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Office of Health Care Quality

DEPARTMENT OF HEALTH & MENTAL HYGIENE

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Maryland Hospital Patient Safety Program Annual Report Fiscal Year 2011



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Foreword

I am pleased to present the 2011 Maryland Hospital Patient Safety Program Annual Report. Maryland hospitals are required to report serious adverse events to the Office of Health Care Quality (OHCQ). These are unexpected events in treatment which result in a patient's death or serious injury. Since the inception of the program and through FY10, events related to Falls had been the most frequently reported Level 1 Adverse Event. For FY11, the most commonly reported event category is Hospital Acquired Pressure Ulcers, which is a shift from the number two position last year. Retained foreign bodies ranked third in the number of events reported to the agency this fiscal year, with Delays in Treatments as the fourth most frequently reported category.

During FY11, hospitals have shown a continued effort in disclosing to affected patients and families the occurrence of Level 1 Adverse Events. Compliance with Maryland regulations as to disclosure continues to improve over past years.

The Maryland Patient Safety Program regulations require that hospitals designate a staff person to function as the patient safety coordinator. FY11 continued the attrition pattern of patient safety coordinators as noted in FY10. The OHCQ has noted significant change in not only reporting rates but interest and engagement in the patient safety process when a hospital loses key patient safety personnel. Patient safety cannot function in a silo under the direction of one person. It must be a hospital wide effort with the direction and involvement of hospital leadership. For that reason, it is critical that a hospital's leadership is committed and involved in the hospital's patient safety program. Leadership involvement continues to be a key element in a hospital's patient safety program. To be successful, the program must employ a multidisciplinary team, establish patient safety goals, monitor hospital performance for these goals, and actively participate in the root cause analyses (RCA) process. These methods, combined with establishing open communication among hospital disciplines, including the patients and their families, are integral to a successful patient safety program.

The OHCQ Maryland Hospital Patient Safety Program has been an important source of information provided to the Department. Our collaboration with the Maryland Patient Safety Center (MPSC) brings patient safety professionals together to study the causes of unsafe practices and put practical improvements in place to prevent errors. Designated in 2004 by the Maryland HealthCare Commission, the Center's vision is to make Maryland hospitals and nursing homes the safest in the nation.

While OHCQ will continue to enforce the mandatory reporting requirements and use our authority to sanction hospitals who purposefully do not report, there is even greater goal than the process of event reporting. Communication and collaboration between the Department and the hospitals along with the hospitals' ability to conduct serious and critical analyses of errors and report those errors will promote successful improvements towards quality patient care.

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

Very truly yours,

Nancy B. Grimm, RN, JD, Director

Maryland Hospital Patient Safety Program Analysis

Fiscal year 2011 (July 1, 2010 to June 30, 2011) marked the seventh year of the Maryland Patient Safety Program. FY11 was also marked by two patient homicides that occurred in Maryland hospitals, as well as 144 reported hospital-acquired pressure ulcers (HAPU). Hospital reports of Level 1 Adverse Events continue to increase in FY11, from 265 reports in FY10 to 348 reports in FY11.

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, but the Office of Health Care Quality has identified improvement in the reporting by individual hospitals, particularly in the rates of falls and pressure ulcers. However, most hospitals continue to struggle with implementing effective, lasting interventions and measuring outcomes. This report includes some creative corrective actions and identifies best practices.

MANDATORY REPORTING OF ADVERSE EVENTS

While most hospitals have integrated the reporting and analysis requirements of COMAR 10.07.06 into their risk, adverse and sentinel event management programs, a few hospitals still struggle with identifying and critically reviewing adverse events. Many hospitals lack staff and leadership commitment for sustaining corrective actions following near misses or actual patient injuries.

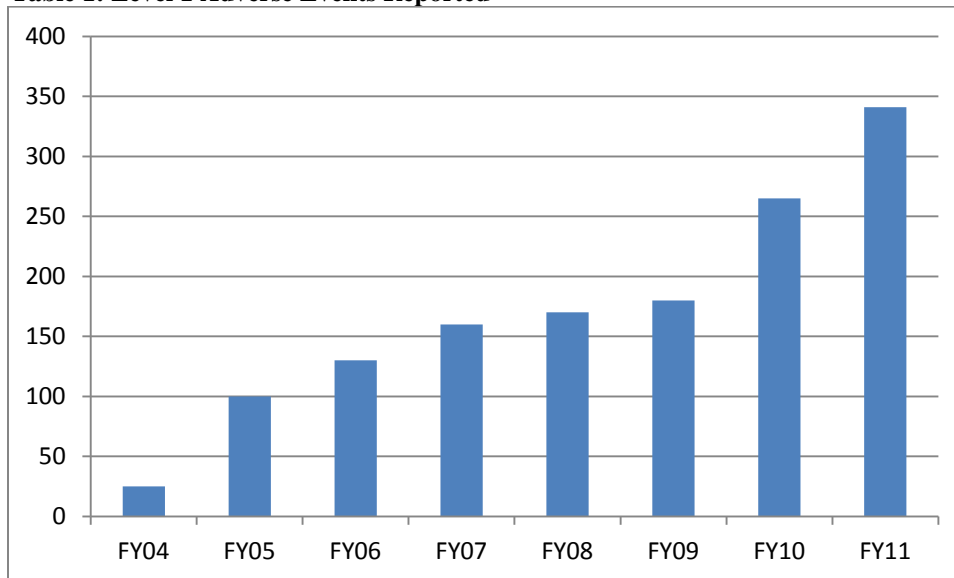
While we assume there is still under reporting, especially of non-fatal events, there is heightened awareness among the general public, other Maryland and federal government payor organizations, and hospitals about the importance of identifying and addressing safety issues. Several agencies now have mandatory reporting of quality/safety data, including infection rates and core measure data to the Maryland Health Care Commission. Additionally, the work of the Maryland Health Services Cost Review Commission in incorporating rates of Potentially Preventable Complications (PPC) into the hospital rate setting process may have resulted in additional quality review and increased reporting.

A Level 1 adverse event is defined in COMAR 10.07.06 as any event that causes death or serious disability. Since the enactment of the Maryland Patient Safety Program regulations on March 15, 2004 and through June 30, 2011, a total of 1518 Level 1 Adverse Events have been reported by Maryland hospitals. In comparing reporting rates from FY11 to years prior, the rate of Level 1 events for maternal/neonatal deaths and injuries and for airway misadventures remained stable at 3.2% and 3.5% respectively. The rate of fatal delays in treatment dropped by half, from nearly 10% to 4.2%, and the rate of suicides also dropped, from 4.2% to 1.8%. The majority of suicides reported in FY11 occurred outside the hospital after the patient had been discharged. The rate of Level 1 falls decreased from 35% to 25%, while the rate of HAPU

increased from 8% to 40%. Falls and HAPU accounted for 65% of the Level 1 events reported in FY11.

An additional 61 non-Level 1 events were reported to the Department in FY11. Some of these adverse events were determined, after further review, by the hospital or the Department to be not reportable (Level 2 or Level 3 Adverse Events or near misses). Another subset of these hospital events were reported strictly due to the significance of the event even if the outcome did not rise to the level of death or a serious disability to the patient. Examples of these include first and second degree burns during surgical procedures or retained foreign bodies that were identified and removed prior to discharge from the hospital. In FY11, one hospital identified an intentionally unsafe infection control practice by a clinician who was new to the organization that affected over 40 patients, although no serious injuries were noted. Since March 15, 2004, a total of 321 events that did not meet the criteria for a reportable event under COMAR 10.07.06 were reported by hospitals.

Table 1: Level 1 Adverse Events Reported



Sixty four of the 65 Maryland acute general and specialty hospitals have reported at least one Level 1 Adverse Event since March 15, 2004. During FY11, 50 of 65 hospitals reported at least one Level 1 Adverse Event. An overview of the types and sizes of hospitals licensed in Maryland is provided in Appendix A.

As noted in our previous reports, the number of events reported is higher for larger hospitals with more complex patient populations. Table 2 identifies the average number of Level 1 Adverse Events reported per hospital.

