OHCQ

Office of Health Care Quality

Department of Health & Mental Hygiene

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Maryland
Hospital Patient Safety Program
Annual Report
Fiscal Year 2010

MARYLAND

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Foreword

I am pleased to present the 2010 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, events related to falls continue to be the most frequently reported Level 1 Adverse Event, and continue to create significant risks to patients. The second most commonly event category is pressure ulcers. During FY10, two major hospital systems were the primary reporters for most of the pressure ulcers causing the increase, but these events still remain the most under-reported category in most hospitals. These hospital systems are commended for their efforts towards robust reviews of these events. Delays in treatment ranked third in the number of events reported to the agency this fiscal year, which prompted the need for a Clinical Alert on the topic and is available on the OHCQ website.

During FY10, hospitals have shown a continued effort in disclosing the occurrence of Level 1 Adverse Events to affected patients and families. In FY10, hospitals disclosed 239 of the 265 reported Level 1 Adverse Events. At the time the remaining 26 events were reported to the Department, the hospitals had not verified that disclosure had occurred. Compliance with Maryland regulations as to disclosure continues to improve over past years.

In FY10, there was a 20% attrition rate in patient safety coordinators among hospitals, creating a potential disengagement in the hospitals' patient safety reporting process and, as a result, system failures that increase the risk of patient injury. Hospital leadership must remain vigorously involved in patient safety activities. To be successful, the hospital patient safety 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, while including the patients and their families in the process, 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. Of the 265 Level 1 Adverse Events reported in FY10, only seven (7) were reported to OHCQ through complaints and other regulatory processes.

While OHCQ will continue to enforce the mandatory reporting requirements and use our authority to sanction hospitals that purposefully do not report, there is even greater goal than the process of reporting events. 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 care and safe outcomes for all patients.

In conclusion, I would like to thank Anne Jones and Renee Webster and the OHCQ team for their continued dedication and commitment 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 2010 (July 1, 2009 to June 30, 2010) marked the sixth year since the implementation of the Maryland Patient Safety Program. While most hospitals have integrated the reporting and analysis requirements of COMAR 10.07.06 into their adverse and sentinel event management programs, a few hospitals still struggle with the identification and critical review of adverse events. For hospitals to be successful in this endeavor, it is imperative that hospital leadership and staff remain engaged in the process of recognizing serious patient safety concerns. Hospital reports of Level 1 Adverse Events increased significantly in FY10.

While there is no specific rationale for the sudden increase in reports, it appears this increase is related to improved reporting of adverse events by hospitals, rather than an increase in actual events. The increase may also coincide with other complementary initiatives within the Department. The recent addition of reporting quality related process and outcome data related to healthcare acquired infections to the Maryland Health Care Commission might have contributed to increased reports in that category of events. Additionally, the work of the Maryland Health Services Cost Review Commission to incorporate rates of potentially preventable complications into the hospital rate setting pay for performance process may have resulted in additional quality review that contributed to an increase in reporting, particularly with pressure ulcers.

The Department recognizes hospitals' continued efforts to improve patient safety in their facilities. Increased reporting by hospitals is an indication of engaged and proactive patient safety programs, which ultimately promotes positive patient safety outcomes. Hospitals who regularly review errors, near-misses and misadventures are empowered to identify system failures and take definitive action to prevent their reoccurrence. Despite the reporting increase, the Department believes that there remain a number of preventable adverse events that hospitals fail to identify and report to the Department. As the result, the Department continues to focus on areas where improvement is necessary, including reporting, that exist in all hospitals. The Department is committed to ensuring that all hospitals comply with the regulations and that all patients receive safe and quality care.

MANDATORY REPORTING OF ADVERSE EVENT

Maryland Hospitals have reported a total of 1091 Level 1 Adverse Events since the enactment of the Maryland Patient Safety Program regulations on March 15, 2004 and through June 30, 2010. In FY10, a 40% increase in the number of Level 1Adverse Events was reported to the Department. Two hundred sixty five Level 1 Adverse Events were reported in FY10 as opposed to 190 in FY09 and 183 in FY08. This increase was largely attributed to an increased reporting of hospital acquired Stage 3 and 4 pressure ulcers. As noted in Table 1, reports have continued to increase each year as hospital staff becomes more comfortable with reporting requirements and have improved internal hospital systems to identify serious adverse events.

In addition to the Level 1 Adverse Events received in FY10, an additional 51 events were reported to the Department. After further review by the hospital and the Department, several Level 1 Adverse Events were considered not reportable (Level 2 or Level 3 Adverse Events or near misses). However, there is another subset of these events that the hospitals 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. Despite the fact that these events did not rise to the level of a reportable event, many of these reports were submitted by the hospitals voluntarily due to the potential severity of the events. Often these events included reports of first and second degree burns during surgical procedures or retained foreign bodies that were identified and removed prior to discharge from the hospital. Since March 15, 2004, a total of 231 additional 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
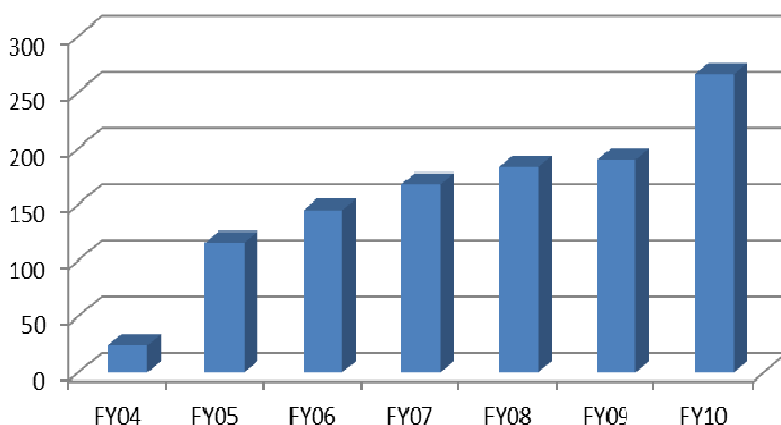
Since March 15, 2004, 65 (94%) of the 69 Maryland hospitals reported at least one Level 1 Adverse Event. During FY10, 52 (75%) of the 69 Maryland hospitals reported at least one Level 1 Adverse Event. An overview of the types and sizes of hospitals licensed in Maryland is provided in Appendix A.

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 number of Level 1 Adverse Events reports received based on the size of the hospital. The fifteen largest hospitals, based on their current licensed bed capacity, accounted for 48% of all reported events in FY10, which is consistent with the previous year (49% in FY09). If hospitals with more than 200 beds are included, 71% of the events were reported by these 30 hospitals, comparable to FY09. Historically, all hospitals with more than 200 beds regularly report adverse events to the Department. Reporting levels remain significantly less for hospitals with less than 100 licensed beds. These smaller hospitals generally perform less complex procedures and reported only 19 Level 1 Adverse Events in FY10. Additionally, only 38% of these hospitals reported a Level 1

Adverse Event in FY10. Since enactment of the regulations, 84% of these smaller hospitals have submitted a reportable event.

TABLE 2 FY 10 - LEVEL 1 ADVERSE EVENTS BASED ON HOSPITAL LICENSED BED CAPACITY			
HOSPITAL SIZE NUMBER OF LICENSED BEDS	NUMBER OF HOSPITALS	NUMBER OF HOSPITALS REPORTING	NUMBER OF LEVEL 1 EVENTS
300 or more beds	15	15	126
200 – 300 beds	15	14	62
100 – 200 beds	18	9	58
Less than 100 beds	21	8	19
TOTALS	69	46	265
*Two hospitals with >100 beds and one hospital with > 200 beds closed during FY10.			

Maryland hospitals are categorized as acute general, psychiatric, chronic, rehabilitation, and/or children's hospitals. Acute care hospitals account for only 68% of all the licensed Maryland hospitals, but reported 247 (93%) of the Level 1 Adverse Events reported in FY10. As noted in Table 3, acute care hospitals historically have accounted for 92% 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 those hospitals.

Psychiatric hospitals reported only nine Level 1 Adverse Events in FY09 and twelve in FY10. The four largest psychiatric hospitals continue to report more events than the smaller facilities with 41 of the 56 events received from 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 FY10.

