

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

**Maryland Hospital Patient Safety Program
Annual Report
Fiscal Year 2014**



*Lawrence J. Hogan, Jr., Governor
Boyd K. Rutherford, Lt. Governor
Van T. Mitchell, Secretary
Patricia Tomsko Nay, M.D., Executive Director*

Table of Contents

Executive Summary	3
Maryland Hospital Patient Safety Program Analysis	5
Mandatory Reporting of Adverse Events	5
Classification of Events	6
Reports of Non-level 1 Events	8
Reporting Adverse Events	9
Event Details	10
Delays in treatment	10
Airway Events	16
Surgical Events	17
Medication Errors	19
Suicides	20
Healthcare-Associated Infections	21
Unusual Adverse Events	22
Causation	23
Patient Age and Adverse Events	24
Review of Root Cause Analyses	25
Corrective Actions	27
Notifying Patients and/or Families	29
Leadership Involvement	30
Clinical Alerts	31
The Maryland Patient Safety Center	31
Future Plans	32
APPENDICES	34
Appendix A: Maryland Hospital Demographics	34
Appendix B: Types of Events	35
Appendix C: Comparison of Fatality Rates	36
Appendix D: Identified Causation per Event Type, FY14	37
Appendix E: Outcomes for FY14 Level 1 Events	38

Executive Summary

On behalf of the Office of Health Care Quality (OHCQ), we are pleased to present the Maryland Hospital Patient Safety Program's Annual Report, State Fiscal Year 2014. Since March 15, 2004, Maryland hospitals have been required to report serious adverse events to OHCQ within five days of becoming aware of an adverse event. These are unexpected events that result in a patient's death or serious injury.

Hospital patient safety is not solely the function of the stand-alone patient safety officer. The Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC) require hospital-wide patient safety activities and integration of patient safety into the medical staff and governing body. Patient safety only succeeds as a hospital-wide effort with the direction, involvement and support of hospital leadership.

The Hospital Patient Safety Report analyzes, both quantitatively and qualitatively, the 206 serious adverse events affecting 227 patients reported by Maryland hospitals to the Office of Health Care Quality in fiscal year 2014 (July 1, 2013 to June 30, 2014). This report compares FY14 with previous reporting years, both in terms of the types of events reported and the outcomes attributable to those events.

Key findings include:

- Hospitals submitted 227 reports of Level 1 adverse events in FY14, consistent with the 223 Level 1 events reported in FY13.
- Hospitals with over 301 beds reported an average of 5.4 events each in FY14, up from FY13, but down significantly from 6.4 events reported per hospital in FY12.
- Falls and pressure ulcers continue to make up the majority of the reports received, with 72 and 63 reports, respectively. These two types of events accounted for 60 per cent of all reports in FY14.
- Inpatient and outpatient suicides, after hitting a high of 16 in FY12, dropped to only seven in FY13 and nine in FY14.
- Reports of airway misadventures, which previously averaged eight reports a year, increased to 12 in FY13 and 11 in FY14. Two-thirds of these reports came from mid-sized hospitals of 201-300 beds.

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

- One way to decrease delays in treatment is to provide timely intervention, such as by supervisors who are actively engaged with assessing the well-being and the care being provided to all patients on the unit. Among other interventions, supervisors can

activate the chain of command and facilitate timely assessments and definitive treatment.

- Hospital processes should be standardized as much as possible across similar care areas. For instance, the obstetrical operating suite should have the same policies for counting equipment as the general OR.
- Hospitals should consider requesting that anesthesia providers evaluate the airways of patients with known or suspected difficult airways upon admission, rather than waiting and being unprepared for emergency interventions.
- Assessments and updates of skills such as dysrhythmia identification must occur periodically, not just at the time of hire.
- Hospitals need to proactively address the contributing factors that are common in medication errors, including communication failures, lack of effective medication reconciliation, dosage calculation failures, and complacency.
- Root cause analysis teams must 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 by a more experienced staff person.
- 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.

As always, we are available for questions or comments.

Sincerely,



Renee B. Webster, REHS
Assistant Director, Hospitals and Labs
Office of Health Care Quality



Anne Jones, RN, BSN, MA
Quality Initiatives Nurse
Office of Health Care Quality

Maryland Hospital Patient Safety Program Analysis

Fiscal year 2014 (July 1, 2013 to June 30, 2014) marked the tenth year of the Maryland 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 individual hospitals, such as decreases in the reported rates of falls and pressure ulcers. Many hospitals continue to struggle with implementing effective, lasting interventions and with measuring outcomes. Nonetheless, this report includes some creative corrective actions and better practices undertaken by hospital-based teams.

The Agency for Healthcare Research and Quality (AHRQ) published a study in late 2014 demonstrating that there had been a 17% decrease in hospital-acquired conditions (HACs) since 2010.¹ Nine percent of the reduction in HACs occurred from 2012 through 2013. The AHRQ reviewed many data sources, including CDC data on healthcare-associated infections (HAIs) and discharge diagnosis data from the Medicare program, to arrive at that number. Our data for FY13 aligned with this national finding. In Maryland, we observed a 22% reduction in reported events from FY12 to FY13. During FY14, hospitals reported 227 Level 1 Adverse Events, consistent with the 223 events previously reported in FY13. Although we were unable to determine factors responsible for the decrease in reported events from FY12 to FY13, this observed reduction is consistent with the nationwide trend. The AHRQ estimates that, from 2010 to 2013, 50,000 lives have been saved by a concerted effort on the part of hospitals to reduce adverse events. A non-risk adjusted extrapolation of this statistic indicates that between 500 and 600 lives have been saved in Maryland during that timeframe.

The March 2014 CDC progress report on HAIs² includes state-specific data. While the overall rate of central line-associated blood stream infections (CLABSI) is down 44% from 2010, Maryland hospital data show mixed results. We have reduced CLABSIs to 45% of the national average of 0.56 per 1000 discharges. Concurrently, catheter-associated urinary tract infections (CAUTIs) are 89% higher than the national average of 1.03 per 1000 discharges. Maryland HAIs will be discussed further in another section of this document.

Mandatory Reporting of Adverse Events

A Level 1 Adverse Event is defined in COMAR 10.07.06 as any event that causes death or serious disability.³ Since the enactment of the Maryland Patient Safety Program regulations on

¹ <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html>

² <http://www.cdc.gov/hai/progress-report/>

³ 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.

March 15, 2004, through June 30, 2014 a total of 2,220 Level 1 Adverse Events have been reported by Maryland hospitals. In comparing reporting rates for specific adverse event categories from FY14 to prior years, we note:

- The percentage of delays in treatment dropped from 15% in FY13 to 9% in FY14.
- The percentage of Level 1 events for maternal/neonatal deaths and injuries has again dropped, from a high in FY11 of 4% of total events to 0.8% in FY14, when two fatal neonatal events associated with delayed C-sections were reported.
- Airway misadventures accounted for 6% of total reported events in FY13 and 5% in FY14.
- Falls and health care acquired pressure ulcers (HAPU) accounted for 60% of the Level 1 events reported in FY14. This percentage has remained stable for four years.
- Reported suicides increased slightly from 4% in FY13 to 5% in FY14. In FY12 6% of reported events were suicides. All nine suicide attempts reported in FY14 were lethal, in contrast to only two such outcomes reported during FY13.
- We received several reports of previously unreported event types, to be discussed later.

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"⁴ taxonomy. This is a nationally known classification schema used by several state reporting systems as their criteria for reporting. Given that the National Quality Forum (NQF) system is nationally recognized, it enables the OHCQ to compare its data with other state reporting systems. Because the Maryland Patient Safety Program is focused on patient outcomes and 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 injury; and
- misdiagnosis.

There is likely to be some under reporting, especially of non-lethal events, as reflected in the wide variability seen in numbers of events reported by very similar hospitals. At the same time, there is heightened awareness among the general public and other Maryland and Federal government payer organizations, as well as 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.

⁴ National Quality Forum. "Serious Reportable Events in Healthcare—2006 Update." Washington DC: 2007

Additionally, the work of the Maryland Health Services Cost Review Commission to incorporate rates of Potentially Preventable Complications (PPC) and Maryland hospital-acquired conditions (MHACs) into the hospital rate setting process has resulted in additional quality review of patient care and potential adverse events.

Maryland hospitals are categorized as acute general, psychiatric, chronic, children’s, and rehabilitation. Acute general hospitals account for 73% of all the licensed Maryland hospitals. They reported 92.5% (210) of the Level 1 Adverse Events in FY14. Non-psychiatric specialty hospitals accounted for 4% of reports, while psychiatric hospitals accounted for the remaining 3.5%. The number of reports received from acute care hospitals is indicative of the acuity of patients served in these hospitals as well as the more invasive and complex services provided in acute care hospitals. The 20 hospitals with less than 100 beds reported 15 Level 1 Adverse Events in FY14. Half of the hospitals with less than 100 beds are specialty hospitals serving chronic, psychiatric, rehabilitation, or pediatric populations. These smaller hospitals typically report adverse events at a lower rate than do the larger hospitals. During FY14, 44 of 63 hospitals reported at least one Level 1 Adverse Event. An overview of the types and sizes of hospitals licensed in Maryland is provided in Appendix A.

Table 1: FY14 – Level 1 Adverse Events

Number of Licensed Beds	Number of Hospitals	Average Reports per Hospital FY13	Average Reports per Hospital FY14
301 or more beds	12	4.0	5.4
201 – 300 beds	18	5.5	4.2
101 – 200 beds	13	3.9	2.8
Less than 100 beds	20	0.9	0.7

In FY13, Maryland’s largest hospitals reported fewer events per hospital, on average, than hospitals with 200-300 beds. This seems to have been an anomaly. Hospitals with over 300 beds accounted for 35% (147) of the adverse events reported in FY14, while hospitals with 201 to 300 beds reported 28% (135) of the adverse events.

