

**Maryland Hospital Patient Safety Program  
Annual Report  
Fiscal Year 2016**

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**Department of Health and Mental Hygiene  
Office of Health Care Quality**



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## Executive Summary

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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 2016 (July 1, 2015 to June 30, 2016). A Level 1 adverse event is defined in COMAR 10.07.06 as any unexpected outcome of medical care caused by a preventable error that causes death or serious disability. They tend to occur in several major categories such as surgical events, which include inadvertently retained foreign bodies and wrong site surgeries, and patient protection events including falls, health care-acquired pressure ulcers/injuries, delays in treatment, and medication errors. These events are costly for both patients and hospitals. Adverse events, by definition, are life- and function-threatening for patients and can result in financial burdens for hospitals while negatively affecting the emotional and physical health of a hospital's workforce, leading to suboptimal performance or personnel loss.

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

The FY16 Hospital Patient Safety Report analyzes, both quantitatively and qualitatively, the 189 serious adverse events affecting 217 patients reported by Maryland hospitals to the Office of Health Care Quality in fiscal year 2016 (July 1, 2015 to June 30, 2016). This report compares FY16 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 five events in FY16, up slightly from 4.8 reports per hospital in FY15.
- The discrepancy between reports received (189) and patients affected (217) 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 61% of the reported events. These two types of events accounted for 50% of all reports in FY15.
- The five most common types of events from FY12 through FY16 were falls (29%), pressure ulcers/injuries (29%), delays, (10%), surgery-related events (6%), and medication errors (3%).
- In 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 compared to the previous average of 18 per annum for each type. In FY 2016, Maryland hospitals reported 30 delays in treatment while reported surgical events dropped to 23.
- The most common causative factors<sup>1</sup> identified in root cause analyses submitted for FY16 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. Along with a lack of standardized policies that apply across all procedure areas, submitted root cause analyses point to a lack of accountability for complying with those policies.

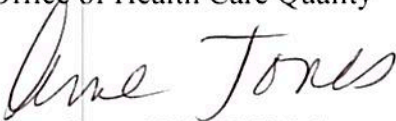
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<sup>1</sup> The use of the terms “causative” or “causal” factors do not connote a proven causal relationship. According to COMAR 10.07.06, causal factors are those event details which significantly contribute to the adverse outcome.

Analysis of the reported events indicates that one person dies per week in a Maryland hospital of a preventable error. Unfortunately, this number has remained stable over the past five years. One of the most commonly reported events, delays in treatment, also carries a very high mortality. Since 2005, when the first delay was reported, 243 of these events have been reported with 205 fatalities, an 85% mortality. That number should acutely focus our attention.



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# Maryland Hospital Patient Safety Program Analysis

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## Introduction

Fiscal year 2016 (July 1, 2015 to June 30, 2016) marked the 12<sup>th</sup> year of the Maryland Hospital Patient Safety Program. As in past years, this report includes comparisons of the current year with previous reporting years. It remains difficult to quantify improvements in quality and safety at a high level of precision. However, the Office of Health Care Quality has been able to identify general areas of improvement demonstrated by hospitals, such as decreases in the reported falls and hospital acquired pressure ulcers (HAPUs). This report includes some creative corrective actions and better practices undertaken by hospital-based teams. Nonetheless, many hospitals continue to struggle with implementing effective, lasting interventions and with 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 2015 Hospital-acquired Condition Rate<sup>2</sup> determined that there was an overall 21% decrease in adverse events nationally from 2010 through 2015. Multiple factors contributed to this decrease in adverse events or hospital-acquired conditions (HACs). There are numerous incentives, both positive and negative, spurring a reduction in harm. On the positive side, the Centers for Medicare and Medicaid Services (CMS) has applied incentives designed to reduce HACs including adverse drug events, falls, pressure ulcers, and readmissions. The AHRQ Progress Report indicated that hospitals had achieved 3.1 million fewer harm events over the time period from 2010.

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

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<sup>2</sup> <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html>

<sup>3</sup> PPCs are defined as complications that are not present on admission and are unlikely to be a consequence of the natural progression of an underlying illness, and as noted, are counted irrespective of patient outcome.

diagnoses with discharge diagnoses and MHAC rates are benchmarked against State-wide rates. MHAC rates are one indicator of hospital quality, and the MHAC rates affect hospital payments. Because of Maryland's unique rate-setting structure, the State had to get a waiver from CMS to track MHACs, and the HSCRC had to prove to CMS that Maryland's method of tracking PPCs was comparable to the federal mandates. In a November, 2015 press release,<sup>4</sup> 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.

### **REPORTED ADVERSE EVENTS**

A Level 1 adverse event is defined in COMAR 10.07.06 as any event that causes death or serious disability.<sup>5</sup> Since the enactment of the Maryland Patient Safety Program regulations on March 15, 2004, through June 30, 2016, over 2800 Level 1 adverse events have been reported by Maryland hospitals. In comparing reporting rates for specific adverse event categories from FY16 to prior years we note:

- The percentage of reported delays in treatment remained at 14% of the total events in FY15 and FY16. This represents a significant, and worrying, increase from an average of 7.7% of total events reported from FY12 through FY14.
- Surgery-related adverse events dropped somewhat this year, from 36 in FY15, or 14% of the total reported events to 21, or 14% of total events. This number includes 10 wrong site/patient/procedures and 11 retained foreign bodies (RFB).
- Suicides and serious suicide attempts accounted for 2.3% of reported events in FY16.
- Falls and Health Care-Acquired Pressure Ulcers (HAPU) accounted for 61% of the Level 1 events reported in FY16.

### **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"<sup>6</sup> taxonomy. This is a nationally known classification schema used by several state reporting systems as their

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

<sup>5</sup> 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.

<sup>6</sup> National Quality Forum. "Serious Reportable Events in Healthcare—2006 Update." Washington DC: 2007

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;
- 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.

In 2012, the NQF added deaths in low mortality diagnosis-related groups as a quality indicator.<sup>7</sup> Their assumption is that deaths in patients with diagnoses that typically carry low mortality, for instance birth related diagnoses, is an indicator of substandard care. We track birth events and have various ways of arriving at these data, such as tracking reported delays in treatments, unanticipated complications, and deaths that occur during or just after a typically low mortality invasive procedure.

There is likely to be some under reporting from Maryland hospitals, especially of non-lethal events, as reflected in the wide variability seen in numbers of events reported by hospitals of similar size and acuity. At the same time, there is heightened awareness among the general public and other Maryland and Federal governmental and private sector payer organizations about the importance of identifying and addressing safety issues.

### **HOSPITAL DEMOGRAPHICS**

Maryland hospitals are classified into five categories—acute general, psychiatric, chronic, children's, and rehabilitation. Acute general hospitals account for 75% of all licensed Maryland hospitals and reported 94% of the Level 1 adverse events in FY16. Statistical analysis of FY16 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

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<sup>7</sup> [Qualityforum.org/0347.pdf](http://Qualityforum.org/0347.pdf)



2.7% of reports, while psychiatric hospitals accounted for the remaining 3.6%. These percentages are consistent with FY15

**Table 1: FY16, Level 1 Adverse Events Reports per Hospital**

Number of Licensed Beds	Number of Hospitals	Average Reports per Hospital FY15	Average Reports per Hospital FY16
300 or more beds	11	4.9	4.9
200 – 299 beds	15	6.5	5
100 – 199 beds	16	3.7	4.1
Less than 100 beds	22	0.9	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. Hospitals with over 300 beds accounted for 25% of the adverse events reported in FY16, while hospitals with 200 to 299 beds reported 36% of the adverse events. Hospitals with 100 to 199 beds reported 30% of the Level 1 events and hospitals with less than 100 beds reported 9% of the total events in FY16.

For FY16, with a few exceptions, the number of reported events is quite consistent with the number reported in FY15 (see Table 2).

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

Death or serious disability associated with...	FY12	FY13	FY14	FY 15	FY16
Suicides or Serious Attempts	16	7	9	5	5
Airway Events	7	12	11	11	5
Maternal/Child	6	2	2	3	4
Medication Errors (ADEs)	12	10	12	13	6
Delays in Treatment	10	28	19	36	30
Surgery-related Events	25	16	14	36	21
Falls	98	73	72	50	58
HAPUs	86	52	63	76	76
Restraint/Seclusion Injuries	5		4	3	1

### **REPORTS OF NON-LEVEL 1 EVENTS**

Since March 15, 2004, a total of 553 events that did not meet the criteria for a reportable event<sup>8</sup> under COMAR 10.07.06 were reported to the Maryland Patient Safety Program by hospitals. Thirty-three of these non-Level 1 events were reported to the Office of Health Care Quality in FY16. 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 uncommon events when they occur even if the injuries are minor. Retained foreign bodies that are removed during the same surgical occurrence and wrong site procedures that do not cause serious harm to patients are also reported by hospitals regardless of the presence of serious disability or death. 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, the following information needs to be provided:

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

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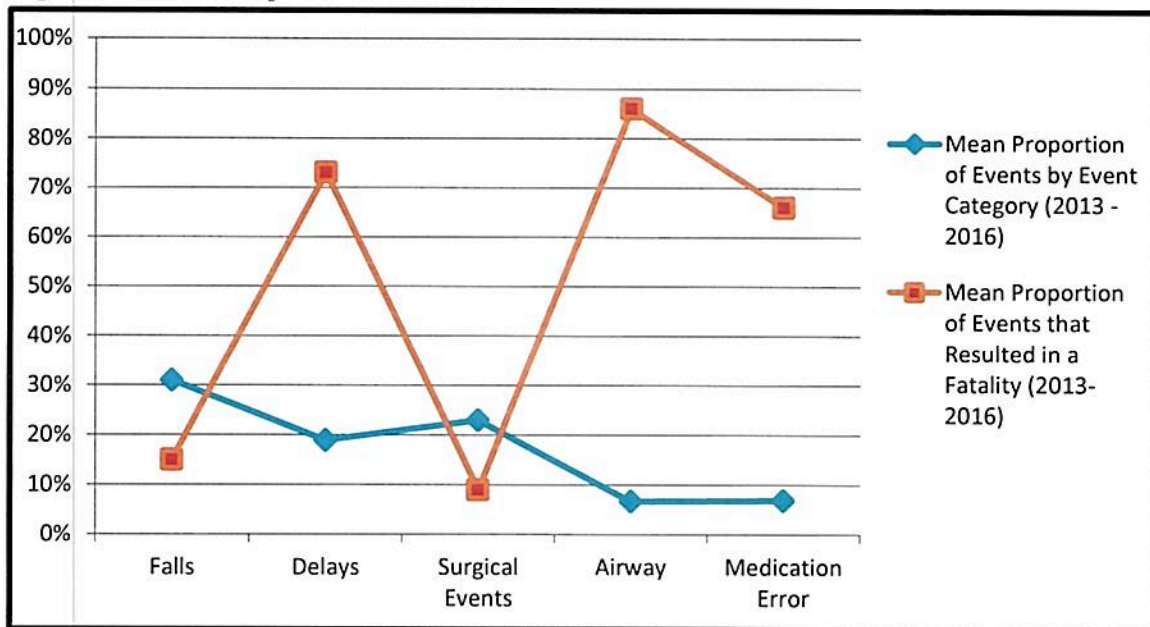
<sup>8</sup> Under COMAR 10.07.06. 02 B (4) the hospitals are required to report all Level 1 events defined as adverse events which result in death or a serious disability to the patient.

## Event Outcomes

### FATALITIES

Figure 1 details the most commonly reported fatal Level 1 adverse events from FY13 through FY16, along with the proportion that were fatal. These five event categories represented 86% of the reported Level 1 events and 75% of the fatalities. As noted, one person dies per week in a Maryland hospital of a preventable error. Unfortunately, this number has remained stable over the past five years. One of the most commonly reported events, delays in treatment, also carries a very high mortality. Since 2005, when the first delay was reported, 243 of these events have been reported with 205 fatalities, an 85% mortality.

**Figure 1: Mean Proportion of Events with Associated Fatalities**

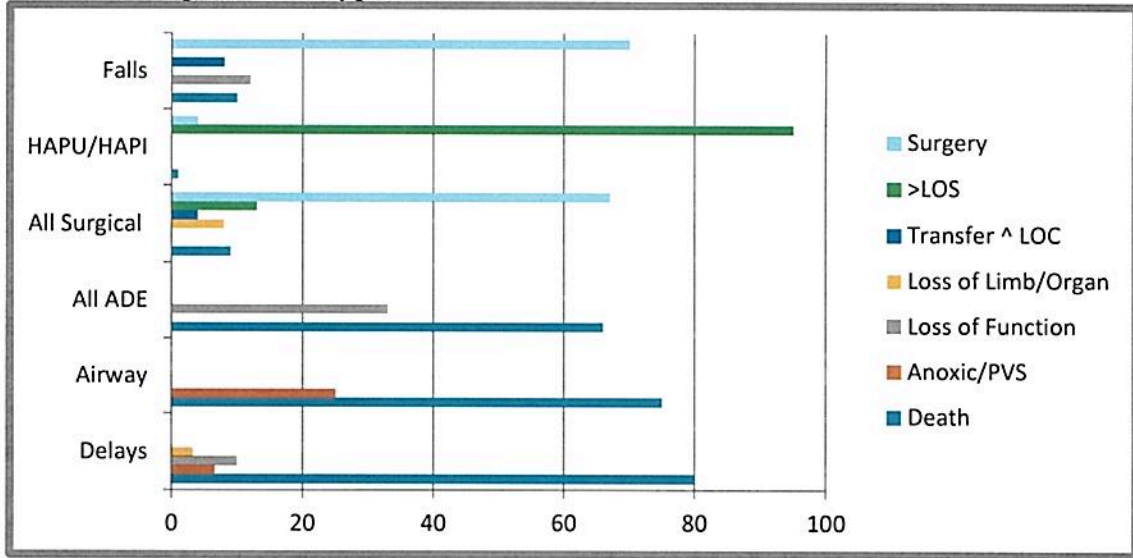


While the formation of hospital-acquired pressure ulcers (HAPUs) is correlated with overall decreased life expectancy, HAPUs are the least likely event to cause inpatient death. Only one HAPU-associated death (due to massive infection) has been reported since 2004. Airway events only represented 7% of events, but on average 86% of airway events resulted in a fatality. Airway events, delays and medication errors were significantly more likely to result in a fatality. 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 patient outcome is determined from adverse event reports and represents the most severe outcome that occurred while the patient was in the hospital following the adverse event. For instance, if a patient suffered a delay in treatment and died four days later, that outcome would of course be classified as a fatality. If another patient suffered an airway mishap and died

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

**Figure 2: Outcomes per Event Type**



The categories of outcomes for Figure 2 are as follows:

>LOS refers to increased length of stay. Transfer to ^LOC refers to transfers to a higher level of care. This transfer could be within the hospital or to another hospital. Anoxic/PVS refers to a brain injury related to a lack of oxygen. When the brain injury is prolonged, the patient may develop a persistent vegetative state, in which there are no cognitive functions but the brain is still keeping the heart beating and the lungs exchanging air.

**AGE AND ADVERSE EVENTS**

According to the Healthcare Cost and Utilization Project (HCUP)<sup>9</sup> from the AHRQ, the percentage of hospital admissions is roughly equal for the age groups encompassing 18 to 84 year olds. However, we see a significant spike in adverse events occurring to patients aged 45 to 84. In FY16, 85% of adverse events were reported in those over 45. Excluding trauma, many patients under 45 are admitted for relatively uncomplicated surgeries such as orthopedic procedures and other low mortality procedures. In addition, since childbirth occurs primarily in the under 45 age bracket, it makes sense that the prevalence of adverse events in this age group would also be low. Those under 45 are also less likely to be afflicted with age-related chronic conditions that add complexity to care in later life.

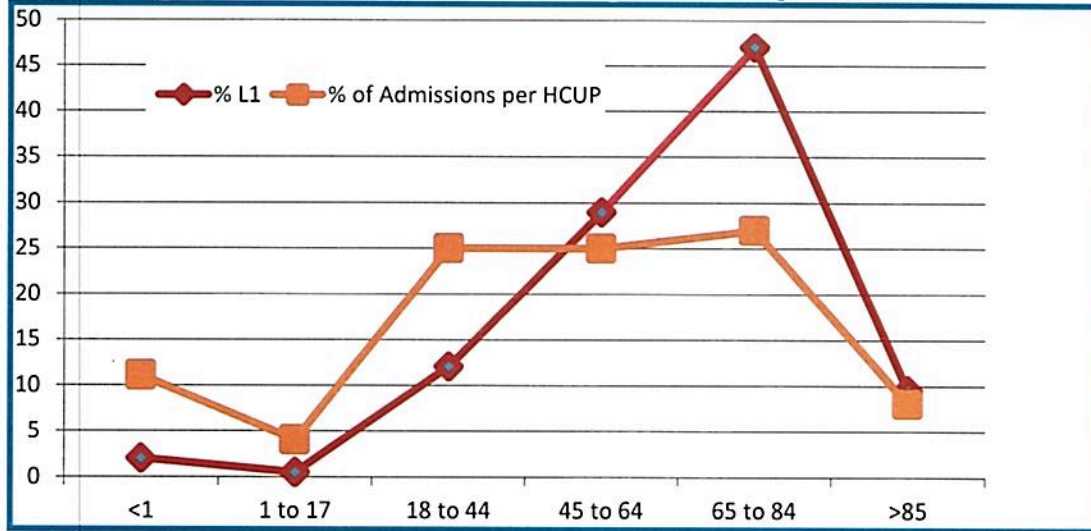
Among those over 65, the CDC<sup>10</sup> estimates that 11% of all accidental deaths are caused by adverse effects, which includes adverse outcomes related to medical care and to medications.

<sup>9</sup> <https://www.hcup-us.ahrq.gov/>

<sup>10</sup> <https://www.cdc.gov/injury>

According to the 2015 census, the population of Marylanders aged 65 or older is approximately 800,000, or 13% of the total. In FY16, 55% of reported Level 1 events occurred to those over 65.

**Figure 3: Age at Onset of Adverse Event Compared to Hospital Admissions**



If we look at the mortality as a result of adverse events rates for each age, we arrive at Figure 4.