Table 3

HOSPITAL TYPE	TOTAL NUMBER OF HOSPITALS	NUMBER of HOSPITALS REPORTING IN FY10	LEVEL 1 ADVERSE EVENTS IN FY10	TOTAL NUMBER OF REPORTING HOSPITALS Since 3/15/ 2004	TOTAL LEVEL 1 ADVERSE EVENTS Since 3/15/2004
Acute General	47 *	44 (94%)	247 (93%)	46(98%)	1001 (92%)
Special Hospital - Psychiatric	13 *	5 (38%)	12 (5%)	11 (85%)	56 (5%)
Special Hospital – Other *	9	3 (33%)	6 (2%)	8 (89%)	34 (3%)
TOTALS	69	52 (75%)	265	65 (93%)	1091

*Two psychiatric hospitals and one acute care hospital closed during FY10

To further identify hospital-reporting patterns, the charts provided in Appendix F identify the number of Level 1 Adverse Event reports received from each acute general hospital. The charts compare reporting patterns from March 15, 2004 to October 31, 2010 for each acute general hospital by size as well as the number of reports of Level 1 adverse events in FY10. Appendix G provides a similar comparison for each psychiatric and special hospital. Hospitals may use these charts to compare their reporting patterns to other similar size and type hospitals.

Falls resulting in the death or a serious disability to the patient remain the most frequently reported event in FY10, accounting for 33% of the Level 1 adverse events. Six patients (7% of the FY10 reports of falls) died from their injuries in FY10. This is consistent with FY09 and FY08 respectively and a continued improvement from the reports received in FY05 and FY06. Reports of patients who developed stage 3 and 4 pressure ulcers after admission increased in FY10 resulting in 22% of all the reports received by the Department. Reports of patients who experienced delays in receiving treatment increased to 20 in FY10. Seventeen of the 20 patients who experienced delays in treatment in FY10 subsequently died. The Department received fifteen reports of retained foreign bodies after surgery. There were thirteen reports of health care acquired infections, ten of which resulted in death. However, the Department still believes that health care acquired infections are underreported. Suicides or attempted suicides were reported by six hospitals. Three of the suicide attempts were not fatal, largely due to the timely intervention of staff monitoring the patients. Appendix C documents the number and types of Level 1 Adverse Events received in FY10 and the patient outcome of those events. The table was expanded in Appendix D to show the outcomes of the reported events over the six-year period.

The reports received by the Department indicate that adverse events occur in all parts of the hospital. Patient rooms in medical surgical inpatient units continue to be the most commonly reported areas where for the occurrence of Level 1 adverse events. The most commonly reported events, including falls and pressure ulcers, occur in inpatient units. Reports over a five-year period indicated that 45% of the reported Level 1 Adverse Events occur in medical surgical unit inpatient rooms and bathrooms. In FY10 the percentage was slightly higher at 50%, indicative of the increase in the number of pressure ulcers reported last year. Events in the surgical suite represent 12% of the reported events annually in FY10. The reports of events occurring in the Emergency Departments and psychiatric units within acute hospitals/psychiatric hospitals each represent 7% of the events in FY10. Events reported for patients receiving care in critical care units during FY10 increased compared to previous years up to 11% (8% in FY09; 7% in FY08). The "Other" category includes infrequently implicated areas such as laboratories and public areas of hospitals.

Table 4   **LOCATION OF LEVEL 1 ADVERSE EVENTS**

Location of Events	Number of Events in FY10	Number of Events in FY09	Number of Events in FY08	Number of Events in FY07	Number of Events in FY06	Number of Events in FY04/05	Total Number of Events
Medical Surgical Units	132	97	83	75	52	53	492
Surgical Suites	32	18	16	22	18	21	127

Location of Events	Number of Events in FY10	Number of Events in FY09	Number of Events in FY08	Number of Events in FY07	Number of Events in FY06	Number of Events in FY04/05	Total Number of Events
Emergency Departments	19	12	17	17	19	16	100
Critical Care Units	28	15	13	13	13	16	98
Psychiatric Units	19	19	21	16	10	8	93
Labor & Delivery	5	7	11	8	9	10	50
Radiology Services (including interventional)	6	4	3	5	7	7	32
Cardiology	7	6	2	1	1	1	18
Rehabilitation	1	6	3	3	1	1	15
Outpatient	7	0	2	1	2	0	12
Pediatrics	2	3	2	0	3	1	11
Nursery	1	0	1	0	1	1	4
Ambulatory Care	0	0	0	0	1	0	1
Other	6	3	9	7	9	5	38
TOTALS	**265**	**190**	**183**	**168**	**145**	**140**	**1091**

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."[1] This is a nationally known classification of events used by several state reporting systems as their criteria for reporting events. Since the NQF system is nationally recognized, it enables OHCQ to compare its data with other state reporting systems. Many states with mandatory and voluntary reporting use the NQF "Serious Reportable Events" to define what is reportable. Since the Maryland Patient Safety Program is focused on patient outcomes and the Office of Health Care Quality 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,
- Unanticipated fetal or neonatal death or disability; and
- Misdiagnosis.

The list of "Serious Reportable Events" has been under review by the National Quality Forum in 2010. Once the list is updated, the Office of Health Care Quality will review and revise its database and regulations to determine what if any changes will be required to reflect

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

this national classification system. The NQF List of Serious Reportable Events has also been used by the Office of Health Care Quality to define what would constitute a serious disability.

REVIEW OF SPECIFIC TYPES OF LEVEL 1 ADVERSE EVENTS

FALLS

Falls have been and continue to be a significant risk to patients. As noted, falls continue to be the most frequently reported Level 1 Adverse Event with 88 reported events that resulted in serious disability to the patient and death for patients who fell in FY10. Four hundred one reports of patient falls have been received since the beginning of the program, accounting for 37% of the received reports. While falls continue to be the most frequently reported event, the reports of deaths as a result of falls have decreased over the past 6 years. There were only six reported deaths (7% of the reports received) from falls in FY10. In the first several years of reporting 15-20% of the reported falls resulted in death (55 deaths from March 15, 2004 to June 30, 2009).

Due to the serious consequences of falls to the patient and the high financial cost of falls to the hospitals, most hospitals have participated in the Falls Collaborative sponsored by the Maryland Patient Safety Center in June 2009.

HEALTH CARE ACQUIRED PRESSURE ULCERS

The Department continues to receive fewer reports of health care acquired pressure ulcers than some other state reporting programs. As noted in previous annual reports, hospital acquired pressure ulcers remain among the most frequently reported events in other states that have similar mandatory reporting requirements such as Minnesota[2] (118 of 305 reported events) and Massachusetts[3] (65 of 383 reported events). Due to the morbidity and mortality associated with Stage 3 and 4 pressure ulcers, we consider them to be Level 1 Adverse Events and expect hospitals to report these events. Pressure ulcers that progressed from Stage 1 or 2 to Stage 3 are excluded from the reporting requirement if the Stage 1 or 2 was present on admission. Deep tissue injuries or "unstageable" pressure ulcers almost always evolve into Stage 4 pressure ulcers and should be reported.

There was a significant increase in the number of reports of Stage 3 or 4 pressure ulcers to the Department in FY10. Fifty-nine events were reported in FY10 compared with nine reports

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[2] Minnesota Department of Health. Adverse Health Events in Minnesota, Seventh Annual Public Report, Minnesota Department of Health, January 2011, page 8.

[3] Office of Health and Human Services; Serious Reportable Events in Massachusetts Acute Care Hospitals in FY2009;
http://www.mass.gov/?pageID=eohhs2terminal&L=6&L0=Home&L1=Provider&L2=Reporting+to+the+State&L3=Reporting+Entities&L4=Hospital&L5=Reporting+Serious+Incidents&sid=Eeohhs2&b=terminalcontent&f=dph_quality_healthcare_p_sre_report_2009&csid=Eeohhs2

in FY09. The vast majority of these reports came from two hospital systems that have been looking closely at this frequently preventable adverse outcome. Hospitals that have not seriously looked at the development of pressure ulcers within their hospital should examine their reporting and review processes to determine the extent of this problem in their hospitals. The hospital's wound care staff must ensure that the quality and patient safety team is aware of the development of preventable Stage 3 and 4 pressure ulcers and that these occurrences are considered reportable adverse events.

One of the hospital systems that was a high reporter and has a robust internal system for identifying and responding to health care acquired pressure ulcers identified several patients in FY10 that developed health care acquired pressure ulcers from medical devices that were used as part of patient treatment. These devices included sequential compression devices and tubing from indwelling catheters, which can cause leg ulcers; and endotracheal tubes, nasogastric tubes, and oxygen tubing, which can cause ulcers of the lips or ears. The hospital's corrective actions included using commercially available holders that keep tubing away from skin, revising their assessment and documentation policies, and increasing staff awareness of the risk posed by medical devices.

