Figure 4: Root Causes of Airway Events FY15



Statistical analysis of the airway events reported since FY12 identified training as the only significant contributor to airway events, implicated in nearly half of the events. The training problems identified in the RCAs covered not just inadequate training of those directly responsible for inserting and maintaining airways, but included inadequate training associated with the absence of drills and practice sessions for difficult airways, recognizing incipient airway problems, and training sitters to recognize emergency situations.

MEDICATION ERRORS

According to the AHRQ Interim Update on 2013 Hospital-acquired Condition Rate,¹⁸ adverse drug events (ADEs) were the most commonly reported hospital-acquired condition between 2011 and 2013, accounting for 40.3 HACs per 1000 discharges. Hypoglycemic agents (given to decrease blood sugar) accounted for 23.3 of the HACs per 1000 discharges and anticoagulants (to reduce clotting) accounted for 16.5 HACs per 1000 discharges. The national ADE rate in 2010 was 49.5 HACs per 1000 discharges, so the current rate represented a rather modest decrease of 19%. In contrast, the national rate of central-line associated bloodstream infections decreased by 49% from 2010 to 2013.

¹⁸ <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html>

The 13 Level 1 adverse events associated with medication use is consistent with 12 events reported in each of FY13 and FY14. Medication events reported in FY15 include two patients who died from untreated hypoglycemia, and three anticoagulation-associated events, two of which were fatal. Three of the remaining medication events were fatal.

One patient was admitted and found to be hyperglycemic and given insulin coverage by sliding scale (meaning that the dose of insulin is adjusted according to blood sugar). The next day, the patient was medicated with insulin based on a finger-stick glucose result of over 350 mg/dL (normal is 90-120 mg/dL). After the patient was found unconscious with profound brain damage, it was noted that her blood glucose was less than 20 mg/dL. The RCA determined that the patient's nurse, who was a temporary employee, medicated the patient based on a glucose result from admission because the electronic medical record listed the oldest lab results at the top of the screen and the nurse was used to working with a system that listed the newest results first.

One patient on a specialty unit in the hospital was given an intravenous dose of erythromycin, an antibiotic. The patient soon exhibited chest pain, shortness of breath, and an irregular heartbeat. The patient was moved to a monitored bed but recovered. Soon after the patient was transferred, a second patient on the unit received a dose of erythromycin and had the same cardiac symptoms as the first patient. The infusion was quickly stopped, and all erythromycin doses were sequestered. An analysis by the pharmacy found not erythromycin but epinephrine (a powerful stimulant usually used only in cardiac emergencies) in the admixture bags. An admixture is a small bag of IV fluid used as a diluent attached to a vial of powdered medication that mixes with the diluent when the seal between the two is broken.

The RCA found that the pharmacy technician who mixed the medications had just completed orientation and was used to mixing up emergency medications like epinephrine and insulin. Because medications were stored alphabetically in the pharmacy, the erythromycin was kept next to the epinephrine. The technicians were supposed to bar code the medication and the diluents when preparing the admixtures, but the system had been inoperable so often that the staff no longer bothered calling the help-desk. On this day, the bar code system had been down for three days. The technician sent all the batch of doses prepared to the pharmacist for review but the pharmacist was busy with other tasks and, assuming the technician had used the bar code, performed only a cursory look at the medications.

In response to this event, the hospital changed the times batch medications were reviewed to a less busy time for the pharmacists. They also upgraded their connectivity to reduce downtimes for the bar code system, and changed the system so that medications not bar coded cannot be released from the pharmacy.

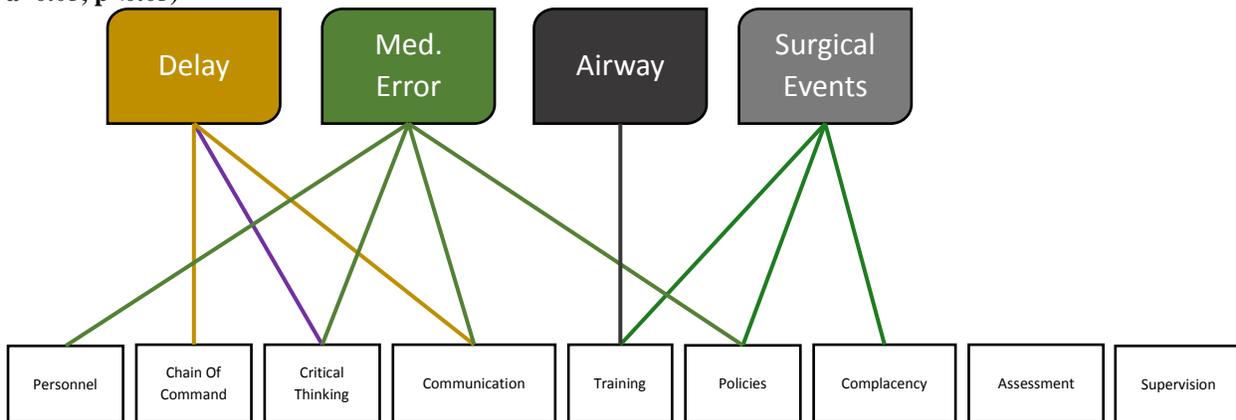
One young person suffered a fatal brainstem herniation from a penicillin allergy. The patient told the staff in the ED that she had no allergies, but the patient's mother told the ED physician that the patient was allergic to penicillin. The ED physician neglected to note this information in the medical record. The next day, when the attending wanted to place the patient on a penicillin derivative, the patient again denied allergies and was placed on the medication. The first dose was given with some minor itching, but the patient rapidly arrested and died during the second infusion. Although the death was first assumed to be a result of the patient's underlying condition, the autopsy showed a massive inflammatory allergic response with brain damage.

Associations between Adverse Events and Causative Factors

The Maryland Hospital Patient Safety Program evaluates the RCAs submitted by hospitals in the wake of a Level 1 safety event. The RCAs include factors that fall into ten categories, as described earlier in this report. These causal factors include: Critical Thinking, Communication, Assessment, Complacency, Training, Policy, Personnel, Chain of Command, Supervision and an "Other" category which includes patient specific variables and health information technology (HIT). These ten causal factors were chosen soon after the implementation of COMAR 10.07.6, and are based on the most commonly reported details of events verified by the expected causal factors identified in the literature.

Figure 5 graphically represents the significant associations between four of the most common types of patient safety events reported from FY12 through FY13. Events that were associated with at least one causative factor (n=764) were included in this logistic regression analysis. The solid lines between each event type and the individual causative factors represent a significant positive association. Additional information regarding the methods utilized during this analysis as well as the tables resulting from this analysis is presented in Appendix G. Although falls were included in this analysis as a type of patient safety event, no significant associations were apparent between any of the individual causative factors and falls.

Figure 5: Significant positive relationships between RCA factors and Level 1 Safety Event types (n=764, $\alpha=0.05$, $p<0.05$)