**Figure 4: Adverse Event Death Rates per Age**

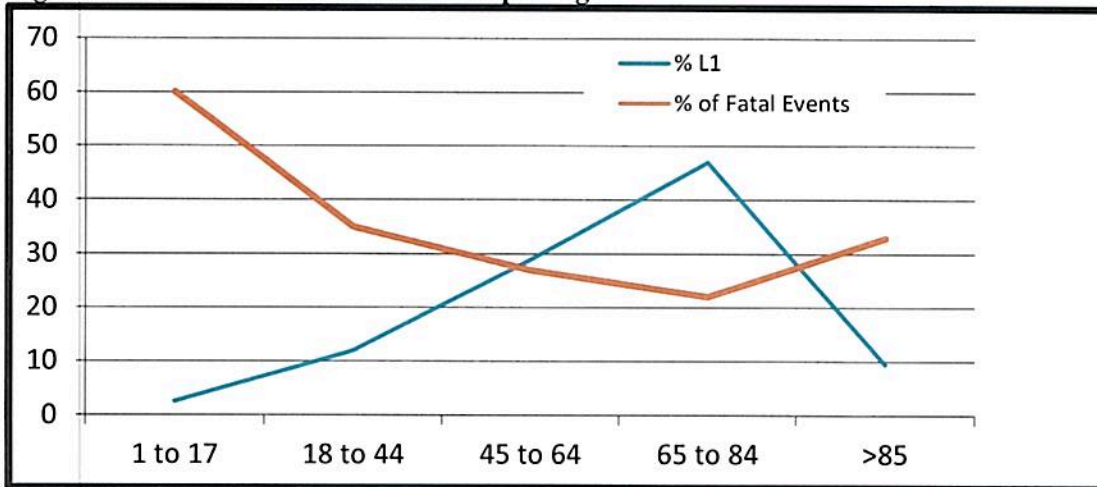
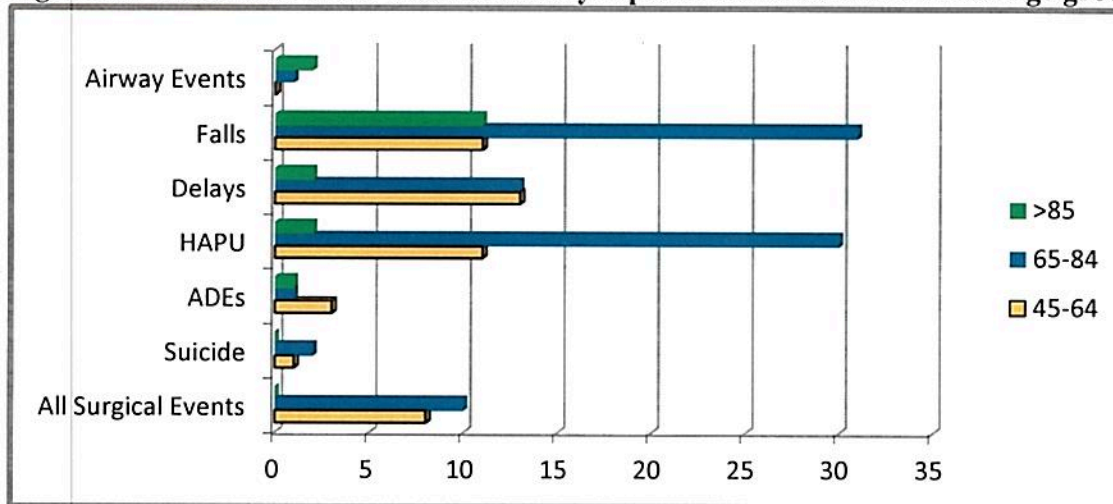


Figure 5 demonstrates the percentage distribution of the most commonly reported adverse events across age groups. One can see that airway events disproportionately affect those over 85 while falls and HAPUs affect those in the 65 to 84 range and delays affect those patients aged 45 to 84.

**Figure 5: Distribution of the most commonly reported adverse events across age groups:**



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

## High Frequency, High Mortality 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. In FY16, there were 30 level 1 delays in treatment reported, with 24 fatalities (80%). Since 2005, when the first delay was reported, 243 of these events have been reported with 205 fatalities, an 85% mortality.

Maryland is the only state that tracks delays in treatment. The NQF has never had delays in treatment or failure to rescue on its list of serious reportable events. The early iterations of the National Database of Nursing Quality Indicators (NDNQI)<sup>11</sup> 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.”<sup>12</sup> The AHRQ and HealthGrades now classify failure to rescue as “deaths among surgical inpatients with treatable, serious complications.”<sup>13 14</sup> This narrow definition misses the many catastrophic events that

<sup>11</sup> [https://www.qualityforum.org/Publications/2004/10/National\\_Voluntary\\_Consensus\\_Standards\\_for\\_Nursing-Sensitive\\_Care\\_An\\_Initial\\_Performance\\_Measure\\_Set.aspx](https://www.qualityforum.org/Publications/2004/10/National_Voluntary_Consensus_Standards_for_Nursing-Sensitive_Care_An_Initial_Performance_Measure_Set.aspx)

<sup>12</sup> [http://psnet.ahrq.gov/popup\\_glossary.aspx?name=failuretorescue](http://psnet.ahrq.gov/popup_glossary.aspx?name=failuretorescue)

<sup>13</sup> HealthGrades Patient Safety in American Hospitals Study, March 2011

<sup>14</sup> [www.qualityindicators.ahrq.gov](http://www.qualityindicators.ahrq.gov)

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

As noted, failure to recognize the risks or to understand the seriousness of a patient's changing condition is evident in nearly all delays in treatment. Many hospitals have implemented decision support software like modified early warning systems (MEWS) as part of the electronic medical record. MEWS tracks patients' vital signs and other physiologic markers, and alerts staff and physicians when a downward trend is occurring. If the trends are displayed on a dashboard-type report, clinicians such as hospitalists who are responsible for many patients can get real-time data on the entire hospital for a high-level view. Then they can drill down to each service, each provider or attending, each unit, and finally to each patient. 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 identify 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.

### EVENTS

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

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

patient safety officer found out about this event only when a hospital surveyor from the Office of Health Care Quality arrived to investigate a complaint lodged by the patient's family.

There were numerous, multidisciplinary proximal and latent errors with this patient's care. Even though the patient was in a high risk situation and was having severe chest pain and other subjective and objective symptoms of a heart attack, he was triaged as only a moderate risk based on the initial EKG that showed a non-ST-elevated myocardial infarction (non-STEMI). Both STEMI and non-STEMI are types of heart attacks, but this hospital had a special protocol and focus on patients suffering from STEMI. The triage nurse started the chest pain protocol but did not complete it when the ED physician was not concerned about the EKG, even after being told the patient was having severe chest pain. Because of the focus on early intervention for STEMI patients, the ED physician was focused on identifying that condition and missed the fact that the patient was suffering a non-STEMI acute heart attack. So the triage RN did not start the patient on oxygen or give him aspirin or another standard medication for chest pain. The patient was not placed on continuous cardiac monitoring as called for by the protocol and the triage nurse did not notify the ED charge nurse that there was a patient waiting who was having a heart attack. When the patient was finally taken to a room, he was left unattended, sitting on the side of the stretcher, still with no oxygen or cardiac monitoring.

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

Another elderly patient was transferred to a hospital from a small community hospital with a severe nose bleed and a rapid, irregular heart rate. Her nose had been packed with gauze at the community hospital in an attempt to stop the bleeding. The patient was admitted to an ICU-step down unit in the late evening and placed on a cardiac monitor. Throughout the night, she vomited blood several times, likely as a result of swallowing the blood dripping down the back of her throat. Around noon the next day, she was found unresponsive, not breathing and without a pulse. During attempts to insert a breathing tube, staff noticed she had a large amount of vomit in her airway and lungs. She was transferred to the ICU but as her condition continued to deteriorate, the family decided to limit life-sustaining interventions and she died approximately 24 hours after she arrested.



The hospital's RCA found a cascade of errors: The patient had fallen soon after arriving at the hospital and the hospitalist had not examined her, despite being notified by the nursing staff. The same hospitalist was notified when the patient started vomiting but again did not examine her and the nursing staff did not activate the chain of command. The very experienced charge nurse cared for the patient overnight. In the morning, a thorough report on the patient's condition was given to the on-coming nurse but the exiting charge nurse to on-coming charge nurse report was much less detailed. The patient's assigned nurse was pulled to another unit shortly after arriving and the day charge nurse took over the care of this patient without an adequate report on her condition. The charge nurse was not carrying her emergency phone because the charge nurses were in the habit of leaving them at the nurses' station for the unit clerks to answer, so when the lab called in the morning with panic values of some labs indicating the patient was becoming septic, the charge nurse did not get the message. The lab called the unit an hour later and gave a message to a nurse, who forgot to pass it on. The unit clerk had not faxed the assignments to the telemetry technicians, so when the patient dropped her heart rate just prior to arresting, the tech did not know who to call and called the clerk, who forgot to pass the message along. As far as medical coverage, the day shift hospitalist had been told about the patient but not in detail since the night hospitalist had never examined her. So when the patient arrested, the hospitalist that responded knew nothing about her.