For FY14, with a few exceptions, the number of reported events is down for all categories of events (see Table 2). According to the AHRQ report,⁵ there are multiple factors contributing to a decrease in adverse events or hospital-acquired conditions. 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) apply incentives designed to reduce HAIs, adverse drug events, falls, pressure ulcers, and readmissions. For example, in 2010 CMS created a program called Partnership for Patients (PfP)⁶ to make care safer and to improve care transitions. One of the project goals was that, by the end of 2014, preventable hospital-acquired

⁵ <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html>

⁶ <http://partnershipforpatients.cms.gov/>

conditions (HACs) would decrease by 40%, thereby resulting in approximately 1.8 million fewer injuries to patients. The AHRQ Progress Report indicated that hospitals had achieved 1.4 million fewer harm events by the end of 2013. The second goal of the PfP project is that errors occurring during transitions in care would decrease by 20%. Achieving this goal would save 1.6 million patients from being readmitted within 30 days of discharge from a hospital.

Table 2: Received Level 1 Event Reports

Death or serious disability associated with...	FY11	FY12	FY13	FY14
Malfunctioning Device	1	1		1
Contaminated Device		2		
Vascular Access	3			1
Blood Incompatibility				1
Intravascular Air Embolus		3		
Burns				2
Elopement				2
Assaults	4	4	2	5
Suicides	5	16	7	9
Failure to Act	6	1	1	1
Complications	7	4	1	1
Healthcare-associated Infections	8	3	9	5
Airway Events	10	7	12	11
Maternal/Child	12	6	2	2
Medication Errors	16	12	10	12
Delays in Treatment	17	10	28	19
Misdiagnosis		2	1	2
OR events	24	25	16	14
Falls	93	98	73	72
Pressure Ulcers	144	86	52	63
Other	3	1	2	1
Infrastructure Failure			1	
Restraint/seclusion injuries		5	4	3

REPORTS OF NON-LEVEL 1 EVENTS

Since March 15, 2004, a total of 479 events that did not meet the criteria for a reportable event⁷ under COMAR 10.07.06 were reported to the Maryland Patient Safety Program by

⁷ 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.

hospitals. Thirty-nine of these non-Level 1 events were reported to the Department of Health and Mental Hygiene (the Department) in FY14. Some were initially reported as Level 1 events; yet, were downgraded after further review by the hospital or the Department. Additionally, many hospitals have also reported events that they are aware do not meet the criteria for mandatory reporting and are not Level 1 Adverse Events. These hospitals have reported these events because they realize that serious systemic problems may have caused the errors and could occur again with more significant consequences. Burns that occur in the OR do not usually cause Level 1 injuries, but many hospitals report these events when they occur even if the injuries are minor. For FY14, the two reported burn events caused one death (from smoking in bed) and one serious disfigurement due to a chemical burn in the OR. Retained foreign bodies that are removed during the same surgical occurrence and wrong site procedures that do not cause serious harm to patients are also reported by hospitals regardless of the presence of serious disability or death. Over the years, we have also received several reports of alleged sexual assaults occurring in hospitals. While most of these reports have turned out to be unfounded or not proved, it is better for all concerned if the Office of Health Care Quality is informed of these types of allegations by the hospitals, rather than by the media. This report will discuss the sexual assaults reported in FY14 later in this document. 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. 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 not caused by preventable error.

Reporting Adverse Events

COMAR 10.07.06, Patient Safety Programs, mandates reporting adverse events within five days after the hospital becomes aware of the event. Reporting events must include the following information:

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

Event Details

DELAYS IN TREATMENT

The OHCQ defines delays in treatment as untimely assessments of evolving symptoms or changes in a patient's condition, and/or a delay in definitive treatment. Most patients who deteriorate do so over hours. Even patients who have an acute cardiac arrest usually show deteriorating vital signs for hours prior to the actual event. Delays in treatment (often referred to as "failure to rescue") are 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.⁸ For instance, as reported in FY14, failing to act during hours of hemorrhage led to the deaths of two patients. Monitoring the patient for changes in vital signs, changes in oxygen saturation, and changes in mental status are basic assessments that should trigger some action when abnormalities are found. However, we find that it is often the failure to perform these simple assessments and then the failure to act on findings that leads to delays in treatment. While failure to act is considered a nursing quality indicator, we prefer the term delay in treatment because the reports and subsequent root cause analyses (RCAs) implicate more disciplines than nursing in the patient outcome.

Delays in treatment, perhaps more than other type of adverse events, involve a cascade of poor decisions made by multiple caregivers. Ineffective communication, erroneous role assumptions, knowledge deficits, complacency, inexperience, and passive supervision all contribute to the serious delays in treatment reported to this office. Nearly every delay in treatment occurs because one or more caregivers failed to understand, or act on, the seriousness of a patient's symptoms. If the bedside nurse does not understand the significance of post-operative bleeding, for example, he will not understand how the patient's rapid heart rate might signal a dangerous change in condition. If he cannot correlate the patient's symptoms with a possible disease path, he will not know what other assessments to make, and any communication about the patient's condition to the physician will be ineffective and likely to focus on a less serious symptom. If the nurse's knowledge deficit, usually based on inexperience, is coupled to a hospitalist or physician's assistant (PA-C) who does not know the patient and is likely being pulled in multiple directions at once, along with a night shift charge nurse or supervisor who thinks no news is good news, a recipe for a disastrous outcome emerges.

There were 19 Level 1 delays in treatment reported in FY14, with 17 fatalities and two patients needing limb amputation. In comparison, twenty-four delays in treatment were reported in FY13. Nineteen reported delays is still higher than the previous average of 10 reports per year from FY04 through FY11. 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 events. In FY13, half of the reported events involved failing to respond in a timely manner to physiologic monitor alarms. This year that number is down to five (28%). Eight of the FY14 reports related to failing to act upon critical laboratory values or the results of diagnostic

⁸ http://psnet.ahrq.gov/popup_glossary.aspx?name=failuretorescue

tests. Two of the events related to failing to act on gastrointestinal or post-operative bleeding. The two patients who lost limbs had suffered complications of their underlying diseases, had not been adequately assessed, and, therefore, their symptoms had not been addressed.

As noted, failure to understand the seriousness of a patient's changing condition is evident in nearly all delays in treatment. For instance, a middle-aged patient with new-onset diabetes developed complete occlusion of several arteries in his leg while in the hospital. Although assessments indicated that he had arterial occlusion, the nurses and PA-Cs treated him as if he had a venous occlusion. So when he complained of an extreme amount of pain and his foot was cold and pale, staff elevated it and applied ice, and no one notified the physician when his foot became cyanotic. It was three days before anyone acted on his symptoms and after three surgeries to try to restore the circulation, he had to have an above-the-knee amputation.

An elderly patient was admitted with a fractured hip following a fall at home and had a surgical repair, during which a unit of blood was given. Her baseline blood pressure (B/P) was in the low normal range, and she became dangerously hypotensive over the first night after surgery. She was given a liter of IV fluid following consultation between the RN and the PA-C; but, received no definitive treatment, nor were any labs drawn to determine her blood count. The following morning she was seen by the surgeon, who noted that she was very confused and had decreased alertness. Her B/P was very low and her heart rate was rapid. She was transferred to the ICU, but was not started on medications to increase her B/P, nor was she given any more blood. She died a few hours later. The RCA determined that the staff had gotten into the habit of only calling the Rapid Response Team (RRT) when they could not contact a physician. Because no one seemed to have made the connection between her vital signs and her deteriorating condition, the registered nurse communicated with the PA-C. However, neither the nurse nor the PA-C called the surgeon.

The other patient who died of untreated bleeding was admitted with lower gastrointestinal bleeding after fainting at home. He complained of four days of dark, tarry stools. His initial blood count was low enough to treat. The emergency department (ED) nurse sent blood to "hold" for a type and cross, which means that the blood was sent to the blood bank without an order to type and screen for blood typing, necessary for a blood transfusion. However, the nurse put a blood band on the patient, signifying that the type and screen had been sent. The patient was admitted to a medical-surgical floor and experienced continual bloody stools all night, which went untreated and unreported to a physician. In the morning, the patient was seen by the physician, who ordered a blood transfusion. The staff thought a specimen had been sent by the ED physician for blood typing. Because the night blood bank technician had not passed on to the day shift that the patient had a specimen there in the blood bank, the day shift staff called the unit for five hours trying to get clarification. As a result, the patient did not receive blood until after he suffered a cardiac arrest on the medical-surgical unit. This hospital also had a rapid response team (RRT), which no one called until the patient arrested. He was initially resuscitated, but died later that day in the intensive care unit (ICU).

Clearly there are many communication, training, and systemic problems that contributed to this event. The blood bank technician who was trying to clarify the order for blood typing never connected with the patient's nurse, the charge nurse, or the physician, and did not activate the chain of command when he could not get an answer. Likewise, the night nurse had tried to manage the patient without help, and did not recognize the seriousness of his symptoms or her obligation to call the physician or the RRT. As is the case with so many delays in treatment, the culture in this hospital encouraged passive supervision and there was no obligation for the night charge nurse to make rounds to check the status of each patient. Given that nurses, mid-level providers, and physicians are trained and socialized to act independently, it seems that the only mitigating practice that might save lives is a culture change that puts the emphasis on cooperation, communication, and active supervision. Charge nurses and house supervisors need to make rounds and ask probing questions. If a hospital has a PA-C and a hospitalist in house overnight, the expectation needs to be that they will communicate with each other frequently, and the physician needs to take the lead in ensuring that problems are addressed in a timely and effective manner.

