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Office of Health Care Quality

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Maryland Hospital Patient Safety Program Annual Report Fiscal Year 2012



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Foreword

I am pleased to present the 2012 Maryland Hospital Patient Safety Program Annual Report. Since March 15, 2004, Maryland hospitals have been required to report serious adverse events to the Office of Health Care Quality (OHCQ). These are unexpected events in treatment which result in a patient's death or serious injury. The Maryland Hospital Patient Safety Program continues to be an important source of information for the Department. There is little overlap between the hospitals' self-reported adverse events and the complaints received from the public. In FY12, only five reports were received as both a complaint and as an adverse event.

This year, the OHCQ is reporting on causative factors leading to adverse events that were identified in the hospital's root cause analyses. Hospitals readily identify bedside, or sharp-end, root causes to adverse events, but are less successful with identifying higher level or latent root causes. If these higher level or latent causes are not fixed, they will lead to a recurrence of the same or a similar type of adverse event. The challenge remains for hospitals to identify all root causes and then implement effective, lasting interventions with measurable outcomes.

Many hospitals have reported events that they were aware did not meet the criteria for mandatory reporting. These hospitals reported these events because they realize that serious system problems caused the errors and could occur again with more significant consequences. The OHCQ appreciates the willingness of hospitals to go beyond the letter of the law so that we can track events that should never happen again. Patient safety is not the function of the lone patient safety officer or the nursing profession in isolation. CMS and TJC require hospital-wide patient safety activities and integration of patient safety into the medical staff and governing body. Patient safety only succeeds as a hospital-wide effort with the direction, involvement and support of hospital leadership.

In conclusion, I would like to thank Anne Jones and Renee Webster for their continued dedication to ensuring quality and safe care to all Marylanders.

Sincerely,



Patricia Tomsko Nay, MD, CMD, CHCQM, FAAFP, FAIHQ, FAAHPM
Acting Executive Director and Medical Director

Executive Summary

The Hospital Patient Safety Report analyzes, both quantitatively and qualitatively, the 286 serious adverse events reported by Maryland hospitals in fiscal year 2012 (July 1, 2011 to June 30, 2012). This report compares FY12 with previous reporting years, both in types of events reported and in outcomes of those events.

Key findings include:

- Hospitals submitted 286 reports of Level 1 adverse events in FY12, down from 348 reports in FY11.
- Acute care hospitals account for 67% of all Maryland licensed hospitals and report 94% of all adverse events. Hospitals with more than 100 beds reported an average of 4.8 adverse events each, while those with less than 100 beds reported an average of 0.9 Level 1 events each.
- Pressure ulcers and falls continue to make up the majority of the reports received, with 98 and 86 reports, respectively. These two types of events account for nearly two-thirds of all reports in FY12.
- The increase in suicides, from five in FY11 to 16 in FY12, represents a troubling trend in reported events. Nine of these occurred outside the hospital shortly after discharge from emergency departments and inpatient behavioral health units.
- The post-surgical retention of foreign bodies (RFB) decreased from 17 in FY11 to 13 in FY12, with most of the reported events occurring during emergency abdominal procedures in obese patients.
- In FY12, there were 12 reports of medication errors leading to death or serious disability including one each untreated hypoglycemia and anticoagulation events. Five of the reported medication errors involved overdoses of sedatives, pain medications, and the anesthetic agent propofol.
- Commonalities among submitted poor-quality root cause analyses include: a focus on what happened, rather than why; lack of identified causality and defined root causes; and ineffective interventions aimed at the bedside with no monitoring to determine the outcomes of the interventions.

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

- Hospitals should consider requesting alert and oriented patients sign an informed declination of services when they refuse basic interventions to prevent falls and pressure ulcers. (pg. 11)
- Assessments of suicidality in patients about to be discharged should include an assessment of hazards and the availability of weapons in the home. (pg.12)

- Each suicide attempt should be considered predictive of future behavior. Inpatients with suicidal intent should be on one-to-one or arms-length supervision. (pg. 13)
- Hospitals should implement evidence based assessments, improved safety protocols, and maintain a keen awareness of environmental hazards. (pg. 13)
- Hospitals should proactively address the contributing factors that are common in medication errors, including communication failures, lack of effective medication reconciliation, dosage calculation failures, and complacency. (pg. 16)
- Root cause analysis teams should pay more attention to the role of staff supervision (or the lack thereof) in the adverse events. Many adverse events could be averted with timely interventions. (pg. 16)
- Hospital leaders should participate in the root cause analysis process to 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 root cause analysis process. Most adverse events require some analysis of latent issues that hospital leadership is in a better position to rectify. (pg.27)

As always, we are available for questions or comments.

Maryland Hospital Patient Safety Program Analysis

Fiscal year 2012 (July 1, 2011 to June 30, 2012) marked the eighth year of the Maryland Patient Safety Program. Hospital reports of Level 1 Adverse Events decreased in FY12, in part because the Office of Health Care Quality clarified the reporting requirements related to deep tissue injuries. Hospitals reported 348 Level 1 Adverse Events in FY11 and 286 events in FY12.

As in past years, this report includes several comparisons of the current year with previous reporting years. It remains difficult to quantify improvements in quality and safety, but the Office of Health Care Quality has identified improvement in individual hospitals, particularly in the rates of falls and pressure ulcers. Many hospitals continue to struggle with implementing effective, lasting interventions and with measuring outcomes, but this report includes some creative corrective actions and identifies some better practices.

For the first time, the Office of Health Care Quality is reporting on the causative factors leading to adverse events. The causative and contributing factors noted in this report are those identified in the root cause analyses (RCAs) submitted by the hospitals. Hospitals are usually very accurate with identifying bedside, or sharp-end, root causes to adverse events, but are less successful with identifying root causes that are a level or two removed from the bedside. It is these higher level or latent causes which, if not fixed, will lead to a recurrence of the same or a similar type of adverse event.

While most hospitals have integrated the reporting and analysis requirements of COMAR 10.07.06 into their risk, adverse and sentinel event management programs, a few hospitals still struggle with identifying and critically reviewing adverse events. Further, many hospitals struggle with ensuring staff and leadership buy-in for making lasting changes following close calls or patient injuries.

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 disability¹. Since the enactment of the Maryland Patient Safety Program regulations on March 15, 2004 and through June 30, 2012, a total of 1804 Level 1 Adverse Events have been reported by Maryland hospitals. In comparing reporting rates for specific adverse event categories from FY12 to prior years, the rate of Level 1 events for maternal/neonatal deaths and injuries has dropped in half, from a high in FY11 of 4% of total events to 2% in FY12. The percentage of airway misadventures also dropped from 3.5% in FY11 to 2.5% in FY12. The rate

¹ Serious disability is defined in COMAR 10.07.06.02B(11) as a physical or mental impairment that substantially limits one or more major life activities of an individual lasting more than seven days or is present at the time of discharge.

of fatal delays in treatment continued to decrease from 4.2% in FY11 to 3% in FY12. Falls and health care acquired pressure ulcers (HAPU) accounted for 64% of the Level 1 events reported in FY12, which is consistent with FY11's rate of 65%. The most significant change is the percentage of suicides, which tripled in FY12, increasing from 1.8% in FY11 to 6% in FY12. Consistent with last year, slightly more than one half of the reported suicides occurred outside the hospital soon after the patient's discharge. Of note; there were two fatal patient-to-patient assaults in FY12 and another assault that resulted in serious but not fatal injuries.

Since March 15, 2004, a total of 377 events that did not meet the criteria for a reportable event² under COMAR 10.07.06 were reported by hospitals. Fifty-six of these non-Level 1 events were reported to the Department in FY12. These events can be characterized in several ways. Some of these were adverse events that were determined after further review by the hospital or the Department to be not reportable (Level 2³ or Level 3⁴ Adverse Events or near misses). 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 system problems 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 within hours of surgery and wrong site procedures that do not harm 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 unprovable, it is better for all concerned if the Office of Health Care Quality is informed of these types of allegations. 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 Department also received two reports in FY12 that caused no immediate, obvious harm but had the potential to harm many patients in the future. In FY12, one hospital identified an error in their endoscope processing a few weeks after making a change in the chemicals used to disinfect the instruments. The company which normally supplied the chemical disinfectant ran out of the concentration in use by the hospital and substituted a chemical that required three times the processing time as the original formulation. The hospital's equipment was programmed for the shorter processing time. By the time this error was discovered, more than 100 patients had had endoscopes with improperly disinfected equipment. Another hospital reported that a patient

² Under COMAR 10.07.06. 02 B (4) the hospitals are required to report all events defined as Level 1 adverse events which result in death or a serious disability to the patient.

³ COMAR 10.07.06.02B (5) states that a Level 2 adverse event means an adverse event that requires a medical intervention to prevent death or serious disability.

⁴ COMAR10.07.06.02B(6) states that a Level 3 adverse event means an adverse event that does not result in death or serious disability and does not require any medical intervention to prevent death or serious disability

who had undergone brain surgery was later discovered to have Crutzfeld-Jacob Disease (CJD). CJD is a rare, almost always fatal brain disease that can be transmitted by infected individuals for a very long time before the infected person starts to show symptoms of the disease. It may be years before symptoms appear and the hospital may never know if other patients were infected. We want to encourage hospitals to continue to report events such as these even when the events may not have had any immediate life-threatening outcomes.