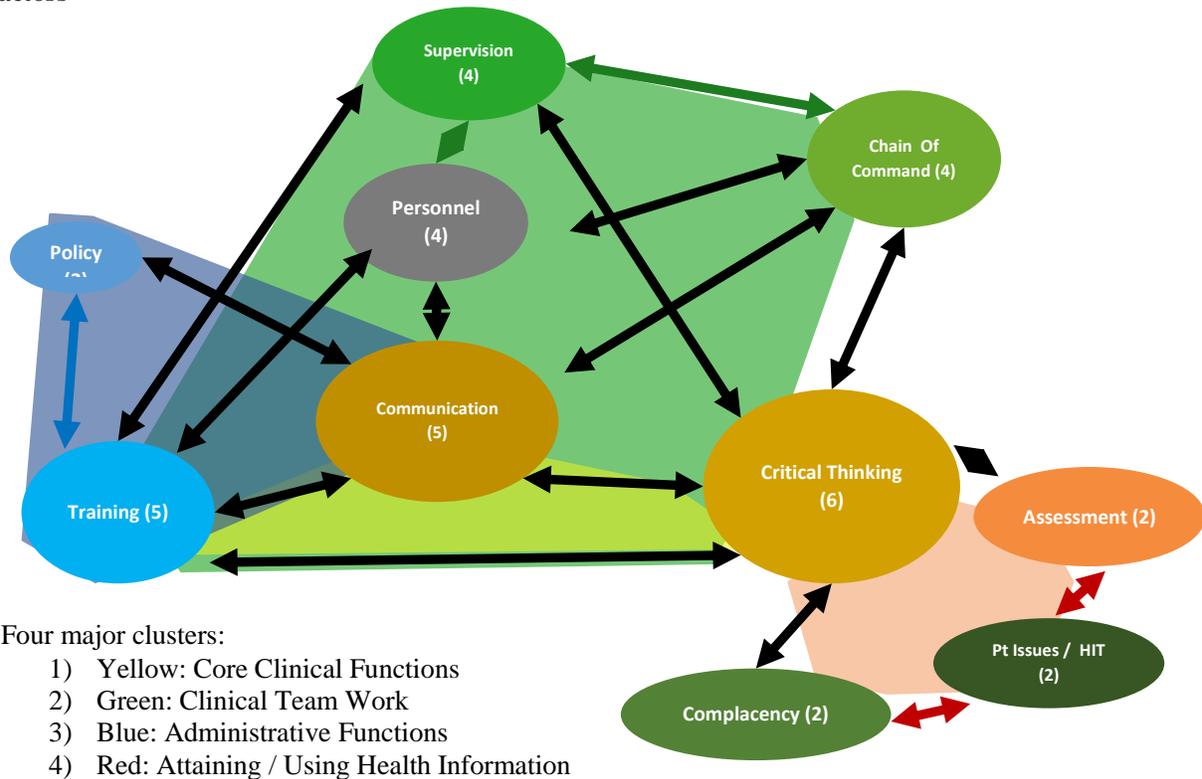
A third of medication errors had deficits in both policy and critical thinking in common. Logistic analysis suggests that these factors, as well as deficits in personnel and communication were significantly more likely to be associated with a medication error than other types of causative factors (OR 4.9 95%CI [2.5 – 9.6], OR 4.0 [OR 1.9 – 8.4], OR 2.5 [1.0 – 6.2], OR 2.1 [1.1.- 4.2])¹⁹ respectively. Airways events were relatively uncommon representing only 4% of the events reported; however, when airway events did occur they tended to be fatal. Forty-six per cent of airway events had the causative factor training in common. Logistic regression suggests that training was significantly more likely to be a causative factor in an airway event than any other type of causative factor (or 2.1 95%CI [1.1-4.3]; see figure 5 above, and Appendix G). Of the surgical events reported, 21% had the two causative factors, complacency and policy, in common. Logistic regression suggested that the causative factors complacency, policy and training were significantly more likely to be associated with surgical events than other types of causative factors (or 3.5 95%CI [2.1 – 5.9], or 1.5 [1.4 – 4.4], or 2.1 [1.2 – 3.7] respectively; see Figure 5 above, and Appendix G). Neither descriptive analysis nor logistic regression models suggested that there was any apparent pattern in the causative factors associated with falls.

ASSOCIATIONS BETWEEN CAUSATIVE FACTORS:

Analysis of the relationships between causative factors determined that certain factors were significantly likely to co-occur with each other during any given level 1 patient safety event than other causative factors. Four clusters of causative factors emerged as a result of this analysis. These associations are graphically represented in Figure 6 (see Appendix G for odds ratios). Each double headed arrow indicates that the factors connected by the arrows were significantly associated with each other. The numbers under each causative factor title represents the number of significant associations between that factor and the other nine causative factors.

¹⁹ OR=Odds Ration, CI= Confidence Interval, See Appendix G for more information.

Figure 6: Associations between RCA Factors



For example, one of the clusters of causative factors that emerged was “attaining / using health information.” This cluster is represented in red in Figure 6 and includes deficits in: assessment, health information/patient factors, complacency, and critical thinking. Assessment was significantly more likely to co-occur with only two out of the nine other causative factors including health IT/patient issues and critical thinking (odds ratios). As we can see, the only causative factor in this cluster significantly likely to co-occur with any of the other causative factors outside of this cluster was critical thinking. In fact, critical thinking had the highest number of significant associations (6) out of the ten factors evaluated suggesting that it is at the crux of virtually every patient safety event, and therefore should be considered in virtually all plans for corrective action. Communication and training were each significantly associated with five other causative factors, followed by personnel, chain of command and supervision with four significant associations respectively. Finally, policy, health IT/patient factors, and complacency were only significantly associated with two other factors.

The other factor clusters that emerged were; 1) “core clinical functions” including critical thinking, communication, and training; 2) “administrative functions” including training, communication and policy; and 3) “clinical team work” including training, communication, critical thinking, personnel, supervision, and chain of command.

The findings of this analysis may assist hospitals in creating more effective corrective action plans. As an example; a level 1 adverse event occurs at a hospital. The root cause analysis team determines that insufficient or untimely assessments was one of the causative factors associated with the event. The team could then utilize these findings by determining the other types of causative factors that are the most likely to co-occur with assessment. From Figure 6, the team determines that assessment is significantly likely to co-occur with deficits in complacency, health IT/patient factors, and critical thinking. The team could then integrate this information into their corrective action plans and utilize this information to create a plan that would not only prevent the event in question from recurring, but also other similar events that are likely to occur when there are deficits in these system functions.

DISCUSSION AND RECOMMENDATIONS

Of course each event is independent and therefore will have its own unique mix of factors. Therefore, the analysis presented here should be used as a means of maximizing the effectiveness of corrective actions. Emphasis should be placed on the positive associations as opposed to the negative associations. Specifically, when hospitals are evaluating and planning the corrective actions to be undertaken in the wake of a specific event, it may be advantageous to also consider addressing the factors that this analysis suggest tend to be significantly associated with that type of safety event, or associated with a particular factor that contributed to the event. One of the reasons to evaluate whether corrective action may be merited for these causative factors, even if they were not attributed to the event in question, is that preemptive action on these fronts may increase the likelihood that other events of this type will be prevented.

Corrective Actions

Hospitals continue to struggle with implementing corrective actions that will be long-lasting and effective at eliminating or controlling hazardous conditions. One can see, in Figure 7 that training is only strongly correlated with airway and surgical events, while policy problems (either lack of a policy or non-compliance with an existing policy) only statistically correlates with adverse medication events and surgery-related events. Even with the relatively weak correlation with other event types, 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.

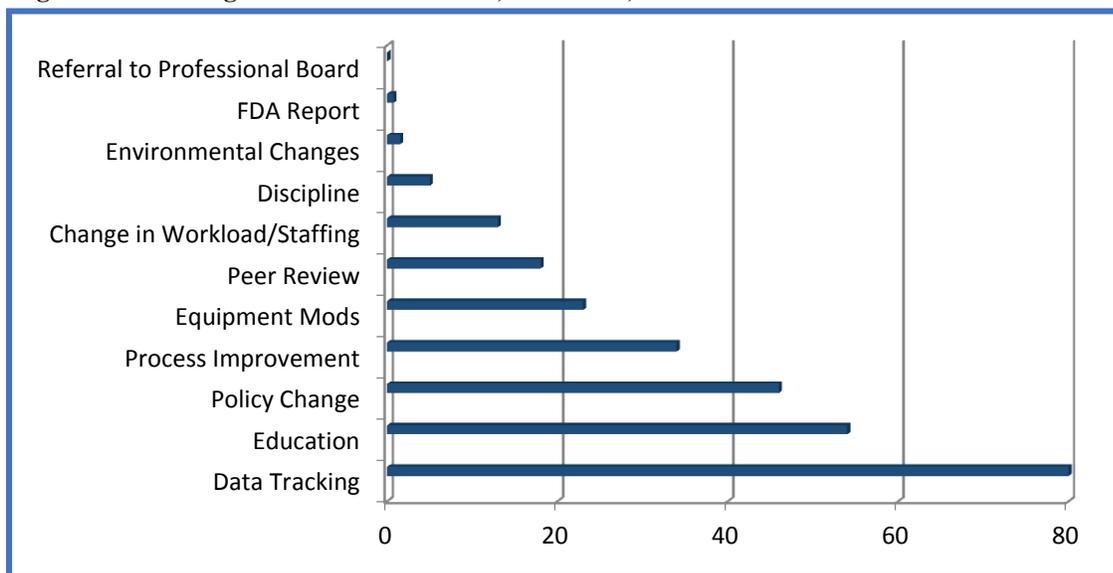
More hospitals are improving problematic processes, usually by streamlining and standardizing, and are making more processes fault-tolerant, which means that safeguards are built into the process *a priori* to compensate for inevitable mistakes. More hospitals are also changing work-loads and staffing in order to provide safer care. This usually does not mean

acquiring additional staff, but deploying staff better and with more focus. Examples of changing the workload include:

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

Hospitals are getting better at tracking and trending patient safety data and are less focused on formal discipline as a first response to an adverse event. In FY15, as in most previous years, no practitioners were referred to professional boards. 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, changing alarm settings on all monitors; 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. See Figure 7 for the most common corrective actions in FY15.