Another feature of health care acquired pressure ulcers noted by hospital surveyors during routine or complaint-driven medical record reviews are the near universal lack of information regarding health care acquired pressure ulcers in patient discharge summaries. In many hospitals, the wound care teams manage all skin issues and write medical orders for treatments and interventions. While this practice ensures expert management, the patient's attending physician must be involved as well. The failure to mention wounds in discharge summaries is problematic for continuity of care, and constitutes a deficient practice under both The Joint Commission and the Center for Medicaid and Medicare Services. Documentation in the discharge summary must include patient information related to wound care and management.

DELAYS IN TREATMENT

Events in which patients suffered death or serious disability as a result of a delay in obtaining needed treatment or services were the third most frequently reported event with 20 reports in FY10. This category of event has routinely been one of the most frequently reported events to the Department. Since March 15, 2004, 83 (82%) of the 102 reports of level 1 adverse events reported were related to a delay in treatment and have resulted in death, 17 of which occurred in FY10.   Because these events are often fatal, a Clinical Alert was published in FY10 with an analysis of delay events reported in FY08 and FY09.   The Clinical Alert on Delays in Treatment, or any previous Clinical Alerts, can be found on the OHCQ website, www.dhmh.state.md.us/ohcq.

Examples of reported events include:

- A 37 year-old came to the emergency department (ED) with multiple injuries after falling from a multi-story building. No spinal x-rays were performed in the ED or at the time of admission. There was a seven-day delay in acting on the patient's complaints of left leg and groin numbness, and low back pain. Hospital staff continued to believe his complaints were related to his diagnosed leg injuries. The patient was taken to physical therapy for several days before the staff recognized that the patient was experiencing additional undiagnosed problems. The patient was subsequently found to have a severe lumbar spine fracture with spinal cord compression. The patient was transferred to another hospital for surgery, but did not regain function in his legs. Besides sending this case to peer review, the hospital revised protocols to require spinal x-rays for all patients presenting to the ED with a cervical spine injury.

- A 57 year-old alcoholic patient had a total knee replacement in a small community hospital. Despite the surgeon informing him to stop drinking two weeks prior surgery, he failed to follow his surgeon's instructions. Postoperatively, he went into DTs and required intubation. He was transferred to the ICU, where he was sedated and placed on Propofol. Despite respites from the Propofol, he remained unresponsive. An EEG (electro-encephalogram) was performed. The hospital's protocols indicated EEGs were to be evaluated once per week. The patient's EEG was not reviewed for 6 days, resulting in a delay in treatment. The EEG reading indicated that the patient was experiencing seizure activity. The nursing staff had not noted these subtle seizures, which were subsequently diagnosed by the neurologist. The patient was placed on Dilantin and other antiepileptic medications without improvement in the seizure activity. His family placed the patient on comfort measures. His cause of death was anoxic encephalopathy and status epilepticus. Hospital policy and procedure was changed to require all EEG performed for ICU patients to be read immediately following the test.

SUICIDE AND SUICIDE ATTEMPTS

Suicides or suicide attempts resulting in serious disabilities to the patient are the sixth most frequently reported Level 1 Adverse Event. Forty-seven (4%) of the 1091 Level 1 adverse events reported since March 15, 2004 were suicides or suicide attempts. While most occur in psychiatric units or psychiatric hospitals, there are a significant number that occur in other areas of acute general hospitals, specifically the ED. There have been 36 successful suicides reported to the Department over the past six years. Eleven patients who attempted suicides sustained significant injuries to qualify as Level 1 Adverse Events, three of which were received in FY10.

Inpatient suicides or attempted suicides included one patient who jumped from the unit's second story window; a self mutilating patient who repeatedly stabbed himself in the abdomen; and a patient who set himself on fire in the ED bathroom. Behavioral health patients with these types of self-destructive behaviors must be subject to frequent and thorough contraband checks.

Two other inpatients attempted to hang themselves from doors, which continues to demonstrate the need for a thorough assessment of risks in the environment of care.

AIRWAY MISADVENTURES

Maintaining a patient's airway is the basic medical intervention. Yet events related to the failure to maintain a patent airway and/or an adequate level of oxygenation increased by a third in FY10 with 9 reported Level 1 Adverse Events. Over the seven years of reporting there have been 64 events reported where patients suffered an airway misadventure with 90% mortality (58). Nine reports of airway misadventures were received in FY10. Eight of these were fatal with the other patient left in a persistent vegetative state.

Examples of reported events include:

- A 70 year-old patient was admitted with progressive weakness and was diagnosed with a degenerative neuromuscular disease. The patient was given a swallowing evaluation that showed no gag reflex and global weakness of the tongue and pharynx. The patient was placed on a mechanical soft diet with a supervised eating plan. Despite a sign on the door identifying the patient's diet restriction, the dietary aide assumed the sign was wrong and delivered a regular tray to the patient without first checking with the nursing staff caring for the patient. The patient ate some of the meal and aspirated the food. He went into acute respiratory failure and ultimately died of the misadventure.

- A patient was admitted to a medical surgical unit from the ED early one morning with severe lower extremity pain. Intravenous fluids were started and intravenous pain medication was administered to the patient. The physician was aware that the patient had obstructive sleep apnea (OSA) and wrote an order for the family to bring in the patient's CPAP machine. The patient requested to be left alone to sleep since he had been up most of the night. Two and a half hours later, the nurse checked on the patient and found him not breathing and without a pulse. A code was called with unsuccessful resuscitation results. The RCA team determined that there was a near-universal assumption that OSA only happened at night.

- Another patient with known OSA expired when she was placed flat for a procedure with a drape over her face. She became restless during the procedure and was given two doses of sedation. The patient was noted to be apneic upon completion of the procedure and resuscitation efforts were futile.

- A critically ill elderly patient, who was on a specialized ventilator protocol, was scheduled for the operating room (OR) for insertion of a tracheostomy. She was given oxygen via an ambo bag during transport from the ICU to the OR but arrested as soon as she arrived to the surgical area. The RCA team determined that, not only was the patient

not maintained on her ventilator settings enroute to the OR, but her vasopressors had been stopped prior to the transfer because there were no IV poles for the bed. The team also determined that the OR ventilators did not have the same features as the ICU ventilators and were bit able to support the patient's ventilator protocol. There had apparently been no communication between the surgical team and the intensivist regarding the plan to take this patient to the OR. Hospitals must assess the likelihood of these types of events occurring in their individual facilities and to ensure equipment is current throughout all areas of the hospital.

SURGICAL EVENTS-RETAINED FOREIGN BODIES

Despite the high profile nature of the events, and Clinical Alerts[4] published by the Office of Health Care Quality in 2007 and 2008, adverse events involving retained foreign bodies (RFBs) continue to occur. There were 15 reports of retained foreign bodies in FY10, more than a 250% increase in these reports over any previous year.

Two cases of retained guide wires were reported subsequent to placement of central venous lines in femoral veins. In both cases, the wires had been noted on x-rays but were believed to be artifacts left on the patients' clothes subsequent to the placement of the line. In one event, a lap towel that did not have a radiopaque tag was left in a patient who was having a takedown of a colostomy. Seven of the cases involved retained sponges.

Consistent with the literature, most RFBs occur during abdominal surgeries, emergency procedures, converting from laparoscopic to an open procedure or in cases with multiple personnel or team changes. Seven of the surgeries were procedures to the gastrointestinal tract. One event involved a brief biopsy surgery. Two reported events occurred when the plastic knee spacer was left in after knee replacement surgery. In two cases, the foreign bodies were retained when a hysterectomy was performed after a Caesarean section. The RCAs noted that the change of surgical procedures and the change of teams contributed to the miscounts.

One RFB deserves special attention, even though it occurred in FY11. A patient was undergoing a laparoscopic abdominal surgery. The surgeon had difficulty passing a naso-gastric tube (NGT) at the end of the case and used a weighted bougie esophageal dilator that was already in the OR. The surgeon placed a suture through the base of the dilator so she could guide it while inserting the NGT. The suture punctured the capsule of weighted material. After the patient had gone to the PACU, mercury was noted to be present in the bedding on the OR table. The OR was locked down and Haz-Mat decontamination procedures were completed. The patient had beads of mercury in his colon and had to undergo another surgery to remove the

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[4] Clinical Alert - Volume 5, Number 2 - Fall 2008 - Preventing Retained Foreign Bodies
Clinical Alert - Volume 4, Number 2 - Fall 2007 - Wrong site procedures and retained foreign bodies: Why are they still happening in Maryland hospitals?

retained beads from his abdominal cavity. The hospital determined that the bougie was more than 15 years old. Even though the hospital had newer dilators that were weighted with an inert material, some of the old, mercury-weighted bougies remained on the shelves. Hospitals must ensure that their hospital does not utilize old or outdated equipment.