While there is likely some under reporting, especially of non-lethal events, due to the wide variability seen in numbers of events reported by very similar hospitals, there is heightened awareness among the general public, other Maryland and Federal government payer organizations, and the hospitals about the importance of identifying and addressing safety issues. Several agencies now have mandatory reporting of quality and safety data, including infection rates and core measure data to the Maryland Health Care Commission. Additionally, the work of the Maryland Health Services Cost Review Commission in incorporating rates of Potentially Preventable Complications (PPC) into the hospital rate setting process almost certainly has resulted in additional quality review and increased reporting.

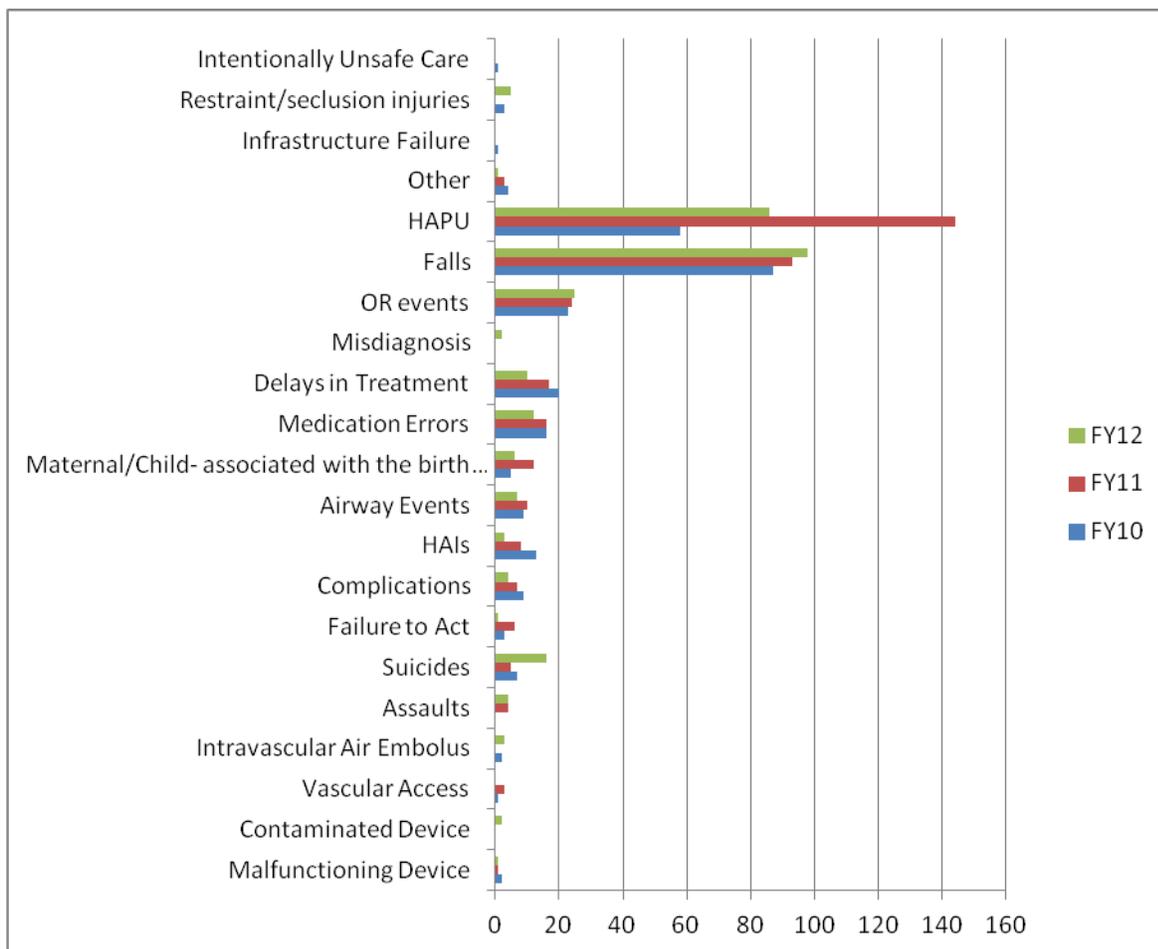
Maryland hospitals are categorized as acute general, psychiatric, chronic, children’s, and rehabilitation. Acute care hospitals account for 67% of all the licensed Maryland hospitals, but reported 94% of the Level 1 Adverse Events in FY12. Non-psychiatric specialty hospitals account for 2% of reports and psychiatric hospitals accounted for the remaining 4%. The number of reports from acute care hospitals is indicative of the acuity of patients served in these hospitals as well as the more invasive and complex services provided in acute care hospitals. During FY12, 51 of 65 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.

As noted in our previous reports, the number of events reported is higher for larger hospitals with more complex patient populations. Table 1 identifies the average number of Level 1 Adverse Events reported per hospital.

TABLE 1: FY 12 – LEVEL 1 ADVERSE EVENTS BASED ON HOSPITAL LICENSED BED CAPACITY			
NUMBER OF LICENSED BEDS	Number of hospitals	Number of hospitals reporting	Average no. of reports
301 or more beds	15	14	6.7
201 – 300 beds	16	13	5
101 – 200 beds	15	14	2.8
Less than 100 beds	19	16	0.9
TOTALS	65	51	

As mentioned, in FY12 the Office of Health Care Quality refined the types of pressure ulcers that had to be reported. We eliminated the requirement to report hospital-acquired deep tissue injuries (DTIs) unless they evolve into, or are debrided into stage III or IV wounds. Since medium sized hospitals (100-300 beds) accounted for the majority of these reports in FY11, eliminating the requirement for reporting DTIs meant that the larger hospitals once again account for more reports than medium sized and smaller hospitals (See Table 1). With a few exceptions, Level 1 reporting rates remain low for the smallest hospitals — those with less than 100 beds. The 19 hospitals with less than 100 beds reported 16 Level 1 Adverse Events in FY12. Half of the hospitals with less than 100 beds are specialty hospitals serving chronic, psychiatric, rehabilitation, or child populations and traditionally have a much lower rate of reporting adverse events.

Table 2: Types of events reported



In reviewing the types of Level 1 events reported (Table 2), the number of falls and surgical events continue to rise while the number of reports for most other events has fallen. Surgical events include all of the wrong site/patient/procedure events and the 13 retained foreign bodies. As previously reported, the number of reported suicide and suicide attempts has risen dramatically in FY12 while pressure ulcer reports have dropped equally dramatically.

OHCQ's Patient Safety Program continues to classify the types of Level 1 Adverse Events in our database using the National Quality Forum's "Serious Reportable Events."⁵ This is a nationally known classification of events used by several state reporting systems as their criteria for reporting. Since the National Quality Forum (NQF) system is nationally recognized, it enables the OHCQ to compare its data with other state reporting systems. Since the Maryland Patient Safety Program is focused on patient outcomes and the OHCQ 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 as result of 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 disability; and
- misdiagnosis.

Event Details

PRESSURE ULCERS AND FALLS

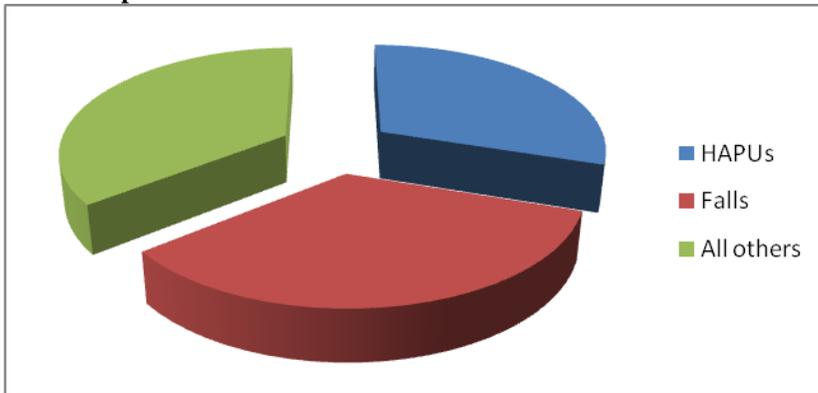
Reports of patients who developed stage III and IV pressure ulcers after admission comprised 30% of all the Level 1 reports received by the Department. The outcomes to the patient reported most frequently when pressure ulcers occur are medical intervention and extended lengths of stay. Thus far, no reported pressure ulcer has resulted in death. The causes of pressure ulcers are multi-factorial, and the prevention and treatment of pressure ulcers remains a priority for most hospitals. A unique action taken by one hospital, after having two patients develop DTIs due to their refusal to be turned and repositioned, was to show pictures of stage III and IV HAPUs to patients who refuse these basic interventions.

Falls resulting in death or serious disability to the patient remain highly reported, accounting for 34% of the Level 1 reports in FY12. Nine of the 98 falls reported in FY12 resulted in death (9.2%). This is slightly higher than the death rate of 8.6% in FY11. According to the Centers for Disease Control (CDC), falls are the leading cause of injury-related deaths in

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

those 65 and older, and most fractures in older adults are caused by falls.⁶ Please see Appendix C for a breakdown of the outcomes of the events reported in FY12.

Table 3: Events Reported in FY12



For alert and oriented patients who refuse to turn or get up, or refuse to use assistive or other fall prevention devices such as call bells, etc., hospitals may want to educate and inform the patient of the likely consequences of not cooperating with interventions, including showing pictures of pressure ulcers and statistics about falls, and get a signature on an informed refusal of care. Obviously, competent patients have the right to refuse care, and it is incumbent on the hospitals to eliminate or control obstacles to compliance (pain, etc.) but it is time to take fall prevention and pressure ulcer prevention as seriously as we take leaving against medical advice because refusing some medically advised interventions also cause dire outcomes.