Figure 7: Percentage of Corrective Actions, All Events, FY15



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 and evaluating how effective a corrective action has been in remediating the set of circumstances that led to the adverse event. Completion of implementation is certainly something the hospital should track, but 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 more 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 entrenched administrative systems that abdicate their own roles in holding other disciplines accountable.

It is these entrenched administrative systems that are considered latent causative factors. Latent causes are generic, in that they affect the entire hospital. For instance, in the oxygen saturation monitor event discussed above under delays in treatment, the proximal cause was that no one heard the alarm. The secondary cause was that the alarms had all been set incorrectly during installation. The latent cause was a hospital-wide practice of implementing new technology without input from the end-users. This event was not the first time that new equipment had not done what the end-users expected because the engineers that installed and set up new equipment were not in the habit of consulting the end-users to find out what their goals were in using the equipment, or what barriers there might be to using the piece of equipment safely and effectively. If RCA teams look hard enough, and ask enough “why” questions during the RCA, they will find latent failures that contributed to the event.

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

Several national initiatives are underway to reduce the number of adverse events. Comprehensive unit-based safety programs (CUSP), originally developed to combat central-line associated blood stream infections, are increasingly being used to target medication errors and

other types of preventable events. CUSP processes seek to combine best clinical practices with safety science principles. The safety principles underlying CUSP are:

1. Standardize as much as possible. Standardization brings processes under examination so decisions can be made about the value and evidence-based nature of activities hospital staff 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.
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.

²⁰ <http://www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/index.html>

In order to comply with the requirements of COMAR 10.07.06, the hospital must submit a root cause analysis for reported Level 1 adverse events that includes an in-depth review of the event by a multi-disciplinary team of individuals to determine, through a series of “why” questions, the actual root causes of the event. Root causes are defined by 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. Several misidentified the level of event. For instance, the airway event discussed above in which the patient aspirated and died with a sitter at the bedside was classified by the hospital as a Level 2 event, even though the patient clearly died from the medical error.
2. Each RCA focused on what happened rather than on why, yet often lacked sufficient description of the adverse event to even determine what happened;
3. These RCAs lacked defined root causes and the information given was insufficient to establish causality;
4. In part because causality had not been determined, the interventions lacked specificity;
5. The listed outcome measures were inadequate to determine if the corrective actions would have any effect on the problematic process(es); and
6. Hospitals continued to focus on bedside, sharp end, corrective actions for adverse events.

In FY15, the Office of Health Care Quality sent out notices to three hospitals regarding RCAs that failed to meet all of the requirements of COMAR 10.07.06. Two of the hospitals had new patient safety officers. Hospitals are free to use any format to submit RCAs; however, they must meet the specific requirements of COMAR 10.07.06. Submitting event summaries with insufficient evidence of a thorough examination of the facts is likely to garner a state deficiency. Our RCA evaluation tool, along with an example of a non-complaint RCA, is available at: [www.http://dhmh.maryland.gov/ohcq/SitePages/PatientSafety.aspx](http://dhmh.maryland.gov/ohcq/SitePages/PatientSafety.aspx)

²¹ COMAR 10.07.06.02 (B)(10)

Following is one example of a poor RCA submitted in FY15:

A patient came to the hospital for a surgery involving the upper abdomen. There were two standard physical approaches to this surgery, but the patient's surgeon was credentialed for only one of these techniques (meaning that the medical staff had found his/her credentials and training prepared him/her for one approach but not the other). The patient was posted for a procedure that the surgeon never intended to perform, although the patient signed a consent for the intended procedure. The circulating nurse in the OR knew the consent was inconsistent with the posted procedure but did nothing prior to surgery. According to the RCA, the surgeon told the OR staff that he had another surgeon standing by if the approach for which he/she was not credentialed was necessary, which turned out to not be true. The surgeon performed the procedure, using a technique for which he or she was not credentialed, without calling another surgeon for assistance.

The patient did not do well after the surgery, and spent several days in the ICU before it became apparent that further surgery was required. The same surgeon decided to do the revision, using the same technique. This time, someone in the ICU went to the chief of surgery to report what happened the first time, and what was planned for the second surgery. The chief apparently approved the original surgeon to do the revision, even knowing that he/she was not credentialed for the procedure. The patient ended up having to be transferred to a tertiary care hospital for several revision surgeries and weeks in the hospital.

The RCA included the corrective action of sending the surgeon to peer review—nine months after the event. No mention was made of the actions taken (or not) by the chief of surgery. Most of the other corrective actions were aimed at the nurses, including retraining on the chain of command. There was no mention of the fact that the chain of command failed in this event. No mention was made of the culture in the hospital in which a surgeon could lie about a procedure he/she was planning, lie about there being another surgeon in waiting, and then get rewarded by being allowed to perform the same procedure again on the hapless patient.

This type of scenario is emblematic of a culture that is the antithesis of patient-centered care and demonstrates the serious latent problems with the entire hierarchy of the hospital. The culture in this hospital, in which no one is held responsible and management has abdicated its responsibilities to hold practitioners accountable for their actions, is dangerous. The RCA, which included the vice president for medical affairs among the participants, was narrow in its scope and shallow in its depth. The latent causes were obvious, yet no definitive and specific corrective actions were undertaken.

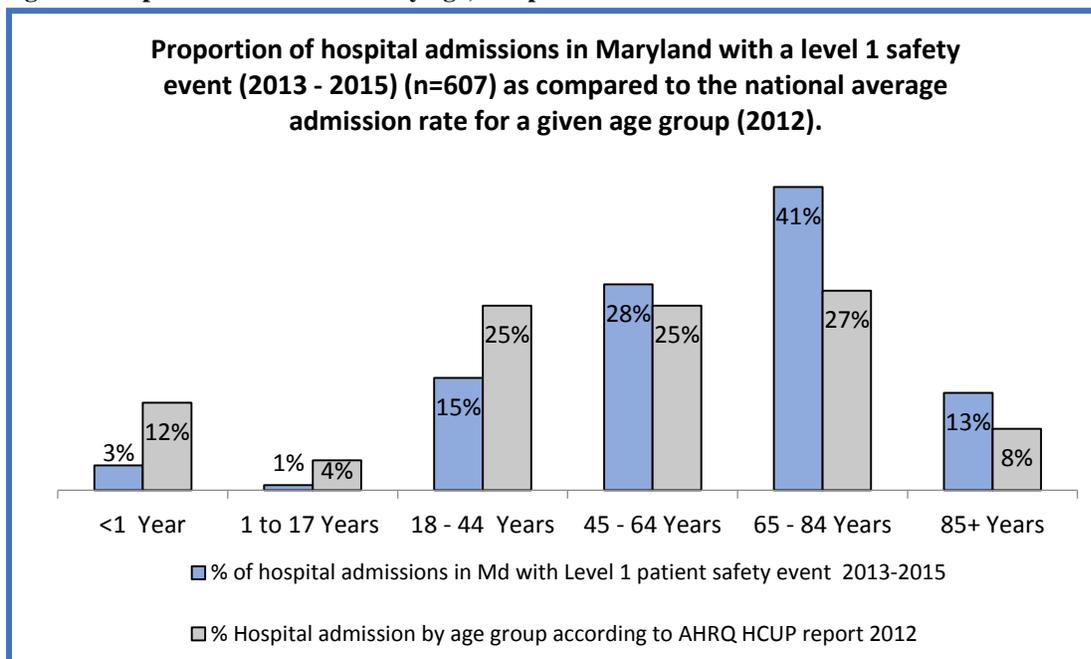
If the Office of Health Care Quality had received a complaint about this event, and investigated the hospital for compliance with the Federal CMS Hospital Conditions of

Participation, the hospital would have been found to be out of compliance with the Conditions of Governing Body, Medical Staff, Quality Assurance and Performance Improvement (QAPI), and Surgical Services. They likely also would be found to be out of compliance with the Condition of Patients’ Rights. The hospital violated the patient’s right to care in a safe setting, violated his/her right to make informed decisions about care by failing to disclose the surgeon’s credential status before surgery, and failed to disclose the cause for the bad outcome after surgery.