The RCA also revealed a widespread reluctance to call the RRT. Rapid response teams were started to try to prevent emergency cardiac and respiratory resuscitations by intervening early during the patient's deterioration. Yet, this RCA, among many others, suggest that hospital staff are reluctant to call for help. One of the reasons given for not calling an RRT in this particular instance is that the staff apparently perceived the RRT responders to be condescending and were afraid of being belittled. Another reason commonly given is that bedside staff do not realize how deep in trouble they are getting, and they overestimate their ability to problem solve. The second scenario presents another opportunity for active supervision and timely intervention by a more experienced clinician.

One fetal demise *in utero* was classified as a delay in treatment rather than a fetal death or injury because it involved both the ED and the obstetrics (OB) unit, and occurred due to a cascade of poor decisions and erroneous assumptions by several clinicians. A woman of advanced maternal age presented to the ED one morning complaining of dizziness, difficulty breathing, and spotting. Her blood pressure was dangerously high, over 200/150. She stated she may be pregnant but was not sure, and had received no prenatal care to date. After giving the patient medication to bring her blood pressure down, and finding a positive urine pregnancy test, the ED physician contacted the obstetrician on call who requested an ultrasound to determine the age of the fetus. This was completed approximately three hours after arrival and verified a viable fetus of 27 weeks. According to the RCA, the attending nurse in the ED was a new nurse and a new hire, although she was no longer on orientation. The nurse apparently did not realize that the patient was an obstetric emergency as she continued to monitor the patient's vital signs but had no sense of urgency to transport the patient to the OB unit. Meanwhile, the OB staff called the ED several times for updates on the patient's condition but neither the nurses nor the on-call obstetrician went to the ED to see the patient. OB staff finally went to the ED to get the patient two hours after the ultrasound had been done, five hours after arrival at the hospital. Upon arrival on the OB unit, an ultrasound was done and no fetal activity or heart rate was detected.

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

Many hospitals have implemented early warning systems as part of the electronic medical record in order to track patients' vital signs and other physiologic markers, and to alert staff and physicians when a downward trend is occurring. If the trends are displayed on a dashboard-type report, clinicians such as hospitalists who are responsible for many patients can get real-time data on the entire hospital for a high-level view. Then they can drill down to each service, each provider or attending, each unit, and finally to each patient. These data 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 into medical-surgical patients who may be deteriorating or ICU patients who may be able to go to a step-down unit. For this information to be effective, the expectation has to be that trends indicating deterioration will be acted upon.

The next delay in treatment event is an example of what happens when the early warning alerts are ignored. A middle-aged patient ignited a small fire as a result of smoking in bed at home. He did not seek treatment right away; many days later he arrived at the ED with low oxygen levels and infected burns to his face and inside his nose. He was admitted to a medical-surgical floor. A day or so later, his oxygen saturation (SpO₂) dropped even further, he had a fever, and his heart rate increased. There were numerous calls overnight between the licensed practical nurse (LPN) caring for him and the PA-C. The PA-C entered an order in the computerized provider order entry (CPOE) system to move the patient to a monitored bed, but did not tell the LPN, and the LPN did not see the order in the record. The PA-C did not come to examine the patient. In the morning, the attending physician saw the patient and, based on incomplete information, ordered an inhaler and some nasal spray. For the next 24 hours, the patient continued to run a fever, had a rapid heart rate roughly double normal, and his SpO₂ remained low. He remained in an unmonitored bed. In the middle of the night, staff found the patient unresponsive and without vital signs. A code was called, but for some reason no one started compressions or opened the code cart until the code team arrived. He did not survive.

This hospital has an early warning system in their electronic medical record (EMR). The RRT is supposed to be notified of any risk score over five. The patient had been at five or six for 24 hours and no RRT had been called. During the RCA, the attending and the nursing staff said

the patient “looked OK” and, consequently, they experienced no sense of urgency. They also said that they were not really familiar with the early warning system. There was also the problem of the lack of supervision of the PA-C and the LPN, neither of whom are independent practitioners. The point of an early warning system for deteriorating patients is to spur action even when, or especially when, they “look OK.”

In regard to the performance of the medical staff, it is relevant to ask whether or not the hospitalists or PA-Cs that cover for attendings are confident that they can get the help they need. Has the hospital experienced other events or close calls associated with the failure of a mid-level provider to go up the chain of command? Does the culture of the hospital, by over reliance, put subtle pressure on the PA-Cs to overstep the bounds of their supervisory agreements? Have any physicians been identified who are less likely to be cooperative with middle of the night telephone calls from hospitalists, mid-levels, or nurses? Has medical staff leadership addressed these problems directly with the physicians under the hospital’s disruptive physician policy? Do employees with in-line authority know what the chain of command is, and how it is accessed? PA-Cs are not licensed independent practitioners; they work under a supervisory agreement with a physician who must be readily available for consultation and assistance. The PA-Cs should be the start of the chain of command, not the end. Were the PA-C and the nurse the only two people on this unit that night? Why did not someone with more experience intervene?

Another fatal delay in treatment occurred to an elderly patient who presented to the ED with mental status changes and pneumonia. The next morning she was sent to the radiology department for an ultrasound (U/S) of both swollen legs to rule out blood clots. She was sent with a transporter and an oxygen mask and tank. The patient had dropped her SpO₂ in the morning and had been placed on oxygen by mask at a fairly high flow rate. Because this hospital used an electronic transport request form, there was no verbal report between the registered nurse (RN) and either the transporter or the U/S technician. The information about the new need for oxygen was not communicated to either. The U/S technician, who was new and working alone on the weekend, failed to attach the oxygen tubing to the piped-in oxygen and the tank ran out during the 90- minute test. Part way through the procedure, the patient became unresponsive and the technician thought she had just gone to sleep. The test was positive for venous blood clots. The patient, still unresponsive, was placed in the waiting area on her stretcher for a few minutes to await the transporter. During the elevator ride to the patient’s unit, the transporter realized she was not breathing and had no pulse. Staff were unable to resuscitate the patient.

Besides the obvious communication, training, supervision, and assessment problems, the U/S should have been done at the bedside. There was no need for this patient, especially with a new change in her condition, to leave the unit to go to radiology. Hospital management, realizing that many diagnostics tests were being done in the department for the convenience of the diagnostic staff, made a list of all testing that could not be done at the bedside, because this list was shorter than the list of tests that could be done at the bedside. They then educated other hospital staff, including physicians, and asked everyone to consider whether ordered testing could be done at the bedside, both for safety and to increase patient satisfaction.

The FY13 Annual Report discussed delays in responding to physiologic monitoring alarms in detail. For FY14 these events dropped from 50% to less than one third of reports. Two of these reports stand out.

A patient was admitted to a monitored telemetry unit with a medication toxicity causing a rapid heart rate. When he suddenly lost his heart rate (asystole), the monitor technician called the nurse. This hospital had a special telephone to be used for dire emergencies, like asystole, but this time the technician used the regular telephone. The RN, not perceiving any urgency because she had been called on the regular telephone, asked another nurse to check the patient. The second RN focused on the telemetry leads and did not notice the patient was not breathing. Nor did she call the telemetry technician while she was at the bedside, as per policy. After a minute or two, the telemetry technician called the nurse back, who did not believe the technician and assumed the patient's monitor leads were the problem, therefore, the nurse did not immediately check the patient. Instead, she got a new telemetry transponder to swap out with the one currently on the patient. It was 20 minutes before a code was called, which was too late. The hospital had already implemented a redundant notification to the charge nurse for all asystole alarms, but during the RCA, a review of all electronic alerts sent by the telemetry system found that the charge nurse had ignored over 35 pages made to his telephone to alert him to asystole alarms on this one shift.

The hospital took disciplinary action against the staff involved in this event. They also changed the policy so that telemetry technicians can call codes. Nurses on all monitored units now have to print out and analyze rhythm strips on each patient at the start of each shift. Furthermore, the texts sent to staff about asystole alarms now read "Patient Dead."

The other significant monitor-related event occurred in the emergency department (ED) to a patient seeking treatment for abdominal pain. She was found to have a metabolic acidosis, a serious condition in which the body makes too much acid, or the kidneys are unable to excrete enough acid. The patient was placed on a cardiac monitor. Very soon after arrival, her heart rhythm changed to a rapid ventricular rate, then to an irregular rapid ventricular rhythm. The ventricular dysrhythmias continued for an hour before she lost her heart rate. No one responded to the asystole alarm for another seven minutes. She could not be resuscitated.

As with most delays in treatment, this event had multiple causes. The ED was part of the telemetry system in the hospital. However, the remote telemetry technicians typically paid little attention to the ED monitors, apparently based upon the assumption that there were plenty of attentive staff caring for ED patients. ED policies for monitored patients failed to assign responsibility for watching the monitors, and failed to set parameters for the alarms, which were typically set for each patient based on their baseline and normal vital signs. This ED experienced many false alarms and alarms which were just left running when patients were off the unit in testing. This practice made for a high level of background noise. For this patient, at one point a friend came out and complained to a nurse's aide that the alarm was too loud so the aide silenced

the alarm and turned the overall volume down. When the RN found the patient in asystole, she found the monitor flashing “red” but not audibly alarming.

AIRWAY EVENTS

The number of adverse events associated with failing to establish and maintain a patent airway increased in FY13 to 12 from a prior average of eight per year. In FY14, 11 of these events were reported, with nine fatalities and two patients who suffered permanent anoxic brain injuries. Two of the reported airway events occurred in the post-anesthesia care unit. Because of the close supervision and ready availability of anesthesiologists, the post-anesthesia care unit (PACU) is the one place in the hospital that should be free of adverse airway events.