Every staff person who interacted, or was supposed to interact, with this patient failed her. Every person downplayed her symptoms because she just had a nosebleed. There was a pervasive lack of accountability, from the hospitalists who did not examine her all night, to the charge nurses not carrying their emergency phones, and the clerks not faxing the assignments to the telemetry techs. The hospital's corrective actions included peer review for all involved providers, reinforcing the policy on phones and auditing for compliance, and auditing the dissemination of critical lab values. This hospital also started Team STEPPS and CUSP, discussed below. It seems that disseminating critical values is ripe for a redundant safeguard, in which the ordering provider would be automatically notified at the same time as the nurse, by phone, text, and/or a pop-up alert the next time the provider logged into any EMR

One-third (11) of the reported delays in treatment were associated with failing to respond to cardiac or oxygen monitoring alarms. Ten of these events were fatal and the 11th patient was left with a severe anoxic injury.

In one monitor event, an elderly patient who had been in the hospital for several weeks with a treatment-resistant rapid heart rate dropped his heart rate over the course of an hour and died with no response by either the remote monitoring (telemetry) technician or any of the RNs on the patient's unit. The hospital's RCA found that the unit had not faxed the staff assignments to the telemetry room, meaning that the telemetry tech did not know who to call when the patient started dropping his heart rate, and the tech had not called the unit to find out the assignments.

The telemetry techs were also accustomed to the nurses not answering the unit's emergency phone, so the tech did not even try to call that number. Even though this lack of responsiveness was widely known to the telemetry techs, no one had reported it up the chain of command. The hospital also found that there was no specific orientation process for the telemetry techs other than a cardiac rhythm recognition test, and no competency-based retraining or retesting.

Another patient, who was recovering from a stroke, died after a lack of response to more than two continuous hours of a low oxygen alarm. The patient was found pulse-less and not breathing in his bed and could not be resuscitated. The RCA determined that the telemetry room was short staffed, with only one tech to monitor approximately 40 remotely-monitored patients. A review by the engineering department found that the overall volume of the central monitoring at the nurses' station had been turned down to 30%. The nursing staff had a policy calling for hourly rounding on the patients and this did not occur.

Several of the monitor-associated events occurred when the alarms were silenced, sometimes repeatedly, by unknown staff without patient assessments. At least two events occurred because the nurses were in the habit of not carrying the phones by which the techs were supposed to communicate emergencies and these hospitals had cultures that did not value accountability. One adverse outcome occurred when the tech and the RN mistook the spiked beat of a pacemaker for the normal rhythm. Several of the monitor events were facilitated by equipment that had not been evaluated for failure modes. That is, the bio-medical and engineering staff had not identified that the button that permanently shuts off all alarms was directly underneath the "pause alarm" button and was accessible to the staff, or engineering had not identified and disabled volume and silence controls.

Two of the delays in treatment occurred, in part, because intensivists scheduled to be in the hospital's intensive care unit either failed to respond to nursing requests for patient evaluation or did not round on patients because they were not actually in the hospital. An intensivist has the primary responsibility for the medical care of patients in intensive care units. The original idea for these specialists was that they would provide 24-7 on-site coverage of ICU patients. If the Office of Health Care Quality receives complaints alleging that a lack of physician coverage has adversely affected patient care, hospitals may be cited for violations of the CMS conditions of participation for Governing Body and Medical Staff.

**CAUSATIVE FACTORS:**

In the adverse events discussed above, the primary causative factor seems to be complacency. 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 nearly all of the delay events, many people made assumptions

and failed to ask or communicate critical information. Staff who accept the status quo do not go up the chain of command or ask for help. For instance, one hospital had a policy that a nurse could not call for a rapid response team (usually an ICU RN and intensivist) if there was a clinician at the bedside. Even if those clinicians are two certified physician assistants (PA-C) with less than one year experience between them. The bedside nurse asked twice over an eight hour period that the very sick and deteriorating patient be transferred to the ICU. The PA-Cs refused but no one tried to get additional help from the patient’s attending physician or a nursing supervisor or nurse manager.

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. Assessments, critical thinking, and communication were the most frequently cited root causes identified in the RCAs submitted in FY16 for delay in treatment adverse events, with assessments coming in third. Only ten 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 6: FY16 Root Causes of Delays in Treatment**

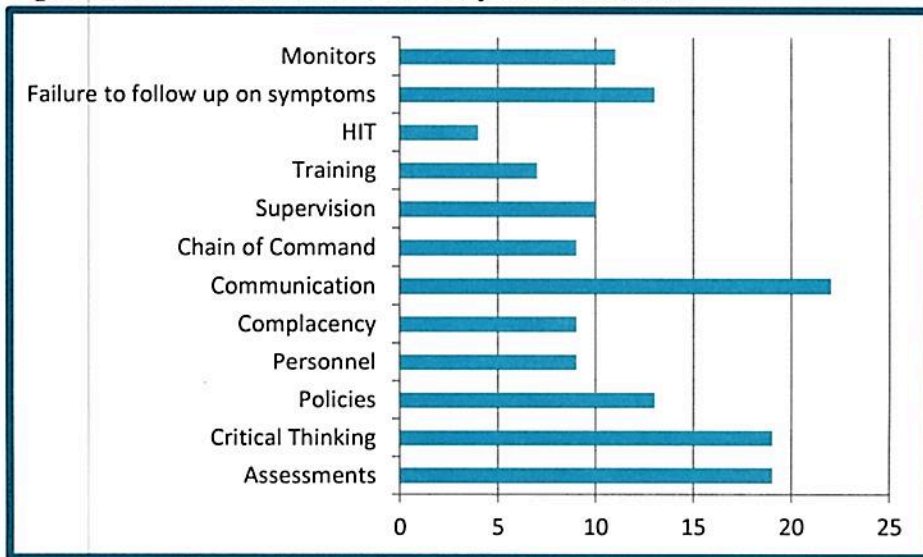


Figure 6 details the raw number of causative factors identified in RCAs submitted in FY16 for delay in treatment events. Since most events are multi-factorial, the total number of factors adds up to more than the number of events.

Since timely intervention by a more experienced clinician and more effective communication between clinical team members about the plan of care could prevent many delays in treatment, one 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 corrective action that might save lives is a culture change that puts the emphasis on cooperation, communication, and active supervision. Charge nurses and house supervisors need to make rounds and ask probing questions. If a hospital uses PA-Cs and hospitalists working overnight, the expectation must 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 FY16, there were ten 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 is consistent with FY15 and double the number reported in FY14. The number of reported retained foreign bodies was 11, Still too many, but consistent with the ten reported in FY14 and half the 23 reported in FY15. Although HealthGrades, the AHRQ HACs, HSCRC MHACs, and the NDNQI no longer track wrong procedures,<sup>15</sup> 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.

Three of the wrong procedures occurred after mix-ups in diagnostic testing. In one, a patient was admitted to a hospital with abdominal and back pain. The patient had had a work-up at an outside hospital, which sent the x-ray and CT images to the hospital electronically. The radiology staff then had to convert the images into the hospital's format and upload them into the patient's medical record. Because this process created a new medical record number for the images, another patient's images were uploaded in error. This patient had emergency surgery to repair an aneurysm that she did not have. Concerned about a possible error, the surgeon (after the surgery was completed) requested radiology review the images and it was discovered that this patient's images were normal.

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<sup>15</sup>[https://www.qualityforum.org/Publications/2004/10/National\\_Voluntary\\_Consensus\\_Standards\\_for\\_Nursing-Sensitive\\_Care\\_\\_An\\_Initial\\_Performance\\_Measure\\_Set.aspx](https://www.qualityforum.org/Publications/2004/10/National_Voluntary_Consensus_Standards_for_Nursing-Sensitive_Care__An_Initial_Performance_Measure_Set.aspx)

<sup>15</sup> [http://psnet.ahrq.gov/popup\\_glossary.aspx?name=failurorescue](http://psnet.ahrq.gov/popup_glossary.aspx?name=failurorescue)

<sup>15</sup> HealthGrades Patient Safety in American Hospitals Study, March 2011

<sup>15</sup> [www.qualityindicators.ahrq.gov](http://www.qualityindicators.ahrq.gov)

Another patient had a mastectomy after biopsy samples were mixed up at the lab. All biopsy samples from outside hospitals were piled on a cart in this lab with requisitions stuffed in the boxes or packets. There was no process for affixing the requisitions to the samples so they couldn't get mishandled, and one person stumbling into the cart would have disrupted the whole system. In addition, the print on the lab's accessioning numbers was so small that it was easy to transpose numbers. This error was not discovered until the biopsy of the patient's removed breast showed no cancer.

The third lab-mediated surgical event was a patient who had a hysterectomy based on a biopsy mix up. This lab also had no way to ensure the requisition stayed with the sample and was short-staffed so the pathologist had clerical duties. There was no private place to view the slides and there were multiple distractions that contributed to switching the results.

Every year we get one or two reports of adverse surgical outcomes associated with vendors or product representatives in the operating rooms (OR). In FY 16, a vendor handed the wrong size joint prosthesis to an orthopedic surgeon, who implanted it without checking the size. The patient had to go back to surgery the same day to put in the correct size. Most hospitals now have policies that the surgeons are not to take equipment or implants directly from vendors, only from trained hospital staff. In addition, one of the regulations under the CMS hospital condition of participation for patient rights states that patients have a right to be informed about everyone present in the OR during their surgery, including non-employee product representatives or observers.