Patient Age and Adverse Events

If we compare the proportion of reportable events by age group (FY13 through FY15) to the national average rate for hospitalization in the same age groups, we would expect to find events distributed consistent with the age distribution of hospitalized patients. Figure 8 demonstrates that patients who are 65 years and older are significantly more likely to experience a Level 1 adverse event than other age groups (chi-squared test of homogeneity, $p < 0.001$). If each group were equally likely to experience an event we would expect to see the proportion of events by age group to be approximately equal to the proportion of admissions for that age group. Even though the distribution of admissions is roughly equal from age 18 to 84, patients who are 65 and older are disproportionately affected by adverse events. There are probably several reasons for this unequal distribution of adverse events. Presumably, a not insignificant proportion of admissions in those 18-44 are healthy women with uncomplicated deliveries, while those 65 to 84 are, overall, presumably sicker than younger patients.

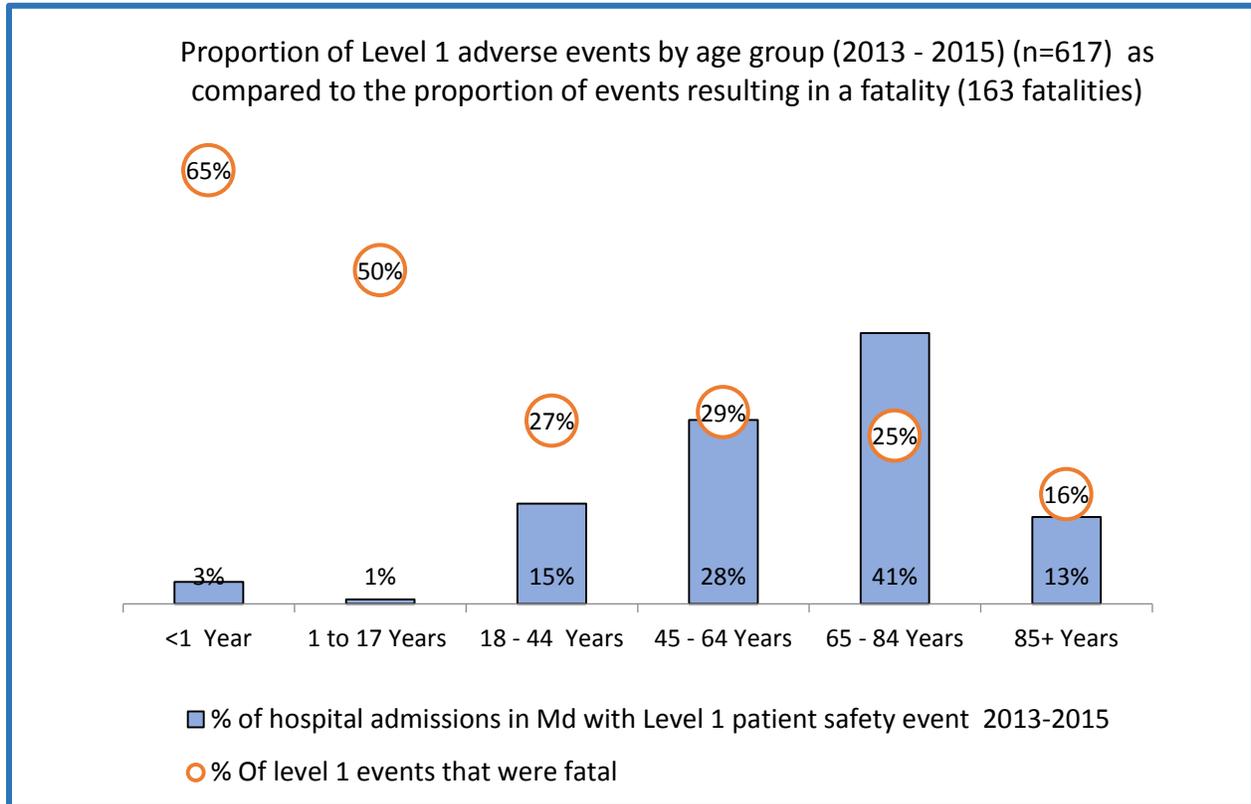
Figure 8: Reported adverse events by age, compared to national admission rates.²²



²² <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb180-Hospitalizations-United-States-2012.jsp>

The mean proportion of Maryland reported events that resulted in a fatality by age group is also reported. On average, 27% of events result in a fatality. We can see from Figure 9 that, although pediatric patients were less likely to experience an event than older patients, they were more likely to die as a result of the event compared to older patients. Extrapolating the number of fatalities reported since FY13, it becomes apparent that approximately one patient dies every week in a Maryland hospital as the result of a preventable event.

Figure 9: Proportion of Level 1 adverse events by age group (2013 - 2015) (n=617) compared to the proportion of events resulting in a fatality (163 fatalities)



On average, pediatric patients accounted for 4% of the level 1 adverse events reported per year to OHCQ. However, pediatric patients were significantly more likely to die as a result of an adverse event than other age groups (chi-squared test for homogeneity, $p < 0.001$). The proportion of adverse events that caused fatalities in patients younger than 17 for FY13 through FY15 was 58%. For FY15 alone, the proportion was 71%. Figure 10 presents the distribution of all outcome types by age group for FY15. Among patients 44 years and younger the most common outcomes were either surgery or a fatality. Among patients aged 45 and older, increases in length of stay become prevalent as well.

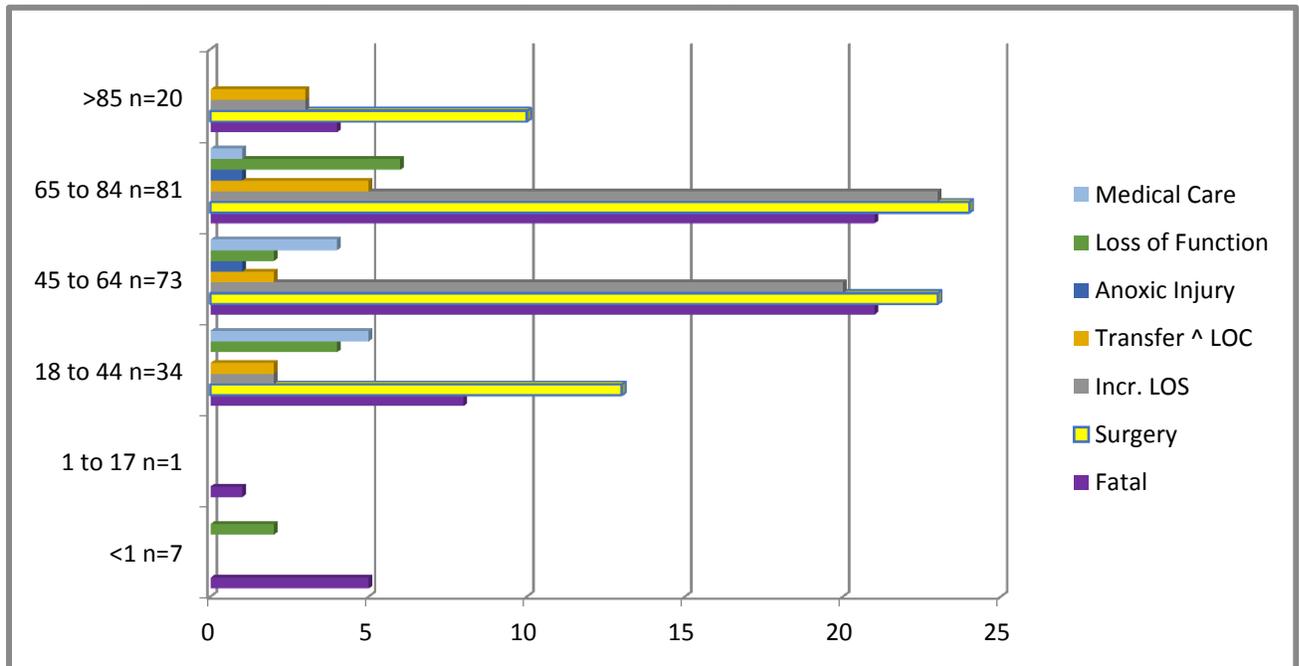
The patient outcome is determined from adverse event reports and represents the most severe outcome that occurred while the patient was in the hospital following the adverse event. For instance, if a patient suffered a delay in treatment and died four days later, that outcome

would of course be classified as a fatality. If another patient suffered an airway mishap and was transferred to a regional referral center where he was diagnosed as having suffered a severe anoxic injury (brain damage resulting from prolonged lack of oxygen) and died three months later, that adverse event would be categorized as an anoxic injury. The categories of outcomes for Figure 10 are as follows:

Transfer to ^LOC (level of care) means the patient was transferred to a higher level of care, either between the units in a hospital or from one hospital to another.