As in FY13, one of the airway events involved a patient who had just had cervical spinal surgery. This elderly patient had been receiving one of the new class of Factor Xa inhibitor anticoagulants for a chronic irregular heart rate. He stopped taking the medication two weeks prior to surgery and it was restarted on post-operative day one. Later that day the patient told the nurse that he was having trouble breathing and felt like his throat was closing up. The hospitalist saw the patient and noted no visible internal or external swelling and a SpO₂ of 100% on room air (normal). Assuming the patient was having an allergic reaction, the hospitalist ordered that the patient receive no more narcotics, and ordered a breathing treatment and medications to reduce any swelling, including steroids and a sedating antihistamine. For the next several hours, the patient continued to complain of difficulty breathing but also had quiet periods, likely due to the sedation. By midnight, the patient had rapid heart and respiratory rates but was maintaining his SpO₂ in the normal range. He was sent for a STAT CT (computerized tomography) scan of his neck. During the test, he was very restless, could not lay flat, and began sweating profusely. Then he became unresponsive. The anesthesiologist responding to the code blue alert said the patient’s airway was deviated to the right. It took several attempts before the patient could be intubated. He was taken to the ICU on a ventilator. His heart rhythm showed that he had suffered an acute heart attack along with the respiratory failure. His family elected not to prolong his intubation in the face of the anoxic injury suffered during the resuscitation attempt.

The CT scan showed that the patient had a large collection of blood (hematoma) adjacent to the surgical site that was impinging on his airway. The radiologist notified the surgeon, who had not been told of the patient’s condition by either the nurse or the hospitalist. There was no policy or protocol for the post-operative management of this high-risk surgical procedure and there seemed to be little awareness of the risk to airway management posed by neck surgery.

Two of the airway events occurred to individuals with intellectual disabilities who were known to have airway malformations. One of these patients had three controlled extubations in the ICU while trying to wean off the vent but had had to be re-intubated each time. He was eventually transferred to a step down unit with an oral breathing tube. No one told the staff of the step down unit that he had a difficult airway, so there was no additional airway equipment at the

bedside. When the patient was able to push out his breathing tube with his tongue a few days later, he could not be re-intubated.

SURGICAL EVENTS

In FY14, there were five reported Level 1 adverse events associated with wrong site/wrong procedure/wrong patient surgeries or procedures. None of these events were fatal.

One of the wrong patient events involved a patient who presented to interventional radiology to have a drain inserted in her pancreas. She was mistakenly placed in a room that was set up for another patient who was to have chemotherapy inserted into her spine. The patient underwent a lumbar puncture and some cerebral spinal fluid was removed. It was only during the double check prior to infusing the medication that the staff determined she was the wrong patient.

While it is unknown why the patient did not speak up during the spinal tap, clearly the other safeguards for patient identification failed. The RCA stated that the patient did not correct the staff or radiologist during the time out procedure. The physician explained the procedure to the patient, but no one actually checked her armband to confirm identity.

In another wrong procedure, the clerk at a physician's office called the hospital to schedule a non-invasive ultrasound of the kidney. For some reason, the clerk was connected with the interventional radiology (IR) laboratory rather than the ultrasound department. The IR clerk did not find U/S of the kidney in the diagnostic library so he ordered an U/S guided kidney biopsy. The IR scheduler got the order and changed it to CT-guided kidney biopsy because she knew that the interventional radiologist would only do a kidney biopsy under CT guidance. When the patient presented for the test, she told the radiologist she thought she was just supposed to get an U/S and was told that she needed the biopsy because her kidney function laboratory tests were elevated. They were not. Everyone involved in this event made erroneous assumptions, failed to verify the original order, failed to listen to the patient when she questioned the invasive procedure, and added indications for the test that did not exist.

The causative factors of several of the wrong surgeries and procedures originated in the physicians' and surgeons' offices. Rarely are patients given anything in writing about the name, nature, and location of their upcoming surgeries. Even if the patients sign informed consents in the office, they may not be given a copy of the consent, and the consent may be signed weeks or months prior to surgery. Although hospitals usually cannot control the clerical practices in surgeon's offices, surgeons operate in hospitals, are part of hospital medical staffs, and are subject to hospital bylaws and performance appraisals. This relationship gives the hospitals some measure of influence over office scheduling procedures. It is reasonable to require that surgeons give patients written information about their upcoming procedures, including the name of the procedure, the reason for the procedure, and a body map pointing out the location for the surgery.

Ten Level 1 events reported in FY14 were associated with the post-surgical retention of foreign bodies (RFB), including two RFB in the vaginas of women undergoing laparoscopic procedures. Ten RFBs, while fewer than FY13's 18 RFBs, is too many considering the attention given to this problem over the past decade. Most of the reported events coincide with the literature about RFBs in that they occurred during emergency abdominal procedures, or during complex abdominal procedures with multiple personnel changes. One patient had a retained sponge following a Cesarean section delivery that resulted in an abscessed ovary several months later. The hospital's RCA found that none of the packs of sponges used in the Labor and Delivery ORs had radiopaque tags, and they were packaged in a different quantity than the main OR.

One hospital reported that a patient suffered a RFB following open heart surgery. The sponge count was incorrect at the end of the case. Per policy, an anterior/posterior (front to back) chest x-ray was done, which did not show any RFB. Over the next few days, the patient had several anterior chest x-rays while in bed in the ICU. Portable x-rays of patients in bed are often of less quality than upright x-rays. The OR staff had filled out an incident report at the end of the patient's surgery and when the risk manager got the report, she asked for a lateral (from the side) x-ray, which found the retained sponge. The patient was taken back to surgery and the RFB was removed.

The RCA team determined there had been several breaks in the count process during the surgery. The nurses failed to account for everything that was used. When the final count was incomplete, the surgeon assumed it was not in the surgical site. In addition, the radiologist had not been told that the intra-operative x-ray was to look for a RFB. A review of all the x-rays done on the patient showed the RFB present but difficult to see in the anterior view.

Several of the RCAs submitted in the wake of RFBs noted reluctance on the part of the surgeon to believe that there could be a RFB. In one event, the final count was incorrect. An x-ray was taken in the OR that showed the RFB; but, the surgeon insisted the radiopaque sponge could not be in the surgical site and had somehow gotten under the sterile drapes. Many times the surgeon had closed the incision and was reluctant to reopen to look for the RFB. An incorrect count should be the proverbial red button that stops all activity until it is resolved. Incisions should not be closed until the RFB is located, and the patient should not leave the OR if there is any question of a RFB. In addition, the radiologist needs to be told that a RFB is suspected when intra-operative x-rays are taken.

In FY12, the Office of Health Care Quality noted a trend in reports of retained 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 is at the discretion of the surgeon. One

reported event involved an inflated surgical glove wrapped in a towel. Other items used included the bulbs from the end of syringes. Given that these objects are not counted as instruments, there is no double check to ensure they have been removed. Although there is not usually any long-term damage from objects left in the vagina, these types of RFBs have been reported to cause infections, discomfort, and difficulty urinating. Two RFBs of this type were reported in FY14.

Two patients had retained parts of latex gloves that apparently broke off during chest tube insertions. The gloves pieces were found when the chest tubes were removed.

MEDICATION ERRORS

In FY14, the Department received 12 reports of medication errors leading to death or serious disability, including two untreated hypoglycemia and three anticoagulation events. This is consistent with reports of 12 Level 1 medication errors received in FY13. There were seven deaths associated with the reported medication errors; one of the hypoglycemia events was fatal as were all three of the anticoagulation events.

Two patients who were unable to eat (NPO) for extended periods were not given medications, including seizure medications. No provision had been made for giving the medications via a route alternative to oral ingestion. The staff of both hospitals appeared to be somewhat complacent regarding initiation of dietary consults and supplemental nutrition for patients on prolonged NPO status. Neither patient received parenteral (IV) nutrition or had feeding tubes placed.

One patient suffered a fatal allergic reaction to an antibiotic. A review of his record after the event showed that he had had a reaction to the same antibiotic several months prior to this hospitalization. However, this reaction had not been labeled as such on his medical record and so did not follow him from one admission to another.

One of the hypoglycemia events occurred to a patient who was given insulin in the evening based on a sliding scale, yet the blood glucose was not re-checked overnight. The other event occurred when a patient who was getting tube feedings and an insulin drip had her tube feedings stopped for an impending procedure, but not her IV insulin.

One patient forgot to stop his Factor Xa inhibitor anticoagulant and his aspirin prior to hip surgery. He told the nurse in the pre-operative prep area, but the nurse apparently failed to recognize that the medication was an anticoagulant so she neglected to tell the surgeon. The patient had uncontrollable bleeding after surgery and died.

Another patient presented to the ED with symptoms of a stroke. He was given a clot-busting medication that is typically used for cardiac blood clots, rather than cerebral clots. The medication caused a catastrophic brain bleed.

The third patient with an adverse event related to anticoagulant use was a patient who had orthopedic surgery. The protocol called for three days of anticoagulation for prevention of blood clots accompanied by blood tests to determine the level of anticoagulation. After three days, the patients were assumed to be discharged. This patient suffered some respiratory complications and did not get discharged on day three. He continued to receive the anticoagulation but the accompanying blood tests were automatically discontinued. After ten days, he suffered massive gastrointestinal bleeding and died. None of the failsafe processes worked for this patient. None of the physicians noted that he had not had any anticoagulation blood tests. The pharmacists who filled the anticoagulation order failed to note the absence of blood tests, and the nurses who administered the medications also failed to note the absence of blood tests.