SURGICAL EVENTS-WRONG PATIENT, WRONG SITE, INCONSISTENT WITH THE CONSENT

Unlike retained foreign bodies, the number of reports of wrong side surgeries, wrong patient surgeries and wrong surgical procedures remain low. Since reporting began in FY04, the Department has received twenty-two reports of wrong side, wrong patient or wrong surgical procedures. Four of the cases were reported in FY10.

Several years ago, the Department received two reports of wrong kidney sites. One of the root causes of both these cases involved errors being made on the consent and preoperative documents pre-prepared in the physicians' offices. Another event occurred, which resulted in the removal of a woman's breast secondary to the misfiling of the patient's biopsy results in the radiologist's office where the biopsy was performed.   In these three extremely serious cases of wrong side/ wrong patient procedures, the hospitals found that the sequence of errors began in the physician's office weeks before the occurrence of the surgeries. Two of the four adverse events reported in FY10 also began in the physician's office. Hospitals must develop pre-surgical procedures that include review of the original diagnostic tests, films or specimens to ensure that the accuracy of the patient's procedure or surgery site.

Examples of reported events include:

- A patient was having a cataract removal with a lens implant. The wrong lens was implanted in the patient's eye because another patient's scan results were placed in his medical records. The error was found during the patient's post-operative office visit requiring the patient to undergo an additional surgical procedure to implant the correct lens.

- A patient underwent a total knee replacement. Several months after surgery, when the patient began experiencing recurrent knee dislocations, he was re-scheduled for surgery for a revision of the replacement. During surgery it was discovered that the tibia insert for a right leg had been inserted into his left tibia, and the left prosthesis had been attached to this insert.

Many hospitals have also reported events that do not necessarily meet the criteria for mandatory reporting and are not Level 1 Adverse Events. These hospitals have reported these events because they realize that serious system problems may exist that caused the errors. Burns that occur in the OR are often not Level 1 Adverse Events but many hospitals report these events when they occur even with minor injuries. Retained foreign bodies that are removed before

hospital discharge and a wrong site procedure that does not harm a patient 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 go beyond their regulatory obligations, which allows the agency to review and trend the occurrence of certain events, even if the event results in a minor injury.

HEALTHCARE ASSOCIATED INFECTIONS

While reports of healthcare acquired infections (HAI) have increased slightly each year, the Department assumes that HAI are under reported by Maryland hospitals. COMAR 10.07.06, Patient Safety Programs require the reporting of HAIs only when the patient is seriously injured or dies. The majority of the received reports are fatalities in which it is fairly certain that the HAI was the cause of death. The Department received ten reports of fatal HAIs in FY10.

There are often significant delays on the part of the hospitals in receiving reports of healthcare acquired infections. Reports of HAI resulting in death or serious disability are often not reported to the department for weeks following care. As with pressure ulcers, infection control has its own separate internal reporting process that may bypass the hospital's patient safety program. Further complicating the reporting of healthcare acquired infections are factors identified in previous annual reports. These include the short length of patient stays in hospitals. HAIs may not be apparent at discharge and the patient may be treated for the infection at the doctor's office postoperatively or at another hospital making it difficult, if not impossible, to capture this information. Confirmatory laboratory cultures may take several days to identify the infection. Therefore, HAIs may not be communicated to the hospital's Patient Safety Program and subsequently to the Department. Infection control regulations included in COMAR 10.07.01 promulgated in 2008 require communication between the hospital's infection control practitioner and the quality assurance department.

Hospitals that have reported HAIs have discussed with the Office of Health Care Quality staff their challenges in obtaining the reports and in determining the root cause of the infection. Only a small number of RCAs can pinpoint a specific time or event (root cause) that lead to the infection. Nevertheless, many hospitals have identified processes and system problems and developed corrective actions to address these in an effort to prevent future infections.

Examples of reported events include:

- A patient had a lumbar laminectomy. Three weeks after discharge he returned to another hospital's ED with a surgical wound infection and dehiscence requiring transfer back to the hospital that performed the surgery. Two days later, the patient was discharged on antibiotics but returned to the ED the following day with pain. After receiving medication the patient was again discharged to home. Four days later the patient was brought back to ED via EMS after being found at home barely responsive, foaming at the mouth, hypotensive, tachycardic, with significant wound drainage and severe abdominal

and back pain. The patient had also developed paraplegia. The patient was taken to surgery for closure of an iatrogenic cerebral spinal fluid leak but died after several days in the ICU. The root cause analysis recognized multiple problems with communication between physicians and between the nurses and physicians as well as failure to adequately investigate the cause of the patient's complaints during repeated visits to the ED.

- Two other patients developed surgical wound infections after spinal surgery. Both patients required readmission - one for debridement, long term antibiotics via a PICC line and a wound vacuum while the other patient was admitted for surgical drainage of a collection of fluid in the wound. In one event, the hospital determined that there had been a break in the sterilization process. Six surgical packs had been prepared and released without sterilization when the central sterile supply technician put the six trays in the sterilizer but failed to turn on the sterilizer. The next shift removed the trays assuming the trays were sterile. Two of the six trays were used on the patient. Environmental changes were made and staff supervision and oversight was modified to address the root causes.

MEDICATION ERRORS

Data reported to the Department continues to indicate that medication errors or adverse drug reactions that result in death or a serious disability are rare or may not be easily identified by hospital patient safety staff.   Only nine medication errors that resulted in death or serious disability were reported in FY10 and 48 reports have been reported over six years. Numerous studies indicate that nearly all patients experience a medication error or adverse drug reaction during hospitalization. Furthermore, in Maryland hospitals, very few seem to result in serious injury.

An example of a reported event includes:

- A 40 year-old alcoholic patient was admitted to the hospital through the emergency department with severe abdominal pain. The patient became agitated and confused after admission. The physician ordered Ativan and a detoxification prophylaxis of Librium, 50 mg. followed by Librium, 25 mg.   The design of the order sheet provided the physician with several detoxification medication protocols from which to select. The physician selected two protocols on the order form. The pharmacist filled the order without checking with the physician, and the nurse gave the medications. As a result, the patient received the Ativan plus Librium, 100 mg. in the morning, then another 150 mg. of Librium and Serax 45 mg. the afternoon of his admission. The nurse on the next shift identified that the patient was poorly responsive and received orders to hold the medications. Shortly thereafter, the patient arrested and could not be resuscitated. The hospital improved protocols for ordering and order fulfillment of medications. A revised

order form for detoxification medications was designed to eliminate the potential for ordering duplicate medications.

ANTICOAGULANTS

Since FY05, the Department has elected to classify deaths or serious disability related to anticoagulation as a category separate from medication errors. In FY10, there were four anticoagulation events reported, two of which resulted in death. Overall, 21 events have been reported over six years resulting in the death of 16 patients.

An example of a reported event includes:

- A 60 year-old patient came to the hospital for a laminectomy with resection of an intradural extramedullary spinal cord tumor. Nine days after surgery the patient developed respiratory distress and was admitted to the ICU with hypotension. Multiple medications were infused through an anticubital peripheral intravenous catheter. The patient developed a superficial blood clot in an upper extremity but it was interpreted as a deep vein thrombosis. As a result, the patient was started on Lovenox by the covering neurosurgeon. After being hospitalized for three days, the patient was transferred to a skilled nursing facility with an order for continued Lovenox for coverage for a sub therapeutic Coumadin level. Three days later the patient was returned to the hospital ED with bilateral lower extremity weakness and decreased sensation along with a dangerously elevated INR. The patient was found to have a hematoma at the site of the previous surgery. The hematoma was evacuated but there was no improvement in the patient's neurological function. The prognosis for functional improvement was poor. As a result of the event, the hospital changed it policies to require all spinal surgical patients who are started on anticoagulants to remain in the hospital until the patient has attained appropriated therapeutic levels.

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 from the previous six years indicating that families and/or the patient were notified of an adverse outcome. In FY10, hospitals reported that disclosure to patients and/or their families was made in 239 of the 266 reported cases. As in previous years, the Department cannot determine the quality of the disclosure, but there is a clear improvement in hospital policies regarding the type of disclosure, with most policies specifying that the attending physician is to make the appropriate 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 that includes an in depth review of the event by a multi-disciplinary team to determine the actual root causes of the event, repeatedly asking "why" did this occur. Root causes are defined by the COMAR 10.07.06 as the basic or contributory causal factors that underlie variations in performance. Root causes are generic, in that the causative factors for error may occur almost anywhere in patient care areas, and may lead to the same or similar events if not corrected. Root cause analyses (RCA) should focus primarily on systems and processes. The hospital staff must also identify risks and contributing factors for recurrence, and determine necessary improvements in systems or processes. In FY10, the Office of Health Care Quality cited three hospitals for the poor quality of their RCAs.