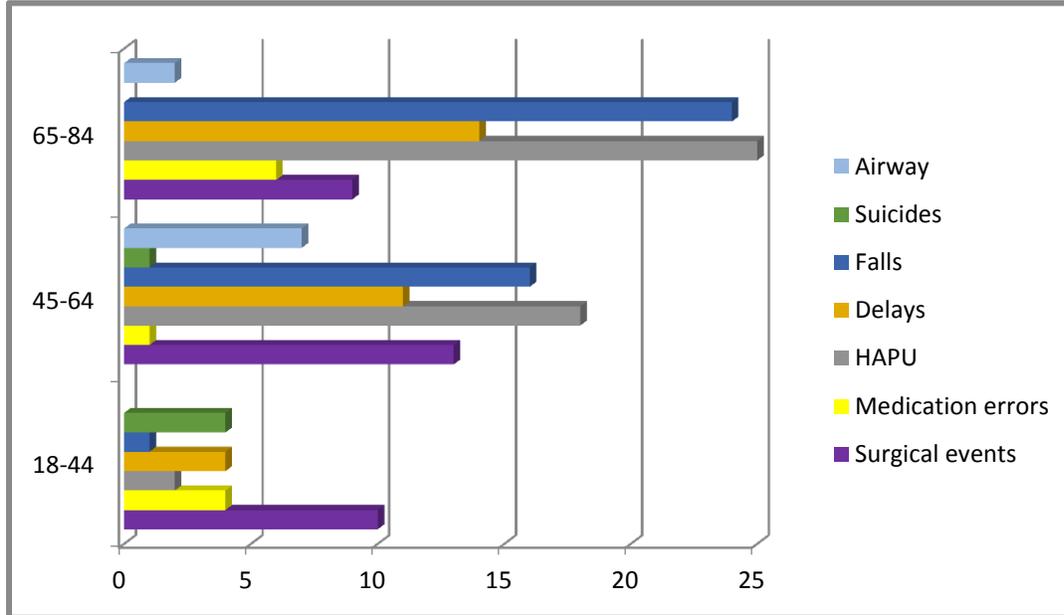
Increased LOS (length of stay) means that the patient’s discharge was delayed due to the event or the need for follow-up treatment.

Figure 10: Age and outcome, all events FY15 (n=216 known ages)



One can see that the outcomes for patients age 45 to 84 are very similar, as are the number of events occurring in each age group. However, if we look at the types of events that occurred to each age group, as in Figure 10, we see that falls and HAPUs occur much more frequently in the 45 to 84 age group. Suicides occur more frequently in those aged 18 to 44, and surgery-related events are more prevalent in the 18 to 64 age.

Figure 11: Most prevalent events per age (n=216 known ages)



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 actually 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. During FY16, we will be performing additional on-site surveys of hospitals thought to be under-reporting events. 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.

In order 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.

In 2014, CMS changed the survey process for the hospital Conditions of Discharge Planning, QAPI, and Infection Control. The goal of the new process is to identify malfunctioning hospital processes that cause patient re-admissions or perpetuate high re-admission rates. When performing these surveys, hospital surveyors will look at RCAs, failure mode and effects analyses (FMEAs), and incident reports. They may identify serious adverse events that may or may not have been reported under the Hospital Patient Safety Program. When that happens, the hospital may be cited for failing to comply with QAPI directives regarding investigating and correcting incidents.

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. Tell the patient's story by describing what happened or failed to happen that resulted in harm;
- Celebrating successes and adverse events avoided;
- Establishing and participating in administrative rounds that focus on patient safety;
- Attending the training on patient safety provided by the hospital or by the Maryland Patient Safety Center;
- Educating new department heads and nurse managers about the hospital's patient safety program and how their department is expected to interface with the patient safety staff and program;
- Establishing patient safety goals and monitoring the hospital's performance for those goals; 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.

Clinical Alerts

Based on the information obtained from the review of the events and the root cause analyses, the OHCQ has developed and distributed hospital clinical alerts. It is hoped that the experience of a hospital or several hospitals disseminated through the clinical alerts will prevent the recurrence of the event in another hospital and will enable the office to share "best practices." Clinical alerts released in FY15 included "Health IT and Maryland Adverse Events" and "The Rights of Psychiatric Patients and Involuntary Medications." Clinical alerts may be obtained at: <http://dhmh.maryland.gov/ohcq/Pages/PatientSafety.aspx>.

The Maryland Hospital Patient Safety Program has a new website: <http://dhmh.maryland.gov/ohcq/Pages/PatientSafety.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.

The Maryland Patient Safety Center

The Maryland Patient Safety Center²³ (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.²⁴ 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.

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; and
- Staff from Office of Health Care Quality have provided an update on new hospital regulations and a patient safety update annually for the past four years and has held a restraint and seclusion seminar with input from Nationally-known experts and local hospital representatives annually for the past two years in conjunction with the Maryland Hospital Educational Institute.²⁵

Future Plans

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

²³ www.marylandpatientsafety.org

²⁴ <http://www.marylandpatientsafety.org/MPSCPSO.aspx>

²⁵ <http://www.mhei.org/>

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.

Additional plans for FY16 include:

- Identifying and disseminating best practices for commonly occurring Level 1 adverse events;
- Supporting the collaboratives aimed at reducing hospital acquired conditions sponsored by the Maryland Patient Safety Center;
- Detecting and analyzing hospital-specific trends and patterns;
- Assisting hospitals to develop methodologies to address repeated similar events;
- Reporting on trends and patterns of poor RCAs submitted by specific hospitals; and
- Working with hospital representatives to make hospital-specific data communicated through the annual report cards more meaningful.

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.

We remain deeply concerned about the number and type of delays in treatment and surgery-related events. So far in FY16, Maryland hospitals are on track to match FY15 numbers. From July 1, 2015 to December 1, 2015, there were 10 reported surgical events and 12 reported delays in treatment. Each of these events is devastating to the patient and the staff. They represent lost lives, lost time, lost productivity, and lost money. We must fix the culture in hospitals that allow these types of event to occur, and recur.

Every year, we ask ourselves if Maryland hospitals are safer than last year. This year we are cautiously optimistic. Although not directly comparable to Level 1 adverse events, Maryland hospitals have reported a 26% decrease in MHACs. 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 Office 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 clinical alerts and other educational offerings in order to communicate patterns and trends identified through the receipt of events and the review of root cause analyses.

APPENDICES

Appendix A: Maryland Hospital Demographics

Maryland regulation classifies hospitals in two groups. The majority (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 three 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.