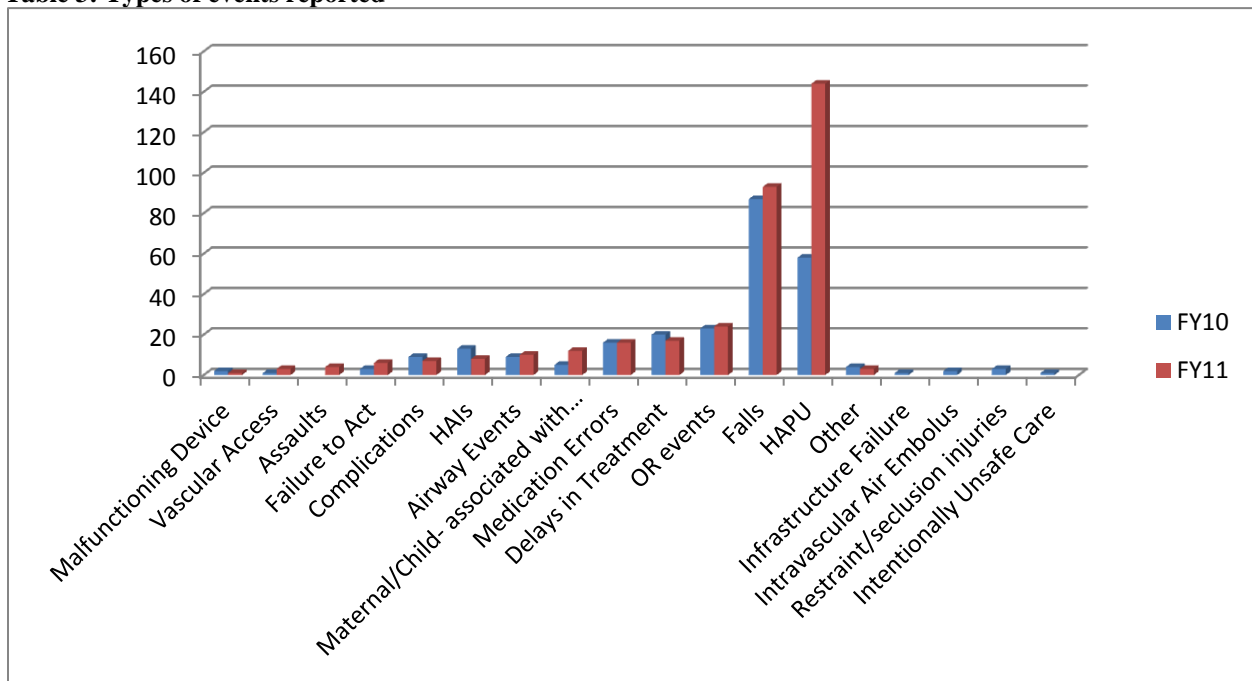
Table 2: Level I adverse events based on Hospital licensed bed capacity

NUMBER OF LICENSED BEDS	Number of hospitals	Number of hospitals reporting	Average no. of reports
300 or more beds	15	15	5.9
200 – 300 beds	16	15	8.6
100 – 200 beds	15	12	2.6
Less than 100 beds	19	8	1.1
TOTALS	65	50	

Unlike previous years, the largest hospitals did not report the majority of Level 1 Adverse Events. Hospitals with between 200 and 300 beds reported 40% of all adverse events in FY11 (See Table 2). With a few exceptions, reporting rates remain low for the smallest hospitals—those with less than 100 beds. These smaller hospitals generally care for less complex patients. The 19 hospitals with less than 100 beds reported 20 Level 1 Adverse Events in FY11. However, 95% of these hospitals have reported at least one Level 1 event since 2004. It should be noted that all hospitals reported one or more non-Level 1 adverse events. Half of the hospitals with less than 100 beds are specialty hospitals serving chronic, psychiatric, rehabilitation, or child populations and are traditionally lower adverse event reporters.

The Office of Health Care Quality has interpreted that the higher reporting rate in FY11 can be generally attributed to the number of pressure ulcers reported. HAPU is the only category of event with a significant increase in the number of events from previous years (See Table 3).

Table 3: Types of events reported



Maryland hospitals are categorized as acute general, psychiatric, chronic, children’s, and rehabilitation. Acute care hospitals account for 68% of all the licensed Maryland hospitals, but reported 97% of the Level 1 Adverse Events in FY11. As noted in Table 4, acute care hospitals historically have accounted for over 90% of all the reports received. The number of reports from acute care hospitals is indicative of the acuity of patients served in these hospitals as well as the more invasive and complex services provided in acute care hospitals.

Psychiatric hospitals reported 12 Level 1 Adverse Events in FY10 and seven in FY11. The four largest psychiatric hospitals continue to report more events than the smaller facilities with six of the seven events received in FY11 reported by the psychiatric hospitals that have more than 200 licensed beds. Of the nine other special hospitals (chronic, rehabilitation, and children’s) only three reported Level 1 Adverse Events in FY 11.

Table 4 Number and types of hospitals reporting

HOSPITAL TYPE	TOTAL NUMBER OF HOSPITALS	NUMBER of HOSPITALS REPORTING IN FY 11	LEVEL 1 ADVERSE EVENTS IN FY 11	TOTAL NUMBER OF REPORTING HOSPITALS Since 3/15/ 2004	TOTAL LEVEL 1 ADVERSE EVENTS Since 3/15/2004
Acute General	45	44 (97%)	338 (97%)	45 (100%)	1417 (93%)
Special Hospital - Psychiatric	11	5 (38%)	7 (5%)	11 (100%)	64 (4.2%)
Special Hospital – Other	9	3 (33%)	3 (2%)	8 (89%)	37 (2.4%)
TOTALS	65	52 (75%)	348	64 (93%)	1518

The Office of Health Care Quality’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.”¹¹ This is a nationally known classification of twenty nine events used by several state reporting systems as their criteria for reporting. Since the NQF system is nationally recognized, it enables the Office of Health Care Quality to compare its data with other state reporting systems. Since the Maryland Patient Safety Program is focused on patient outcomes and the agency does not define or limit the types of events reported by hospitals, the agency has supplemented the NQF list with other types of events that have been frequently reported in Maryland. 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; and
- Misdiagnosis.

¹¹ National Quality Forum. “Serious Reportable Events in Healthcare—2011 Update.” Washington DC: 2007

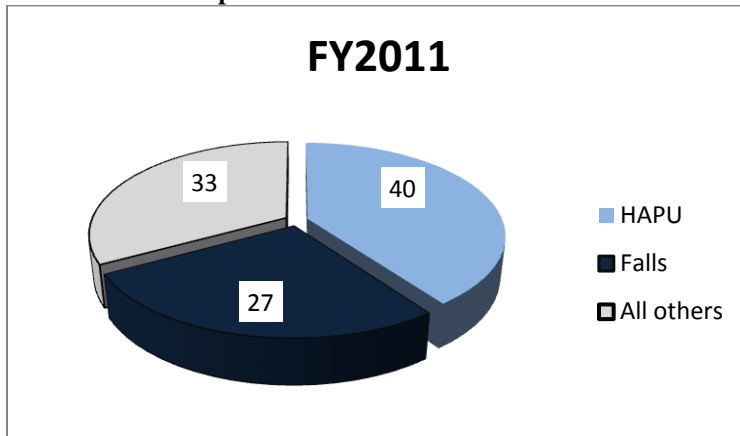
Event Details

PRESSURE ULCERS AND FALLS

Reports of patients who developed stage III and IV pressure ulcers after admission increased to the most frequently reported event type in FY11, making up 40% of all the Level 1 reports received by the Department. The majority of these (80%) were actually deep tissue injuries (DTIs) that had not yet become open ulcers. The outcomes reported most often for patients with pressure ulcers are medical intervention and extended lengths of stay. Thus far, no reported pressure ulcer has proven fatal. Obviously the causes of pressure ulcers are multi-factorial, and the prevention and treatment of them remains a priority for most hospitals. One reported approach utilized by a hospital included educating patients on the need to cooperate with turning and positioning to avoid the development of pressure ulcers. This included showing pictures of stage III and IV HAPUs to patients who refused basic interventions.

Falls resulting in death or serious disability to the patient remain highly reported, accounting for 27% of the Level 1 reports. Eight of the 93 falls reported in FY11 resulted in death (8.6%). This is slightly higher than the death rate of 7% in FY10. Please see Appendix C for a breakdown of the outcomes of the events reported in FY11.

Table 5: Events Reported



PATIENT PROTECTION EVENTS

There were 2 highly publicized homicides in Maryland hospitals in FY11. In one case the alleged perpetrator was a family member and in the second it was another patient. In both cases the hospitals reviewed and scrutinized their patient supervision and security processes. The Department has also noted an increase in the number of reports in patient-to-patient and patient-to-staff assaults. Examples of these reports include a patient who fell and fractured her wrist while assaulting a hospital security officer. Another patient was pushed by a patient in a

psychiatric holding area of a hospital emergency department. This patient was a frail 90 year old who sustained a fractured hip after being placed in a room with younger and more aggressive patients.