Once the root causes are identified, the hospital must determine those processes and systems that require review and develop corrective action plans to prevent the recurrence of the root causes. The hospital is also expected to prioritize the corrective actions with timelines for implementation and plans to monitor the effectiveness of the corrective actions.
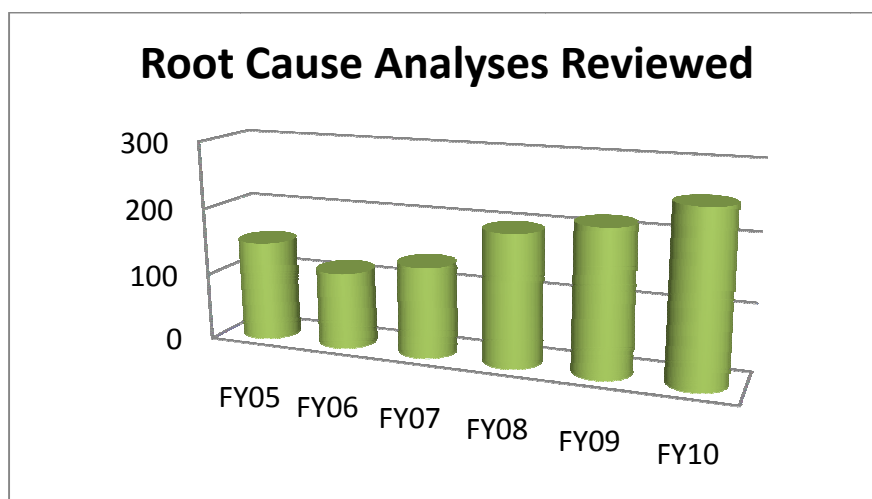
Table 5 – Root Cause Analyses Reviewed

As identified in Table 5, the number of RCAs reviewed has increased each year since the FY06. In FY10, hospitals submitted 250 root cause analyses to the Office of Health Care Quality. These root cause analyses were reviewed by the Office of Health Care Quality staff, with information provided to the hospitals. The Office of Health Care Quality continues to utilize the root cause analysis evaluation tool designed for the purpose of providing feedback related to the event to the hospitals. Since the program began, 1054 root cause analysis have been reviewed and feedback provided to the hospitals. Additionally, over 90% of that feedback is provided within sixty days of the receipt of the RCA.

The overwhelming issue with RCAs continues to be superficial analyses where the hospital fails to discover the real root cause of the event. Those hospitals often do not "drill down" beyond the 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 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 the nature of the adverse event. The following is one of the RCAs received in FY10, with discussion:

Root Cause Analysis:

- A patient in her 30's had a complicated cervical spine surgery and was sent to the recovery room (PACU) with a nearly circumferential neck dressing. She began complaining of difficulty breathing. The PACU nurse did not call the surgeon or anesthesiologist because his experience was that the surgeon would say that the patient's dressing was making her feel like she could not breathe properly. The patient continued to complain of shortness of breath once she arrived on the Medical -Surgical unit. The nurse assessed the patient 4 times over the next hour as the patient continued to complain of shortness of breath. The patient's heart rate, blood pressure and respiratory rate increased significantly. The nurse called the hospitalist when the patient developed respiratory stridor. The hospitalist immediately called the surgeon, who told the hospitalist to call the intensivist. On evaluation by the intensivist, it was noted that the patient's neck was visibly swollen. After calling for an anesthesiologist, the intensivist took the patient back to the OR to open up the incision in an attempt to relieve some of the neck pressure. Shortly thereafter, the patient's heart went into pulseless electrical activity, requiring a code blue. The patient was determined to be anoxic without brain function two days later and was taken off life support by the family.

  The hospital claimed that the root cause for this event was a faulty assessment by the physician. Even though the staff identified many significant factors contributing to the outcome, such as the recovery room's (PACU) nurse's reluctance to call the surgeon, the medical-surgical nurse's reluctance to call the rapid response team (RRT) due to her experience that the RRT would berate her for calling them, the surgeon's lack of responsiveness, and surgical coverage issues, the action plan failed to address the real root causes for the event. Instead the RCA identified various committee meetings and discussions. For example, someone was to discuss with the medical –surgical nurses the proper time and way to contact the RRT. However, no follow-up plan was identified with the actual RRT team members. Because the RCA explored what happened and not **WHY** any of the cascades of poor decisions occurred, no concrete interventions were planned and the completion date for the actions did not occur until eight months after the patient's death. Furthermore, there was no mention of the apparent lack of supervisory and resource personnel, the failure to follow the chain of command, or the apparent absence of respiratory and anesthesia personnel in the care of this patient.

The Office of Health Care Quality initially sent the hospital a letter detailing the problems associated with the initial RCA with a request for a new action plan. The hospital's response was a letter claiming that they had met the requirements of 10.07.06, only providing to the agency a longer explanation of the same action plan. The Office of Health Care Quality then issued a deficiency statement.

The Office of Health Care Quality will respond in writing to RCAs submitted to the Department. These responses serve as informational in nature and do not require a response from the hospital, unless the Department requests specific or additional information. Often this action occurs because our analysis of the RCA leads us to the conclusion that the hospital has only identified proximal causes and has not performed an analysis of sufficient depth to identify and resolve root causes.

The RCA process under 10.07.06 requires the hospital to develop an action plan for the correction of the identified root causes of the adverse event. Consistent with other years, the hospital RCAs for FY10 indicated that policies and procedures would be changed to address the root causes in 62% of the RCAs reviewed, which is similar to FY09 (61%). When a policy or procedure is changed, the hospitals must train staff on the changes. Therefore, 68% of the RCAs include education as a part of its action plan. Process and system changes were identified on 55% of the RCAs reviewed in FY10 and the need for workload or staffing changes were addressed in 17% of the action plans. Environmental changes were identified as an intervention on 5 % of the RCAs, while equipment modifications were required on 24% of the RCAs. Only 11% of the RCAs were referred to Peer Review. More than three actions were identified on each reviewed RCA in FY10. Appendix H includes the data for the types of actions taken for the recent and past fiscal years.

Measures of effectiveness also continue to be problematic in many RCAs. COMAR 10.07.06 requires the hospital to monitor the results and effectiveness of all action plans. Hospitals continue to struggle with differentiating between process steps and evaluating the effectiveness in remediating the set of circumstances that led to the adverse event. Completion of implementation is certainly necessary, but that is not a measure of effectiveness. Hospitals need to determine what the goal of the corrective action is, and how to measure that goal. Hospitals must recognize the impact the corrective action will have on the problematic process and how to eliminate or control the problem. Communicating the corrective action to the staff, including what is expected from the staff and ensuring expectations are met is crucial to an effective RCA process. Even relatively weak actions like policy changes can be made more effective with frequent, random staff observations.

Complaints

The Office of Health Care Quality, to which adverse events are reported, is also the regulatory and licensing agency for the State of Maryland. In that role, the agency receives complaints regarding Maryland hospitals. In FY10, the Office of Health Care Quality received

485 complaints from patients, families and other citizens. A total of 2290 complaints have been received since the Patient Safety regulations were enacted on March 15, 2004. During that same period of time the Office of Health Care Quality received 1091 Level 1 Adverse Events. Only 25 reported Level 1 Adverse Events have been duplicated as a complaint received through the OHCQs regulatory system since reporting began. 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.

Patient Safety Surveys

The Patient Safety Program regulations set forth in 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 the serious events that may occur in the hospital. The first six years of mandated reporting to the Department resulted in 97% of Maryland hospitals reporting a Level 1, 2, or 3 Adverse Events or serious near miss events. Level 1 Adverse Events were reported by 93% of all hospitals over the six years with 44-52 hospitals reporting in any given year. The Department believes that many events go unreported for a variety of reasons and consequently has performed on-site surveys of hospitals to review the patient safety program.

Initially, these on-site reviews focused on low- or non-reporting hospitals. In FY10, the Office of Health Care Quality also surveyed hospitals that have reported few Level 1 Adverse Events or that have suddenly declined in the number of reported events, or have reported significantly less than hospitals with similar capacities and services. Seven reviews of this type occurred in FY10. One selected hospital did not report any Level 1 Adverse Events but had reported at least several lower level events. Two hospitals had a change in their pattern of reporting after the loss of long standing patient safety officers. One hospital was reviewed following receipt of a complaint that was found to be an unreported Level 1 Adverse Event. Two of these surveys resulted in deficiencies under COMAR 10.07.06, and one hospital received a fine for noncompliance with the requirement to report a Level 1 Adverse Event.

