DEPARTMENT OF HEALTH & MENTAL HYGIENE

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Maryland
Hospital Patient Safety Program

Annual Report

Fiscal Year 2009

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Foreword

I am pleased to present the 2009 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. Falls continue to be the most frequently reported Level 1 Adverse Event. The second most commonly reported event category is a delay in treatment (Appendix B). During FY09, hospitals have shown a continued effort in disclosing to affected patients and families the occurrence of Level 1 Adverse Events. OHCQ is also pleased to see an increase in the reporting of healthcare acquired infections and pressure ulcers.

The increase in the number of reported Level 1 Adverse Events does not necessarily mean that errors are occurring more frequently but may represent greater compliance on behalf of the hospitals and a continued collaboration between OHCQ and the hospitals, thereby increasing the reporting of events. Most Maryland hospitals have affirmed the need to critically examine adverse events. While errors will always occur, analysis of errors will better enable hospitals to revise systems and processes to ensure that proper checks and balances are in place to avoid mistakes reaching the patient.

As a health care professional who is committed to improving patient safety, I have experienced the benefits of "telling of the story." Hospitals have informed OHCQ that it is helpful to review examples and ask, "Could this happen in my facility?" Hospital leadership must take an active role in reviewing the root cause analysis (RCA) submitted by their facilities in response to a Level 1 Adverse Events. RCAs should be the product of a multidisciplinary team in order to identify basic contributory causal factors. An RCA should never be viewed as a simple paper exercise to meet the regulations, which often tends to focus on individual performance and not on processes or systems which may be deficient. Open communication among hospital disciplines and with the affected patient and family is key to a successful patient safety program. The inability or reluctance to disclose events is one of the most common root causes that can lead to system failures. Including the patient and the family in the RCA process can also be valuable in improving processes and future patient outcomes.

The OHCQ Maryland Hospital Patient Safety Program has been an important source of information that would otherwise have been unknown to the Department. Of the 190 Level 1 Adverse Events reported in FY09, only three were reported to OHCQ through complaints and other regulatory processes.

While we 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. We firmly believe those hospitals which have worked hard to conduct serious and critical analysis of errors will see an improvement towards quality patient care.

Lastly, I would like to thank Anne Jones, Renee Webster, and Mark Paugh for their continued dedication to ensuring quality and safe care to all residents of the State of Maryland.

Very truly yours,

Nancy B. Grimm, RN, JD, Director

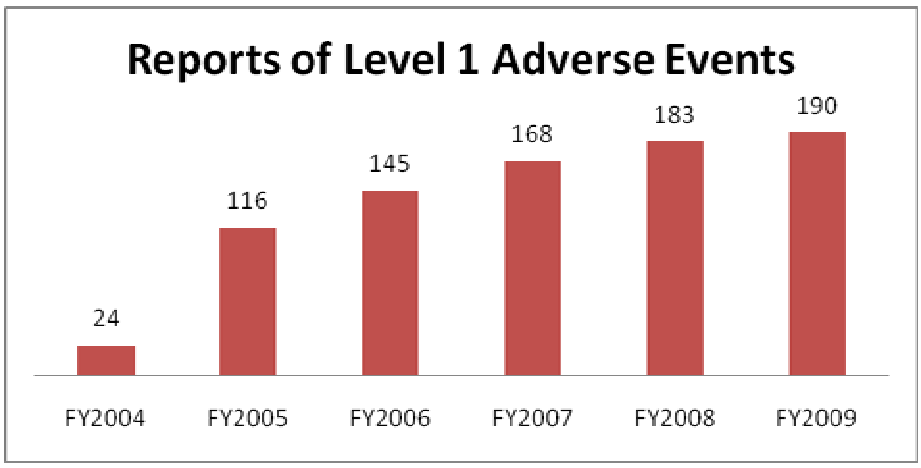
Maryland Hospital Patient Safety Program Analysis

Fiscal Year 2009 (July 1, 2008 to June 30, 2009) was the fifth year of the Maryland Patient Safety Program. While some hospitals have integrated the reporting and analysis requirements of COMAR 10.07.06 into their adverse and sentinel event management programs, other hospitals still struggle with identifying which adverse events need to be reported and how to critically examine the contributing practices, policies, processes, and attitudes. While the staff of the Department believes that we are capturing the most serious events that are occurring in Maryland hospitals, a look back over the first five years reveals that some event types remain under-reported and unexamined.

MANDATORY REPORTING OF ADVERSE EVENTS

Level 1 Adverse Events reported to the Department increase only by 4 percent with 190 reports as opposed to 183 in FY08. Since reporting began on March 15, 2004, a total of 826 Level 1 Adverse Events have been reported by Maryland hospitals. As noted in Table 1, reports have increased each year as hospital staff become more familiar with reporting requirements.