Five suicides were reported in FY11. Three occurred outside the hospital, specifically, one patient had been discharged while two others eloped from emergency departments prior to admission. Although these events occurred outside the hospital, it is important for hospitals to recognize the importance of identifying, through the RCA process, those areas related to the improvement of practices regarding patient supervision, environmental safety, and staff accountability.

While reports of airway misadventures remain low as a percentage of the whole, accounting for just ten of the events reported in FY11, the fatality rate remains high at 70%. The root causes for one preventable death was related to the fact that more than half of the hospitalists did not have ACLS (advanced cardiac life support) certification. Another event involved a patient who was admitted after food aspiration but was ordered and given oral medications in the emergency department.

SURGICAL EVENTS

In FY11, 17 Level I adverse effects were associated with the post-surgical retention of foreign bodies (RFB). This is compared with 15 RFBs reported in FY10. These two years account for 62% of all reported RFBs since FY04.

While rarely fatal, RFBs are entirely preventable. Since the risk factors and prevention methods are so well established, the fact that Maryland continues to have so many each year is of concern. Consistent with the literature, most RFBs in Maryland hospitals occur during abdominal surgeries, emergency procedures, converting from laparoscopic to an open procedure, or in cases with multiple personnel or team changes. The RCAs noted that the change of surgical procedures and the change of teams contributed to the miscounts of foreign bodies. Five of these events involved retained non-radiopaque sponges. It is difficult to understand why hospitals continue to use non-radiopaque equipment when best practices suggest otherwise. In 2 of the retained sponge events, it was documented that the final count was incorrect. However, X-rays taken in the OR failed to identify the sponge resulting in days or weeks before the foreign body was identified and removed. Two other events, involved retained wound packings or dressings. Another 2 RFBs in patients were related to plastic spacers used in joint replacement. Faulty of out of date equipment resulted in three of the RFB events, including an event in which the surgeon used a very old bougie to dilate an orifice, resulting an exposure of mercury to the patient and the OR staff when the bulb ruptured while inside the patient. This event was reported in the FY10 Maryland Hospital Patient Safety Annual Report. As a result of the publication, hospitals responded by investigating and removing similar mercury weighted dilators from patient treatment areas.

Unlike retained foreign bodies, the number of reports of wrong site surgeries, wrong patient surgeries and wrong surgical procedures remains low. Since reporting began in FY04, 25 reports of wrong site, wrong patient or the wrong surgical procedure have been received by the Department. Three cases of wrong site surgery were reported in FY11, including a joint surgery event in which all of the paperwork, site marking, consent etc. specified the right side. In this case, the room was set up for the left side resulting in a wrong side procedure. The hospital OR staff was accustomed to surgeons marking sites with non-indelible ink that could be easily removed during the prepping procedure. The circulating nurses had habitually acted as leads for time outs, instead of the surgeons. In another case, a wrong side surgery was performed on a patient's kidney. The surgeon failed to review any imaging studies or reports prior to operating on the patient, but relied solely on a verbal conversation with the patient's nephrologist. While this event is clearly appropriate for peer review, it is incumbent upon the hospital to evaluate its systems of accountability, lack of redundant safeguards, and culture of safety.

DELAYS IN TREATMENT

The Department received 17 reports in FY11 of delays in treatment leading to 14 fatalities. Four of these adverse events involved a delay in reporting or intervening in regards to critical lab values. Another 4 events occurred when there was a delay in recognizing and responding to critical monitor alarms, including an ED patient fatality, which occurred as a result of failure of the nursing staff to respond to the monitor alarms when the patient's heart rate dropped precipitously. The results of the RCA revealed a culture of complacency by the monitor technicians to the frequent alarms, thus failing to notify the nurses. An additional 4 events were related to ineffective interventions done for such symptoms as low blood oxygen, low blood pressure, or low heart rate, including a failure to properly re-assess the patient's condition. One particular ED patient who presented with signs of a CVA (stroke) was given a sedative for agitation with no reassessment or follow-up neurological evaluation. The patient was found to have no neurological functioning a few hours later as he was being prepared for transport to another hospital. Of special mention are 3 patients for whom signs of neurological impairment following head injuries were diagnosed as behavioral in nature and essentially ignored by the staff.

MATERNAL/FETAL DEATH OR INJURY ASSOCIATED WITH THE BIRTH PROCESS

In FY10, the Department received no reports of maternal death or injury associated with the birth process, while in FY11 the OHCQ received 4 reports. Three of these women expired while 1 patient was left in a persistent vegetative state. During FY11, the agency also received 8 reports of neonatal death or injury that occurred during the perinatal period. Seven of these events were fatal. These 12 events more than double the 5 reports the Department received in FY10. Since FY04, the Department has received nearly 50 Level 1 reports of maternal and/or fetal deaths or injuries associated with the birth process. Following is an example of the types of reports we receive:

An expectant patient went to the obstetrics (OB) clinic on a Friday for her normal appointment. Her delivery date was scheduled the following Monday. The patient had submitted a 24-hour urine the previous week. However, the patient's obstetrician did not review the results until the patient left the clinic. The patient had a very high urine protein, which could indicate preeclampsia. This condition is commonly fatal to both the mother and child and is generally be treated by inducing delivery or performing a C-section. The patient was contacted and an induction was scheduled for the following Saturday. The obstetrician failed to notify the Labor and Delivery (L&D) staff of the scheduled induction, although he did document the procedure in his clinic notes. When the patient arrived on Saturday no one was aware of the planned procedure. Consequently, she was observed for four hours and discharged. Neither staff nor the OB hospitalist accessed the patient's clinic record or lab results. Furthermore, the patient did not inform staff of the reasons for her admission. The patient returned to the hospital on Monday for delivery. During assessment, the nursing staff discovered non-reassuring fetal heart rate rhythms. The OB hospitalist reviewed these remotely (he was in the hospital, but not on the OB unit) and advised the nurses to contact the attending physician. The Attending was called, but did not inform the RN that it would take at least one hour to arrive at the hospital. When the physician did not present in a timely manner, the staff neglected to follow the chain of command, including contacting the OB rapid response team or the OB hospitalist. The infant was born by C-section and was discharged home after three weeks in the hospital.

The hospital found that there was a lack of redundant safeguards and an ineffective communication process. Neither the OB clinic nor the OB unit had a standardized process for reporting from physician to physician. There also was no expectation that staff would review the patient's known medical history. Additionally, the hospital found that none of the common perinatal mother-baby test results were on the hospital's list of critical values. The hospital implemented TeamSTEPPS and simulation training, along with changing lab and clinic processes for following up on test results and patient directions.

In another case, a full-term, seemingly healthy infant was stillborn after the L&D staff spent more than three hours attempting to operate a fetal heart monitor without seeking clinical correlation for the findings. By the time everyone realized that the neonate was in distress, the baby had expired.

Three women died post partum of disseminated intravascular coagulation (DIC), a serious condition, which creates debris in the bloodstream (which can occur during the delivery process) causing the blood to clot, affect clotting factors, and lead to hemorrhage. In one case, when the patient began to hemorrhage, the decision was made to move her to the main OR from the delivery room. The RCA identified that the equipment and the environment between the two OR's were so dissimilar that the staff was unable to resuscitate the patient.

Another post-partum patient died of DIC while recovering in the main recovery room instead of the OB recovery room. She had also had a C-section in the main OR. The staff in the

PACU was not familiar with caring for post-partum patients and did not recognize the seriousness of the patient's symptoms.

In a similar case, a patient had to have an emergency C-section in the main OR because the obstetrical OR was being terminally cleaned. The staff found themselves working between the 2 ORs to obtain needed equipment as the main OR was not stocked with commonly used OB sterile equipment. Also, the staff was not familiar with the environment or the location of required equipment. As a result, the hospital began cross-training the staff and stocked the main OR with essential equipment, such as a baby warmer, infant resuscitation equipment, and a C-section tray of instruments.

MEDICATION ERRORS

In FY11, the Department received 12 reports of medication errors leading to death or serious disability. Three of these events were caused by inadequate medication reconciliation, including a patient who was mistakenly prescribed methadone on admission to the hospital. Neither the PA-C who wrote the order, the attending physician, nor the pharmacist questioned this order even though the dose was high and not in accordance with the hospital's methadone protocol. One nurse attempted to clarify the order before giving the medication, but was not successful. This resulted in other nurses administering the medication for the following 2 days, at which time the patient became somnolent, severely hypoxic and could not be resuscitated.