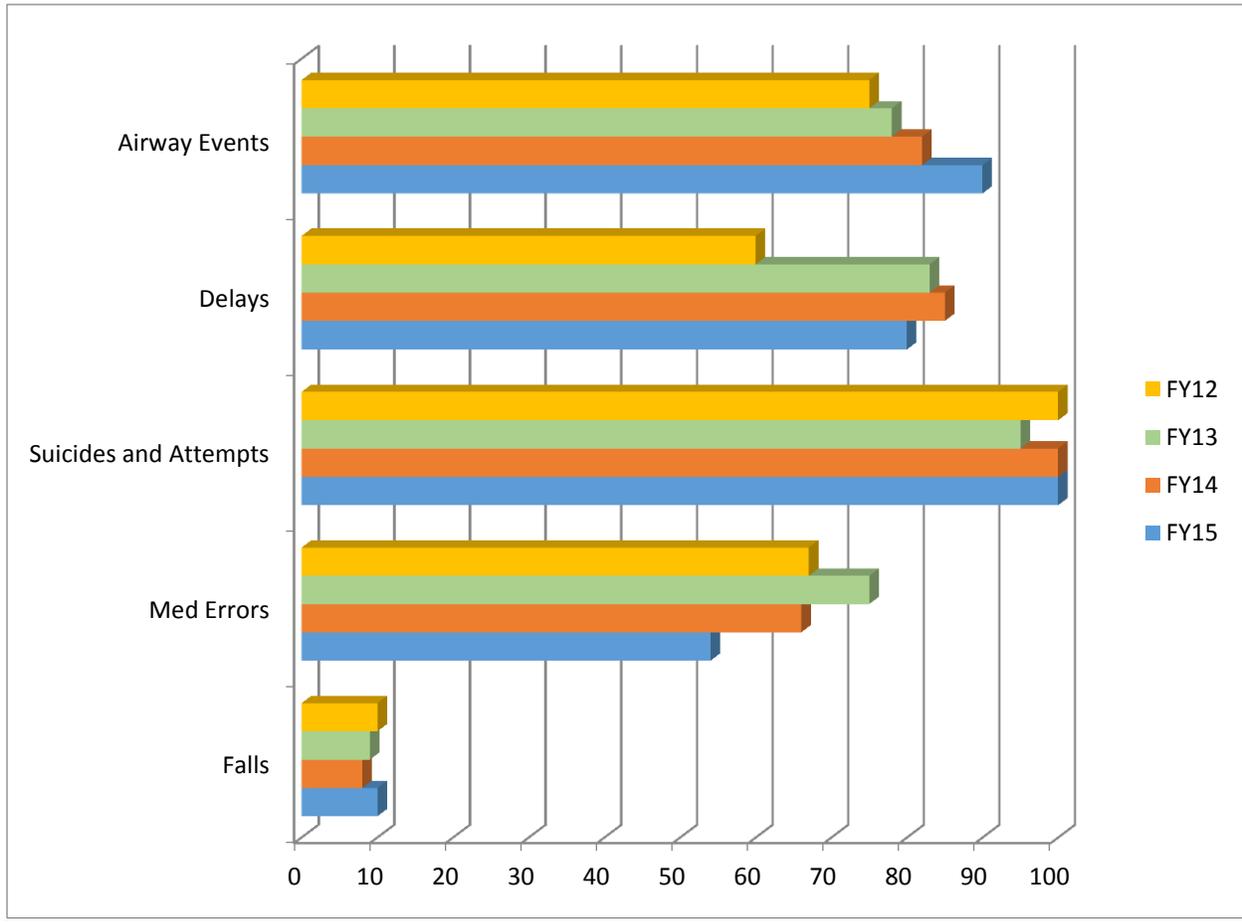
There are two Special Hospitals-Rehabilitation and two Special Hospitals-Children. The latter are also dually licensed as rehabilitation hospitals. The children's and rehabilitation hospitals have less than 100 beds each and offer limited outpatient services.

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

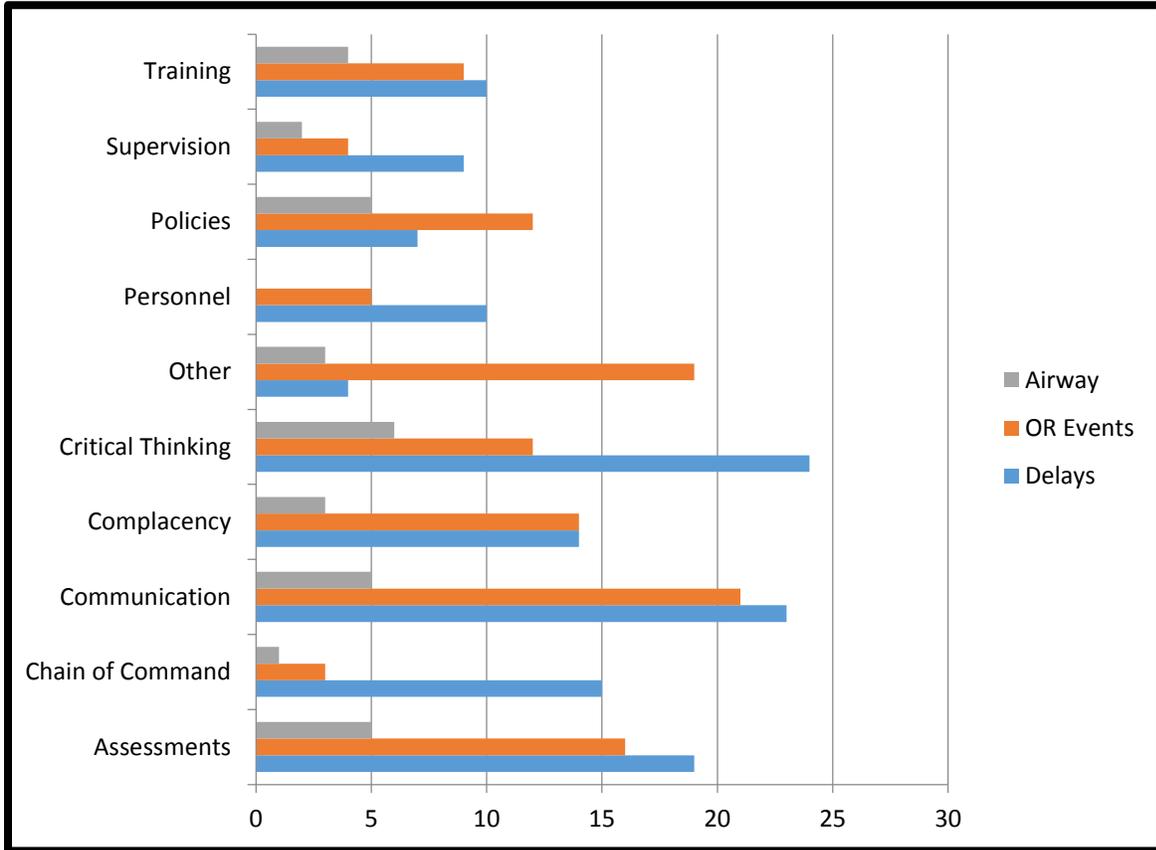
| Death or serious disability associated with... | FY12 | FY13 | FY14 | FY15 |
|---|-------------|-------------|-------------|-------------|
| Abuse/Sexual abuse | | | | 2 |
| Airway Events | 7 | 12 | 11 | 11 |
| Assaults | 4 | 2 | 5 | 5 |
| Blood Incompatibility | | | 1 | |
| Burns | | | 2 | |
| Contaminated Device | 2 | | | |
| Delays in treatment | 10 | 28 | 19 | 36 |
| Elopement | | | 2 | |
| Failure to Act | 1 | 1 | 1 | 1 |
| Falls | 98 | 73 | 72 | 50 |
| HAPUs | 86 | 52 | 63 | 76 |
| Healthcare-associated Infections | 3 | 9 | 5 | 3 |
| Hyperbilirubinemia | | | | 1 |
| Infrastructure Failure | | 1 | | 1 |
| Intravascular Air Embolus | 3 | | | |
| Malfunctioning Device | 1 | | 1 | |
| Maternal/Child | 6 | 2 | 2 | 3 |
| Medication Errors | 12 | 10 | 12 | 13 |
| Misdiagnosis | 2 | 1 | 2 | 2 |
| Surgical Events | 25 | 16 | 14 | 36 |
| Other | 1 | 2 | 1 | 2 |
| Restraint/Seclusion Injuries | 5 | 4 | 3 | 2 |
| Suicides | 16 | 7 | 8 | 5 |
| Unanticipated Complications | 4 | 1 | 1 | 1 |
| Vascular Access | | | 1 | 2 |