PATIENT PROTECTION EVENTS

There were two highly publicized homicides in Maryland hospitals in FY11, and two more in early FY12. Three of the events occurred in one hospital and resulted in an overhaul of patient supervision and security processes. These events are certainly tragic and raise awareness of workplace violence, which has been increasing in all industries over recent years. There has also been an uptick in restraint and seclusion injuries to patients, including fractures from physical take-downs by staff, and a death in a seclusion room when the staff failed to assess the patient's condition in a timely manner. Even though the death was not caused by the seclusion episode, the staff were slow to attempt resuscitation and were not adept in using the resuscitation equipment.

As noted, 15 suicides and one attempted suicide were reported in FY12. This is a significant increase from the five reported in FY11. Nine of the suicides occurred after discharge

⁶ Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. [Web-based Injury Statistics Query and Reporting System \(WISQARS\)](#)

from the inpatient behavioral health unit or the emergency department. Three patients hung themselves, two jumped off buildings or bridges, one patient drove her car into a local body of water, one patient jumped in front of a train, one patient stabbed himself, and one patient took sleeping pills and set himself on fire.

One patient who committed suicide shortly after discharge deserves special mention. This patient had suffered from an intensely annoying medical condition (tinnitus) for a year with a half dozen ED visits and had expressed to a family member that if she did not get some help, she would kill herself because of the ringing in her ears. The family convinced the patient to go into the hospital, and she was admitted for six days to the behavioral health unit. She was placed on antidepressants but did not have any medical intervention or follow-up for the tinnitus. Shortly after discharge, she drowned after driving her car into a body of water. Because of billing realities, it is difficult for a patient to be treated for both medical and psychiatric disorders while on a behavioral health unit, but there should be a mechanism for referral or consultation when a medical condition is the primary contributing factor to the patient's mood disorder.

In a meta-analysis of world-wide studies related to suicidality and the current standard of care, published by The Suicide Prevention Resource Center in 2011,⁷ Knesper, *et al*, many evidenced-based practices to improve screening and intervention in EDs and inpatient psychiatric units were detailed. For instance, while it is difficult to determine suicidality in patients who deliberately conceal suicidal intent, better screening tools can indicate those at high risk as well as screen for access to lethal methods of suicide. Although none of the Maryland reported post-hospital suicides in FY12 used firearms, guns remain the most popular method nationwide. A quick screening in the ED can identify if the patient has access to guns and provide education for families regarding gun safety in a house with a depressed and suicidal person. Obviously, the earlier post-hospital behavioral health care can be accessed the better the outcome. Several studies cited in the above report found that simply giving a patient at risk a card with the phone number of a clinician who can be reached at any time, or even the number for the National Suicide Prevention Lifeline (1-800-273-TALK [8255]) can present the person with an alternative when in crisis.

In looking at the root causes identified in the RCAs for the reported suicides, training was not identified as a root cause. In fact, suicides are the only reported event type that does not identify training as a causative factor. But the training of clinicians who interact with at risk patients in the emergency departments (ED) is a big factor in how thorough the screening for suicide risk is performed. For instance, one of the successful post-hospital suicides was a patient with a severe hearing impairment who was seen by a mental health practitioner in the ED for expressing suicidal ideation. Without accessing any interpreter services, the mental health worker determined the patient was not suicidal and he was discharged from the ED, only to commit suicide soon after discharge. Better training of ED staff can also help eliminate some of the discrimination and subconscious bias that many somatic clinicians hold against the mentally

⁷ http://www.suicidology.org/c/document_library/get_file?folderId=266&name=DLFE-612.pdf

ill. Patients with dual symptomatology of substance abuse and mental illness can be particularly difficult to care for, yet are at higher risk for suicide than either substance abusers without mental illness, or the non-substance abusing mentally ill.

According to Knesper, the focus of care both inpatient and in the ED, needs to be on treating any suicide attempt as a distinct and dire predictor of future behavior. Rather than assuming suicide attempts are just the manifestation of the patient's underlying mental illness, similar to hallucinations and other acute psychiatric symptoms, clinicians must treat each attempt as if the next attempt will be successful (3, pg. 8).

The reported suicides that occurred on inpatient behavioral health units in Maryland were all hangings. One patient was able to poke a sheet through the grate on the exhaust fan in the bathroom; the others used sheets knotted over the hinges on the bathroom doors. As with most adverse events, communication was identified as a causative factor in all of these inpatient suicides. For instance, one patient expressed suicidal ideation to the ED nurse, but denied it to the mental health clinician. Since the ED nurse failed to document the conversation with the patient or pass the information on to the mental health clinician or to the staff on the inpatient unit during report, no specific safety interventions were implemented. Another patient had a verbal altercation with his mother and her boyfriend one evening. The next morning, the patient took a shower and washed his clothes for the first time in the four days he had been on the unit. Since the day shift was not aware of the fight the patient had the previous night, they did not consider that this new behavior indicated a new determination to kill himself. One hospital found that a patient had been evaluated twice for suicidal risk just before she killed herself, but each clinician had used a different assessment tool, and neither tool was evidence based or sufficiently rigorous to identify the imminent risk.

When caring for the patients at risk for suicide on inpatient behavioral health units, the emphasis is usually on maintaining a safe environment, assessments, and observation. And yet these fail. A patient who is actively suicidal should probably not be on every 15 minute checks but should be on continuous visual or arms-length observation. Some hospitals only assess for suicidal ideation or intent on admission, without reassessment of suicidality throughout the stay. Unfortunately these common practices are not identified as problematic until someone dies. Since behavioral health hospital stays are short, it behooves hospitals to implement evidence based assessments, improved safety protocols, and maintain a keen awareness of environmental hazards.

AIRWAY EVENTS

Four of the seven Level 1 airway events reported in FY12 occurred in specialty areas with three occurring in endoscopy labs and one occurring in the cardiac catheterization lab. Five of the seven airway events were fatal along with one patient who aspirated during an esophagogastroduodenoscopy (EGD) and recovered, and another patient who was left in a

persistent vegetative state following an endoscopic procedure when he was placed on his stomach and had low perfusion/low oxygen for approximately 30 minutes while the nurse anesthetist tried fixing the monitors rather than the patient. Two other patients had fatal aspiration events.

One very complex patient died in the endoscopy suite when he had a bronchoscopy without anesthesia present, despite the fact that both the anesthesiologist and the intensivist knew the patient was medically fragile and had a difficult airway. Neither practitioner responded to the endoscopy lab in person despite repeated phone calls; they unsuccessfully tried to manage the patient by phone.

Another patient arrested in the cardiac catheterization lab and could not be resuscitated. He had had no pre-procedure anesthesia assessment, which would have identified his difficult airway; there was no anesthesiologist on the hospital's code team, none of the interventional cardiologists had any training in managing difficult airways, and there was no difficult airway equipment on the code cart.

SURGICAL EVENTS

Thirteen Level 1 events reported in FY12 were associated with the post-surgical retention of foreign bodies (RFB). This is fewer than the 17 reported in FY11 but still too many considering the attention given to this category of events over the past decade. While most of the reported events followed the literature in that they occurred during emergency abdominal procedures in obese patients, Maryland hospitals have also reported two cases of surgical towels retained during cardiac bypass surgery and a patient who retained the tip of the arterial line after removal. The alert nurse noticed it and surgical intervention was swift. One report involved a patient in the ED who underwent three tries at peripheral IV insertion before the tip was sheared off the end of the catheter. The patient had to undergo surgery under moderate sedation to retrieve the tip when the broken IV was removed four days later. It turned out that the ED techs that commonly insert IVs are only tested for competency upon hire and receive no refreshers or retests.

One trend in RFBs deserves special mention. The Office of Health Care Quality has noted an increase in reports of objects inserted into the vagina 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 seems to be an individual decision on the part of the surgeon; one reported event involved an inflated surgical glove wrapped in a towel. Since these objects are not counted as instruments, there is no double check to ensure they have been removed. These types of RFBs have been reported to cause infections, discomfort, and difficulty urinating and, according to the COMAR, are Level 2

events, which require the hospital to perform a RCA, but the hospital is not required to submit the RCA to the office. Regardless of the level of these events, these events are serious and system changes should be implemented to prevent their recurrence.

The number of reports of wrong side surgeries, wrong patient surgeries, and wrong procedures increased in FY12 to nine. For instance, after a bowel resection, the wrong end of the colon (the proximal end of the distal colon) was made into the colostomy. The patient developed severe sepsis leading to fatal multi-system failure. In another hospital, a retrospective review of all paired internal organ surgeries was done as part of the RCA following the removal of the wrong ovary. The review revealed widespread problems with specifying laterality in gynecological procedures. No such problems were found with other paired organs (lungs, kidneys, etc.). Hospitals reported two wrong site surgeries having to do with surgery to the wrong level or side of the spinal column. There also was a report of a wrong patient undergoing a cardiac angioplasty with stent placement. The cardiologist reading the morning EKGs reported that this patient was having an acute myocardial infarction. The error was discovered after the patient had already had a stent inserted, and even though he was not having an acute MI, his condition improved. The patient who was actually having an acute myocardial infarction also went to the cardiac catheterization lab for intervention.

DELAYS IN TREATMENT

The Department received 11 reports in FY12 of delays in treatment leading to six fatalities. Two of these adverse events involved delays in reporting, reacting, or intervening in critical lab values, including one young patient who was seen in the ED for a fever with a history of a recent fall. The next day, her blood cultures showed MRSA bacteremia. This critical result was not reported to the ED physician or the patient's parents, and the child was brought back to the ED two days later in a working code and could not be resuscitated. Another four events occurred when there was a delay in recognizing and responding to critical monitor alarms; three of these delays occurred at change of shift.