Patient safety reviews include all aspects of the hospital's program as follows:

- Accident and incident reports,
- Various committee meeting minutes including the governing body meetings,
- Policy and procedure review,
- Internal reports of less-serious adverse events and near misses,
- FMEAs and root cause analyses for hospital-identified events, and
- Staff training related to patient safety.

Leadership Involvement

The Maryland Patient Safety Program regulations require that hospitals designate a staff person to function as the patient safety coordinator. During FY10, there was a 20% attrition rate associated with patient safety designees at Maryland hospitals. The Office of Health Care Quality has noted significant change in reporting, as well as increased interest and engagement in the patient safety process when a hospital loses these key team members. Patient safety cannot function under the direction of one person. The program, to be successful, 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:

- Regular scheduling of 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.

- Reviewing actual RCAs, not merely data related to the numbers of events per patient days.

- Actively participating in a root cause analysis. Participation by leadership can provide valuable insight into the challenges faced by patients and by front line staff. Leadership participation also lets the staff know that administration supports the RCA process.

- Providing 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.

- Establishing and participating in administrative rounds that focus on patient safety.

- Attending the training on patient safety provided by your hospital or by the Maryland Patient Safety Center.

- Educating 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.

- Establishing 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 anticipated 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." The following Clinical Alerts were developed in FY10:

- Delays In Treatment
- Assessing Physician Quality

Clinical Alerts can be obtained at;
http://dhmh.state.md.us/ohcq/regulated_programs/h_alerts.htm?id=1

Maryland Patient Safety Center

The Maryland Patient Safety Center[5] brings together health care providers 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 such as the Falls Management Collaboration in FY08; Bandwagon for Patient Safety Program in FY09.

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 encourage further improvements in root cause analysis and to provide data to support the valuable collaborative offered by MPSC.

Future Plans and Conclusions

Over the past six years, the Department and the hospitals have both grown in their understanding of patient safety. The Department will be embarking on a review of the patient

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[5] Maryland Patient Safety Center www.marylandpatientsafety.org

safety regulations in FY11. The Department will be working with the hospital representatives and others to refine ambiguous areas of the reporting requirements and clarify the requirements for the root cause analysis.

As previously noted, we recognize that there are many new patient safety coordinators at the hospitals. In order to assist patient safety staff, the Office of Health Care Quality has consolidated its patient safety tools and has made it available to hospital staff for training for hospital staff. OHCQ would like to formally 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.

Many other state reporting systems require hospitals that fail to report to submit attestation affirming that the hospital has reviewed its records and affirmed that no adverse events have occurred. This office is reviewing this process to determine a similar attestation should be implemented to improve all hospitals' engagement in their patient safety program.

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 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 as a means of disseminating information to hospitals and other healthcare providers. The Office of Health Care Quality staff continues to be available to provide training to interested groups and organizations.

The Office of Health Care Quality also takes advantage of opportunities to interact and share information with other state patient safety programs. Beginning in FY10, the staff of the Office of Health Care Quality has been an 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 he reporting programs.

Additional plans for the dissemination of information continue through:

- Researching and publishing best practices for commonly occurring Level 1 Adverse Events;
- Supporting collaboratives sponsored by the Maryland Patient Safety Center;
- Identifying hospital specific trends and patterns and develop a methodology to address repeated similar events;
- Identifying trends and patterns of poor RCAs submitted by specific hospitals; and
- Participating 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 to the Department 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 Department 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.

Appendix A

Maryland Hospital Demographics

Maryland regulation classifies hospitals in two groups. The majority (47) are licensed as acute care hospitals ranging in bed capacity from nine to 960 beds. All but one of these facilities 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. One acute general hospital closed during FY10.

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

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

1. The 13 Special Hospitals-Psychiatric range in size from 15 licensed beds to 639 beds. (2 closed during FY10)

    a. Seven of these hospitals are operated by the State of Maryland.
    b. Three psychiatric hospitals serve only specific populations (children, forensics, and clergy).

2. Of the five Special Hospitals - Chronic, four serve patients who are ventilator-dependent or who have chronic respiratory problems. These hospitals range in size from 52 to 180 beds.

    a. Two are operated by the State of Maryland. While all provide some rehabilitation services, two of the hospitals are dually licensed as rehabilitation hospitals.

3. There are two Special Hospitals-Rehabilitation and two Special Hospitals - Children. The latter are also dually licensed as rehabilitation hospitals. The children's and rehabilitation hospitals have less than 102 beds and all offer outpatient services.

<div align="center">Appendix B: TYPES OF EVENTS</div>

Type of Event	FY04	FY05	FY06	FY07	FY08	FY09	FY10	Totals
Death or serious disability - a fall	3	27	46	56	83	98	88	**401**
Death or serious disability - a delay in treatment	1	12	9	24	20	16	20	**102**
Hospital acquired Stage III or IV pressure ulcers	0	0	0	4	1	9	59	**73**
Death or serious disability - airway management	3	11	15	7	7	6	9	**58**
Death or serious disability - medication error	0	11	8	10	8	2	9	**48**
Suicide or attempted suicide	1	6	10	5	11	8	6	**47**
Unanticipated complication of treatment	2	5	9	5	2	7	9	**39**
Death or serious injury of patient -HAI	0	0	2	7	5	9	13	**36**
Post-surgical retention of foreign body	0	3	1	6	3	6	15	**34**
Unanticipated fetal death or injury	0	3	7	5	9	3	5	**32**
Misdiagnosis	7	6	5	2	2	3	2	**27**
Malfunctioning device	1	3	5	5	4	2	2	**22**
Death or serious disability - anticoagulants	1	3	2	6	3	2	4	**21**
Surgical procedure not consistent with consent/ wrong patient / wrong body part	1	1	2	7	4	3	4	**22**
Unanticipated intra-op or immediate post-op death	0	6	5	1	3	3	2	**20**
Death or serious disability - vascular access device	1	6	3	2	2	2	1	**17**
Death or serious disability - failure to act	0	2	3	2	2	1	3	**13**
Maternal death or serious disability associated with Labor & Delivery	1	2	0	2	2	1	0	**8**
Death or serious disability - hypoglycemia	0	2	1	1	1	2	1	**8**
Intra-op or post-op death in ASA 1 patient	2	0	1	1	1	1	1	**7**
Death or serious disability -restraints seclusion, or side rails	0	1	1	1	1	0	3	**7**
Death or serious disability - intravascular air embolism	0	2	2	0	1	0	2	**7**
Death or serious injury - physical/sexual assault occurring within or on hospitals grounds	0	0	2	2	2	0	0	**6**
Death or serious disability - burn	0	0	0	3	1	1	1	**6**
Hemolytic reaction to ABO incompatible blood products	0	0	1	1	0	0	0	**2**
Death or serious disability - contaminated drug, device or biologic	0	1	0	0	0	0	0	**1**
Infrastructure Failure	0	0	0	0	0	0	1	**1**
Intentionally Unsafe Care	0	0	0	0	0	0	1	**1**
Other	0	2	5	3	5	4	4	**25**
Totals	**24**	**116**	**145**	**168**	**183**	**190**	**265**	**1091**

Appendix C   **TYPES OF EVENTS AND SUBSEQUENT OUTCOMES - FY10**

Type of Event	Loss of limb/ function	Surgical Intervention	Medical Intervention	Death	Total
Death or serious disability - a fall	10	52	20	6	**88**
Stage 3 or 4 pressure ulcers acquired after admission	1	7	51		**59**
Death or serious disability - a delay in treatment	2		1	17	**20**
Post-surgical retention of foreign body		15			**15**
Death or serious injury -HAI	1	1	1	10	**13**
Death or serious disability - medication error			4	5	**9**
Death or serious disability - airway management	1			8	**9**
Unanticipated complication of treatment		1	2	6	**9**
Suicide or attempted suicide resulting in serious disability		1	3	2	**6**
Other		2		2	**4**
Unanticipated fetal death or injury				5	**5**
Surgical procedure/body part not consistent with consent; wrong patient	4				**4**
Death or serious disability - anticoagulants	1		1	2	**4**
Death or serious disability -failure to act				3	**3**
Death or serious disability -restraints seclusion, or side rails	3				**3**
Unanticipated intra-op or immediate post-op death				2	**2**
Misdiagnosis				2	**2**
Death or serious disability - intravascular air embolism			1	1	**2**
Malfunctioning device			1	1	**2**
Death or serious - vascular access device				1	**1**
Death or serious disability -burn			1		**1**
Intra-op or post-op death in ASA 1 patient			1		**1**
Death or serious disability - hypoglycemia			1		**1**
Intentionally unsafe care			1		**1**
Infrastructure failure		1			**1**
Totals	**23**	**80**	**90**	**73**	**265**