Two fatal medication errors occurred in emergency departments (ED). One nurse gave aspirin and an anticoagulant to the wrong patient diagnosed with severe gastrointestinal bleed, leading to the death of the patient. The other ED event occurred during an attempted resuscitation of a patient who presented with symptoms of myocardial infarction. The nurses miscalculated the drip rate for a cardiac drug, causing the patient to receive a fatal overdose. In this case, the nurses not only failed to contact the pharmacist to verify the calculations, but utilized a dated IV pump, which was not equipped with an automatic flow interrupter. As a result, the patient received the entire bolus and expired.

Several years ago, the Department decided to separate medication errors related to anticoagulants from the general medication error category. For FY11, the Department received two Level 1 anticoagulation events. In an attempt to improve the safety of managing patients receiving anticoagulant therapy, several hospital have standardized dosing and testing while increasing pharmacist involvement and control over the process. One of the FY11 events occurred in an anticoagulation clinic managed by the hospital's pharmacists. A patient became critically ill after the pharmacist dispensed the wrong dose of Warfarin. In reviewing the event, the hospital found two prior less serious adverse events associated with dispensing incorrect dosages to clinic patients. The hospital's investigation also revealed that because of the similarity between Warfarin 1 mg and 5 mg tablets, the clinic lacked safeguards to prevent the wrong tablets from being dispensed. The clinic stopped dispensing the tablets and sent patients to the hospital's outpatient pharmacy to fill the prescriptions. This event helps illustrate the need to

closely track and trend near miss events. If the hospital had corrected the dispensing problem after the first two non-lethal events, this patient event may have been avoided.

Untreated hypoglycemia events are often related to medication errors component and are reviewed as a separate category. Of the 12 reports of Level 1 hypoglycemic events received since 2004, 4 events were reported in FY11. Two of these events occurred to patients who continued to receive hypoglycemic agents (insulin and glypizide) even as their blood sugars were dropping to dangerously low levels. The RCAs for these events identified a disconnect with physicians and nurses regarding the use of hypoglycemic agents and subsequent hypoglycemia. Patient safety literature refers to this state as *attentional lockup*, or lacking situational awareness. According to Dekker, these terms refer to how individuals shift attention or focus based on prior assessments or future expectations, how individuals activate and apply knowledge in context, and how they use past experience to recognize patterns of data.² The task for the RCA teams in these types of events is to determine if (and why) the clinicians' thought processes made sense at the time of the event given all other demands on time and attention. Neither hospital had flow sheets or protocols for blood sugar testing to alert the staff. Both hospitals were able to implement changes to their electronic medical records to reflect evidence-based care of diabetic patients.

HEALTHCARE ASSOCIATED INFECTIONS

While reports of healthcare associated infections (HAI) have increased slightly each year, the Department recognized that HAIs are probably underreported by Maryland hospitals. Since COMAR 10.07.06, Patient Safety Programs, requires reporting of HAIs only when the patient is seriously injured or dies, the majority of the received reports are often fatalities in which it is fairly clear that the HAI was the cause of death. HAIs also are required to be reported to another agency in the Department, possibly causing a burden for the reporting hospital. The Office of Health Care Quality received 7 reports of HAIs in FY11, 4 of which were thought to be the cause of death. Two patients died of central-line associated blood stream infections (CLABSI), with 1 patient developing a ventilator-associated pneumonia (VAP), which ultimately led to fatal meningitis with the same infectious agent. Two patients developed abscessed peripheral IV sites from IVs left in longer than recommended, causing 1 patient to expire from a subsequent overwhelming infection. One patient endured repeat surgeries and weeks of IV antibiotics after developing a deep wound and bone infection post back surgery. In this case, a vendor who had been in the operating room left the hospital to retrieve instruments from the trunk of his car. These instruments and hardware were not sterilized appropriately before use in the patient. For more on the issue of vendors and company representatives in the OR, see our Clinical Alert: An Unnecessary Distraction, Vendors in the OR, Volume 4, Number 3, Winter 2007³.

Reports of HAI resulting in death or serious disability are often not reported to the department for weeks after the care was rendered. Further complicating the reporting of healthcare acquired infections are factors identified in previous annual reports. These include the

² Dekker, Sydney *The Field Guide to Human Error Investigations*, Ashgate Publishing, 2002

³ <http://dhmh.maryland.gov/ohcq/HOS/sitePages/Alerts.aspx>

short length of patient stays in hospitals. HAIs may not be apparent at discharge and the patient may be treated for the infection at the doctor's office postoperatively or at another hospital, making it difficult to capture this information. Confirmatory laboratory cultures may take several days to identify the infection. Therefore, HAIs may not be communicated in a timely manner to the hospital's patient safety officer or to the Department. Infection control regulations added to COMAR 10.07.01 in 2008 require collaboration between the hospital's infection control practitioner and the patient safety/quality assurance departments.

VASCULAR ACCESS

The reports of Level 1 adverse events associated with vascular access devices remain small. However, these events have a great impact on patients' lives, even if the patient survives the event. Since 2004, 20 adverse events associated with vascular access devices have been reported to the Department. Overall, 16 of the 20 events reported produced fatal results. For FY11, 2 of the 3 events reported resulted in fatalities. The two fatalities were associated with the use of large-bore temporary dialysis access catheters. Since the Department began collecting data, the majority of fatalities have occurred when these catheters have become dislodged, used in place of regular IVs, or been tampered with by the patients. Although the use of these types of catheters is often necessary, hospitals should have a mechanism to improve oversight of usage and to ensure additional safety mechanisms are in place.

The third vascular access adverse event reported in FY11 resulted in a patient's loss of limb when contrast material was administered too quickly through a small peripheral IV and leaked into the muscle, causing severe tissue damage.

OTHER EVENTS

Each year, the Department receives a number of Level 1 adverse events are reported that do fall into a particular category. In FY11, 2 such reports were received. In one case, a patient who was ordered on complete bed rest following the removal of an infected hip prosthesis, was assisted out of bed to a bedside commode. Not only did the spacer in her hip dislocate, but she suffered a femur fracture, requiring her to spend several months in a hip cast.

The other event occurred to a patient who was suffering a miscarriage on arrival to the ED. A mid-level provider from the OB performed an hCG level (a hormone present in the blood of pregnant women). The hCG level was above normal ranges. The result could have signified a molar cyst, which is a genetic cellular mutation that mimics pregnancy and may cause invasive cancer if not treated immediately with evacuation of the contents of the uterus. The patient had a sonogram which was also consistent with a molar cyst. The mid-level provider failed to follow up on these results and did not have the obstetrician examine the patient before discharging her with clear instructions from the ED. Two months later, the patient returned to the ED with excessive bleeding requiring an emergency hysterectomy. The hospital's investigation revealed that the patient and her husband spoke little to no English. There were no interpreter services provided by the staff and, consequently, it was unlikely that the patient understood any of the

instructions she had been given at the first ED visit. After the event, the hospital strengthened their processes for physician oversight of mid-level providers in the ED and reinforced the expectations to provide interpreter services, when required.

This event illustrates issues seen in many ED occurring adverse events. The emphasis on short length of stays in EDs often encourages unsafe practices that quickly become engrained in the unit culture. All hospitals must have appropriate processes in place that ensure oversight of mid level providers and that policies and procedures support due diligence on the part of all providers to recognize when they need the assistance of a higher level health care provider.

Many hospitals have also reported events that do not meet the criteria for mandatory reporting and are not Level 1 Adverse Events. These hospitals have reported these events because they recognize the potential for serious system problems. Burns that occur in the OR are usually not Level 1 Adverse Events. However, hospitals often report these events when they occur even if the resultant injuries are minor. Retained foreign bodies that are removed hours of surgery and wrong site procedures that do not harm patients are also reported by hospitals regardless of presence of serious disability or death. The Office of Health Care Quality appreciates the willingness of hospitals to report beyond their obligation to do so. This practice assists the agency in tracking never events, even if the injury is relatively minor or no injury occurred.

Notifying Patients and/or Families

The Maryland Hospital Patient Safety Program and Maryland regulations require a hospital to notify a patient, or if appropriate, a patient's family member, whenever an outcome of care differs significantly from an anticipated outcome. Hospitals continued the trend of reporting that patients and/or the family were notified of an adverse outcome over the previous 6 years. In FY11, although 7% of the adverse events were not reported to the patient/family, the hospitals could frequently identify a reason (i.e., the patient had no family). 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 family notification, with most policies specifying that the attending physician is to make disclosure.