Table 1



In FY09, another 53 events were received that were not considered reportable (Level 2 or Level 3 Adverse Events or near misses), with a cumulative total of 180 reported events since March 15, 2004 that did not meet the criteria of a Level 1 Adverse Event. Many of those events were reported by hospitals because the hospital's preliminary review of the event indicated the event was a possible Level 1 Adverse Event. Some of the events were also reported because hospitals felt the events were significant and warranted reporting even if the event would not be classified as a Level 1 Adverse Event. These included reports of first and second degree burns during surgical procedures or retained foreign bodies that were identified and removed prior to discharge.

Of the 69 licensed Maryland hospitals, 49 reported at least one Level 1 Adverse Event in FY09; this is a 5 percent decrease in the number of reporting hospitals over FY08. However, 65 of the 69 Maryland hospitals or 94 percent of the hospitals reported at least one adverse event since March 15, 2004. 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.

TABLE 2 FY09 - 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	17	16	93
200 – 300 beds	13	13	42
100 – 200 beds	15	9	25
Less than 100 beds	24	12	30
TOTALS	**69**	**50**	**190**

The largest 16 hospitals by licensed bed capacity accounted for 49% of all reported event in FY09. The hospitals with over 200 licensed beds accounted for 71% of all Level 1 Adverse Events, which is consistent with the previous year (FY08 – 70%). Hospitals with less than 100 licensed beds reported 30 Level 1 Adverse Events in FY09 or 16% of all the reported Level 1 Adverse Events, an 11% increase over the preceding fiscal year. Only one hospital with 200 or more licensed beds did not report a Level 1 Adverse Event in FY09. Fifty percent (50%) of the smallest hospitals contacted the Department with at least one Level 1 Adverse Event.

In Maryland, licensed hospitals include acute general, psychiatric, chronic, rehabilitation, and children's hospitals. Acute care hospitals account for only 68% of all the licensed Maryland hospitals, but reported 179 (94%) of the Level 1 Adverse Events in FY09. As noted in Table 3, acute care hospitals historically have accounted for more than 91 percent 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.

However, psychiatric hospitals reported only nine Level 1 Adverse Events in FY09. Three of these reports came from hospitals that had not reported any events in the previous four years. The four largest psychiatric hospitals continue to report more events than the smaller facilities with 30 of the 44 events received from these types of hospitals. Of the nine other special hospitals (chronic, rehabilitation and children's) only two reported Level 1 Adverse Events in FY09.

Table 3

HOSPITAL TYPE	TOTAL NUMBER OF HOSPITALS	NUMBER of HOSPITALS REPORTING IN FY09	LEVEL 1 ADVERSE EVENTS IN FY09	TOTAL NUMBER OF REPORTING HOSPITALS Since 3/15/2004	TOTAL LEVEL 1 ADVERSE EVENTS Since 3/15/2004
Acute General	**47**	**41 (87%)**	**179 (94%)**	**45(96%)**	**754 (91%)**
Special Hospital – Psychiatric	**13**	**7 (54%)**	**9 (5%)**	**11 (85%)**	**44 (5.3%)**
Special Hospital – Other *	**9**	**2 (22%)**	**2 (1%)**	**8 (89%)**	**28 (3.4%)**
TOTALS	**69**	**50 (72%)**	**190**	**64 (93%)**	**826**

The following charts were developed from last year's report in response to queries from Patient Safety Officers and administrative staff as to their hospital's reporting rates for Level 1 Adverse Events. Tables 4 and 5 illustrate the numbers of Level 1 Adverse Event reports to the Department as comparable to similarly sized and types of hospitals. Table 4 identifies the number of Level 1 Adverse Event reports based on the number of licensed hospital beds[1] and by the type of hospital. The median number of reports received for 14 largest acute care hospitals over the past five years was 23 or on average 4.6 reports per year.

Table 4: Level 1 Adverse Events by Hospital Type & Size (3/15/04 – 10/31/2009)