SUICIDES

There were eight completed suicides reported in FY14. Two patients were in their 20's, three others were in their 30's. Two inpatients committed suicide. One patient had injured herself prior to admission and had a fairly significant blood loss. She was admitted to a telemetry bed. She was evasive about the injury but was not thought to present a danger to herself. Several hours after admission, the telemetry technician called the nurse to tell her that the patient was alarming "leads off." The nurse found the patient locked in the bathroom. When the staff were finally able to locate the key and get the door open, they found the patient hanging from the shower head.

Two people jumped to their deaths, two used mass transit, three hanged themselves, and one patient shot herself. The discharge plans for two patients who committed suicide at home were inadequate and require comment. The first, an elderly woman, was evaluated in the ED for a change in mental status. She did not meet criteria for involuntary admission and refused voluntary admission to the behavioral health unit. The patient told staff that her daughter, with whom she lived, was abusive. Despite the fact that the daughter refused to come to the hospital to get the patient and refused to listen to the discharge instructions, the patient was discharged without any kind of a home risk assessment. She got a ride home and then shot herself.

The second patient with an inadequate discharge plan was a patient who had recently been released from a long prison term. After a week on the behavioral health unit during which he repeatedly expressed homicidal ideation and paranoia focused on the husband of a relative, he was discharged to that relative's home and hanged himself a day later. No risk assessment was done prior to discharge, nor was the relative warned about the patient's focus on her husband.

Neither of these patients had a risk assessment done regarding lethal methods of suicide in the home, and the discharge instructions failed to include basic information such as the telephone numbers of crisis centers or the suicide prevention hotline. One of the RCAs said that the hospital's crisis psychiatric evaluators were afraid to ask patients about risk factors, including the presence of guns in the home, for fear of "putting ideas in their heads." Time and again, studies have shown that talking about suicide prevention does not cause non-suicidal patients to

commit suicide and does not increase the likelihood that patients ambivalent about suicide will commit suicide. When indicated, clinicians must ask about guns, medications, and other available lethal methods of suicide. In addition, they have an obligation to advise families to remove or secure these threats prior to sending a patient home. It is not enough to start a patient on medication and give him or her a follow up appointment. Risk factors present in the environment to which the patient is to be discharged, including the family's contribution to the patient's psychiatric state and safety, have to be assessed and addressed.

HEALTHCARE-ASSOCIATED INFECTIONS

The Centers for Disease Control and Prevention (CDC) tracks healthcare associated infections (HAIs) through its National Healthcare Safety Network (NHSN).⁹ Maryland requires hospitals to report infection data to the NHSN. The CDC assigns a standardized infection ratio (SIR) to the data acquired through reporting. The SIR is risk-adjusted and accounts for factors such as hospital size and teaching status. In 2012, the last year analyzed, Maryland's statewide SIR was similar to the national SIR for central-line associated blood stream infections (CLABSI) and for surgical site infections associated with colon surgery. However, our hospitals reported significantly more infections than the national benchmarks in the following two measures: surgical site infections following abdominal hysterectomy and catheter-associated urinary tract infection (CAUTIs).

As part of its overall focus on preventing readmissions through the Partnership for Patients (PfP) program, CMS has created a new survey process for the infection control Condition of Participation. This is a more in-depth review of infection control processes, including antimicrobial stewardship, hand hygiene, isolation, and the care and use of invasive lines and catheters. In performing this new survey process, our hospital surveyors have noted anecdotally that many hospitals seem to be using urinary catheters for longer than absolutely necessary by failing to review the patient's need for a catheter on a regular basis. The PfP infection control module calls for reviewing the indications for retaining the urinary catheter in each patient on a daily basis and discontinuing them as soon as possible. There is also a CAUTI collaborative available through the Maryland Hospital Association¹⁰ dedicated to lowering the CAUTI rate.

Because COMAR 10.07.06 requires reporting only those adverse events that cause death or serious disability, we do not receive many reports of HAIs. It is often difficult to pinpoint one HAI as the cause of the patient's death. Two HAIs were reported in FY14 involving five patients. One report concerned an outbreak of MRSA in a neonatal intensive care unit that infected four patients with one fatality. The other reported HAI involved an elderly patient who died of *Clostridium difficile* colitis.

⁹ www.cdc.gov/hai/progress-report

¹⁰ <http://www.mhaonline.org/quality/cauti>

UNUSUAL ADVERSE EVENTS

In FY14, we received reports of several types of events that had not been previously reported or were associated with unusual outcomes. The next section discusses some of these events.

Every year, two or three allegations of sexual assault are reported to the Office of Health Care Quality. These allegations are usually put forth by patients admitted to behavioral health units. These claims often turn out to be unfounded or unprovable. However, during FY14 three confirmed occurrences of sexual assaults on vulnerable adults were reported. In one case, an unconscious female patient was on a stretcher in front of the nurse's station in a busy ED. Toe to toe with her stretcher was an intoxicated male patient with a minor injury, also on a stretcher. Several times, the male patient got up to use the bathroom and each time he passed the female patient he would uncover her and expose her breasts. The nurses, apparently believing she was waking up and uncovering herself, just kept covering her back up. Eventually, the male patient acted more boldly and was directly observed molesting the female patient by a security guard making rounds in the ED. The security cameras in the public areas of the ED corroborated the guard's account.

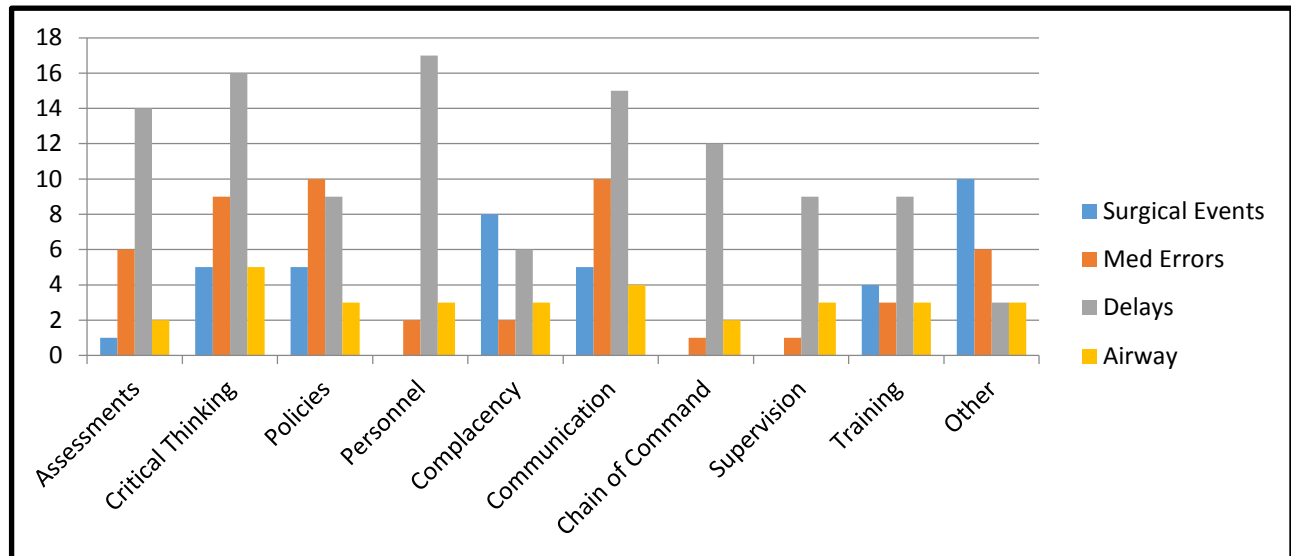
Two mentally incompetent patients eloped from Maryland hospitals. One patient died of exposure. The other patient was placed in a wheelchair van to go to another hospital for a diagnostic test. He and his girlfriend were able to talk the ambulance drivers into stopping at the patient's house on the way to the other hospital. Once there, the patient hopped out and was last seen driving away in his car.

Restraint use causes serious injuries to three or four patients every year. In FY14, two of these serious injuries occurred to patients over age 90. One patient was positioned in the OR to facilitate surgery. No one noticed that his arm was restrained below the operating table and the table was raised several feet to bring it up to the proper level for surgery. When the drapes were removed after surgery, it was discovered that the restraint had pulled all of the skin off the patient's forearm and hand. The other patient with a serious restraint injury had an IV in the back of his hand and also had mitten-type restraints on both hands. When the mittens were removed after several days, it was discovered that the IV had caused a tunneled infection from the back of the patient's hand to his forearm.

One instance of intentionally unsafe care was reported in FY14. A psychotic patient was seen in the ED. The nurse told him that if he did not take his medication orally, he would insert the pills rectally. When the patient spit his medications out, the nurse did just that with the pills that he picked up off the floor. There was a security guard present who reported the threat the nurse made, but not the actual act. The hospital became aware of this event when the patient became more lucid after a few days on the behavioral health unit and reported what had happened. A physical exam provided further proof.

Causation

Table 3: Causative Factors for Four Event Types FY14



In FY14, personnel, that is, the number and qualifications of staff present during the event, was listed as the prime causative factor reported for delays in treatment, followed closely by critical thinking, assessments, communication, and chain of command. Personnel was named as a causative factor because many of these events occurred in the company of relatively new practitioners. Although inadequate (either in content or frequency) training is noted as a causative factor in nearly all RCAs, and provision of additional training is the most popular corrective action, it is difficult to see how retraining skilled professionals will be sufficient in and of itself as a means of prevention. Many of the reported delays, medication errors, and RFBs were ultimately failures of basic, generic, hospital procedures such as hand-offs, on-call systems, supervision, role delineation, and personal accountability. Many of the airway events shared these causative factors but also frequently had a technical component such as the lack of equipment sufficient for maintaining a difficult airway or, rarely, malfunctioning monitoring equipment.