Since 2004, 158 retained foreign bodies (RFBs) have been reported. Many of the 11 retained foreign bodies (RFBs) reported in FY16 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. For patients and procedures that carry a known high risk, the need for greater policy and procedural compliance and clear communication is also high.

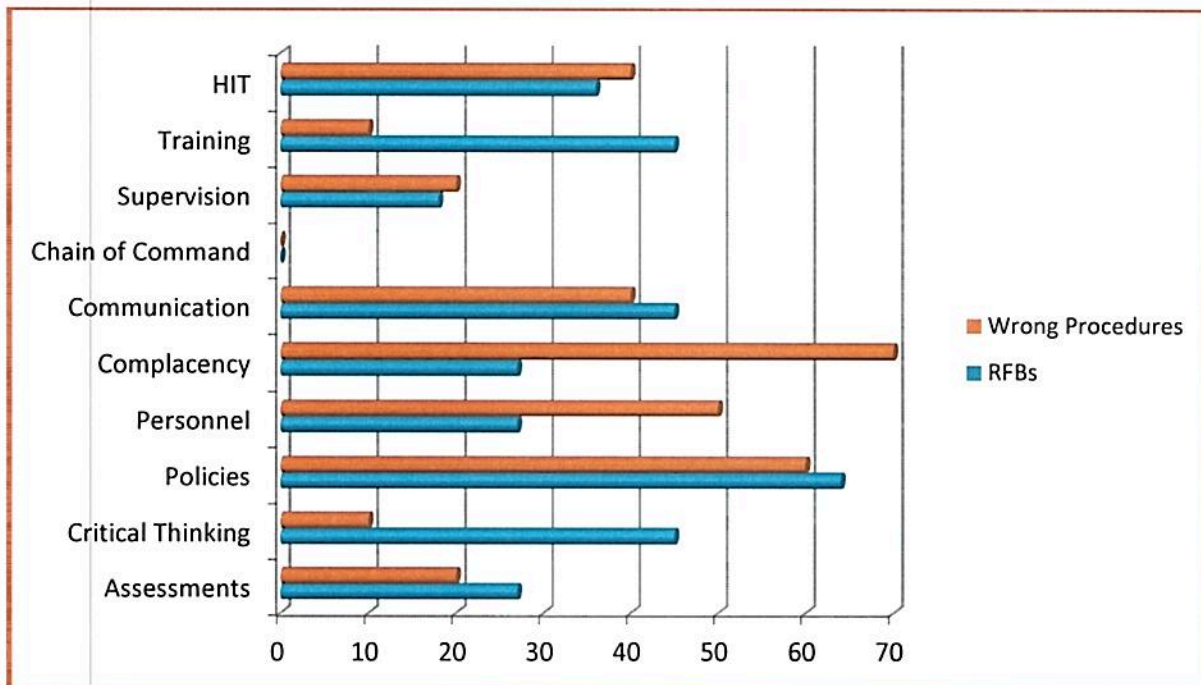
One patient had surgery and a wound vacuum was installed to pull drainage away from the wound. The wound became infected after the wound vacuum was discontinued and a CT scan identified a retained sponge used in the wound vacuum. The hospital has no policy for counting sponges, etc. used in wound dressings, even when the wounds are open or through all skin layers.

Two patients had inadvertently retained plastic molds (spacers) inserted during various surgeries to test the fit of an implanted device, for instance in a knee replacement or breast

reconstruction surgery. These hospitals also lacked policies for counting things assumed to be inserted temporarily. If something goes into a body part or cavity, it should be counted and noted.

Figure 7 details the percentage of causative factors for surgical events derived from the submitted RCAs. Since most events are multi-factorial, the total number of factors adds up to more than the number of events.

**Figure 7: FY16 Percentage Root Causes for Retained Foreign Bodies and Wrong Procedures**



According to the causative factors identified in the submitted RCAs, training and policy compliance are more problematic for RFBs than for wrong procedures. 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.

**ADVERSE DRUG EVENTS (ADE)**

Adverse drug events include both medication errors and unforeseen side effects of medications given in accordance with acceptable standards of practice. According to the AHRQ

Interim Update on 2013 Hospital-acquired Condition Rate,<sup>16</sup> 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.

The Office of Health Care Quality expects only Level 1 medication errors (those causing death or serious disability) to be reported. The eight Level 1 adverse events associated with medication use reported in FY16 is down somewhat from the previous average of 11 per year. Medication events reported in FY16 include two patients who died from untreated hypoglycemia, one fatal anticoagulation-associated event, and two patients who suffered kidney failure from antibiotics. In both of the antibiotic-associated adverse events, the physicians assumed that the pharmacy was monitoring blood levels and kidney function labs and dosing the antibiotics accordingly. One of these hospitals had not yet implemented such a robust antibiotic stewardship program. The other patient was receiving two antibiotics known for their effects on the kidneys. The pharmacy was doing an excellent job monitoring the blood levels of one of the drugs but was not monitoring the other. In addition, this hospital had recently upgraded their electronic medical record and was unaware that the blood test most relied upon to judge kidney function was no longer on the list of critical results that should have been automatically reported to the physician and the nurse.

While untreated hypoglycemia events are rarely reported, they carry an almost 80% mortality. Since 2004, 22 of these events have been reported with 17 fatalities. Of the two fatal hypoglycemia events reported in FY16, one involved an elderly patient who was admitted with sepsis, a massive infection that affected more than one body system or organ. The ED physician was very concerned about starting the sepsis protocol, but the MD and the nurses missed the very low blood sugar in this diabetic patient and no orders were written for blood glucose checks. The patient also needed dialysis prior to transfer from the ED—a delay that caused the hand-off between the ED nurse and the ICU nurse to occur three hours prior to transfer. Both the ED and the ICU nurse then left at shift change. The patient was transferred with a second-hand report. Glucose monitoring was not ordered or implemented and the patient arrested and died the next morning with a glucose of 3 (normal is 90 to 120).

There was one fatal narcotic overdose reported in FY16. It occurred to a post-surgical patient who had been prescribed acetaminophen for pain relief. The pharmacy rejected the order and rather than investigating why, the surgeon ordered 4 mg of hydromorphone intravenously

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<sup>16</sup> <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html>

(IV) as needed. Hydromorphone (Dilaudid) is 10 times stronger than morphine and the normal starting dose for an opioid naive patient is 0.6 to 1 mg. The nurse, who was fairly new and did not have a good understanding of narcotic equivalencies, gave the patient the dose after she returned from surgery. When the nurse checked on the patient an hour later, the patient was found pulseless and not breathing and did not survive resuscitation efforts.

## **Corrective Actions**

Hospitals are improving tracking and trending patient safety data and are less focused on formal discipline as a first response to an adverse event. In FY16, as in most previous years, no practitioners were referred to professional boards. But the notion of a just culture in service of patient safety does not preclude instances of individual discipline. Hospitals have a regulatory and, some would say, a moral obligation to hold staff accountable for following established, evidence-based processes and procedures. The intent of the staff member who makes an error must be considered. Was the error the result of at-risk behavior, in which a staff person willfully deviates from policy or procedure? Or was the error the result of risky behavior, that is, was the staff person impaired or otherwise incapable of complying with policy and procedure? If the answer to these questions is no, then the underlying causes of individual variations in performance must be investigated. Very few of the adverse events reported to the Office of Health Care Quality since 2004 can be laid at the feet of one clinician. Clearly, people who willfully deviate from standards by, for instance, falsifying records in an attempt to cover up an error must go through the hospital's disciplinary process. This activity should take place in parallel with the root cause analysis of the error itself.

Hospitals are advised to teach their supervisory staff how to engage in active supervision. Supervisors must look for clinicians who 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 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 one of the most often cited causes for delays, the hospital's responsibility is to design decision support systems to compensate for lapses in clinical judgment. Of course hospitals must also have systems of accountability to hold staff responsible for carrying (and answering) their emergency phones and systems to ensure periodic updates and training of monitoring technicians.

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



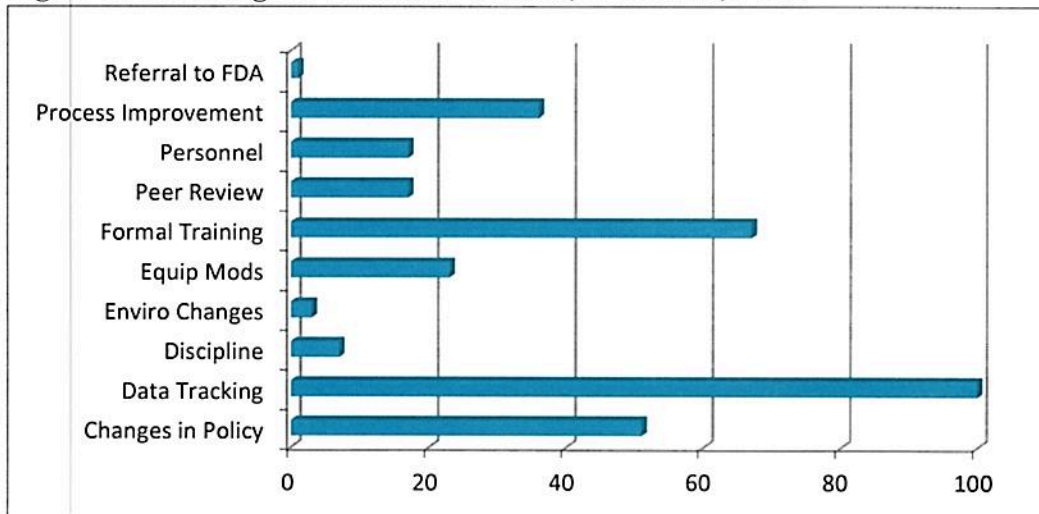
action plan. Even weak interventions like education and policy changes can be made stronger with frequent, random observations of staff behavior. Staff are unlikely to continue a short cut or policy deviation if they are observed doing so and receive on the spot correction once or twice.