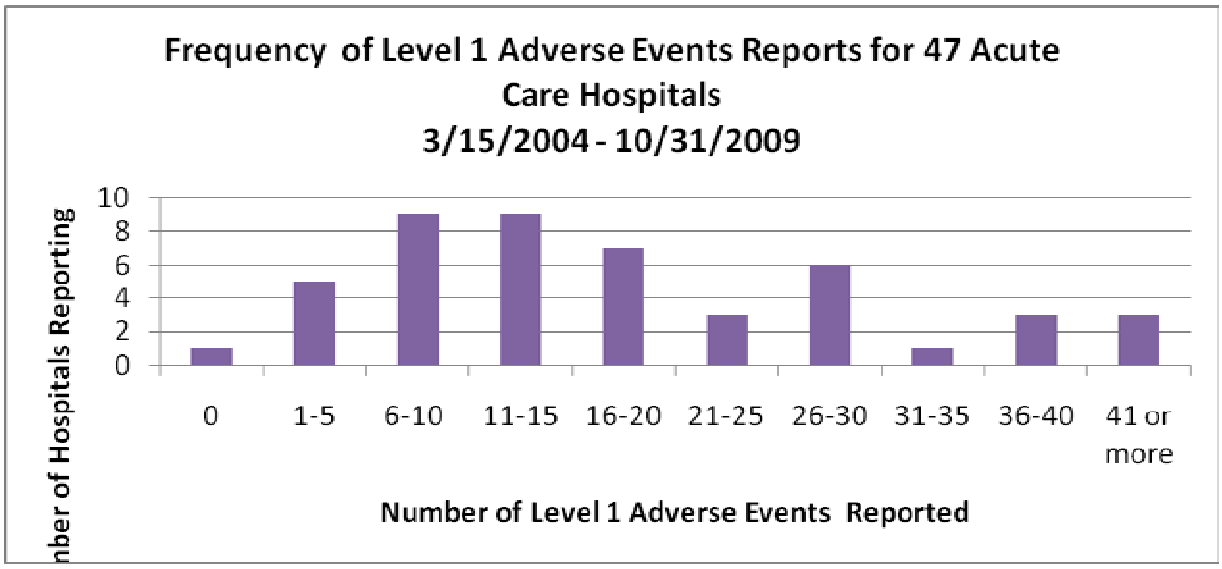
	Number of Hospitals	Number of Adverse Events	Median Number of Adverse Events
Acute Care Hospitals with over 300 beds	14	370	23
Acute Care Hospitals 200-300 beds	12	248	21
Acute Care Hospitals 100-200 beds	13	155	11
Acute Care Hospitals Less Than 100 beds	8	63	6
Psychiatric Hospitals More Than 300 beds	4	29	9
Psychiatric Hospital Less than 150 beds	9	12	1
Other Special Hospitals	9	30	2

In Table 5, the data for acute care hospitals is further refined to demonstrate the frequency of reporting Level 1 Adverse Events by hospitals. Sixteen acute care hospitals have each reported more than 20 Level 1 Adverse Events since March 15, 2004, averaging between four to nine reports per year. The hospital that reported most frequently reported 48 Level 1 Adverse Events over the five years of the program. Interactions with these hospitals by the OHCQ staff indicate that these hospitals have developed thorough systematic approaches to identifying and responding to adverse events and near misses. There were six acute care

[1] The number of licensed beds is based on the hospital's license capacity on June 30, 2009.

hospitals that have reported an average of one Level 1 Adverse Events each year. The remaining 25 acute care hospitals each contacted OHCQ between two to four times per year to report a Level 1 Adverse Event. The data in both Table 5 and Table 6 do not include voluntary reports of events that were not classified as Level 1 Adverse Events or reports that were determined not to be Level 1 Adverse Events after the RCA was received and reviewed.

Table 5



Falls with death or serious disability remain the most frequently reported event in FY09, accounting for 52% of the Level 1 Adverse Events. Fourteen patients died of their injuries in FY09, an 8 percent increase over FY08 at which time only 6% of the patients who fell were reported to have died as a result of the fall. Patients who experienced delays in receiving treatment continue to be the second most frequently reported event as it was in three of the last four fiscal years. Nine of the sixteen patients who experienced delays in treatment in FY09 subsequently died. There were seven successful suicides and one suicide attempt that resulted in serious disability. Appendix C documents the number and types of Level 1 Adverse Events received in FY09 and the patient outcome of those events. The table was expanded in Appendix D to show the outcomes of the reported events over the five year period.

As noted in Table 6, Level 1 Adverse Events can occur in any place within a hospital where care is rendered. Probably due to the prevalence of falls with injuries, patient rooms in medical surgical units continue to be the most likely areas for adverse events. Reports over five years indicated that 44% of the reported Level 1 Adverse Events occur in medical surgical unit inpatient rooms and bathrooms. Events in the surgical suite represent 12% of the reported events. Emergency departments and psychiatric units within acute hospitals and psychiatric hospitals account for 10% and 9% of reported events, respectively. Level 1 Adverse Events are also highly likely to occur in critical care units and labor and delivery. The “Other” category includes infrequently implicated areas such as laboratories and public areas of hospitals.