Appendix D   TYPES OF EVENTS AND SUBSEQUENT OUTCOMES   3/15/04 -6/30/10

Type of Event	Loss of limb/ function	Surgical Intervention	Medical Intervention	Death	Total
Death or serious disability - falls	22	230	88	61	**401**
Death or serious disability - a delay in treatment	11	4	4	83	**102**
Stage 3 or 4 pressure ulcers acquired after admission	2	11	60		**73**
Death or serious disability - airway management	4		3	51	**58**
Death or serious disability - medication error	4	2	11	31	**48**
Suicide or attempted suicide resulting in disability	1	1	9	36	**47**
Unanticipated complication of treatment	3	5	8	23	**39**
Death or serious injury of patient or staff - health care acquired infections	1	3	4	28	**36**
Post-surgical retention of foreign body		32		2	**34**
Unanticipated fetal death or injury	3		4	25	**32**
Misdiagnosis	3	4	4	16	**27**
Surgical procedure/body part not consistent with consent/wrong patient	8	13		1	**22**
Malfunctioning device	2	2	4	14	**22**
Death or serious disability - the use of anticoagulants	3	1	1	16	**21**
Unanticipated intra-op or immediate post-op death				20	**20**
Death or serious disability - the use of a vascular access device		1		16	**17**
Death or serious disability - a staff member's failure to act	1			12	**13**
Maternal death or serious disability - Labor & Delivery		2	1	5	**8**
Death or serious disability - hypoglycemia	1		3	4	**8**
Intra-op or post-op death in ASA 1 patient			2	5	**7**
Death or serious disability - the use of restraints seclusion, or side rails	4	1	1	1	**7**
Death or serious disability as a result of an intravascular air embolism	1		1	5	**7**
Death or serious injury resulting from physical/sexual assault or abuse			5	1	**6**
Death or serious disability - a burn that occurred in a hospital			6		**6**
Death or serious disability from a hemolytic reaction to ABO incompatible blood products			1	2	**3**
Death or serious disability resulting from a contaminated drug or biological				1	**1**
Intentionally Unsafe Care			1		**1**
Infrastructure failure		1			**1**
Other	3	3	3	15	**25**
Totals	**77**	**316**	**224**	**474**	**1091**