Review of Root Cause Analyses

In order to comply with the requirements of COMAR 10.07.06 , the hospital must submit a root cause analysis for reported Level 1 adverse events that includes an in depth review of the event by a multi-disciplinary team of individuals to determine, through a series of "why" questions, the actual root causes of the event. Root causes are defined by the COMAR 10.07.06 as the basic or contributory causal factors that underlie variations in performance.⁴ 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 corrected. Root cause analyses (RCA) should focus primarily on systems and processes. The hospital staff must also identify

⁴ COMAR 10.07.06.02 (B)(10)

risks and contributing factors for recurrence, and determine what improvements in systems or processes are needed.

In FY11, hospitals submitted 316 root cause analyses to the Department. These root cause analysis were reviewed by the Office of Health Care Quality staff with feedback provided to the hospitals. The Office of Health Care Quality continues to utilize the root cause analysis evaluation tool designed for that purpose. Since the program began, approximately 1350 root cause analyses have been reviewed, with comments provided to the hospitals. Additionally, over 90% of that feedback is provided within sixty days of the receipt of the RCA.

If a RCA fails to meet one or all of the requirements of 10.07.06, the Office of Health Care Quality may issue a deficiency statement or may send the hospital an extended review of the RCA identifying exactly which elements of the COMAR were not met and providing direction on resources to use to improve the quality of future RCAs. In FY11, the Department singled out five RCAs from four different hospitals for this type of review. The RCAs had been submitted by new patient safety officers and the decision was made to provide direction and assistance rather than deficiencies. There were several commonalities among these poor-quality RCAs:

1. Even though each RCA focused on what happened, rather than why, they lacked sufficient description of the adverse event to even determine what happened;
2. These five RCAs lacked defined root causes and the information given was insufficient to establish causality; and
3. Probably because causality had not been determined, the interventions lacked specificity and had outcome measurements that were inadequate to determine if the corrective actions had any effect on the problematic process(es).

The overwhelming problems with poor RCAs continues to be superficial analyses that fail to uncover anything other than first level or proximate causes for the events. Many of the RCAs reviewed mentioned that “why” questions had been asked, but no answers were given in the RCA and the corrective action did not reflect an in-depth level of analysis. In some RCAs, there is not enough information provided for Office of Health Care Quality reviewers to determine what the adverse event was. Following is one of the RCAs received in FY11, with discussion.

ROOT CAUSE ANALYSIS:

A 90 year old patient with dementia and abdominal pain was scheduled for an abdominal CT with contrast. Because the patient could not swallow, the nurse tried twice to insert a nasogastric (NG) tube to give oral contrast, which was unsuccessful. The hospitalist was able to insert the tube without difficulty. An x-ray was taken to check placement. However, the x-ray results were not available for 12 hours. In the meantime, the patient had pulled the tube out. The nurse then inserted a larger, firmer NG tube and checked for placement. According to hospital

policy, this type of NG tube did not require an x-ray to verify placement. The nurse then gave two bottles of oral contrast through the NG tube. The patient had his CT scan approximately 8 hours later. The radiologist immediately recognized that the oral contrast had gone into the patient's pleural space (between the lung and the chest wall) instead of the gastrointestinal tract. The lung had collapsed so the patient requiring the insertion of 2 chest tubes with ventilator support. The patient eventually died after he developed a pus-filled pocket of fluid in the lung and did not survive surgery.

The RCA assigned causation to the fact that the first nurse and hospitalist did not know that routine x-rays are not read at night. The RCA stated that these 2 individuals were not knowledgeable about the policy for radiology coverage. The corrective actions focused on educating the staff about night time radiology functions. The corrective action plan also included the education of the staff in an effort to eliminate the possibility of a recurrence.

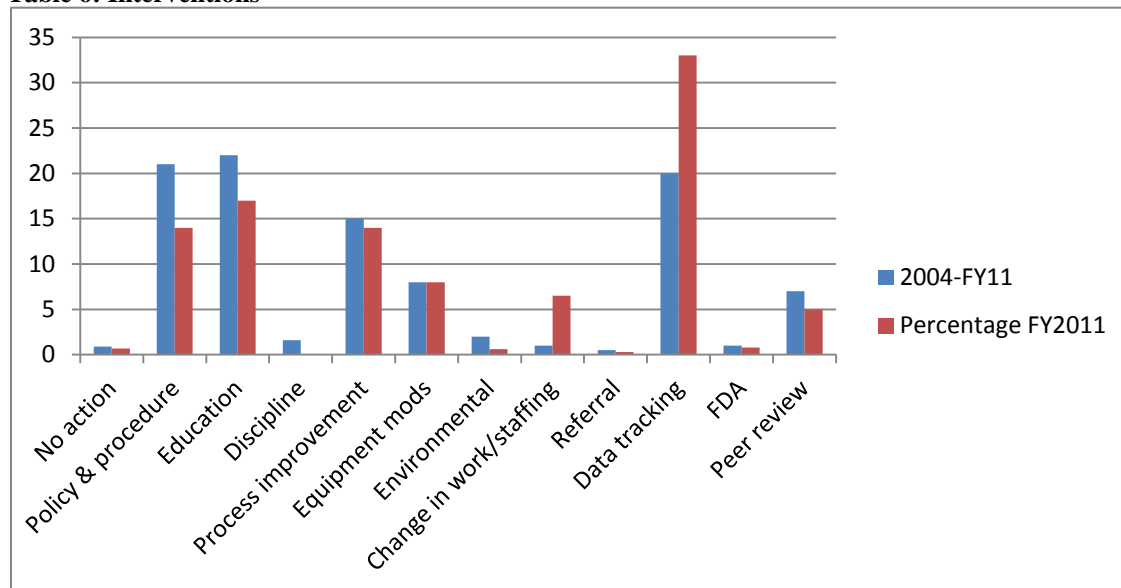
This approach to a corrective action plan does not "drill down" address the significant failures, particularly related to processes. The RCA did not provide enough information to determine why this patient needed an abdominal CT, why there was a delay of 8 hours between the hospitalist orders and the insertion of the NG tube and why more than 24 hours passed before the CT scan was performed.

There are also several latent issues apparent in this event. This event illustrates problems with staff supervision, training, coverage, professional accountability, and ethical care. Many more "why" questions should have been asked.

Since the root causes identified were superficial, the corrective actions consisted of revising the NG tube policy and re-educating the staff and hospitalists. Re-educating a group of supposedly highly trained and skilled professionals is not a long term solution to the latent issues. If education and policy changes were the solutions, Maryland hospitals would be adverse event free.

Hospitals continue to struggle with implementing corrective actions that are sustainable and that will be effective at controlling or eliminating the hazardous condition. As noted above and in Table 6, education and policy changes are frequently used interventions. However, in FY11, the Department noted a trend toward more significant and sustainable corrective actions. More hospitals are improving problematic processes through standardization while building more safeguards into the process. Hospitals are also reviewing staffing patterns to promote and provide safer patient care environments. Dedicating certain staff members as unit preceptors, relieving charge nurses of patient assignments to focus on supervision, and holding surgeons accountable for leading the time outs are all examples of how hospitals can adjust staff workloads. Hospitals continue to improve their tracking and trending of patient safety data, and are less focused on formal discipline as a first response to an adverse event.

Table 6: Interventions



COMAR 10.07.06 requires the hospital to monitor the results and effectiveness of all action plans derived from the RCA. Hospitals continue to struggle with differentiating between process steps and evaluating how effective a corrective action has been in remediating the set of circumstances that led to the adverse event. Hospitals need to determine what the goal of the corrective action is, and how to measure that goal. This assessment would include the impact the action has on the problematic process, whether the action will control or eliminate the problem, the goals for other patients, staff expectations, and, in some situations, frequent, and random staff observations.