Patient Age and Adverse Events

Table 4: Age at Onset of the Most Commonly Reported Events

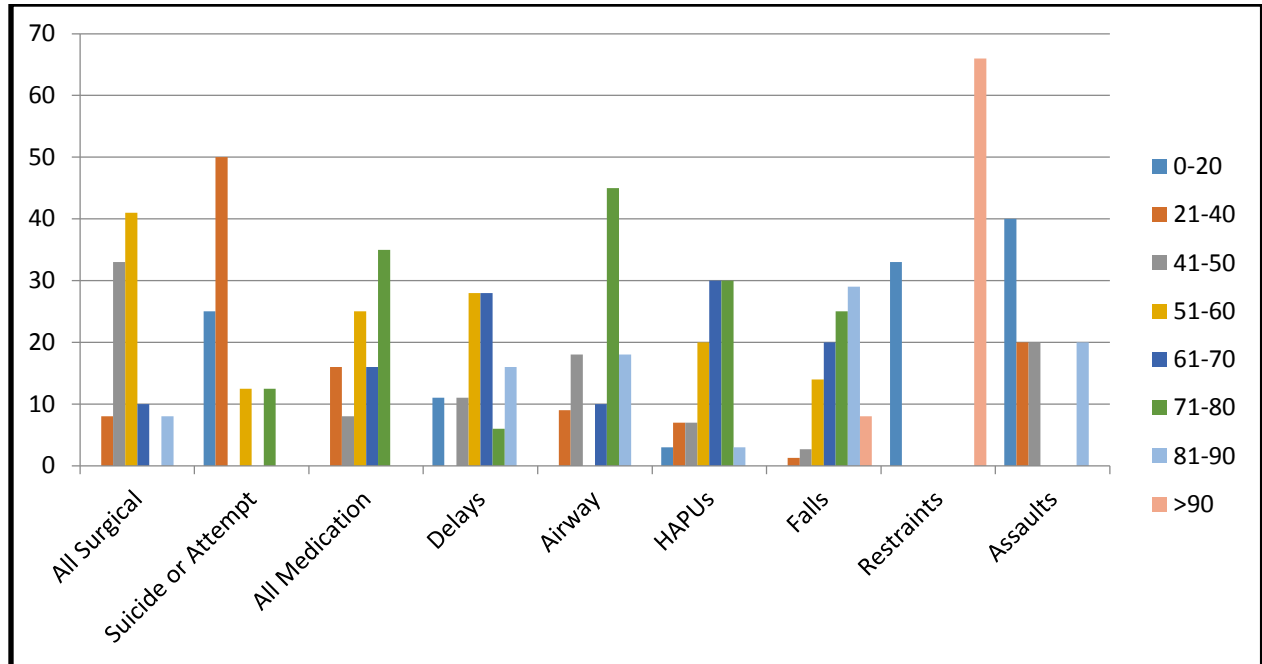


Table 4 represents the age of patients per common event types. As we discussed, two of the three serious restraint injuries occurred to patients over age 90.

Table 5: Age and Outcome of all Event Types

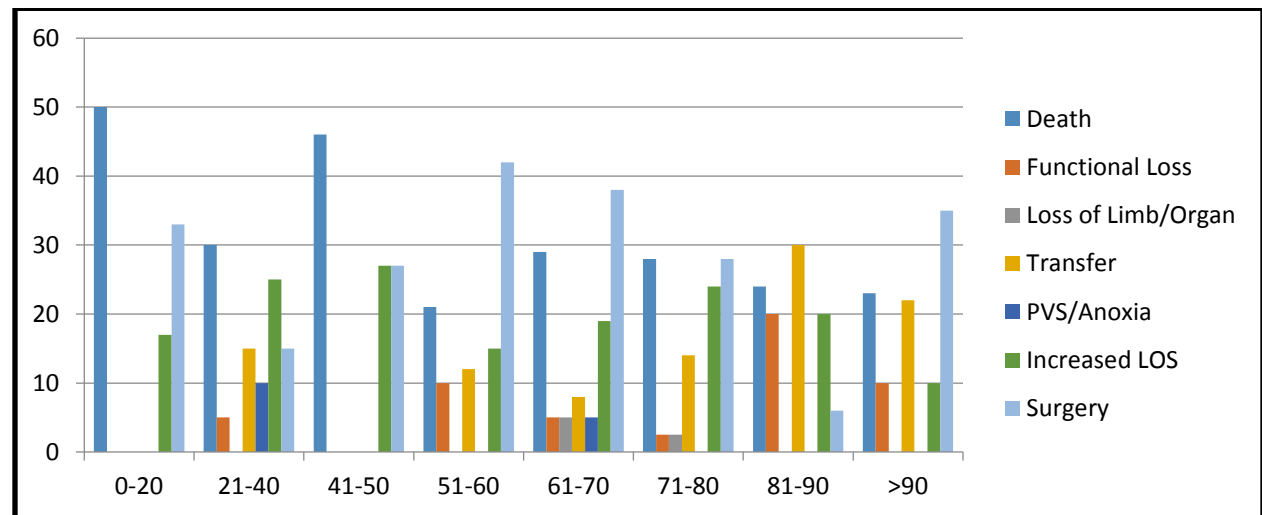


Table 5 represents the percentage of each age group affected by each type of outcome. From ages 60 to 90, falls are the most common type of event and the overall fatality rate for falls is approximately 10%. Fewer adverse events happen to younger people. What looks like a high mortality rate in patients younger than 50 is an artifact of the low overall numbers of reported events.

Review of Root Cause Analyses

COMAR 10.07.06.06 states:

- C. The root cause analysis shall examine the cause and effect of the event through an impartial process by:
- (1) Analysis of human and other factors;
 - (2) Analysis of related processes and systems;
 - (3) Analysis of underlying cause and effect systems through a series of "why" questions;
 - (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.¹¹ 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. Each RCA focused on what happened rather than on why; yet, they lacked sufficient description of the adverse event to even determine what happened;
2. These RCAs lacked defined root causes and the information given was insufficient to establish causality;
3. In part because causality had not been determined, the interventions lacked specificity;
4. The listed outcome measurements were inadequate to determine if the corrective actions had any effect on the problematic process(es); and

¹¹ COMAR 10.07.06.02 (B)(10)

5. Hospitals continued to focus on bedside, sharp end, corrective actions for adverse events.

In FY14, the Office of Health Care Quality sent out notices to four hospitals regarding RCAs that failed to meet all of the requirements of COMAR 10.07.06. Two examples of poor RCAs submitted in FY14 follow.

Example 1: A hospital reported that a patient who was recovering from spinal anesthesia had fallen twice in the post-anesthesia care unit (PACU), leading to nerve impingement and an emergency transfer to a regional referral center. Even though the patient was still numb in his legs, he was placed in a wheelchair in a room adjacent to the PACU to await the return of sensation. He got up and fell, was assessed for injuries and placed back in this same area, and fell again. The room he was waiting in was part of the PACU, but there was no formal assignment of patient monitoring duties.

The RCA failed to answer any of the obvious “why” questions, like why was the patient left alone? What are the criteria that allow for the move of a patient from the PACU to this unmonitored area? Why was he not assisted to the bathroom before being placed in an area with no clinical staff and no way to call clinical staff? Why was there no formal process for clinical supervision of this area? Why was he not placed on a higher level of supervision after the first fall?

Because the RCA did not identify causation other than that the patient did not follow directions, the corrective actions were not sufficient to prevent a recurrence. Blaming the patient is an easy way to avoid having to fix a faulty process. Additionally, the outcome measures for this RCA consisted of medical record review. While record review will almost certainly be a part of all action plans, it is an action, not an outcome. The outcome is what the hospital expects to have happen as a result of implementing the action plan. Outcomes should be patient-focused and clinically based.

Example 2: A patient lost her airway when her tracheostomy tube became dislodged while being turned. Only proximal causes were noted, meaning that the person who turned the patient was blamed for the event. The facility had a policy that all patients had to be turned with two people, and this particular staff person tried to turn the patient by herself.

No “why” questions were answered and the RCA did not go beyond the policy violation to look for any other causative or contributory factors. When patients are harmed by policy violations, the analysis has to go beyond the most obvious cause. Was the policy violation a work-around employed by many bedside staff to avoid having to call and wait for help? Or, was this practice a habit for only one or two staff persons?

Patrice Spath, in her RCA training sessions for the Maryland Hospital Association, identified three main reasons for non-compliance with policies:¹²

1. Lack of knowledge, attributable to poor training, forgetfulness, lack of experience, and/or lack of guidance;
2. Inability to achieve compliance with policy resulting from scarce resources, or an inability to perform the required action;
3. Refusal to comply because the staff person disagrees with the policy, or there is no incentive to comply and/or no penalty for not complying.

Analyzing the underlying causes of policy non-compliance can often yield substantive results. Root causes are generic, in that the causal factors affecting one patient are usually present throughout the hospital. Uncovering these latent conditions requires more work than blaming the bedside provider or the patient. Some level of analysis must occur on a facility-wide basis. The latent issues underlying event No. 1 include but are not limited to role delineation, communication, assessments, staff supervision, performance expectations, and critical thinking. The latent causation for event No. 2 includes performance expectations, resources (staff), communication, and policy formation. It is only by looking beyond the bedside that opportunities for lasting change can be found.

CORRECTIVE ACTIONS

Hospitals continue to struggle with implementing corrective actions that will be long-lasting and effective at controlling or eliminating hazardous conditions. As already noted, educational interventions and policy changes are very popular remedies. Although each is considered a weak intervention on its own, both are likely to be part of the overall 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 then receive on the spot correction once or twice.