Appendix C: Comparison of Fatality Rates



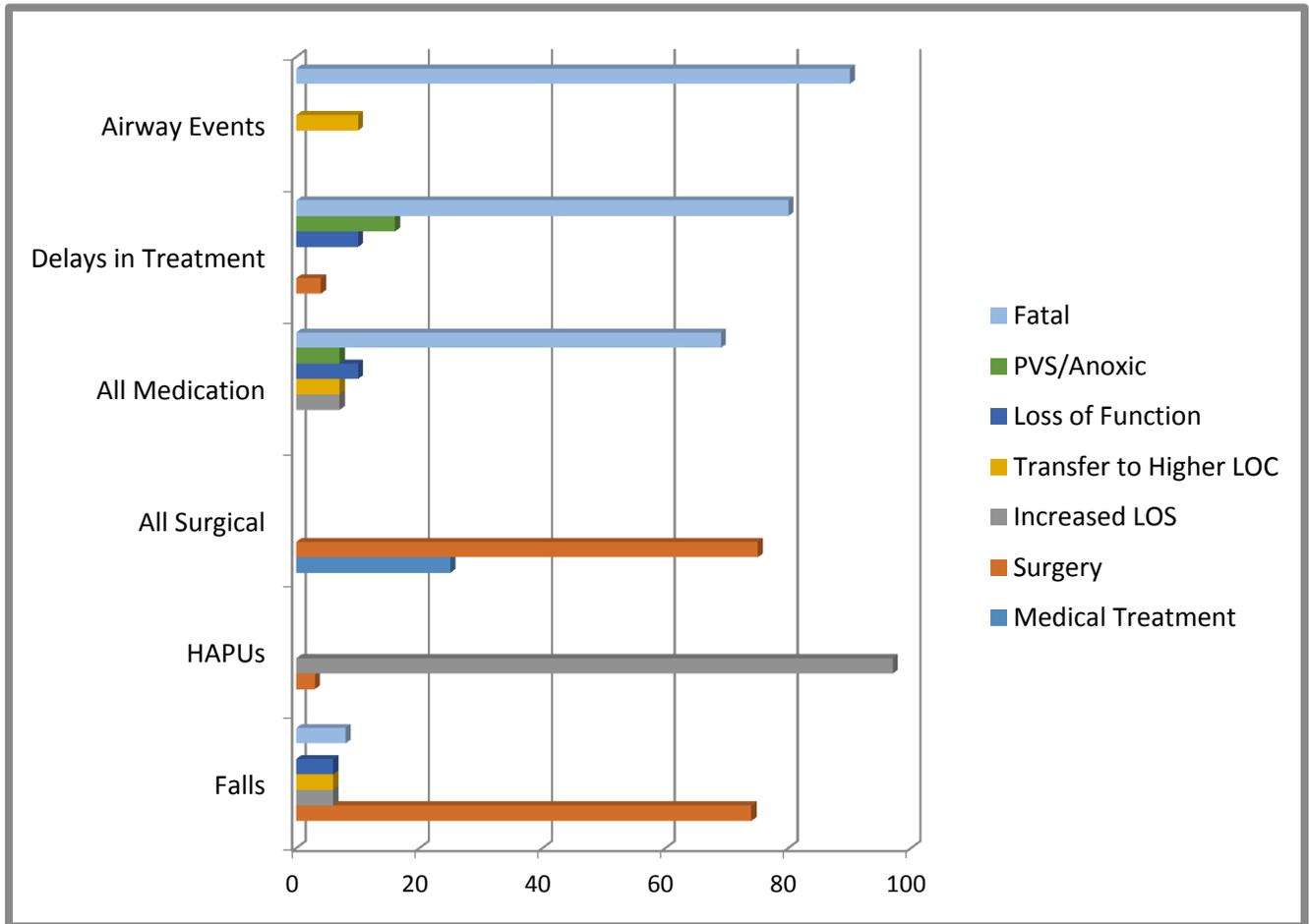
For some event, the number of events reported per year is large, but the fatality rate is low. For instance, we received 50 reports of falls with injury in FY15, but the fatality rate for those falls was 10%. The 8 to 10% fatality rate for falls has been consistent for 10 years. Many other event types have consistently high fatality rates, but occur less often. Airway events, as an example, carry a fatality rate between 70-90%, but only 10-12 are reported per year.

Appendix D: Identified Causation per Event Type, FY15



Most of the adverse events citing “Other” causes refer to health IT and or patient factors.

Appendix E: Outcomes for Six Most Common Level 1 Events, FY15



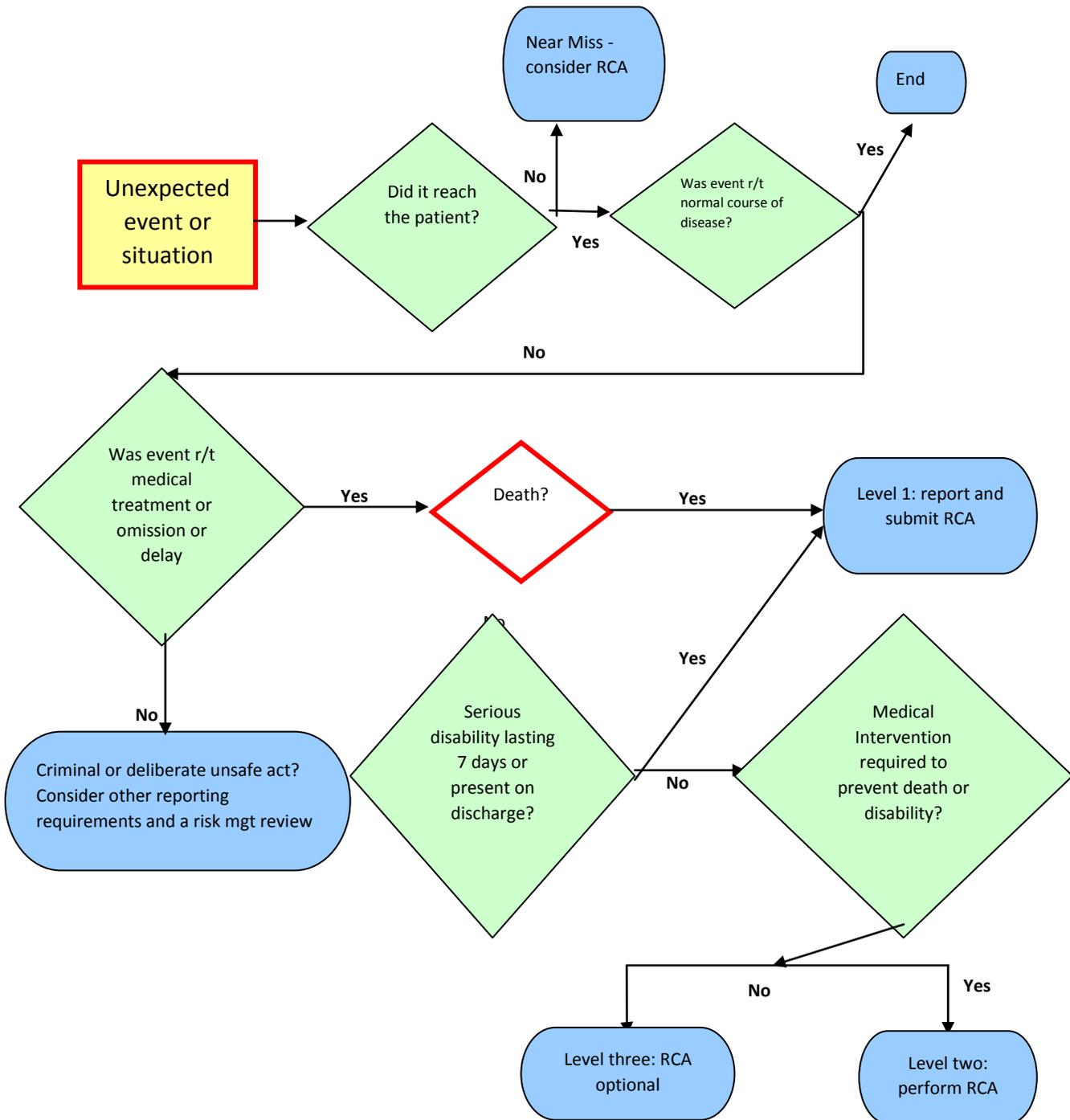
The outcome classification for adverse events is based on the most severe outcome the patient has suffered while in the hospital. For instance, if the patient suffered an anoxic injury from an airway event and was transferred to a tertiary care center, then died two weeks after the event, the outcome would be classified as an anoxic injury. The anoxic injury was the precursor to all following outcomes. In the same scenario, if the patient died without being transferred to another hospital, the outcome would have been classified as a death related to the event.