Rational Care

The majority of reported adverse events in Maryland hospitals occur to patients who are between 60 and 89 years old (See Appendix C). The majority of fatalities also happen in this age group. As in the above example, some of these events occur during, or are the result of, extraordinary interventions and procedures for elderly patients with multiple co-morbidities. For example, a patient in her late 80s, with metastatic bladder cancer, was admitted for weakness and weight loss. Over the next three days, she had several invasive diagnostic procedures, including a colonoscopy which ruptured her colon and caused her death. Another patient, also in his late 80s, had an elective vascular procedure and was placed on an infusion of anticoagulation post-operatively. His blood levels and coagulation status were not monitored closely enough and he died 24 hours after surgery from a massive brain hemorrhage. The Office of Health Care Quality is certainly not advocating rationing care based on a patient's age, but we are advocating a culture that creates processes that consider rational care for all patients. Hospitals should be able to support clinical decision making, which includes evaluating the risks and benefits of procedures before committing to a course of diagnostics and treatment that may carry undue risks of complications. Physicians must engage elderly patients and their families in honest and

frank discussions regarding the increased risk invasive procedures and testing may pose to them based on their current medical condition.

Complaints

The Office of Health Care Quality, to which adverse events are reported, is also the state regulatory, enforcement and licensing agency. In that role, the Office of Health Care Quality receives complaints regarding Maryland hospitals. In FY11, the agency received 431 complaints from patients, families and other citizens. A total of 2706 complaints have been received since the Patient Safety regulations were enacted on March 15, 2004. Only 27 Level 1 Adverse Events have been duplicated as a complaint as reported through the Office of Health Care Quality's regulatory system since reporting began, with only 2 duplicated in FY11. The data obtained from the complaint process has little relevance to the number and type of adverse events occurring in Maryland hospitals. This lack of duplication indicates that most patients or families affected by serious adverse events do not file complaints about those events. The mandatory reporting and the review of RCAs provides another avenue for the Department to evaluate how hospitals are providing care and exemplifies the value of the Patient Safety Program.

Enforcement Actions

The Patient Safety Program regulations under COMAR 10.07.06 require patient safety engagement throughout all levels of the hospital organization, including the governing body. The Department staff continues to be concerned that some hospitals may not have internal reporting systems capable of capturing adverse events. After 7 years, the Office of Health Care Quality has received reports from all acute general hospitals and from all but one specialty hospital. The Office of Health Care Quality believes that hospitals with robust reporting systems are actually safer than hospitals that under report events. It is of interest that 2 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 does not have a well integrated patient safety program, or a complaint is verified regarding an event that should have been reported to the Department and was not, the agency will perform an on-site survey of the hospital's compliance with COMAR 10.07.06. In FY11, the Office of Health Care Quality performed 2 such on-site surveys. Another hospital was sanctioned for failure to report adverse events and to submit root cause analyses as required under COMAR regulations. These enforcement actions do not focus on the adverse event itself, but investigate systems, culture, reporting and analysis, and policies and procedures required to sustain a robust patient safety program.

Leadership Involvement

The Maryland Patient Safety Program regulations require that hospitals designate a staff person to function as the patient safety coordinator. FY11 continued the pattern of changing patient safety designees. The Office of Health Care Quality has noted significant change in not only reporting rates but interest and engagement in the patient safety process when a hospital

loses these key staff. Patient safety programs cannot function with one individual. It must be a hospital wide effort with the direction and involvement of hospital leadership.

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

- Regularly scheduled meetings between risk, quality improvement, infection control, patient safety, and medical staff leaders to discuss events and to determine how the events should be addressed by the hospital.
- Review actual RCAs, not merely data related to the numbers of events per patient days.
- Actively participate in a root cause analysis. Participation by leadership can provide valuable insight into the challenges faced by patients and by front line staff. Leadership participation also lets the staff know that administration supports the RCA process.
- Provide regular reports regarding adverse events to the Board and other executive level committees. Tell the story about the patient by describing what happened or failed to happen that resulted in harm.
- Establish and participate in administrative rounds that focus on patient safety.
- Attend the training on patient safety provided by your hospital or by the Maryland Patient Safety Center.
- Educate new department heads about the hospital's patient safety program and how their department is expected to interface with the patient safety staff and program.
- Establish patient safety goals and monitor the hospital's performance for those goals.

Clinical Alerts

Based on the information obtained from the review of the events and the root cause analyses, the Office of Health Care Quality has developed and distributed hospital Clinical Alerts. It is hoped that the experience of 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." The following Clinical Alerts were published in FY11:

- "Delays In Treatment"
- "Assessing Physician Quality"

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

The Maryland Patient Safety Center

The Maryland Patient Safety Center⁵ (MPSC) brings patient safety professionals together to study the causes of unsafe practices and put practical improvements in place to prevent errors. Designated in 2004 by the Maryland HealthCare Commission, the Center's vision is to make Maryland hospitals and nursing homes the safest in the nation.

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

- Representation on the MPSC Board of Directors;
- Regular contribution to training workshops sponsored by MPSC;
- Attendance when requested at the MPSC Patient Safety Directors' meetings; and
- Attendance and assistance with special projects.

In addition, the Office of Health Care Quality's Patient Safety Program staff continues to provide redacted RCAs and other data to the trainer for the MPSC RCA training classes to assist in the development of a curriculum that will drive further improvements in root cause analysis and to provide data to support the valuable collaboratives offered by MPSC.

Future Plans and Conclusion

Starting in FY12, the Office of Health Care Quality began providing hospitals with yearly report cards that list the number and type of event reported, and any downgraded or outstanding RCAs. The report cards are sent out on a quarterly basis to approximately 25% of facilities. They include an attestation, modeled after those used in other states, in which the patient safety officer agrees with the list and attests that there were no other Level 1 events during that 12-month period. We have sent report cards to approximately 75% of hospital as of the date of this report with encouraging response. The report cards are another way for Office of Health Care Quality to track and trend events and for the hospital patient safety officers to verify their records.

Early in FY12, the Office of Health Care Quality has revised its database to better capture information regarding root causes related to patient events. We anticipate being able to analyze and interpret these data in our FY2012 report.

As previously noted, we recognize that there are many newly hired patient safety coordinators in hospitals. In order to assist patient safety staff, the Office of Health Care Quality has consolidated its patient safety tools and makes it available to hospitals for staff education. The Office of Health Care Quality would like to formally compile this information to develop a Patient Safety Tool Kit and make it available on its 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

⁵ Maryland Patient Safety Center www.marylandpatientsafety.org

provides hospitals with 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 hospital. The Department will continue to review events and RCAs to develop Clinical Alerts to disseminate information to hospitals and other healthcare providers. The Office of Health Care Quality continues to be available to provide educational programs to interested groups and organizations.

The Office of Health Care Quality also takes advantage of opportunities to interact and share with other state patient safety programs. Beginning in FY10, the agency staff has been actively participating 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 state operated reporting programs a forum for staff of state based reporting programs to exchange ideas, discuss best practices and share the challenges faced in operating the reporting programs.

Additional plans for the dissemination of information continue to include:

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

In conclusion, the Department is pleased that most hospitals are engaged in patient safety activities through the increased reporting of events, the continued improvement of the quality of root cause analyses submitted and the continued reported disclosure of adverse outcomes to patients and families. The department will be pursuing activities to engage other hospitals through our participation in opportunities for outreach and training. The Office of Health Care Quality will continue to develop Clinical Alerts as a means to communicate patterns and trends identified through the receipt of events and the review of root cause analyses.

APPENDICES

APPENDIX A: MARYLAND HOSPITAL DEMOGRAPHICS

Maryland regulation classifies hospitals in two groups. The majority (46) are licensed as acute general hospitals ranging in bed capacity from nine to nearly 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. As a result, the number of beds the hospital is allowed to operate changes on an annual basis. This statute does not apply to special hospitals.