One vascular patient was in need of a transfer to a higher level of care. Because of a series of miscommunications, he was still awaiting transfer 10 hours after the decision to transfer had been made, and he had been short of breath all day. When the shift changed, the patient was not assigned a nurse because everyone thought the transfer was imminent. He was found pulseless and apneic an hour and a half later and could not be resuscitated.

Two patients suffered serious neurological impairment when those caring for them failed to appreciate the seriousness of their symptoms. One of these events was an elderly patient who developed paraplegia after falling from a step ladder. He was managed in the ED by a new nurse and a second-year resident. Both documented very thorough assessments, but failed to understand the seriousness of his deteriorating function. This adverse event illustrates very well

that supervision, especially of relatively new practitioners, must be active rather than passive. The attending ED physician and the charge nurse or unit manager must be responsible for seeking out input from staff. Do your supervisory personnel make rounds, go into rooms, and otherwise seek out input from staff, or do they wait to be told the status of patients, perhaps at the end of the shift? Delays in treatment, perhaps more than any other type of adverse event, can often be prevented by timely interventions from more experienced practitioners.

MEDICATION ERRORS

In FY12, the Department received 12 reports of medication errors leading to death or serious disability including one each untreated hypoglycemia and anticoagulation events. Two of the events involved the new direct factor Xa inhibitor anticoagulants Arixtra and Pradaxa. The timing of these drugs relative to stopping heparin or low-molecular weight heparin is different from warfarin. Arixtra and Pradaxa must be started within a couple hours of discontinuing heparin. In one case involving these drugs, the pharmacy order defaulted to starting the Arixtra 24 hours after the heparin was discontinued. The patient developed a pulmonary embolus and arrested and died before the Arixtra was started. In the other case, the low-molecular weight heparin was not discontinued when the Arixtra was started, resulting in a fatal massive intracranial hemorrhage.

Five of the reported medication errors involved overdoses of sedatives, pain medications, and the anesthetic agent propofol. Consistent with the literature, these events had several contributing factors in common including communication failures, lack of effective medication reconciliation, dosage calculation failures, and complacency. Hospitals should proactively address these contributing factors associated with medication errors. In one instance, a very obese patient with known obstructive sleep apnea came to the ED with a painful non-healing wound of the abdomen. She was given Dilaudid twice for pain and each time, she became hypoxic and required doses of Narcan. These events were not passed on to the admitting physician, and were not included in the report to the medical-surgical floor. Included in the admitting orders was an order for Dilaudid 0.5 mg intravenously for pain. She was given a dose soon after arrival on the floor and within one half-hour, was found in respiratory failure, had to be intubated, and spent two weeks in the ICU.

Another patient arrived in the ED from a long-term care facility with respiratory distress, a pre-existing tracheotomy and an order for lorazepam 0.25 mg twice a day. While writing the admitting orders, the physician neglected to consult the medication list sent with the patient from the facility and apparently guessed at the dosages of medications. This resulted in the patient getting 1 mg of lorazepam twice a day. Because the patient had cognitive impairment, she was not able to make her needs known. She was boarded in the ED for two days and received the lorazepam. After she was admitted to the floor, the nurse failed to differentiate between the patient's pre-existing anxiety and the anxiety caused by respiratory failure. The patient suffered a

profound anoxic injury and died two weeks later. Part of the hospital's corrective actions included designating four beds in the ED as medical-surgical beds with dedicated nursing, physicians, and pharmacy coverage. One factor contributing to both of these events is that the EDs use an electronic medical record that is not visible to the staff on the inpatient units. When beds in the ED are designated medical-surgical, the documentation is done in the main hospital system.

Two of the reported medication errors involved rarely used and poorly understood protocols. One patient was given two doses of heparin and aspirin within 24 hours of receiving a clot-busting drug in the ED. The protocol for this treatment is only used two to three times a month and the actual form of the protocol is very similar to other protocols for heparin. The hospital made several changes to the form to differentiate it from the others and created several visual aids to assist decision making. In the second event, the patient affected by a poorly understood protocol actually had three medication errors during her brief hospitalization. This patient had been found in an arrest situation, was resuscitated in the field and brought to the ED and was placed on a hypothermia protocol. The first medication error was an overdose of propofol during intubation. The second error was an overdose of fentanyl just after the dose of propofol. The order was written as micrograms per kilogram of bodyweight per hour (mcg/kg/hr) rather than micrograms per hour (mcg/hr). The patient received 175 cc of fentanyl in 45 minutes before the error was discovered. Both of these errors occurred in the ED, and caused respiratory failure and severe low blood pressure. When the patient was sent to the ICU, she was supposed to start on an anticonvulsant after getting a loading dose over one hour. The electronic order entry defaulted to 60 hours rather than 60 minutes, and the nurse started the medication at a rate of 1.6 cc per hour, equivalent to 60 hours. The error was discovered several hours later by the on-coming shift. The patient continued to seize and died a few days later.

One of the medication errors involved medications in use in the operating room when the circulating nurse and the first assistant drew up the surgeon's preferred mixture of ropivacaine, Toradol, and epinephrine to be injected into a joint. These medications were all drawn up in one 60cc syringe. The nurse miscalculated the dose of epinephrine and 15cc was drawn up, instead of 1.5cc. When this mixture was injected, the patient went into ventricular tachycardia and had a ST-elevated myocardial infarction. She spent several days in the ICU before recovering. The root cause analysis (RCA) focused on sharp-end interventions, including enforcing the rule that all injectable medications must be drawn up in separate syringes and labeled. The RCA did not mention the latent cause of this event, which was the use of non-standard and non-evidence based preference cards in the operating room.

Another reported medication adverse event had to do with a patient in the post-anesthesia care unit (PACU) who had low blood pressure and was ordered a dose of ephedrine. Since ephedrine was not kept in the drug dispensing machine in the PACU, the nurse went to the operating room. The medication dispensing machine was being restocked and the pharmacy technician held up a vial of epinephrine that was to be used for irrigation in surgery. The RN took the epinephrine and administered it to the patient, who had cardiac symptoms, then went

into acute renal failure and had to undergo hemodialysis for several weeks until he regained renal function. The hospital found several problems; the PACU staff rarely gives ephedrine and was unfamiliar with dosing and administering it, and the epinephrine in use in the OR is packaged in multidose vials but it was not clear from the labeling that it was intended for a diluted irrigation. In addition, neither the EPINEPHrine nor ePHEDdrine were labeled in the recommended distinctive tall-man lettering. The pharmacy promptly removed all medications intended for irrigation from the OR and PACU and will now make the irrigating solutions in the pharmacy, they changed the labels to make them easier to tell apart, and they retrained the PACU staff on the use of ephedrine.

HEALTHCARE ASSOCIATED INFECTIONS

The Department received only three reports of healthcare associated infections (HAIs) in FY12. Since COMAR 10.07.06, Patient Safety Programs, requires reporting of HAIs only when the patient is seriously injured or dies, the majority of the received reports are of fatalities in which it is fairly clear that the HAI was the cause of death. Two of the three reported HAIs were fatal; the non-fatal event was a patient who developed cellulitis following surgery and had to undergo several surgical debridements and weeks of antibiotics. One patient developed fatal encephalitis two days after back surgery. The other patient died of a septicemia from a catheter-associated urinary tract infection. The patient had a urinary catheter inserted for the critical monitoring of his output. After the critical period had passed, he kept the catheter for another two weeks. The hospital instituted a policy that anyone needing that acute level of monitoring should be in the ICU, and the catheter should be discontinued no later than transfer out of the ICU.

Reports of HAI resulting in death or serious disability are often not reported to the department for weeks after the care was rendered. Further complicating the reporting of healthcare acquired infections are factors identified in previous annual reports. These include the short length of patient stays in hospitals; HAIs may not be apparent at discharge and the patient may be treated for the infection at the doctor's office postoperatively or at another hospital, making it difficult if not impossible to capture this information. Confirmatory laboratory cultures may take several days to identify the infection. Therefore, HAIs may not be communicated in a timely manner to the hospital's patient safety officer or to the Department. Infection control regulations added to COMAR 10.07.01 in 2008 require collaboration between the hospital's infection control practitioner and the patient safety/quality assurance departments. The CMS Condition of Participation (COP) for Infection Control also requires interaction between the hospital's governing body, infection control, and quality assurance departments.