Table 6: LOCATION OF LEVEL 1 ADVERSE EVENTS

Location of Events	Number of Events in FY09	Number of Events in FY08	Number of Events in FY 2007	Number of Events in FY 2006	Number of Events in FY 2004/2005	Total Number of Events
Medical Surgical Units	97	83	75	52	53	360
Surgical Suites	18	16	22	18	21	95
Emergency Departments	12	17	17	19	16	81
Psychiatric Units	19	21	16	10	8	74
Critical Care Units	15	13	13	13	16	70
Labor & Delivery	7	11	8	9	10	45
Radiology Services (including interventional)	4	3	5	7	7	26
Rehabilitation	6	3	3	1	1	14
Outpatient	0	2	1	2	0	5
Cardiology	6	2	1	1	1	11
Pediatrics	3	2	0	3	1	9
Nursery	0	1	0	1	1	3
Ambulatory Care	0	0	0	1	0	1
Other	3	9	7	9	5	32
TOTALS	**190**	**183**	**168**	**145**	**140**	**826**

OHCQ's Patient Safety Program continues to classify the types of Level 1 Adverse Events using the National Quality Forum's "Serious Reportable Events."[2] This is a nationally known classification of events used by several state reporting systems as their criteria for reporting. Since the NQF system is nationally recognized, it enables OHCQ to compare its data with other state reporting systems. Since the Maryland Patient Safety Program is focused on patient outcomes and OHCQ does not define or limit the types of events reported by hospitals, we have supplemented the NQF list with other types of frequently reported events. These additional classifications include:

- Death or serious disability related to the use of anticoagulants;
- Death or serious disability related to the failure to maintain a patient's airway;
- Death or serious disability as result of an unanticipated complication;
- Death or serious disability related to a delay in treatment;
- Unanticipated fetal or neonatal death or disability; and
- Misdiagnosis.

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

Patient Safety Surveys

During the first five years of mandated reporting to the department, 97% of Maryland hospitals have either reported a Level 1, 2, or 3 Adverse Event or serious near miss with 94% reporting at least one Level 1 Adverse Event. The Department believes that many events go unreported for a variety of reasons. Even though COMAR 10.07.06 calls for patient safety engagement throughout all levels of the hospital, including the governing body, Department staff continue to be concerned that some hospitals may not have effective internal reporting systems.

Through on site patient safety reviews, the department has been focusing on this issue. Hospitals that have reported few Level 1 Adverse Events, have suddenly declined in the reporting of events or have reported significantly less than hospitals with similar capacities and complexity, have been selected for reviews by the Department. Seven reviews of this type occurred in FY09. Three selected hospitals had not reported any adverse events; three had previously reported adverse events but had not reported anything in the preceding six to eighteen months. These surveys resulted in deficiencies of COMAR 10.07.06 Maryland Patient Safety Programs for two hospitals; one of which received a fine for noncompliance with the requirements to have an effective patient safety program.

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

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

One key factor that continues to impact the effectiveness of hospital patient safety programs is the leadership of the hospital. When a change in the Patient Safety Officer occurs, we see changes in the numbers of reports received by the Department, as discussed in the FY08 report. In one hospital that reported very frequently from FY 2004 through FY08, the hospital reported only three events in FY09 after the original Patient Safety Officer was no longer employed by the hospital. Another hospital that frequently reported events during the first four years of the legislation has reported no Adverse Events since their Patient Safety Officer left the facility. It is unlikely that these hospitals have eliminated all or nearly all Adverse Events coincident with a change in Patient Safety Officer.

REVIEW OF LEVEL 1 ADVERSE EVENTS

Falls

Falls were discussed at length in the FY08 Maryland Patient Safety Program report. As previously noted, falls continue to be the most frequently reported Level 1 Adverse Event with

deaths resulting from 14% of the falls with surgery required for 56% of those patients. Due to concern regarding the dire consequences of falls to patients and hospitals, hospital Patient Safety Officers and OHCQ staff collaborated with staff of the Maryland Patient Safety Center in FY08 to develop protocols to prevent patient falls. OHCQ staff provided data to the workgroup from the reports of falls and the RCAs received from Maryland hospitals. Subsequently in June 2009 the Maryland Patient Safety Center launched a yearlong hospital collaborative to reduce the occurrences of falls in Maryland hospitals.

Delays in Treatment

As in four of the past five years, delays in treatment were the second most frequently reported adverse event leading to death or serious disability. These events encompass many different scenarios and situations but in all cases the patient did not receive needed treatment in time to prevent a negative outcome. Seventy-seven percent (77%) of adverse events associated with a delay in treatment that ended in death. The OHCQ staff is in the process of analyzing the delays in treatment reported in FY08 and FY09 for commonalities in circumstance or causality and will be releasing a report in January, 2010. We have tentatively classified the causative factors as:

1. Failure to communicate patient information during transitions in care;
2. Failure to take action on obvious information or symptoms; and
3. Failure to utilize critical thinking techniques; and
4. Failure to grasp the seriousness of a situation.

One representative case is discussed below.