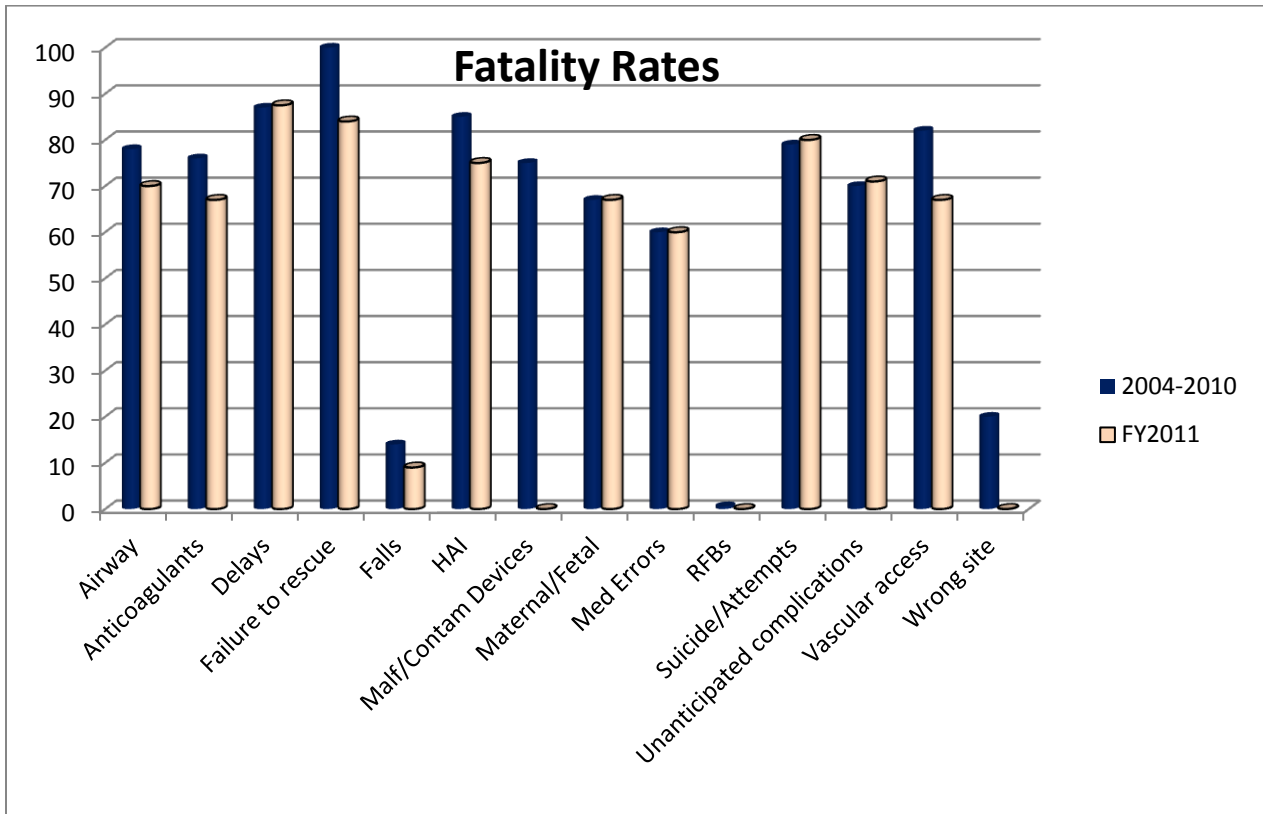
Twenty (20) hospitals are licensed as special hospitals. There are 4 types: rehabilitation, chronic, children's, or psychiatric. Special hospitals do not have operating rooms, emergency departments or intensive care units where patients would undergo more invasive and complicated procedures.

- The 11 Special Hospitals-Psychiatric range in size from 15 licensed beds to 639 beds. Five of these hospitals are State operated. Three psychiatric hospitals serve only specific populations (children, forensics, and clergy).
- Of the 5 Special Hospitals - Chronic, 4 serve patients who are ventilator-dependent or who have chronic respiratory problems. These hospitals range in size from 52 to 180 beds. Two are operated by the State of Maryland. While all provide some rehabilitation services, 2 of the hospitals are dually licensed as rehabilitation hospitals.
- There are 2 Special Hospitals-Rehabilitation and 2 Special Hospitals-Children. The latter are also dually licensed as rehabilitation hospitals. The children's and rehabilitation hospitals have less than 102 beds each and all offer outpatient services.

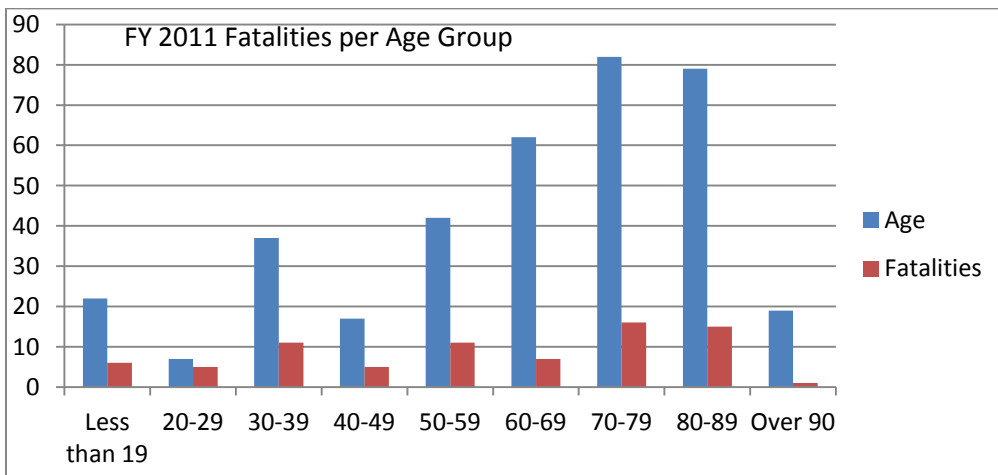
APPENDIX B: TYPES OF EVENTS

Type of Event	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11	Totals
Death or serious disability - fall	3	27	46	56	83	98	88	93	494
Hospital acquired Stage III or IV pressure ulcers	0	0	0	4	1	9	59	144	217
Death or serious disability - delay in treatment	1	12	9	24	20	16	20	17	137
Death or serious disability - airway management	3	11	15	7	7	6	9	10	68
Death or serious disability - medication error	0	11	8	10	8	2	9	10	58
Suicide or attempted suicide	1	6	10	5	11	8	6	5	52
Post-surgical retention of foreign body	0	3	1	6	3	6	15	17	51
Unanticipated complication of treatment	2	5	9	5	2	7	9	7	46
Death or serious injury of patient -HAI	0	0	2	7	5	9	13	8	44
Unanticipated fetal death or injury	0	3	7	5	9	3	5	8	32
Surgical procedure not consistent with consent/ wrong patient / wrong body part	1	1	2	7	4	3	4	2	24
Malfunctioning device	1	3	5	5	4	2	2	1	23
Death or serious disability - anticoagulants	1	3	2	6	3	2	4	2	23
Surgical procedure not consistent with consent/ wrong patient / wrong body part	1	1	2	7	4	3	4	2	24
Unanticipated intra-op or immediate post-op death	0	6	5	1	3	3	2	2	22
Misdiagnosis	7	6	5	2	2	3	2	1	21
Death or serious disability - vascular access device	1	6	3	2	2	2	1	3	20
Death or serious disability - failure to act	0	2	3	2	2	1	3	6	19
Maternal death or serious disability associated with Labor & Delivery	1	2	0	2	2	1	0	4	12
Death or serious disability - hypoglycemia	0	2	1	1	1	2	1	4	12
Death or serious injury - physical/sexual assault occurring within or on hospitals grounds	0	0	2	2	2	0	0	4	10
Intra-op or post-op death in ASA 1 patient	2	0	1	1	1	1	1	1	8
Death or serious disability -restraints seclusion, or side rails	0	1	1	1	1	0	3	0	7
Death or serious disability - intravascular air embolism	0	2	2	0	1	0	2	0	7
Death or serious disability - burn	0	0	0	3	1	1	1	1	7
Hemolytic reaction to ABO incompatible blood products	0	0	1	1	0	0	0	0	2
Death or serious disability - contaminated drug, device or biologic	0	1	0	0	0	0	0	0	1
Infrastructure Failure	0	0	0	0	0	0	1	0	1
Intentionally Unsafe Care	0	0	0	0	0	0	1	0	1
Other	0	2	5	3	5	4	4	3	26

APPENDIX C: COMPARISON OF FATALITY RATES



For some events, such as falls, while the number is very large, the fatality rate remains low, as noted over the past 7 years. Many other event types have consistent fatality rates, but occur less often. The following graph depicts the fatality rate by patient age group.