Age and Adverse Events

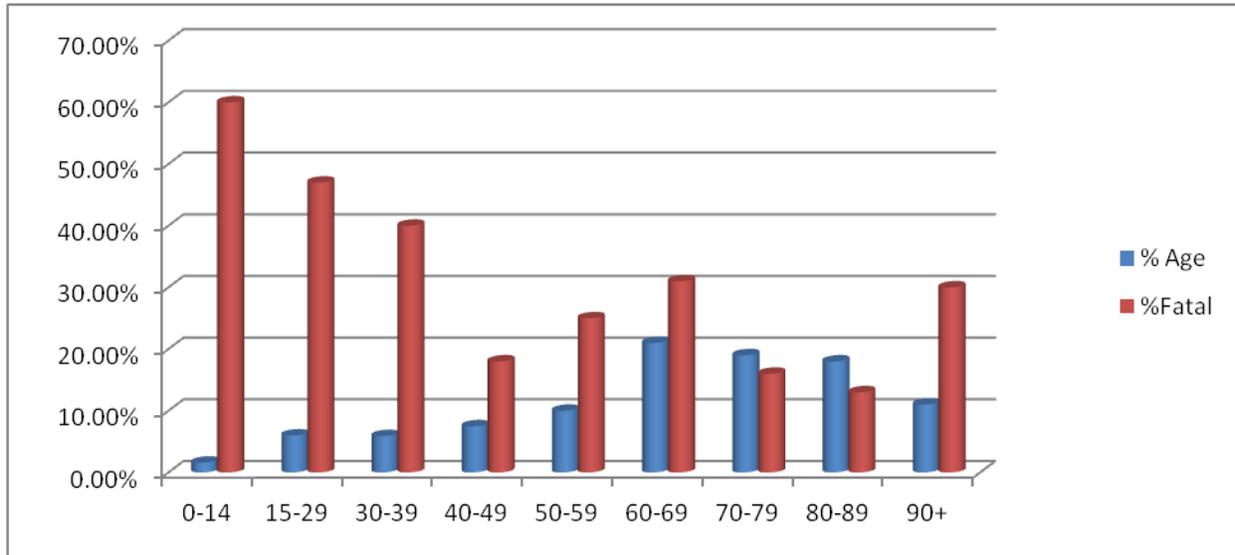


Table 4: All Years Age and Fatality Rate

Table 4 is an expression of the fatality rate for all event types for all years by age of patient (when known). The number of adverse event occurring to the young are low as a percentage of the total, but the fatality rate is high. The distribution of event types across age groups is consistent with three exceptions: Obviously perinatal deaths only occur during the birth process; then starting around the mid-sixties, falls and pressure ulcers begin to make up the bulk of the reported events. Falls and pressure ulcers have a high incidence but low mortality which is why the mortality rate reverses from age 70 to 90. After 90, patients are generally sicker, more debilitated, have fewer reserves and are less able to survive adverse events. See Appendix C for more data on age and outcomes.

Notifying Patients and/or Families

The Maryland Hospital Patient Safety Program and Maryland regulations require a hospital to notify a patient, or if appropriate, a patient's family member, whenever an outcome of care differs significantly from an anticipated outcome. Hospitals continued the trend of the previous six years of reporting that patients and/or the family were notified of an adverse outcome. In FY12, 6% of the adverse events were not reported to the patient/family but the hospitals almost always had a reason, for instance, the patient had no family or specifically requested they not be told. More than a few patients who fall are embarrassed and request that the staff not notify their family members. As in previous years the Department cannot determine the quality of the disclosure, but we can tell that there is improvement in hospital policies regarding the type of disclosure, with most policies specifying that the attending physician is to make disclosure as he or she already has the relationship with the patient.

Review of Root Cause Analyses

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.⁸ Root causes are generic, in that the causative factors for a given error may occur almost anywhere in patient care areas, and may lead to the same or similar outcomes if not fixed. Root cause analyses (RCAs) 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.

In FY12, hospitals submitted over 300 root cause analyses to the Department. These root cause analyses were reviewed by the staff of the OHCQ and feedback was provided to the hospitals. The OHCQ continues to utilize the root cause analysis evaluation tool designed for that purpose. Since the program began, nearly 1600 root cause analyses have been reviewed and feedback provided to the hospitals. Additionally, over 90% of that feedback is provided within sixty days of the receipt of the RCA.

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. In FY12, the Department singled out six RCAs from five different hospitals for this type of review. The RCAs had been submitted by new patient safety officers and the decision was made to provide direction and assistance rather than deficiencies. There were several commonalities among these poor-quality RCAs:

1. Each RCA focused on what happened, rather than why, yet they lacked sufficient description of the adverse event to even determine what happened;
2. These six RCAs lacked defined root causes and the information given was insufficient to establish causality;
3. Probably because causality had not been determined, the interventions lacked specificity and had outcome measurements that were inadequate to determine if the corrective actions had any effect on the problematic process(es); and
4. Hospitals continue to focus on bedside, sharp end, corrective actions for adverse events.

⁸ COMAR 10.07.06.02 (B)(10)

The overwhelming problems with poor RCAs continues to be superficial analyses that fail to uncover anything other than first level or proximate causes for the events. Many of the RCAs reviewed mentioned that “why” questions had been asked, but no answers were given in the RCA and the corrective action did not reflect an in-depth level of analysis. In some RCAs, there is not enough information provided for Office of Health Care Quality reviewers to determine what the adverse event was. Following are summaries of two of the RCAs received in FY12, with discussion.

ROOT CAUSE ANALYSIS NO.1

A young patient was taken to the PACU following orthopedic surgery. The physician wrote orders for pain medication to be given in the PACU as Dilaudid, 0.25 to 0.5 mg IV, not to exceed 2 mgs an hour. The PACU RN documented that she gave the patient 3 mgs over the first hour. The patient’s monitor then alarmed low heart rate and low oxygen saturation for approximately 20 minutes, which went unnoticed until the patient arrested. He was resuscitated, intubated, and spent two weeks in the ICU while the staff tried to wean him off the ventilator.

The RCA focused solely on the actions of the RN. The analysis was very superficial and was focused on what happened with little investigation into why it happened. The RCA mentioned that the staff are highly trained and up-to-date on competencies, but this statement is contradicted by the event itself. The RCA does not mention what the other staff were doing at the time of the event. Did no one else notice the monitor alarms? Who was in charge of the PACU and what was that person doing during the time this patient was deteriorating? Most performance deviations have an antecedent system failure, and this RCA, like many others, does not investigate deeply enough to find that antecedent.

Since the RCA team could not identify causality other than the nurse’s failure to follow orders and closely monitor the patient, the corrective actions are likewise superficial and focused at the bedside. Re-training a highly trained workforce and admonishing them to more closely monitor their patients will have no lasting effect and will certainly not prevent a recurrence.

ROOT CAUSE ANALYSIS NO.2

In the second event, an elderly patient was admitted after falling at home and fracturing her hip. Since she had been on anticoagulation for some time, she had to wait four days for her coagulation status to normalize before undergoing an internal fixation of the fracture. The patient had also been on a mood stabilizer and an antipsychotic, which were not continued after admission. This abrupt discontinuation of her medications meant that by the time the patient underwent surgery, she was agitated, combative, in a lot of pain, and stating her intent to kill herself. During surgery, the patient suffered a mild myocardial infarction (heart attack). On post-operative day one, an agency nurse was caring for the patient and was trying to get some pain

relief for her. However the nurse was calling a physician who was not on call. When the physician called back to say that she was not on call, the message never got to the nurse. In addition, the wrong attending was listed on the medical record. The family came in later and called the actual attending, who came at once. It was later determined that the patient had dislocated her hip.

The RCA says there were knowledge deficits regarding the differences in the care delivery models between the two units the patient was on, but does not define these or explain why the differences are relevant to the outcome. Many more “why” questions needed to be asked. Why did the nurse not go up the chain of command when he/she did not get an answer from the physician? Where was the unit manager or charge nurse? Is it within the standard of care to admit a patient to a medical – surgical unit who had suffered an intra-op myocardial infarction? Why was medication reconciliation not done upon admission? Why was the family not consulted about the patient’s medications? Why was the fact that the wrong attending was listed on the medical record not caught for five days? Why was the on-call list not up-to date.

Instead of answering these questions, the RCA focused on the bedside nurse. While there are certainly questions to be asked about the nurse’s failure to go up the chain of command, this nurse was set up for failure by the lack of effective supervision, the lack of an up-to date on-call schedule, the missed communication from the physician, and the lack of training regarding care specific to the orthopedic population. In addition, the poor patient management regarding psychiatric and pain medication made the patient much more difficult to manage, and made it impossible to tell if the patient was having more post-op pain than expected—a clue that might have prompted earlier identification of the dislocated hip.

Because the RCA was superficial, so too were the corrective actions. One good idea was that the orthopedic unit would create a one-page fact sheet that would explain care issues specific to the orthopedic population. This sheet would be given to agency or other temporary staff at the start of their shifts. This is the kind of generic corrective action that should be expanded to other units. Creating a fact sheet, which notes care needs, specialty equipment, and the chain of command should be developed and used by each unit with a specialized population.

Most of the RCAs that fail to meet the requirements of COMAR 10.07.06 have failed to consider the latent issues of accountability, supervision, training, and decision support for staff. Hospitals must start addressing these problem areas or adverse events will continue. For instance, in the PACU event noted above, was that nurse the only nurse in the PACU at the time of the event? It seems unlikely. How does the hospital support individual accountability and adherence to standards of practice? Is unit supervision active or passive? Do your charge and management personnel receive additional training about effective supervision and intervention? Do your charge nurses have the resources (time and staff) needed to effectively manage their shifts?

ROOT CAUSES

The following table looks at the root causes identified in the RCAs for the most common events, excepting falls and pressure ulcers.