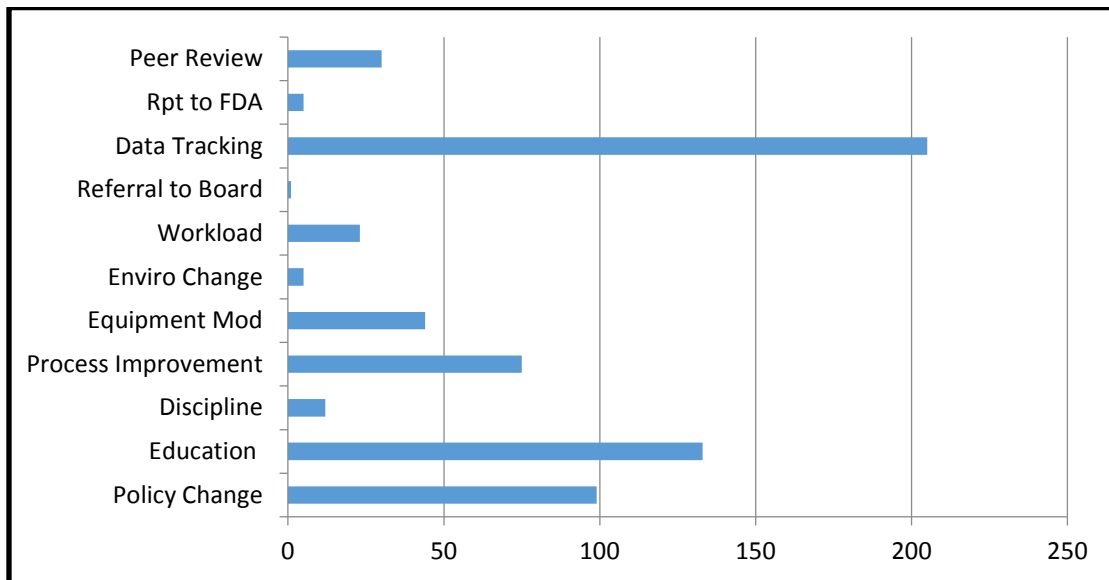
More hospitals are improving problematic processes, usually by streamlining and standardizing, and are making more processes fault-tolerant, which means that more safeguards are built into the process *a priori* to compensate for inevitable mistakes. More hospitals are also changing work-loads and staffing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

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

¹² Spath, P., Patient Safety Tools Training: Root Cause Analysis. 2012

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.

Table 6: Corrective Actions



COMAR 10.07.06 requires hospitals to monitor the results and effectiveness of all action plans derived from the RCAs. Hospitals continue to struggle with differentiating between process steps and evaluating how effective a corrective action has been in remediating the set of circumstances that led to the adverse event. Completion of implementation is certainly something the hospital should track, but this, in and of itself, is not a measure of effectiveness. Hospitals need to determine the goals of the corrective action, and how to measure goal attainment. Hospitals need to ensure the corrective action is aimed at the correct cause. For instance, changing the way nurses verify that the correct patient is getting the correct procedure is not going to fix the problem of posting patients for the wrong surgical procedure. It may help catch more incorrect postings but the solution needs to be aimed at the surgeons and their offices as the originators of the problem.

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

Notifying Patients and/or Families

The Maryland Hospital Patient Safety Program and Maryland regulations require a hospital to notify a patient, or if more 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 FY14, 13% 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 the patient had specifically requested that the family not be informed. 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.

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 licensed facilities. In FY14, the OHCQ received 353 complaints from patients, families and others regarding care in Maryland Hospitals

Since the Maryland Patient Safety regulations were implemented on March 15, 2004, the OHCQ has received more than 2,200 reports of Level 1 Adverse Events in hospitals. During that same time frame the OHCQ has received 3,475 complaints from citizens. There continues to be little overlap between the self-reported adverse events and the complaints received from the public. Five reports were received through both sources (as a complaint and as a self-reported adverse event) in FY14. Since adverse event reporting became mandatory, only 38 or 1.1% of the adverse events received were also received as a complaint submitted to the Office of Health Care Quality. The data obtained from the complaint process has little direct relevance to the number and type of adverse events occurring in Maryland hospitals. This lack of duplication indicates that the majority of patients and families affected by serious adverse events do not file complaints about those events, and may suggest that what we and hospital staff consider to be significant adverse events may not be considered so by families. Mandatory reporting and the review of RCAs provide additional tools for the Department to evaluate the quality of care delivered in Maryland hospitals.

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 federal or state complaint investigation process. If the findings indicate that the complaint was an adverse event and 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 citation of deficiencies and possible imposition of sanctions or civil money penalties by the OHCQ.

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 all adverse events. Heading into our tenth year, we have received reports from all acute general and specialty hospitals. 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 but was not, 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, focuses on the systems, culture, reporting and analysis, and policies and procedures needed for a robust patient safety program.

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.

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 changes 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:

- Provide resources for additional training of charge nurses and supervisors focused on effective patient management, leadership, and interpersonal skills.

- 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 patient's story 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 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.
- 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 caregivers 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." Clinical alerts may be obtained at: <http://dhmh.maryland.gov/ohcq/HOS/SitePages/Alerts.aspx>

The Office of Health Care Quality sent out several patient safety notices in FY14 through the Maryland Patient Safety Center's patient safety manager listserv on various topics of immediate interest. In addition, staff from the office's education and patient safety departments presented at the Health Facilities Association of Maryland (HFAM) conference in October 2014 on IT-mediated adverse events.

The Maryland Patient Safety Center

The Maryland Patient Safety Center¹³ (MPSC) brings patient safety professionals together to study the causes of unsafe practices and put practical improvements in place to

¹³ Maryland Patient Safety Center www.marylandpatientsafety.org

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 of Health and Mental Hygiene 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
- For the past two years, the Office of Health Care Quality has held an annual update workshop in conjunction with the Maryland Hospital Educational Institute. This seminar updates hospitals on any new or changed regulations and contains an update on the Patient Safety Program.
- Attendance and assistance with special projects on an ad hoc basis.

Future Plans

As previously noted, we recognize that there is turnover in 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 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 provide 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 aimed at reducing hospital acquired conditions 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;
- Identification of 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. Every year, we ask ourselves if Maryland hospitals are safer than last year. This year we can answer in the affirmative. Our hospitals have done an enormous amount of work in ensuring that patients are not harmed by medical errors. They have taken proactive steps to go beyond the bedside and expand patient safety practices to outpatient and community settings. The Department will continue to support that work and engage hospitals in the process through our participation in opportunities for outreach and training. We will continue to develop clinical alerts and other educational offerings in order to communicate patterns and trends identified through the receipt of events and the review of root cause analyses.

APPENDICES

APPENDIX A: MARYLAND HOSPITAL DEMOGRAPHICS

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

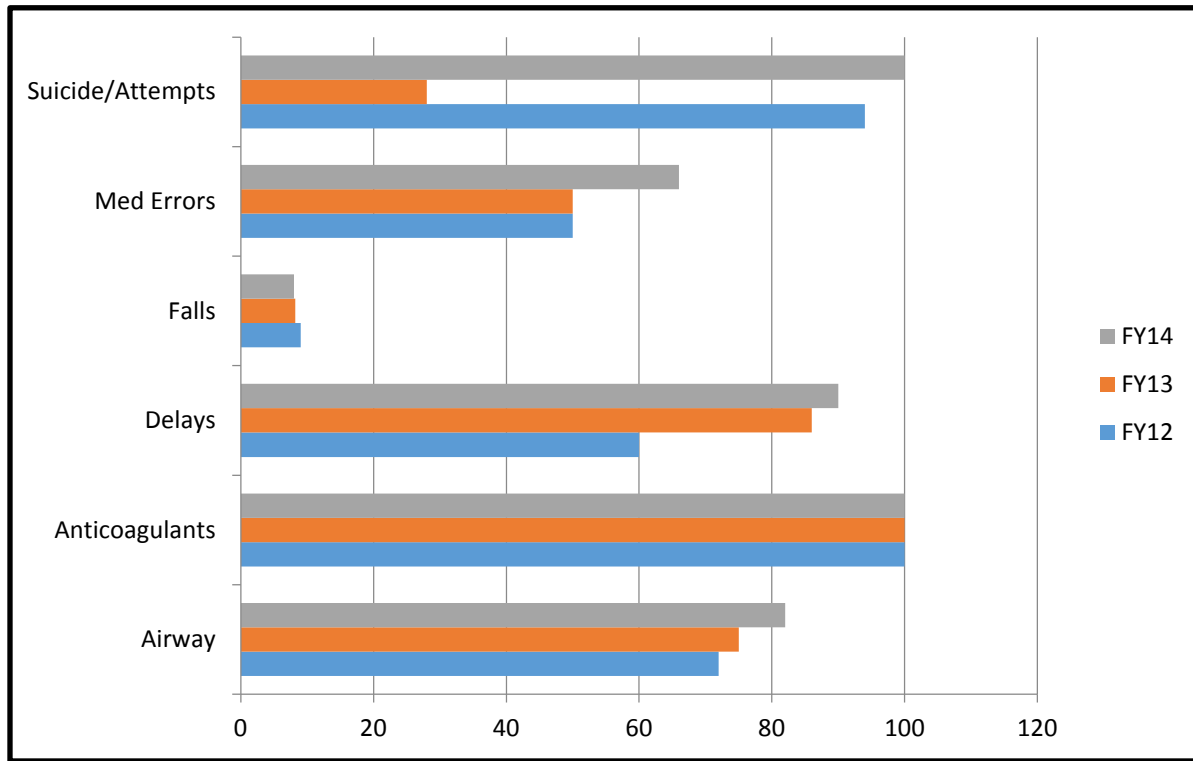
The licensed bed capacity of each acute care hospital is adjusted annually at the beginning of the fiscal year based on Health General Article §19-307.2 and is based on 140% of the hospital's average daily census. Therefore, the number of beds the hospital is allowed to operate changes on an annual basis.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