- A 75 year-old patient presented to the emergency department (ED) in the afternoon complaining of a severe headache since the night before his ED arrival. His vital signs were taken. He was then seen by the physician, medicated for pain and left alone to sleep. The nurse thought the patient was sleeping even though she documented that the patient was unresponsive to sternal pressure. The documentation also indicated that the ED physician was notified of the patient's condition but he did not see the patient until 6 AM. He then documented that the patient was sleeping and he did not wake him for an examination. The physician also documented that the patient would be sent home with a diagnosis of sinusitis as soon as his family arrived. The nurse that arrived at 7AM immediately noted that the patient was non-responsive and had an ineffective respiratory pattern. He could not be resuscitated.

In this case, the nurse failed to act on what would seem like obvious symptoms of non-responsiveness and the physician failed to grasp the seriousness of the situation. Both practitioners failed to satisfy the standard of care. While it may be tempting to blame the physician and nurse, there are some vital questions to ask the team. What was the supervision in the ED that night? Was there a charge nurse who should have made rounds? What are the policies for frequency of vital signs and assessments? Does other ED staff routinely fail to follow procedures? Had there been other care issues with either of these practitioners that should have

been acted on prior to these events? What is the atmosphere in the ED? As with other types of events, meaningful change can occur following an objective examination of all of the contributing factors.

Patient Monitoring

Many of the delays in treatment are associated with, or occur to patients on cardio-respiratory monitors. Whether from malfunction, misuse, maintenance failures, inadequate staff training, or systems that allow for adjusting according to staff convenience, six of thirteen monitor events resulted in patient death in FY09. The following adverse events are representative of monitor related cases seen in FY09.

- A monitor-mediated fatality occurred when a patient with sepsis arrested on the telemetry unit and there was a delay in resuscitation. This unit had an automated system that would call the nurse's phone with any dysrythmia alarms. A review of the system after the patient's cardiac arrest revealed that the patient's nurse was in another room with her other patient. She happened to take the other patient off his ventilator at the same time that the first patient started alarming. This coincidence enabled the ventilator alarm to cancel out the phone alarm for the first patient's asystole and cancel out the marquee message in the hall. Since the first patient was in an isolation room with the door closed, it was many minutes before anyone heard the alarm coming from the room. The third redundant alarm system, the audible alarm in the hall, also failed to work because a cord had come loose at the control panel behind the nurse's station.

- A patient died after going into a sustained ventricular tachycardia for 10 minutes before losing his heart rate. The monitor tech failed to recognize the dire rhythm and silenced the alarm. A review showed that this technician was unable to recognize any aberrant rhythm despite training and annual competencies.

- A 72-year-old ventilator dependent patient was admitted from a long term care facility with a change in mental status. Since the patient was also positive for Acinetobacter and Pseudomonas he was placed in closed door isolation with monitoring. Ventilator alarms were not connected to the central monitor. When the ventilator alarmed, no one heard it until the patient's heart rate dropped. Staff responded within minutes, the patient was resuscitated and sent to ICU.

Suicide and Suicide Attempts

Suicides or suicide attempts resulting in serious disabilities to the patient are the fourth most frequently reported Level 1 Adverse Events. Forty one of the 826 Level 1 Adverse Events (5 percent) reported since March 15, 2004, were suicides or suicide attempts. While most occur in psychiatric units or psychiatric hospitals, a significant number have occurred in other areas of acute general hospitals, particularly in the ED. Most reported suicides involve methods resulting in asphyxiation. For this reason it is imperative that hospitals perform the environmental risk

assessments to eliminate or minimize risks wherever possible. Equally important is the need to repeatedly assess the patient for suicide risks. Reports received indicate that patients may have been suicidal at any time during an admission including the day of planned discharge. Triggers that cause a change in the patient's suicidality can occur at any time and staff assessment can be critical in assessing changes in mood and remediating triggers.

The following suicide and attempted suicide demonstrate the need to not only eliminate risks but also ensure that the staff is trained to recognize and deal with these emergencies.

- A patient with a mood disorder who gave no indication of suicidality was voluntarily admitted to an inpatient behavioral health unit. After dinner on the day of admission, the patient showered and returned to the bedroom where he was informed that group therapy was about to begin. The patient indicated that he would be coming to group. When the patient failed to show at group the staff checked on the patient who was still in the bathroom and did not respond to the staff's queries. Staff tried to enter the bathroom, but could not open the bathroom door as the patient's unconscious body was blocking the door from opening. Additional staff came to assist but no one recalled that the door, as all doors on this unit, was double-hinged so it opened in or out. Within a few minutes a staff person arrived who was able to open the door but the patient could not be resuscitated. The patient was found to have ingested bar soap and asphyxiated on a hotel-sized bottle of shampoo. A critical part of the RCA was adding the operation of the door latches to all staff competencies.