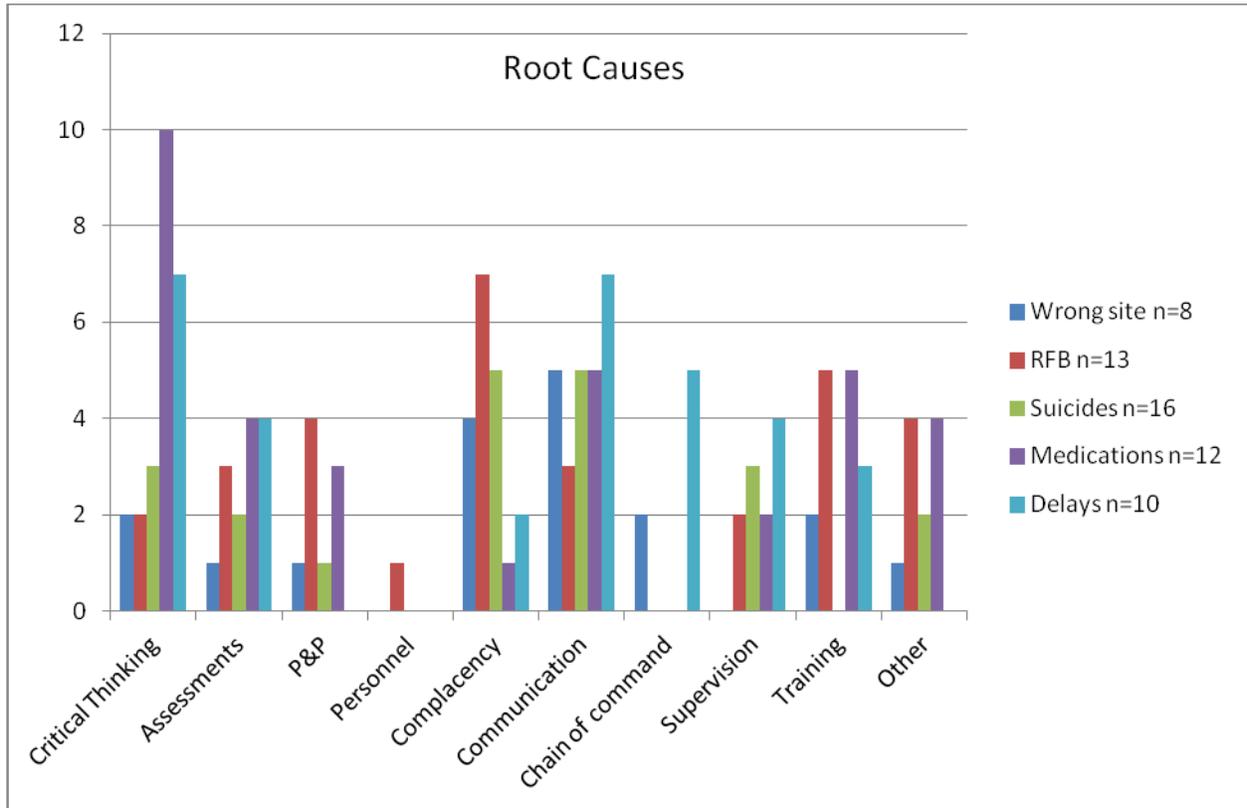


Table 5: Root Causes, FY12

Chain of command is noted to be a root cause in only wrong site procedures and delays in treatment. Training is identified as a root cause in all types of events except suicides; supervision is noted to be a root cause in all but wrong site surgery while personnel is noted to be a root cause only in RFB events. Out of 59 Level 1 events reviewed for table 5, only 11 note supervision as a root cause and only seven identify chain of command as a root cause. Clearly, most adverse events are multi-factorial and occur after a cascade of system failures and poor decisions on the part of several people. It is troubling that supervision and chain of command are not identified as root causes in every event since a timely intervention by someone with more knowledge or expertise could prevent most adverse events.

CORRECTIVE ACTIONS

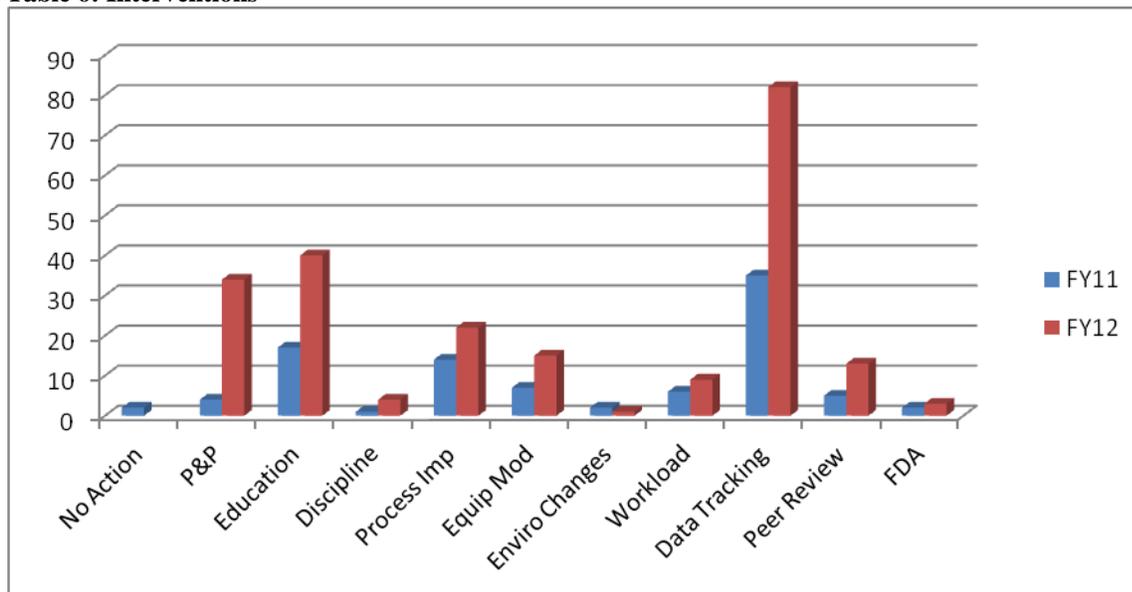
Hospitals continue to struggle with implementing corrective actions that will be long-lasting and effective at controlling or eliminating the hazardous condition. As noted in Table 6, education and policy changes are very popular interventions. In FY12, we also noted some stronger actions. More hospitals are improving problematic processes, usually by streamlining and standardizing, and are making more processes fault-tolerant, which means that more safeguards are built into the process 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 can supervise and assist all the nurses, or
- 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.

COMAR 10.07.06 requires the hospital to monitor the results and effectiveness of all action plans derived from the RCA. 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 that is not a measure of effectiveness. Hospitals need to determine what the goal of the corrective action is, and how to measure that goal. What impact will this action have on the problematic process? Will this action eliminate or control the problem and how will you know? What is the goal for other patients undergoing this process? What do you expect from the staff and how will you ensure they are meeting expectations? Even relatively weak actions like policy changes can be made more effective with frequent, random staff observations.

Table 6: Interventions



Complaints

In addition to receiving the reports of adverse events, the Office of Health Care Quality serves as the state regulatory and licensing agency for hospitals and other health care providers. As the regulatory agency, the OHCQ is the recipient of complaints regarding Maryland hospitals. Regulatory agencies consider complaint investigation to be a valuable tool in the monitoring of quality in a licensed facility. In FY12, the OHCQ received 432 complaints from patients, families and other citizens.

Since the Maryland Patient Safety regulations were implemented on March 15, 2004, the OHCQ has also received 1804 reports of Level 1 Adverse Events. Through the review of RCAs these reports have also proven to be a valuable tool in the monitoring of hospitals. During that same time frame the OHCQ has received 3,122 complaints from citizens. There continues to be little overlap between the self-reported adverse events and the complaints received from the public. Approximately five reports were received through both sources (as a complaint and as an adverse event) in FY12. Since adverse event reporting became mandatory, only 33 or 1.8% of the adverse events received were also received as a complaint submitted to the OHCQ from other sources. The data obtained from the complaint process has little relevance to the number and type of adverse events occurring in Maryland hospitals. This lack of duplication indicates that the vast majority of patients or families affected by serious adverse events do not file complaints about those events. The mandatory reporting and the review of RCAs provides another tool for the Department to evaluate how well hospitals are addressing serious problems.

When a complaint is received by the OHCQ that appears to be a reportable Level 1 Adverse Event, a surveyor is assigned to investigate the complaint in accordance with the complaint investigation processes. If the findings indicate that the complaint was an adverse event and that the event was not reported by the hospital, additional review may be warranted to examine the hospital's patient safety program. Evidence that the hospital failed to have a program or failed to report may result in deficiencies and possible sanctions.

The 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 adverse events. After eight years, we have received reports from all acute general hospitals and from all but one specialty hospital. We assume that hospitals with robust reporting systems are actually safer than hospitals that under report. What is 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%? 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, an on-site survey of the hospital's compliance with COMAR 10.07.06 can 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.

Leadership Involvement

The Maryland Patient Safety Program regulations require that hospitals designate a staff person to function as the patient safety coordinator. The OHCQ has noted significant change in not only reporting rates but interest and engagement in the patient safety process when a hospital loses or changes its patient safety coordinator. Patient safety cannot function in a silo under the direction of one person. Keeping patients safe is not just a nursing function. It must be a hospital-wide effort with the direction and involvement of hospital leadership. In addition, both CMS and 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:

- Regularly scheduled 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.

- Review actual RCAs, not merely data related to the numbers of events per patient days.
- Actively participate 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.
- Provide regular reports regarding adverse events to the Board and other executive level committees. Tell the story about the patient by describing what happened or failed to happen that resulted in harm.
- Celebrate successes and adverse events avoided.
- Establish and participate in administrative rounds that focus on patient safety.
- Attend the training on patient safety provided by your hospital or by the Maryland Patient Safety Center.
- Educate new department heads about the hospital's patient safety program and how their department is expected to interface with the patient safety staff and program.
- Establish patient safety goals and monitor the hospital's performance for those goals.
- Consider having a leadership representative on RCA teams during development of corrective actions. Front line staff are focused on front line solutions, and most adverse events require some part of the focus be on latent issues that hospital leadership is in a better position to rectify.

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." In FY12, *Perinatal Deaths: A Call for Teamwork* was published.

Clinical Alerts may be obtained at: <http://dhmh.maryland.gov/ohcq/HOS/SitePages/Alerts.aspx>

The Office of Health Care Quality also sent out several patient safety notices through the Maryland Patient Safety Center's patient safety manager listserv on various topics of immediate interest.