Appendix E

Patient Safety Decision Tree
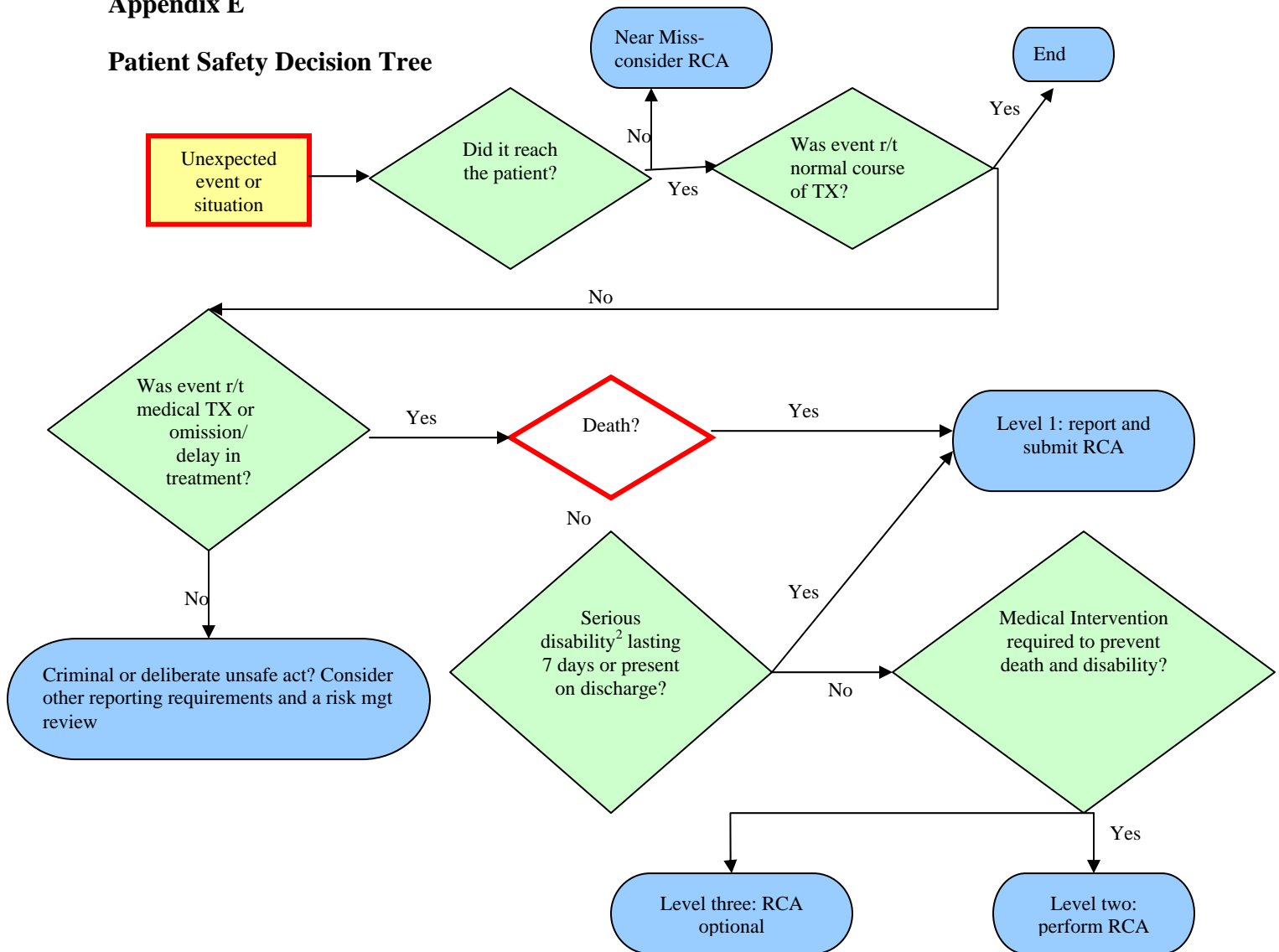
When in doubt about whether to do a RCA for Level 3 and near misses, remember that a lot of valuable information can be gained in the process. Asking these questions may help you decide if a RCA is needed:
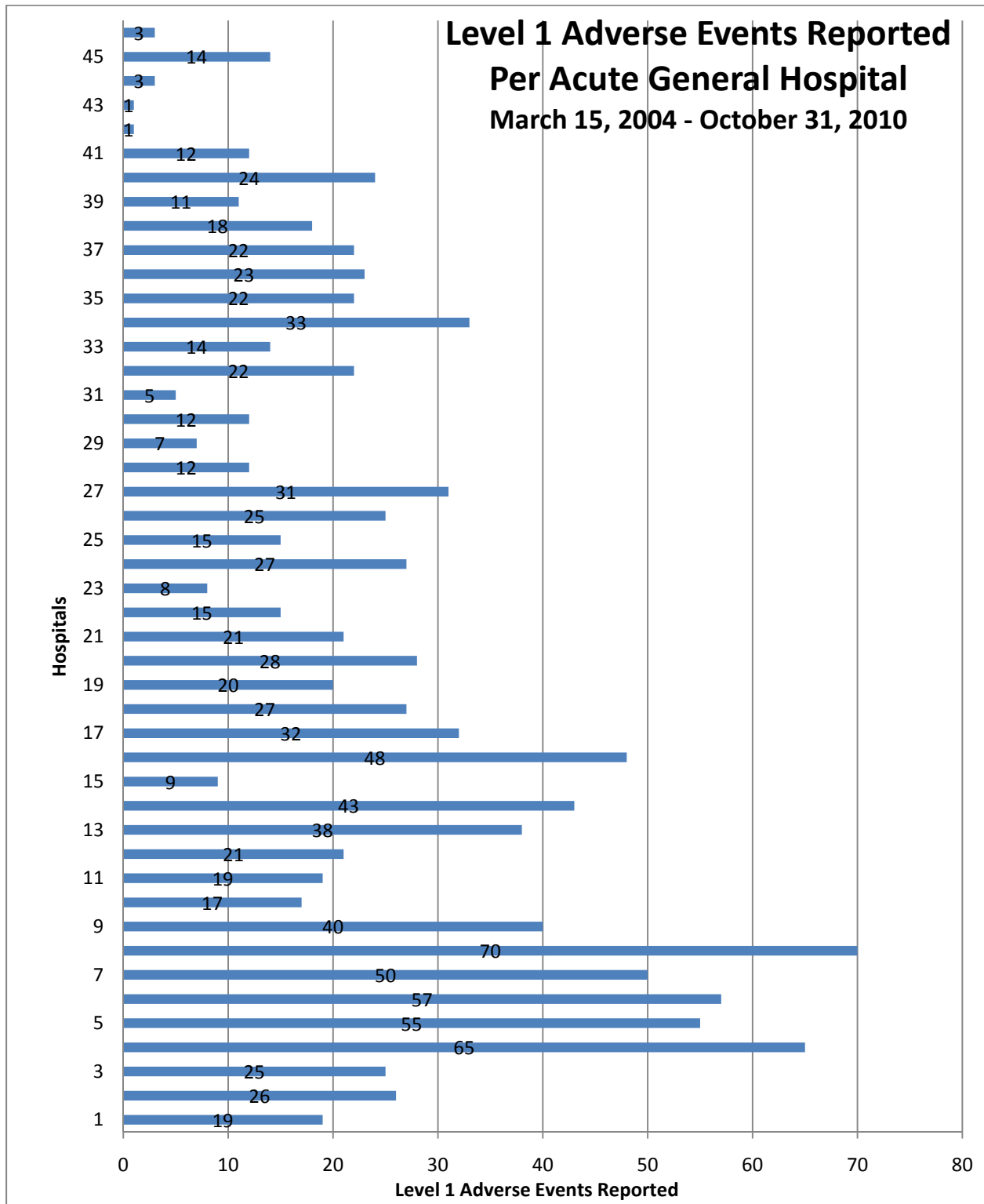
1. Does this event or hazard represent a substantial risk to patient safety?
2. Is the event due to faulty processes or system failures that are likely to cause a similar, perhaps more harmful event if not corrected?
3. If the hazardous condition is not corrected, is there a high probability that a sentinel 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? [6]
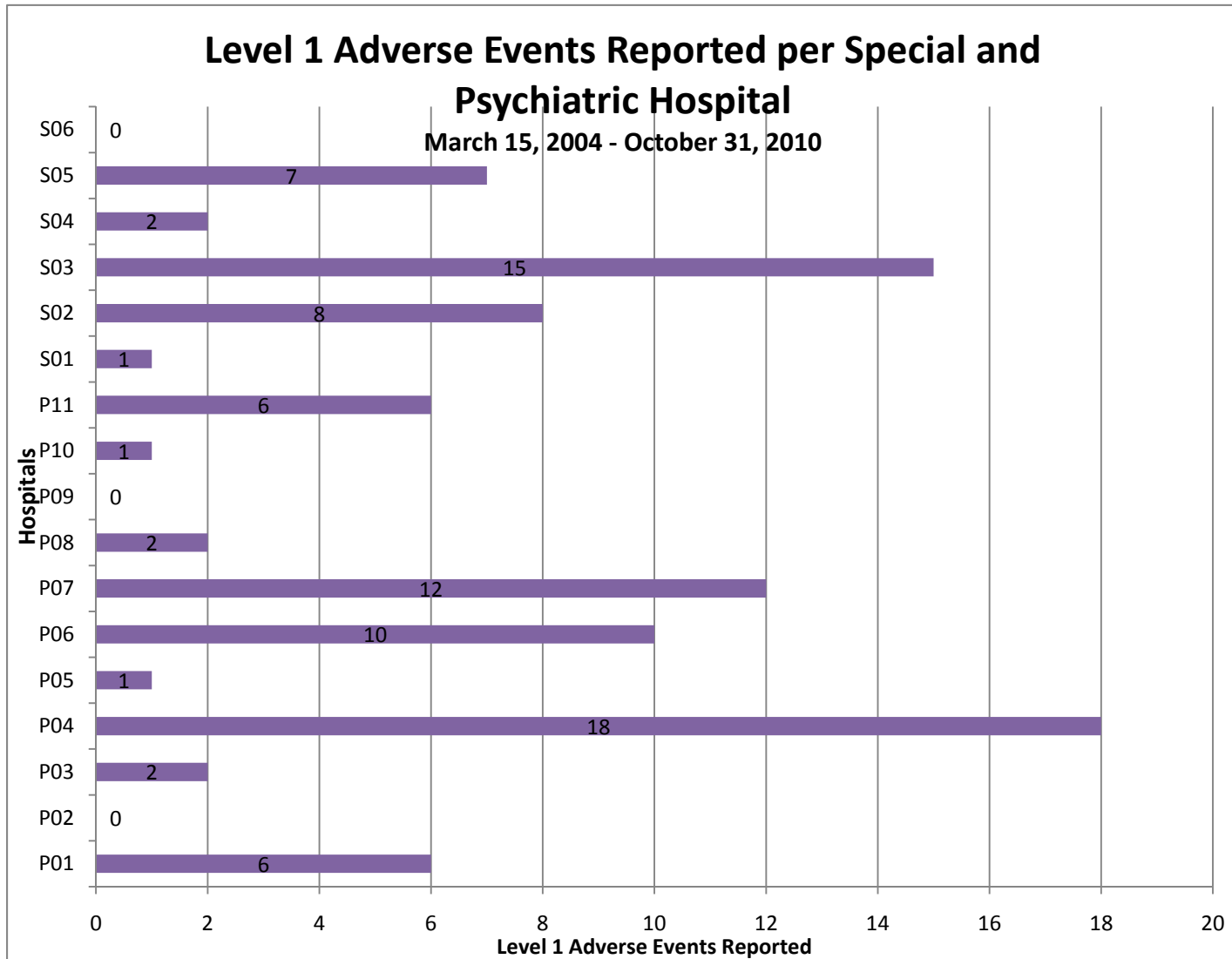
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[6] An event would be considered to be part of a patient's normal disease course if the untoward event arose from the patient's intrinsic condition, rather than from the exogenous medical treatment. For instance, a patient goes into disseminated intravascular coagulation and dies. If the patient has an underlying coagulopathy or sepsis, or any other condition that caused the DIC, this would not be considered a reportable event. However, if the patient has a hemolytic transfusion reaction because of incorrect typing and goes into DIC and dies that is a reportable level 1 event. Another example is if a patient falls and develops a subdural hematoma and dies, this is a reportable level 1 event, even if the development of the SDH was the result of an underlying coagulopathy. The patient would not have developed the SDH that killed him had he not fallen. The event is the fall, not the development of the SDH. 2 Serious disability is defined in 10.07.06 as a physical or mental impairment that substantially limits one or more major life activities of an individual lasting more than seven days or still present at the time of discharge.

Appendix F

Level 1 Adverse Events Reported Per Acute General Hospital
March 15, 2004 - October 31, 2010

Appendix G

Level 1 Adverse Events Reported per Special and Psychiatric Hospital
March 15, 2004 - October 31, 2010

Hospital	Level 1 Adverse Events Reported
S06	0
S05	7
S04	2
S03	15
S02	8
S01	1
P11	6
P10	1
P09	0
P08	2
P07	12
P06	10
P05	1
P04	18
P03	2
P02	0
P01	6

Y-axis: Hospitals
X-axis: Level 1 Adverse Events Reported (0, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20)

Appendix H

CORRECTIVE ACTIONS IDENTIFIED IN ROOT CAUSE ANALYSES

Percentages of the RCAs Identifying This Action

	FY 2004 –FY 2005 (N=148)	FY 2006 (N=113)	FY 2007 (N=134)	FY 2008 (N=194)	FY 2009 (N=213)	FY 2010 (N=250)
Change In Policy/procedures	79%	71%	51%	58%	61%	62%
Formal education	79%	70%	67%	62%	56%	68%
Disciplinary actions	4%	2%	10%	2%	3%	0.8%
Process improvement	10%	42%	34%	30%	40%	55%
Equipment Modifications	31%	27%	17%	23%	25%	24%
Environmental Changes	11%	9 %	3%	6%	6%	5%
Workload/Staffing Changes	18%	31%	13%	15%	13%	17%
Referral to Professional Board	0%	0%	3 %	0.5%	0%	0.8%
Data Tracking/Trending	36%	42%	35%	61%	83%	58%
Reported to FDA	1%	2%	2%	1%	1%	0.8%
Peer Review	12 %	14 %	21%	24%	21%	11%

Hospitals took an average of 3 actions for each reviewed RCA.