- A young female presented to the ED after taking a medication overdose. She had left a suicide note. She was treated and stabilized medically in a trauma suite then moved to a seclusion area where she was continually monitored. Another patient was brought in to the ED who was combative and agitated. The suicidal patient was moved to an ED cubicle since it was determined that the combative patient needed to be placed in the designated monitored seclusion room. The suicidal patient was able to obtain a scalpel from a cart near the nurses' station and cut her forearm. The patient required 100 stitches and was eventually transferred to a private psychiatric hospital.

Surgical Events

In FY07, hospitals reported an increased number of surgical-related events particularly retained foreign bodies after surgery, wrong side surgeries, wrong patient surgeries and surgical procedures performed that were not consistent with the informed consent. The numbers of these reports decreased in FY08 and FY09. Nonetheless, there were a number of surgical cases reported. During FY09 six cases of retained foreign bodies were reported that were Level 1 Adverse Events and several additional reported cases that did not cause death or serious disability. Among these were several unique cases of retained foreign bodies that resulted from items not generally considered as part of the surgical counts, including knife blades, drill tips, and other pieces of broken equipment.

Since reporting began in FY04, eighteen reports of wrong side, wrong patient or the wrong surgical procedure have been received by the Department. Three of the cases were reported in FY09.

- A 60-year-old man came to hospital for a renal biopsy. A history and physical was performed prior to procedure. The procedure was posted for left kidney but the order from physician said "CT-guided biopsy of kidney mass." The signed consent was consistent with the physician's order and did not specify laterality. The patient indicated on the informed consent that he understood the procedure was to be performed on the left kidney. The interventional radiologist reviewed the CT films which showed the larger mass on right side and, as a result, biopsied the right kidney. The patient and the patient's spouse expressed to the physician their distress regarding the biopsy procedure as they had previously known of the right kidney's prognosis and thought the left kidney was to be biopsied to determine its salvageability and the patient's appropriateness for dialysis. The radiologist then biopsied the left kidney. Although, technically this was a Level 2 Adverse Event, absent a disability, the hospital chose to report the incident as they considered it to be a serious event.

- A 40-year-old had a colonoscopy with removal of several polyps in the descending colon. A large (6 centimeter) polyp was found in the ascending part of the colon and the area was marked for removal. However, in the procedure note the gastroenterologist described the polyp as being in the descending colon. The patient was scheduled for surgery several weeks later and had several inches of the descending colon removed with no polyp found. The ascending colon was then resected to remove the previously marked polyp. The surgeon did not talk directly with gastroenterologist who performed the endoscopy. The surgeon could not find the tattooed polyp. The surgeon performed the surgery based on a procedure note that had identified the wrong site. The hospital now requires an intraoperative colonoscopy or pre-op CT if the area for resection is in question.

Hospital Acquired Pressure Ulcers

The Department continues to receive few reports of hospital acquired pressure ulcers. Due to the morbidity and mortality associated with Stage III and IV pressure ulcers, we consider them to be Level 1 Adverse Events and expect hospitals to report them. Pressure ulcers that progressed from Stage I or II to Stage III are excluded from the reporting requirement if the Stage I or II was present on admission. Deep tissue injuries or "unstagable" pressure ulcers almost always devolve into Stage IV pressure ulcers and should be reported as well.

In FY08, only one report of a hospital acquired Stage III or Stage IV pressure ulcer was received. Nine reports of Stage III and IV pressure ulcers were received in FY09 from two hospitals that have began to review this costly and frequently preventable event. As noted in last year's report, hospital acquired pressure ulcers remain among the most frequently reported events in other states. While reports this year increased in Maryland, the number of these reports

(9) is not consistent with what is seen in other states such as Minnesota[3], Indiana[4] and New Jersey[5].

Sinai Hospital of Baltimore, in response to reviewing a case of a hospital acquired pressure ulcer, developed a short RCA tool similar to the tool already available for assessing patient falls. The OHCQ staff revised the form and it is available in Appendix H. The Department would like to thank the staff of Sinai for developing the prototype. The short form can be used in lieu of a full RCA for hospital acquired pressure ulcers. Additionally, a Clinical Alert on hospital acquired pressure ulcers is available on the OHCQ website.

Healthcare Associated Infections

Another largely under reported category of events is healthcare acquired infections that result in death and serious disability. The Department has received only 23 reports of healthcare associated infections (HAI)—nine of these were reported in FY09—nearly twice the number for each of the previous two years. Seven of the nine HAIs reported in FY09 resulted in patient death.

Infection control professionals (ICPs) have been monitoring data related to hospital acquired infections for quite some time, but this information may not be linked with the patient safety activities. According to the Maryland Infection Control Regulations, enacted in 2008, hospital ICPs and patient safety officers must share information about individual patient infections as well as outbreaks.