The Maryland Patient Safety Center

The Maryland Patient Safety Center⁹ (MPSC) brings patient safety professionals together to study the causes of unsafe practices and put practical improvements in place to prevent errors. Designated in 2004 by the Maryland Health Care Commission, the Center's vision is to make Maryland hospitals and nursing homes the safest in the nation.

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

- Regular contribution to training workshops sponsored by MPSC;
- Speaking at various events including the annual Maryland Patient Safety Conference, MedSafe, and the Falls Collaborative Update conference.
- Attendance and updates when requested at the MPSC Patient Safety Directors' meetings; and
- Attendance and assistance with special projects.

Future Plans and Conclusion

Starting in FY12, the Office of Health Care Quality started sending hospitals yearly report cards that list the number and type of event reported, and any downgraded or outstanding RCAs. The report cards are sent out on a quarterly basis to approximately 25% of facilities. They include an attestation, modeled after those in use in other states, in which the patient safety officer agrees with the list and attests that there were no other Level 1 events during that 12-month period. We have sent report cards to all hospital as of the date of this report and the feedback has been encouraging. The report cards are another way for Office of Health Care Quality to track and trend events and for the hospital patient safety officers to double-check their records.

As previously noted, we recognize that there are many new patient safety coordinators at the hospitals. In order to assist patient safety staff, the OHCQ has consolidated its patient safety tools into a folder and made it available for training or as a refresher for hospital staff. The OHCQ would like to compile this information to develop a Patient Safety Tool Kit and make it available on the OHCQ website. We ask that hospitals provide contact information, including email addresses, for new patient safety coordinators to our office.

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

⁹ Maryland Patient Safety Center www.marylandpatientsafety.org

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 organizations.

The OHCQ also takes advantage of opportunities to interact and share with other state patient safety programs. Beginning in FY10, the staff of the OHCQ has actively participated in the National Quality Forums /Agency for Healthcare Research and Quality sponsored *Improving Patient Safety through State Based Reporting in Healthcare* initiative. Meetings and periodic conference calls provides a forum for staff of state based reporting programs to exchange ideas, discuss best practices and share the challenges faced in operating reporting programs.

Additional plans for the dissemination of information continue to include:

- Research and publish best practices for commonly occurring Level 1 Adverse Events;
- Support for the collaboratives sponsored by the Maryland Patient Safety Center;
- Identification of hospital-specific trends and patterns and assisting hospital to develop methodologies to address repeated similar events;
- Identify trends and patterns of poor RCAs submitted by specific hospitals; and
- Participation in the educational offerings provided by Maryland Patient Safety Center.

In conclusion, the Department is pleased to see that most hospitals are engaged in patient safety activities through the increased reporting of events, the continued improvement of the quality of root cause analyses submitted and the continued reported disclosure of adverse outcomes to patients and families. The Department will continue to engage hospitals in the process through our participation in opportunities for outreach and training. We will continue to develop Clinical Alerts as a means 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 (46) are licensed as acute general hospitals ranging in bed capacity from nine to 1000 beds. All but one of these has an Emergency Department. Certain hospitals also provide specialized services such as trauma, burn and stroke care. However, not all hospitals offer certain other services, such as pediatrics, labor and delivery and/or behavioral health. Several acute general hospitals also operate separate units that are dually licensed as Special Hospitals, either Chronic or Rehabilitation types.

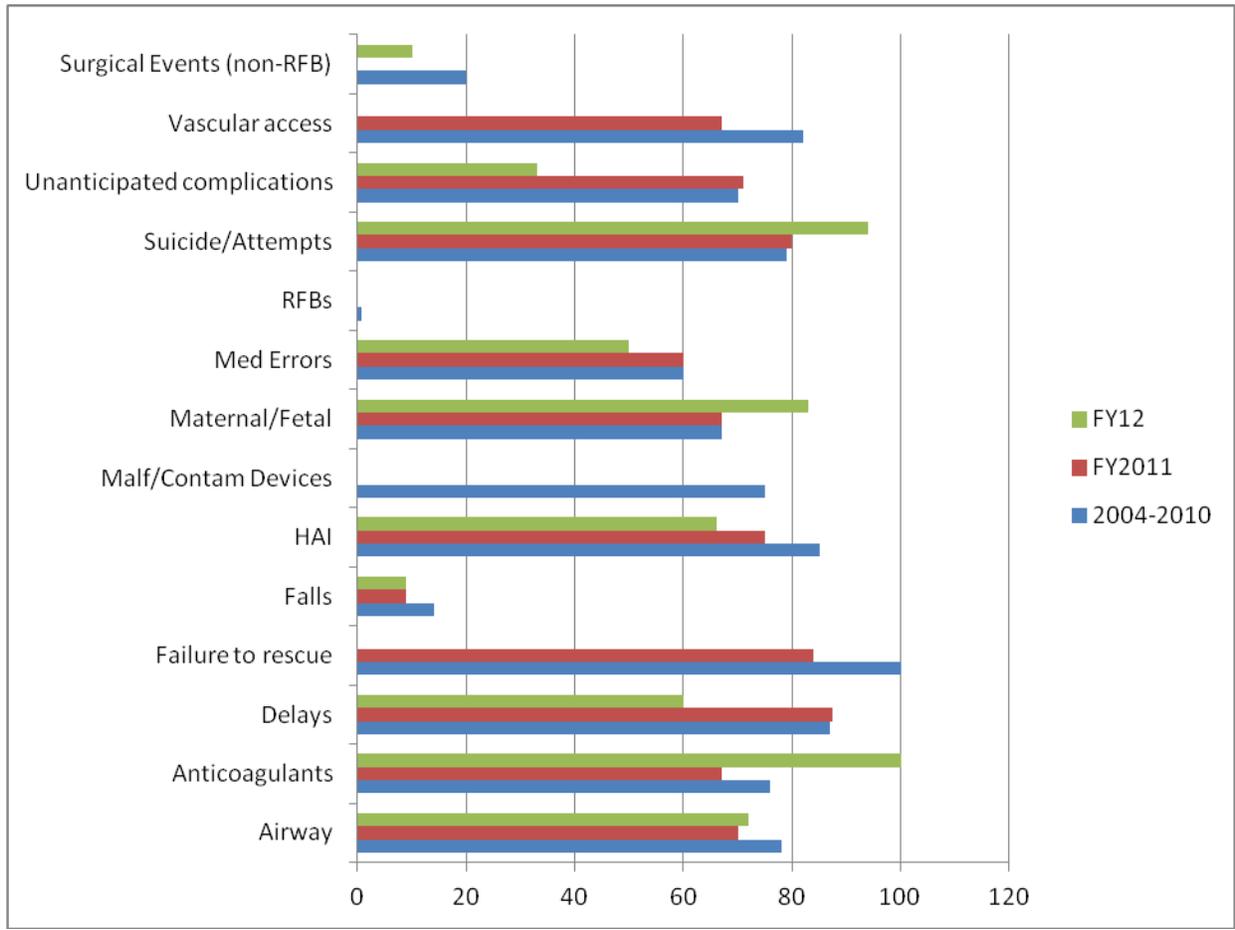
The licensed bed capacity of each acute care hospital is adjusted annually at the beginning of the fiscal year based on Health General Article §19-307.2 and is based on 140% of the hospital's average daily census. The number of beds the hospital is allowed to operate therefore changes on an annual basis. This statute does not apply to special hospitals.

1. Twenty two hospitals are licensed as special hospitals. There are four types: rehabilitation, chronic, children's, or psychiatric. Special hospitals do not have operating rooms, emergency departments or intensive care units where patients would undergo more invasive and complicated procedures.
 - a. The 11 Special Hospitals-Psychiatric range in size from 15 licensed beds to 639 beds.
 - b. Five of these hospitals are State operated.
 - c. Three psychiatric hospitals serve only specific populations (children, forensics, and clergy).
2. Of the four Special Hospitals - Chronic, four serve patients who are ventilator-dependent or who have chronic respiratory problems. These hospitals range in size from 60 to 180 beds.
 - a. Two are operated by the State of Maryland. While all provide some rehabilitation services, two of the hospitals are dually licensed as rehabilitation hospitals.
3. 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 102 beds each and all offer outpatient services.