More hospitals are improving problematic processes, usually by streamlining and standardizing, and are making more processes fault-tolerant, which means that safeguards are built into processes *a priori* to compensate for inevitable mistakes. More hospitals are also changing workloads and staffing in order to provide safer care. This usually does not mean acquiring additional staff, but deploying staff with more focus on patient outcomes. Examples of changing the workload include:

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

Environmental changes refer to structural changes; discipline refers to individual counseling or performance improvement plans; changes in workload generally refers to changes in staff tasks, responsibilities, or deployment; equipment modifications refers to changing the function or configuration of equipment, for instance, eliminating the ability to decrease the volume on monitor alarms; data tracking and trending refers to either mid-term or long-term tracking of performance improvement measures; the other corrective actions should need no explanation. See Figure 8 for the most common corrective actions in FY15.

**Figure 8: Percentage of Corrective Actions, All Events, FY16**



COMAR 10.07.06.03C requires hospitals to monitor the results and effectiveness of all action plans derived from the RCAs. Hospitals continue to struggle with differentiating between process steps (process measures) and evaluating how effective a corrective action has been in

remediating the set of circumstances that led to the adverse event (outcome measures). Completion of implementation is certainly something the hospital should track, but this, in and of itself, is not a measure of effectiveness. Hospitals need to determine the goals of the corrective action, and how to measure goal attainment. Each corrective action should, if at all possible, have a patient-focused outcome.

Hospitals need to ensure the corrective action is aimed at the correct cause. For instance, changing the way nurses verify that the correct patient is getting the correct procedure is not going to fix the problem of posting patients for the wrong surgical procedure. It may help catch some incorrect postings but the solution needs to be aimed at the surgeons and their offices as the originators of the problem. Many of the submitted RCAs aim all or nearly all corrective actions at bedside providers. This fact is probably due to multiple factors. Hospitals may have only, or predominantly, bedside providers on the RCA team. This type of team would naturally look at the proximal causes of events and at proximal solutions. RCA teams made up chiefly of nurses are likely to only look at nursing solutions because they may believe, rightly or wrongly, that they are powerless to affect change in other disciplines. In many of the RCAs, the corrective actions may be multidisciplinary, but the implementation and continued monitoring are assigned to nurses. Although most nurses are willing to do almost anything to improve patient outcomes, they are often powerless against 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 or an examination of failure modes. 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. If the hospitalist did not examine a patient who fell, it is

likely a habit affecting multiple hospitalist on multiple units and shifts. Piloting a solution on one or two units is a good way to start, but successful solutions will likely require wider deployment. If latent causative factors are not fixed, adverse events will recur.

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

1. Standardize as much as possible. Standardization brings processes under examination so decisions can be made about the value and evidence-based nature of activities hospital staff 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. Preference cards should be periodically reviewed for compliance with evidence-based standards.
2. Create independent checks. Independent double checks of information being used to make decisions can catch cognitive errors. To do this effectively, the person confirming the information should not be the person seeking confirmation. In other words, one person should be blind to the expected finding. Systems should be built to be fault-tolerant, in that there are sufficient safeguards built into them to make errors visible and contain them before they reach the patient.
3. Learn from mistakes. Learning from errors is a task that can be facilitated by thorough investigation into the root causes of the errors, and by sharing the results throughout the organization.

CUSP and TeamSTEPPS, another team work tool which has been around for several years, are trying to change the way clinicians interact and share information. Both CUSP and TeamSTEPPS are available through the AHRQ.<sup>17</sup>

## **Review of Root Cause Analyses**

COMAR 10.07.06.06 states:

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<sup>17</sup> <http://www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/index.html>

C. The root cause analysis shall examine the cause and effect of the event through an impartial process by:

- (1) Analysis of human and other factors;
- (2) Analysis of related processes and systems;
- (3) Analysis of underlying cause and effect systems through a series of "why" questions; and
- (4) Identification of risks and possible contributing factors.

In order to comply with the requirements of COMAR 10.07.06, the hospital must submit a root cause analysis for reported Level 1 adverse events that includes an in-depth review of the event by a multi-disciplinary team of individuals to determine, through a series of "why" questions, the actual root causes of the event. Root causes are defined by the COMAR 10.07.06 as the basic or contributory causal factors that underlie variations in performance.<sup>18</sup> Root causes are generic, in that the causative factors for a given error may occur almost anywhere in patient care areas, and may lead to the same or similar outcomes if not fixed. Root cause analyses should focus primarily on systems and processes. The hospital staff must also identify risks and contributing factors for recurrence, and determine what improvements in systems or processes are needed to prevent recurrence.

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

1. A few misidentified the level of event.
2. Several RCAs focused on what happened rather than on why, yet often lacked sufficient description of the adverse event to even determine what happened;
3. The poor quality RCAs lacked defined root causes and the information given was insufficient to establish causality;
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.

Our RCA evaluation tool, along with an example of a non-compliant RCA, is available at: [www.http://dhmh.maryland.gov/ohcq/SitePages/PatientSafety.aspx](http://dhmh.maryland.gov/ohcq/SitePages/PatientSafety.aspx)

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<sup>18</sup> COMAR 10.07.06.02 (B)(10)

## **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.

Recent changes to the federal survey process for hospitals calls for more attention to be paid to patient safety activities. During surveys for compliance with quality assurance, performance improvement (QAPI) surveyors must now look at incident reports, at the incident reporting process, and at RCAs and failure mode analyses. This process provides a double check on a hospital's patient safety program. While there has been very little overlap between patient and family complaints and the reported adverse events, our hospital surveyors have found a few reportable events through the new survey process that had not been reported to the hospital patient safety or quality manager.

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.

## **Hospital Leadership Involvement**

The Maryland Patient Safety Program regulations require that hospitals designate a staff person to function as the patient safety coordinator. When a hospital loses or changes its patient safety coordinator, the OHCQ has noted significant changes in not only reporting rates, but interest and engagement in the patient safety process. Patient safety cannot function in a silo under the direction of one person. Keeping patients safe is not just a nursing function. There must be a hospital-wide effort with the direction and involvement of hospital leadership. In addition, both CMS and The Joint Commission (TJC) require hospital-wide patient safety activities and integration of patient safety into the quality improvement, medical staff, and governing body.

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

- Providing resources for additional training of charge nurses and supervisors focused on effective patient management, leadership, and interpersonal skills;
- Regularly scheduling meetings between risk management, quality improvement, infection control, patient safety, and medical staff leaders to discuss events and to determine how the events should be addressed by the hospital;
- Reviewing actual RCAs, not merely data related to the numbers of events per patient days;
- Actively participating in a root cause analysis. Participation by leadership can provide valuable insight into the challenges faced by patients and by front line staff;
- Leadership participation also lets the staff know that administration supports the RCA process;
- Providing general oversight to the corrective action implementation process;
- Providing regular reports regarding adverse events to the Board and other executive level committees. Telling the patient's story by describing what happened or failed to happen that resulted in harm;
- Celebrating successes and adverse events avoided;
- Establishing and participating in administrative rounds that focus on patient safety;
- Educating new department heads and nurse managers about the hospital's patient safety program and how their department is expected to interface with the patient safety staff and program;

- Establishing patient safety goals and monitoring the hospital's performance for those goals; and
- Appointing a leadership representative on RCA teams during development of corrective actions. Front line caregivers are focused on front line solutions and most adverse events require some part of the focus to be on latent issues that hospital leadership is in a better position to rectify.

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

## Resources

The Maryland Hospital Patient Safety Program has a new website: <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.

Many hospitals report quality data to the Maryland Health Care Commission. Their web site is a good source for comparison data on quality in several health care settings: <https://healthcarequality.mhcc.maryland.gov/>

The Maryland Patient Safety Center<sup>19</sup> (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.<sup>20</sup> 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

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<sup>19</sup> [www.marylandpatientsafety.org](http://www.marylandpatientsafety.org)

<sup>20</sup> <http://www.marylandpatientsafety.org/MPSCPSO.aspx>

- Staff from Office of Health Care Quality have provided an update on new hospital regulations and a patient safety update annually for the past five years and have held a restraint and seclusion seminar with input from regional and nationally-known experts and local hospital representatives annually for the past three years in conjunction with the Maryland Hospital Educational Institute.<sup>21</sup>

## **Future Plans**

Integral to the success of the Maryland Patient Safety Program is the sharing of information between hospitals and in forums such as this 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 disseminate information to hospitals and other healthcare providers. The OHCQ staff continues to be available to provide training to interested groups and organizations. As noted, additional on-site surveys will be performed to identify hospitals that may not be complying with the COMAR requirements for adverse event reporting.