Hospitals that have reported HAIs have provided OHCQ with some of the challenges they face in reporting and reviewing HAI events. Due to the short length of patient stay, HAIs may not be evident prior to discharge from the facility. It also takes several days for some laboratory tests results which could confirm the presence of an HAI. ICPs may only present their surveillance data in committee on a quarterly or less frequent basis. For these reasons, the reports of a level 1 HAI may be delayed in being communicated to the Patient Safety program and subsequently to the Department. Hospitals have a responsibility to educate physicians and other staff about the value of reporting these events to improve processes and systems within the hospitals.

Patient Safety officers also communicate the difficulty the teams have in determining how the patient became infected. They often cannot find that one transgression or point in time where the patient first developed the infection. However, once a case is reviewed, the hospitals' RCA teams do identify system and process issues that may have contributed to the HAI.

[3] Minnesota Department of Health. Adverse Health Events in Minnesota, Fifth Annual Report, Minnesota Department of Health, January 2009, page 21.
[4] Indiana Department of Health, Indiana Medical Error Reporting System, Final Report for 2008, August 20, 2009, pages 25 and 29.
[5] Health Care Quality Assessment, New Jersey Department of Health and Senior Services, Patient Safety Initiatives, 2007 Summary Report, Office of Health Care Quality Assessment, page 15.

Below is an example of an adverse outcome associated with an HAI in FY09. This case illustrates some of the challenges faced when hospitals are trying to decide if an HAI requires reporting.

- A young woman delivered a healthy infant via a normal spontaneous vaginal delivery. She had tested positive for group B streptococcus before delivery and had a post-operative fever of 100.3. She was given a few doses of Clindamycin and Penicillin while an inpatient but was not discharged on antibiotics. The patient started having diarrhea a week later. After another week, she returned to the hospital ED due to weakness and continued diarrhea. She tested positive for Clostridium difficile in her stool. She soon became septic, required a total colectomy, and expired from her infection. According to the Infectious Disease physician, the infection qualified as a healthcare acquired infection due to the antibiotics given during her post-partum period. While causation cannot be proven, the hospital identified deficiencies with its post-partum protocol for management of patients with group B streptococcus and with patient education.

Medication Errors and Anticoagulants

Data reported to the Department indicates 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. Medication errors that result in death or serious disability averaged eight per year with only two in FY09. Nonetheless, numerous studies indicate that nearly all patients experience a medication error or adverse drug reaction during hospitalization. Maryland has elected to classify deaths or serious disability related to anticoagulation as its own category of event. There have been seventeen of the medication errors related to anticoagulants with two of these being reported in FY09. The following two examples are representative of reports received:

- A 70-year-old male was admitted with chest pain radiating to both shoulders. A cardiac catheterization revealed a 100 percent blockage in the right coronary artery. The evaluation also revealed a small retroperitoneal hemorrhage that did not require surgical intervention. Subsequent to the procedure he received one dose each of the anticoagulants Lovenox and Coumadin, which were then discontinued. The Lovenox was re-ordered the next day and the Coumadin was added the following day. That day he received two doses of Coumadin 5 mg and the usual two doses of Lovenox 70 mg. The following day the patient had a dose of Coumadin and 2 doses of Lovenox then was discharged home. The day after discharge, the patient experienced severe abdominal pain and was emergently taken from home to another hospital where he was found to have an extension of the retroperitoneal hemorrhage. The patient's PT was 42, PTT of 53.4 and an INR of 4.1. He required surgical intervention and was intubated. The hospital believed that this was a prescribing error. The patient had a dose of Coumadin, then none for 36 hrs, then two doses within twelve hours. The laboratory work was done but it was not reviewed prior to discharge at which time the PTT was over 31. As part of its review the hospital is examining the possibility of creating a "dependant discharge" category in the electronic

medical records, so that a patient could have a discharge order written pending review of lab results.

- A 30-year-old was admitted for surgical repair of a dislocated shoulder. The patient was managed by a surgical PA-C but was not seen by a physician or orthopedic surgeon before surgery. In 24 hours, between arrival and surgery, the patient received 15 mg Dilaudid IV (intravenously), 8 mg Morphine IV, 250 mcg Fentanyl IV, 50 mg Benadryl IV, and 30 mg Toradol. While in the recovery room after surgical repair of her shoulder, the patient went into respiratory failure, was intubated and admitted to the ICU. The patient continued to deteriorate and was transferred to another hospital at the family's request. The patient remained in that hospital's ICU with no spontaneous movement or respirations for several days, but eventually recovered and was discharged in stable condition.