APPENDIX B: TYPES OF EVENTS

Type of Event	FY10	FY11	FY12
Death or serious disability - fall	88	93	98
Hospital acquired Stage III or IV pressure ulcers	59	144	86
Suicide or attempted suicide	6	5	16
Post-surgical retention of foreign body	15	17	13
Death or serious disability - medication error	9	10	10
Death or serious disability - delay in treatment	20	17	10
Surgical Procedure not consistent with consent/ wrong patient/ wrong body part	4	2	8
Death or serious disability – airway management	9	10	7
Death or serious disability -restraints seclusion, or side rails	3	0	5
Unanticipated fetal death or injury	5	8	5
Death or serious injury - physical/sexual assault occurring within or on hospitals grounds	0	4	4
Unanticipated complication of treatment	9	7	4
Death or serious injury of patient -HAI	13	8	3
Death or serious disability - intravascular air embolism	2	0	3
Intra-op or post-op death in ASA 1 patient	1	1	2
Misdiagnosis	2	1	2
Death or serious disability - contaminated drug, device or biologic	0	0	2
Death or serious disability - burn	1	1	2
Maternal death or serious disability associated with Labor & Delivery	0	4	1
Death or serious disability - anticoagulants	4	2	1
Death or serious disability - failure to act	3	6	1
Death or serious disability - hypoglycemia	1	4	1
Malfunctioning device	2	1	1
Other	4	3	1
Unanticipated intra-op or immediate post-op death	2	2	0
Intentionally Unsafe Care	1	0	0
Infrastructure Failure	1	0	0
Death or serious disability - vascular access device	1	3	0

APPENDIX C: COMPARISON OF FATALITY RATES

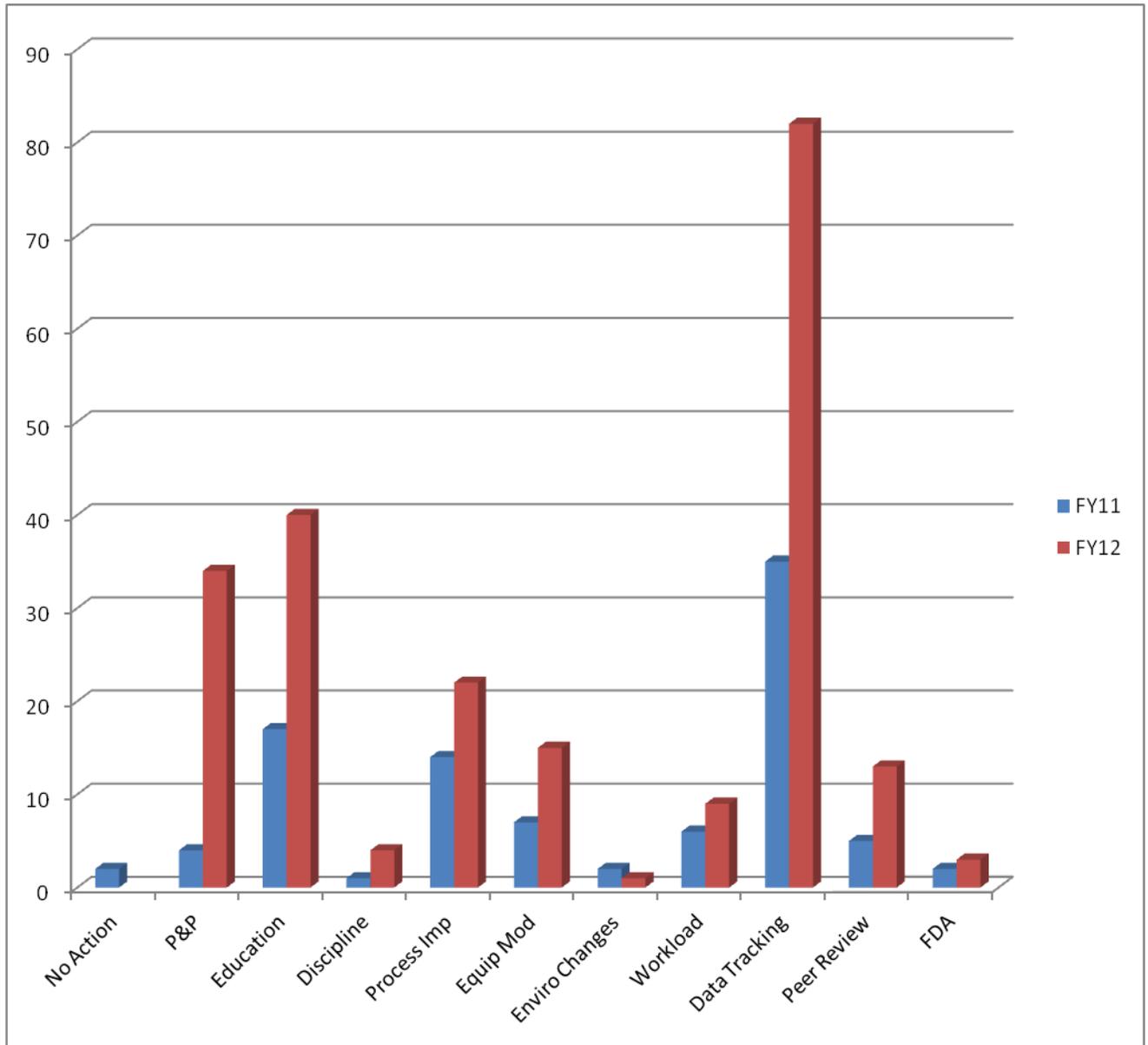


For some events, like falls, the number is very large but the fatality rate over the past seven years is low. Many other event types have consistent fatality rates, but occur less often. For instance, in FY12, anticoagulant events had 100 percent mortality, but only one event was reported. The following graph depicts the fatality rate by patient age group.

APPENDIX D: OUTCOMES FOR FY12 LEVEL 1 EVENTS

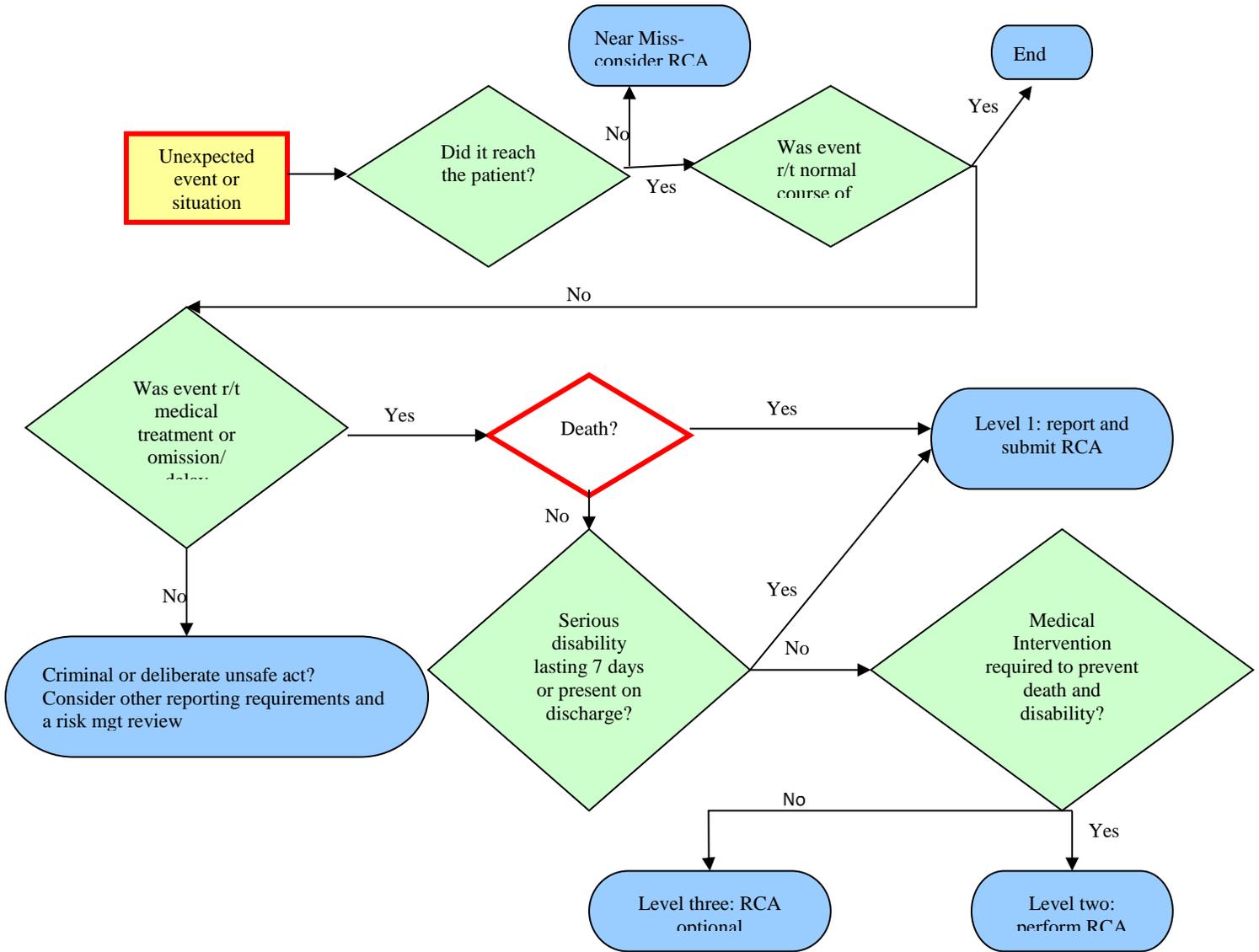
	Fatal	Anoxic injury/ PVS	Surgery	Increased Length of Stay	Transfer to a Higher Level of Care	Loss of Function	Loss of Limb Or Organ
Air embolism	1				1	1	
Airway	5	1			1		
Anticoagulation	1						
Burns					2		
Contaminated device							
Delay	6	1	1			2	
Fail to act							
Falls	9		55	5	13	14	2
Fetal Death or injury	4	1					
Healthcare acquired infections	2		1				
Pressure ulcers				82	3		1
Intra-op deaths	2						
Malfunctioning device			1				
Medication Error	5	1	1	1	1	1	
Misdiagnosis	2						
Other							1
Physical Assault	2				1		
Restraints	3		2				
Retained foreign bodies			11		1		1
Sexual Assault				1			
Suicide	15				1		
Surgical events	1	1	5	1			1
Unanticipated Complication	1		1			1	

APPENDIX E: CORRECTIVE ACTIONS IDENTIFIED IN RCAs



Percentage of interventions for all RCAs, FY11 and FY12.

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 goes into disseminated intravascular coagulation 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 and dies, this is a reportable Level 1 event, even if the development of the SDH was the result of an underlying coagulopathy. 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. Serious disability is defined in 10.07.06 as a physical or mental impairment that substantially limits one or more major life activities of an individual lasting more than seven days or still present at the time of discharge.