Persistent vegetative state (PVS) and anoxic injury refer to permanent severe brain injuries caused (generally) by a prolonged lack of oxygen.

Transfer to higher level of care (LOC) refers to those patients who required transfer for care in a tertiary hospital or regional referral center.

Increased length of stay (LOS) refers to those patients who require additional treatment, delaying transfer or discharge.

Appendix F: 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.

Appendix G: Statistical Analysis Methods

1. Associations between Level 1 Safety Events and RCA factors:

Of the 882 events reported from FY12 through FY15, 764 were associated with at least one of the ten causative factors²⁶ used by the Maryland Hospital Patient Safety program to classify and evaluate events. Descriptive statistics and multivariate logistic regression models were used to gain a better understanding of the associations between the classes of the most common types of Level 1 adverse events and the ten causative factors identified in Table G1.

Full multivariate logistic regression models including all ten of the causative factors were used to evaluate the associations between Level 1 adverse events and causative factors. Statistically significant associations were observed between each type of event and causative factors except for the initial full model for airway events. The full model suggested that there was a significant association between training and airway events however, in part due to the relatively small number of airway events (n=35 reported between FY12-FY15), this relationship was not significant. Therefore a univariate logistic regression was used to evaluate the individual associations between airway events and each causative factor. In the univariate models the only significant relationship was between Airway events and Training.

Table G1: Associations between Level 1 Adverse Events and RCA factors. Logistic regression models using all ten RCA factors for a full model, $\alpha=0.05$, n=764 Level 1 Events reported FY12-FY15.

| RCA FACTOR | Surgical Event | | Delay | | Medication Error | | HAPU ¹ | | Fall | | Airway | |
|-----------------------|----------------|-----------|-------|-----------|------------------|-----------|-------------------|-----------|-------|-----------|--------|-----------|
| | OR | 95% CI | OR | 95% CI | OR | 95% CI | OR | 95% CI | OR | 95% CI | OR | 95% CI |
| Critical Thinking | 0.4** | 0.2 - 0.7 | 1.9 | 1.1 - 3.3 | 4.0** | 1.9 - 8.4 | 0.6* | 0.4 - 0.9 | | | | |
| Communication | | | 2.1* | 1.2 - 3.6 | 2.1 | 1.1 - 4.2 | | | 0.6* | 0.4 - 0.8 | | |
| Training | 2.1* | 1.2 - 3.7 | | | | | | | | | 2.1 | 1.1 - 4.3 |
| Chain Of Command | | | 4.9** | 2.6 - 9.3 | | | 0.2 | 0.1 - 0.8 | 0.2* | 0.1 - 0.7 | | |
| Personnel Supervision | | | | | 2.5 | 1.0 - 6.2 | | | | | | |
| Policy | 2.5** | 1.4 - 4.4 | | | 4.9** | 2.5 - 9.6 | 0.5 | 0.3 - 0.9 | 0.3** | 0.2 - 0.6 | | |
| Assessments | 0.6 | 0.3 - 0.9 | | | | | 3.6** | 2.4 - 5.5 | 0.7 | 0.5 - 0.9 | | |
| Complacency | 3.5** | 2.1 - 5.9 | | | | | 0.6 | 0.4 - 0.9 | | | | |
| HIT / Pt. Issues | | | 0.5 | 0.3 - 0.9 | | | | | | | | |

¹ HAPU is a Hospital Acquired Pressure Ulcer *p<0.01 **p<0.001 Note: Only significant relationships reflected in table. $\alpha=0.05$

2. Associations between Causative Factors

In the second arm of this analysis the associations *between* causal factors were explored. Using full logistic regression models the associations between the ten causal factors was elucidated. For example, in order to evaluate whether the causal factor Critical Thinking tended

²⁶ As noted in the main document, the use of the term “causative” or “causal” factors does not connote a proven causal relation. According to COMAR10.07.06, causal factors are those event details which significantly contribute to the adverse outcome.

to co-occur more regularly with certain causal factors more frequently than others, a logistic regression model with Critical Thinking as the *dependent* variable and the remaining nine causal factors as *independent* variables was constructed. Both arms of this analysis were descriptive in nature which is appropriate given that this is the first time that the Maryland Hospital Patient Safety Program has evaluated these associations in this manner. It may be appropriate to utilize more complex statistical analysis techniques such as Factor Analysis or Structural Equation Modeling in the future.

Table G2: Logistic regression models of the associations between causal factors (n=764 Level 1 Pt. Safety Events 2012 – 2015 a=0.05).

| RCA FACTOR | Critical Thinking | | Communication | | Training | | Chain Of Command | | Personnel | |
|-------------------|-------------------|-----------|---------------|-----------|----------|-----------|------------------|-----------|-----------|-----------|
| | OR | 95%CI | OR | 95%CI | OR | 95%CI | OR | 95%CI | OR | 95%CI |
| Critical Thinking | | | 1.8* | 1.3 - 2.4 | 1.6 | 1.1 - 2.4 | 2.6* | 1.3 - 5.1 | | |
| Communication | 1.7* | 1.2 - 2.4 | | | 1.6 | 1.1 - 2.3 | 4.3** | 2.1 - 8.6 | 2.5* | 1.3 - 4.5 |
| Training | 1.6 | 1.1 - 2.4 | 1.6 | 1.1 - 2.3 | | | | | 1.8 | 1.0 - 3.2 |
| Chain Of Command | 2.5* | 1.3 - 4.9 | 4.3** | 2.1 - 8.7 | | | | | 3.2* | 1.6 - 6.3 |
| Personnel | | | 2.3* | 1.3 - 4.3 | 1.8 | 1.0 - 3.1 | 3.5** | 1.8 - 7.0 | | |
| Supervision | 1.9 | 1.2 - 3.1 | | | 2.3** | 1.5 - 3.7 | 3.6** | 2.0 - 6.6 | 2.8* | 1.5 - 5.2 |
| Policy | | | 1.8* | 1.2 - 2.6 | 2.7** | 1.8 - 4.0 | | | | |
| Assessments | 2.5** | 1.8 - 3.4 | | | | | | | | |
| Complacency | 1.7* | 1.2 - 2.5 | | | | | | | | |
| HIT / Pt. Issues | 0.6* | 0.5 - 0.9 | | | | | | | | |

*p<0.01 **p<0.001 Note: Only significant relationships reflected in table.

| RCA FACTOR | Supervision | | Policy | | Assessment | | Complacency | | HIT / Pt. Issues | |
|-------------------|-------------|-----------|--------|-----------|------------|-----------|-------------|-----------|------------------|-----------|
| | OR | 95%CI | OR | 95%CI | OR | 95%CI | OR | 95%CI | OR | 95%CI |
| Critical Thinking | 1.9 | 1.2 - 3.0 | | | 2.4** | 1.8 - 3.3 | 1.7* | 1.2 - 2.5 | 0.6* | 0.5 - 0.9 |
| Communication | | | 1.7* | 1.2 - 2.6 | | | | | | |
| Training | 2.3** | 1.5 - 3.6 | 2.7** | 1.8 - 4.0 | | | | | | |
| Chain Of Command | 3.6** | 2.0 - 6.7 | | | | | | | 0.4 | 0.2 - 0.8 |
| Personnel | 2.8* | 1.5 - 5.2 | | | | | | | | |
| Supervision | | | | | | | | | 0.5* | 0.3 - 0.8 |
| Policy | | | | | | | | | | |
| Assessments | | | | | | | | | 1.5 | 1.1 - 2.0 |
| Complacency | | | | | | | | | 1.6* | 1.2 - 2.3 |
| HIT / Pt. Issues | 0.5 | 0.3 - 0.8 | | | 1.5 | 1.1 - 2.1 | 1.6* | 1.1 - 2.3 | | |

*p<0.01 **p<0.001 Note: Only significant relationships reflected in table.