1. Twenty two hospitals are licensed as special hospitals. There are four types: rehabilitation, chronic, 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.
 - 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. Two psychiatric hospitals serve only specific populations (children, forensics).
2. 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. These hospitals range in size from 60 to 180 beds. Two are operated by the State of Maryland. 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

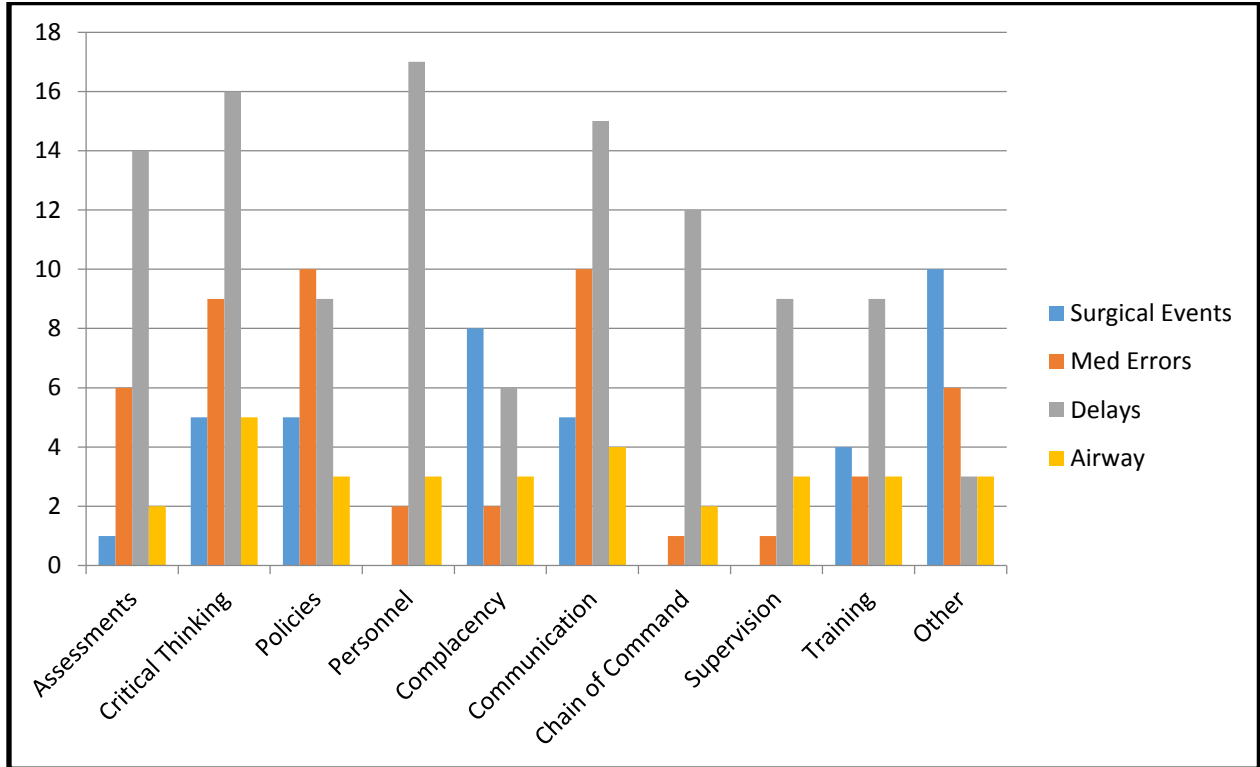
Death or serious disability associated with...	FY11	FY12	FY13	FY14
Malfunctioning Device	1	1		1
Contaminated Device		2		
Vascular Access	3			1
Blood Incompatibility				1
Intravascular Air Embolus		3		
Burns				2
Elopement				2
Assaults	4	4	2	5
Suicides	5	16	7	8
Failure to Act	6	1	1	1
Complications	7	4	1	1
Healthcare-associated Infections	8	3	9	5
Airway Events	10	7	12	11
Maternal/Child	12	6	2	2
Medication Errors	16	12	10	12
Delays in Treatment	17	10	28	19
Misdiagnosis		2	1	2
OR Events	24	25	16	14
Falls	93	98	73	72
Pressure Ulcers	144	86	52	63
Other	3	1	2	1
Infrastructure Failure			1	
Restraint/Seclusion Injuries		5	4	3

APPENDIX C: COMPARISON OF FATALITY RATES



For some events, like falls, the number of events per year is large. However, the fatality rate over the past nine out of ten years is low. Many other event types have consistent fatality rates, but occur less often. For instance, in FY13 and FY14, anticoagulant events had 100 percent mortality, but only one event was reported each year.

APPENDIX D: IDENTIFIED CAUSATION PER EVENT TYPE, FY14



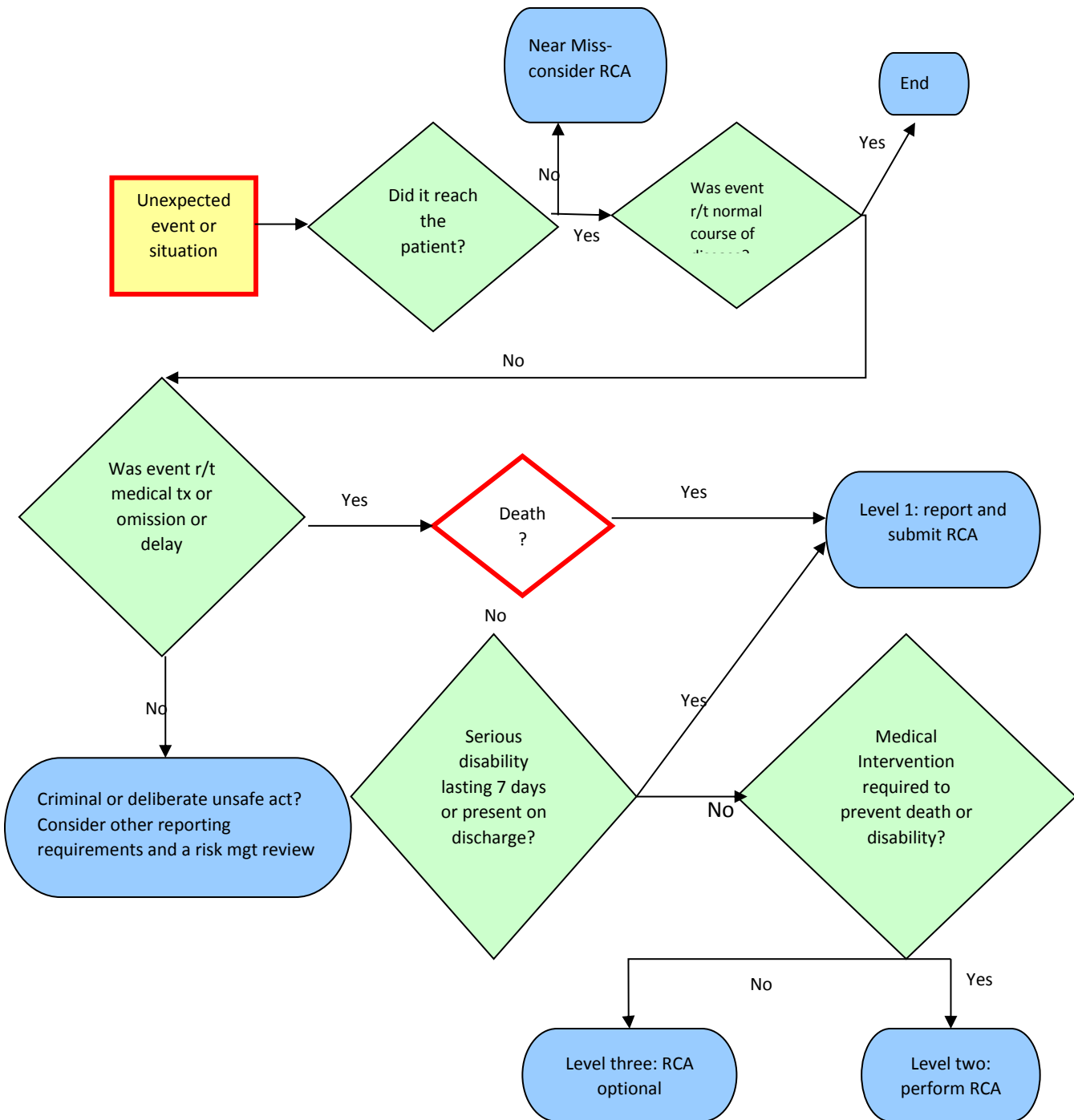
APPENDIX E: OUTCOMES FOR FY14 LEVEL 1 EVENTS

	Death	Anoxic injury or PVS	Surgery	Increased Length of Stay	Transfer to Higher Level of Care	Loss of Function	Loss of Limb or Organ
Air embolism							
Airway	9	2					
Burns	1		1				
Contaminated device							
Delay	16						2
Fail to act	1						
Falls	8		46	1	5	13	
Fetal death or injury	2						
Healthcare acquired infections	2			3			
HAPU			5	58			
Infrastructure failure	1						
Malfunctioning device							
Medication error	5	1			3	2	
Misdiagnosis	1						
Other						2	
Physical assault	1		1		1		
Restraints			2	1			
Retained foreign bodies**			6				
Sexual assault*							
Suicide	8						
Surgical events	1		3				

* Neither patient required physical care.

** Two of the six required no follow up care.

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) 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 COMAR10.07.06 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.