## **Conclusion**

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

We remain deeply concerned about the number and type of delays in treatment and surgery-related events. So far in FY17, Maryland hospitals are on track to match FY16 numbers. From July 1, 2016 to January 30, 2017, there were 14 reported surgical events, including nine RFBs, and 16 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

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<sup>21</sup> <http://www.mhei.org/>



outreach and training and in discussions with individual patient safety officers. We will continue to develop educational offerings in order to communicate patterns and trends identified through the receipt of events and the review of root cause analyses.

## APPENDICES

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### Appendix A: Maryland Hospital Demographics

Maryland regulation classifies hospitals in two groups. The majority (47) are licensed as acute general hospitals ranging in bed capacity from four to over 1000 beds. All but one of these has an Emergency Department. Some hospitals also provide specialized services such as trauma, burn, or stroke care. However, not all hospitals offer other services, such as pediatrics, labor and delivery, or behavioral health. Several acute general hospitals also operate separate units that are dually licensed as Special Hospitals, either Chronic or Rehabilitation types.

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

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

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

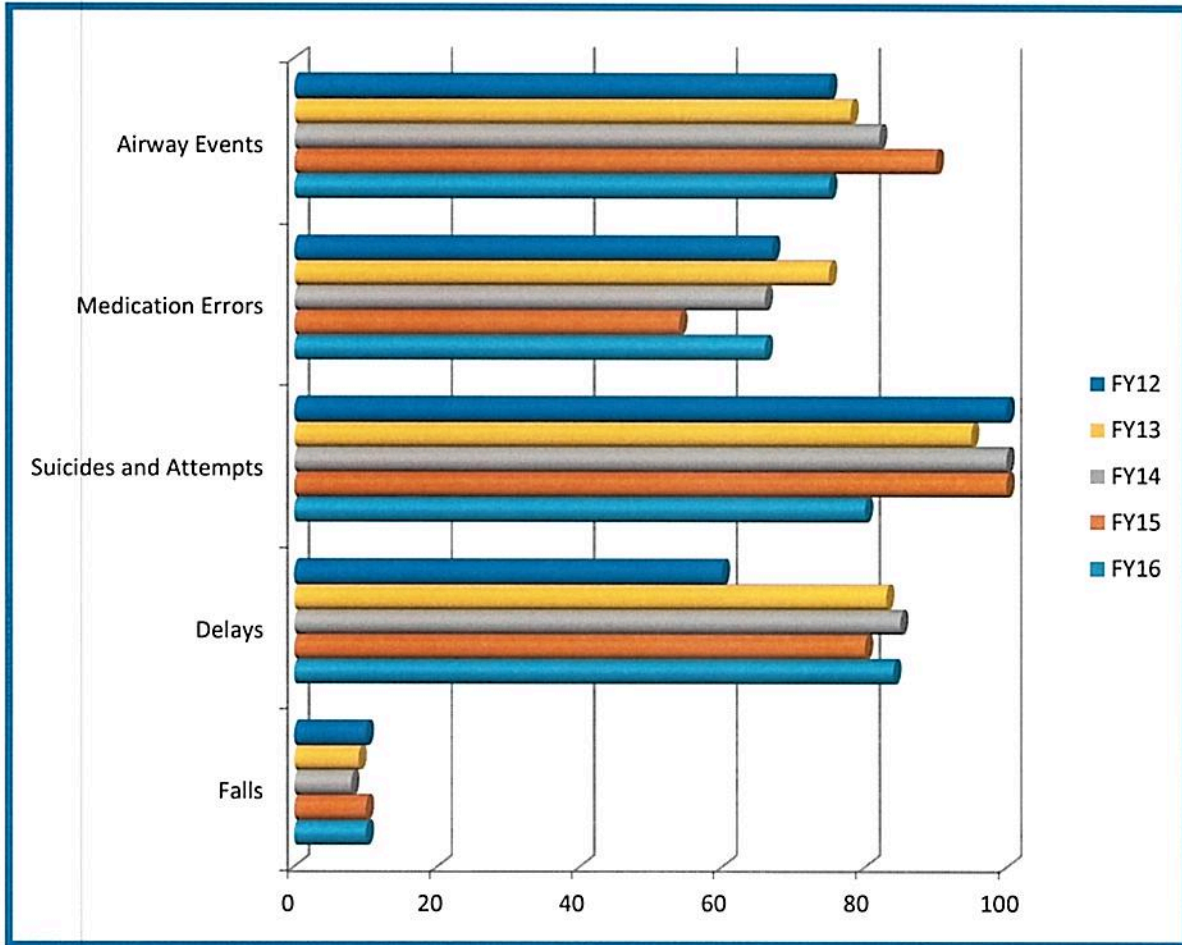
There are two Special Hospitals-Rehabilitation and two Special Hospitals-Children. The latter are also dually licensed as rehabilitation hospitals. The children's and rehabilitation hospitals have less than 100 beds each and offer limited outpatient services.

The licensed bed capacity of each acute care hospital is adjusted annually at the beginning of the fiscal year based on Health General Article §19-307.2. The licensed bed capacity is based on 140% of the hospital's average daily census. Therefore, the number of beds the hospital is licensed to operate changes on an annual basis.

## Appendix B: Types of Events

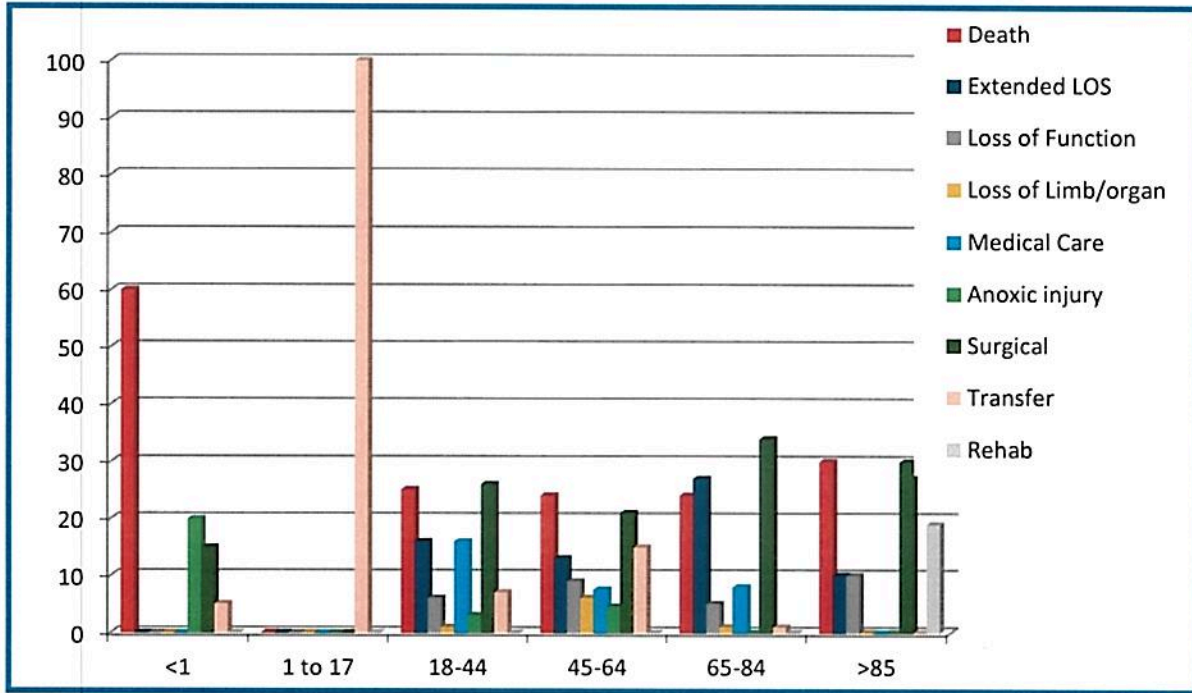
Death or serious disability associated with...	FY12	FY13	FY14	FY 15	FY16
Staff to Patient Abuse or Sexual Assault				2	4
Suicides or Serious Attempts	16	7	9	5	5
Airway Events	7	12	11	11	5
Maternal/Child	6	2	2	3	4
Medication Errors	12	10	12	13	8
Delays in Treatment	10	28	19	36	30
Misdiagnosis	2	1	2	2	1
Surgery-related Events	25	16	14	36	21
Falls	98	73	72	50	58
HAPUs	86	52	63	76	76
Restraint/Seclusion Injuries	5		4	3	1

## 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 58 reports of falls with injury in FY16, 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 and only 8 were reported in FY16.

## Appendix D: Outcomes of Adverse Events per Age



This table represents the percentage of outcomes for all affected patients by age group. There was only one reported event in the 1-17 age.