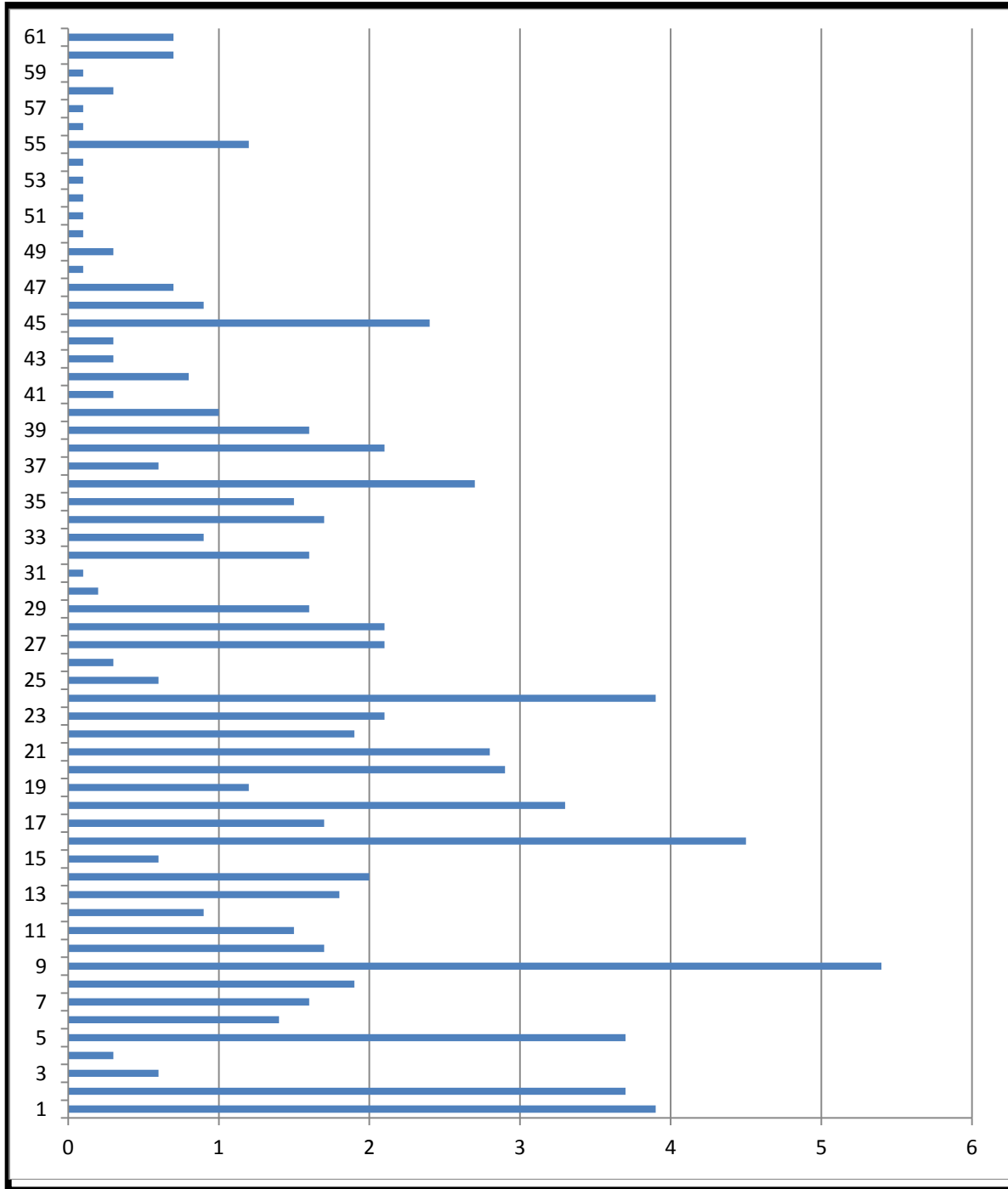


APPENDIX D: TYPES AND OUTCOMES OF LEVEL I EVENTS

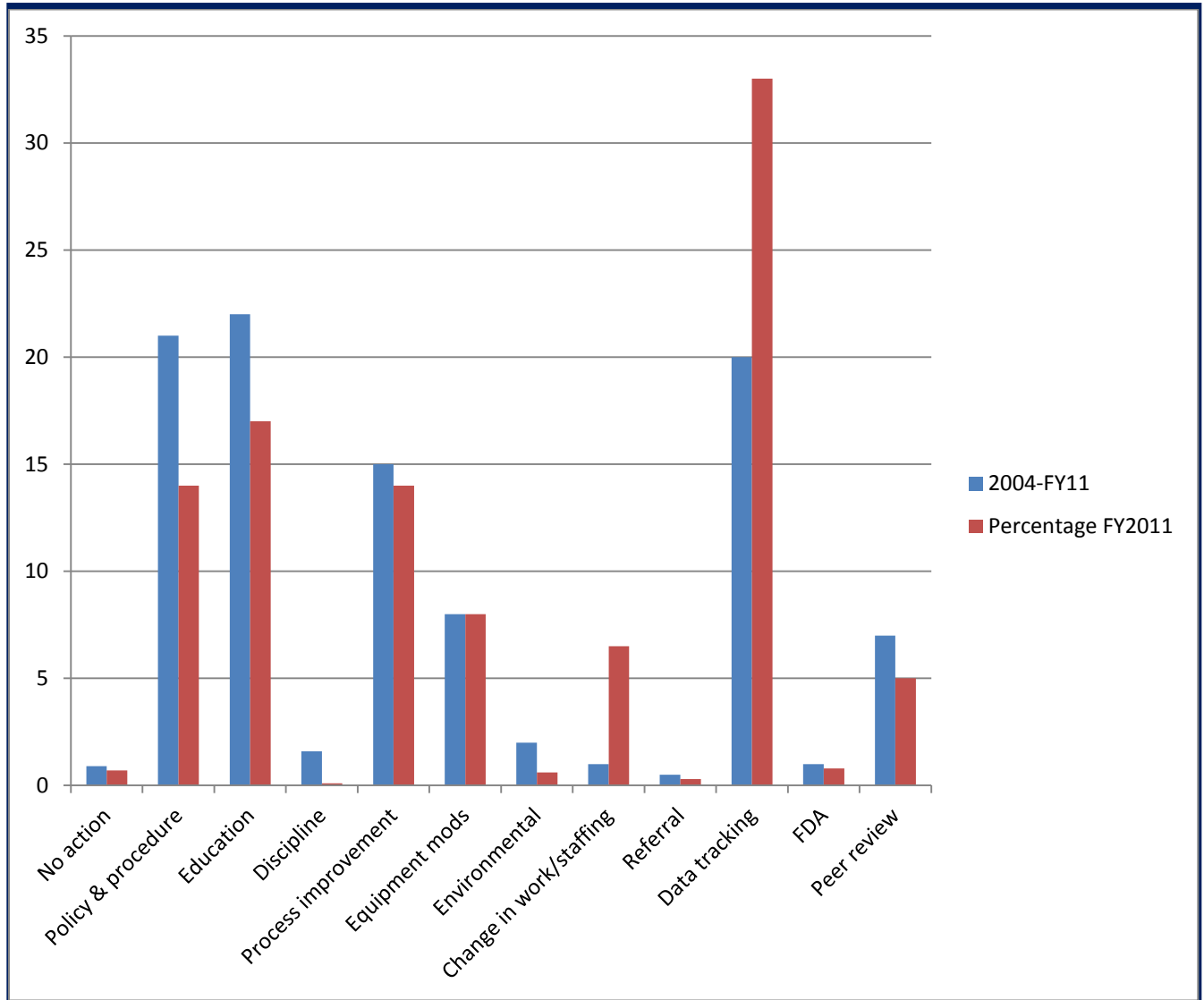
Type of Event	Loss of limb/ function	Surgical Intervention	Medical Intervention	PVS/Anoxic injury	Death	Total
Stage 3 or 4 pressure ulcers acquired after admission	0	9	135		0	144
Death or serious disability - a fall	14	63	8		8	93
Death or serious disability - a delay in treatment	2	1			14	17
Post-surgical retention of foreign body		15	2			17
Death or serious disability - medication error			4		6	10
Death or serious disability - airway management				3	7	10
Unanticipated fetal death or injury			2		6	8
Death or serious injury -HAI		1	1		6	8
Unanticipated complication of treatment		1	1		5	7
Death or serious disability -failure to act		1			5	6
Suicide or attempted suicide resulting in serious disability			1		4	5
Maternal death or serious disability					4	4
Other		1	1		1	3
Death or serious - vascular access device			1		2	3
Death or serious disability - hypoglycemia				1	2	3
Surgical procedure/body part not consistent with consent; wrong patient		2				2
Death or serious disability - anticoagulants					2	2
Unanticipated intra-op or immediate post-op death					2	2
Misdiagnosis					1	1
Malfunctioning device			1			1
Death or serious disability -burn			1			1
Intra-op or post-op death in ASA 1 patient					1	1

APPENDIX E: HOSPITAL REPORTING RATES

This graph represents the reporting percentage of a randomized list of Maryland hospitals



APPENDIX F: CORRECTIVE ACTIONS IDENTIFIED IN RCA



Patient Event Decision Tree