## Appendix E: Root Causes and Corrective Actions, all Event Types FY16

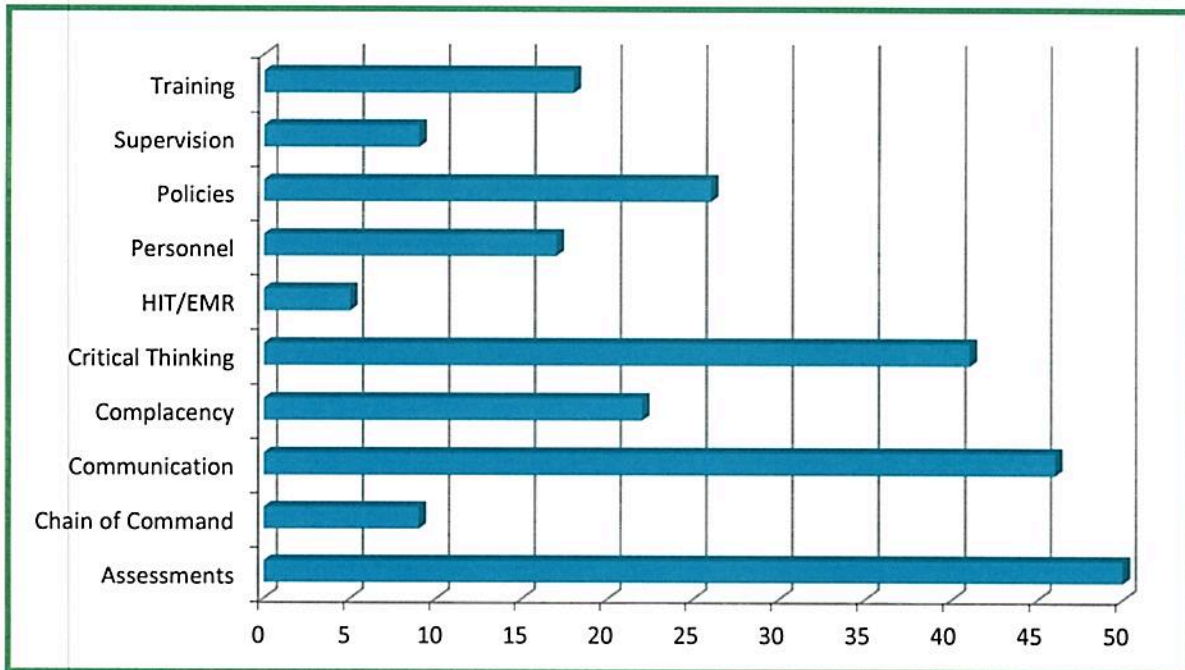
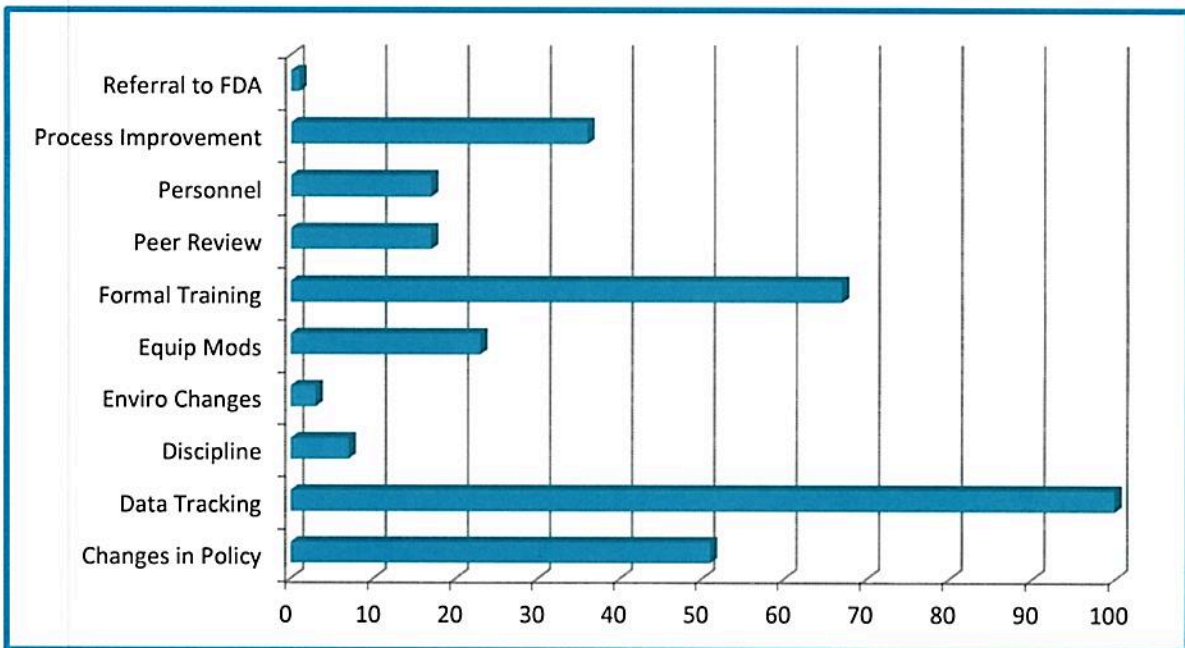
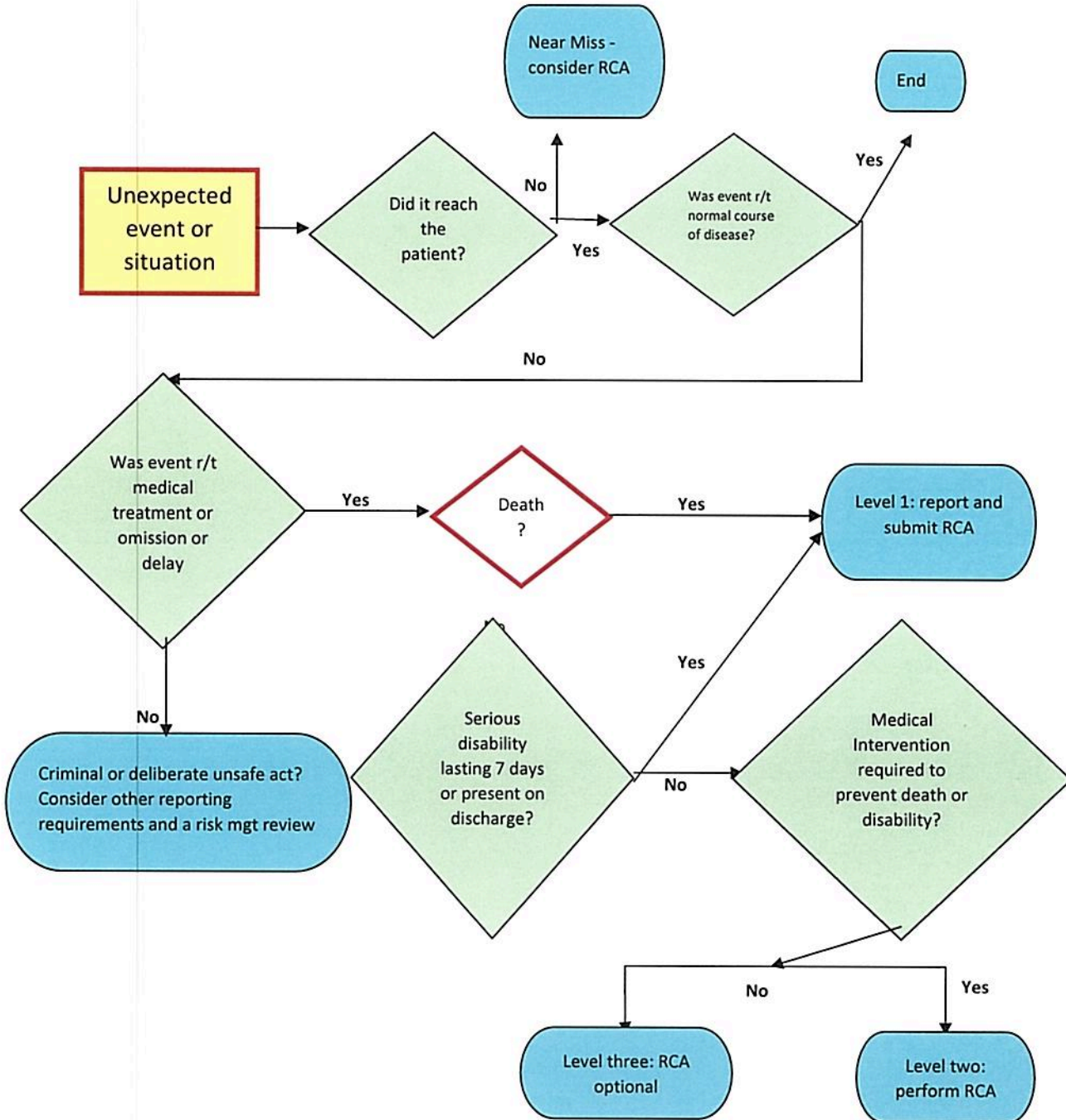


Figure E1 shows the identified root causes for all reported events, identified by RCAs, in percentage. Figure E2, below, shows the corrective action identified in the RCAs, by percentage. The reader may note that even though training is only identified as causative in 18% of events, 67% of corrective action plans include training.



## 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.