Burns

As noted in previous reports, burns that occur during surgical procedures are frequently reported even when the patient injury does not qualify as a Level 1 Adverse Event. To date, we have received reports of five burns that were determined to be Level 1 Adverse Events. All of these serious injuries occurred during operative procedures. However, in FY09, one reported Level 2 Adverse Event demonstrates how environmental factors can lead to a serious event:

- A 40-year-old female was taken to the hospital with aspiration pneumonia and was admitted to the ICU. She was receiving 2 liters oxygen via a nasal cannula. A visitor came to visit and leaned over to kiss the patient just after removing her wool coat. A static spark ignited the oxygen. The fire was quickly extinguished but the nasal cannula tubing melted to the patient's face and her hospital gown ignited. The patient was intubated and transferred to a burn center. Further evaluation determined that her injuries were superficial. There were no apparent equipment malfunctions that contributed to the event; however, the humidity level in the unit was only 29 percent.

Aspiration and Dietary Concerns

In FY09, two patients in inpatient medical beds who were not provided the correct consistency diet and appropriate supervision for meals suffered fatal consequences:

- An elderly patient admitted with hypertension, heart failure, history of stroke with left sided weakness was transferred from the ICU to a progressive cardiology service. Three days later the patient had a videoflouroscopic swallowing evaluation, which showed moderate dysphasia with silent aspiration. The patient was started on a pureed diet with honey-thick liquids. The following day, the patient was transferred to a medical surgical unit. Although his nurse was aware the patient was to be on special diet, the admitting physician ordered a cardiac diet. No one reconciled the new diet order with the previous order. The patient had a lunch tray delivered which included a chicken sandwich. The

nurse cut the sandwich into small pieces and asked a nurse's aide to stay with the patient. The patient started choking when another nurse arrived. She performed the Heimlich maneuver which released the food. The patient quickly stopped breathing and was pulseless. A code was called and the patient was intubated but circulation was not restored for nine minutes. Food particles were suctioned through the endotracheal tube. The patient died after several days in the ICU. The RCA revealed that there was no policy for reconciling diet orders for unit transfers. Dietary aides do not have to reconcile trays upon delivery. The nurse knew the patient needed a mechanical soft diet but thought cutting the chicken sandwich into small pieces was sufficient. Action items include expanding the dietary advisory committee and charging them with developing policy for diet reconciliations on transitions of care.

- An elderly patient was admitted with progressive weakness and diagnosed with new onset of probable Amyotrophic Lateral Sclerosis (ALS). A swallowing evaluation showed no gag reflex and global weakness of the tongue and mouth. The patient was ordered a mechanical soft, thin liquids diet with supervised swallowing. Several days into the admission, the dietary aide delivered a regular tray to the patient. The aide noted the sign on the door with the correct consistency diet, but assumed the sign was wrong and left the unit without telling the staff that she had delivered the tray. The patient ate some of the meal and aspirated, leading to acute respiratory failure. The rapid response team was called and the patient was intubated. An EKG revealed signs of heart failure. The patient was moved to the CCU and later died. The RCA found that dietary staff had to manually enter diet orders and the person entering the regular diet order for another patient entered the wrong medical records number thus pulling the wrong patient's medical record. The tray deliverer noted the discrepancy, but assumed the sign was wrong. The hospital policy has been changed requiring dietary staff to not deliver trays if there is a discrepancy. The computer order system now automatically populates the diet field.

Safe Discharge

Adverse events related to discharge over the past five years frequently involve medication reconciliation. One adverse event related to discharge reported in FY09 was unique.

- An elderly patient who was had been on two liters of oxygen for a period of time was discharged from a psychiatric hospital to a nursing home. He was transported in a handicapped van which did not have oxygen. Upon arrival at the nursing home the patient had low oxygen saturation and was sent to an acute general hospital for treatment. At the acute general hospital the patient was placed on a ventilator and died four days later. While it is not known if the lack of oxygen in transport was the cause of the patient's death, the hospital now includes a patient's transport needs on its discharge planning tool.

Notifying Patients and/or Families

The Maryland Hospital Patient Safety Program and Maryland regulations require a hospital to notify a patient, or if appropriate, a patient's family member, whenever an outcome of care differs significantly from an anticipated outcome. Hospitals continued the trend of the previous two years of reporting and indicated that families and/ or the patient were notified of an adverse outcome. In FY09, hospitals indicated as part of the report of 179 Level 1 Adverse Events, that the patient or family had been informed that an Adverse Event had occurred in the care provided to them or their loved one.

Review of Root Cause Analyses

In addition to mandatory reporting the Maryland Patient Safety Program requires that the hospital submit a root cause analysis to OHCQ for each reported Level 1 Adverse Event. OHCQ expects a very detailed report of what occurred and a plan of correction to the deficient practices (root causes) with timelines and a means to monitor the effectiveness of the corrective actions.

"Root causes" are defined by 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, not individual performance, and seek to determine not only the "what" but the "why" of the event. The regulations require that a multi-disciplinary team at the hospital review human factors, processes and systems, and underlying cause and effect. The hospital staff must also identify risks and contributing factors for recurrence, and determine what improvements in systems of processes are needed.

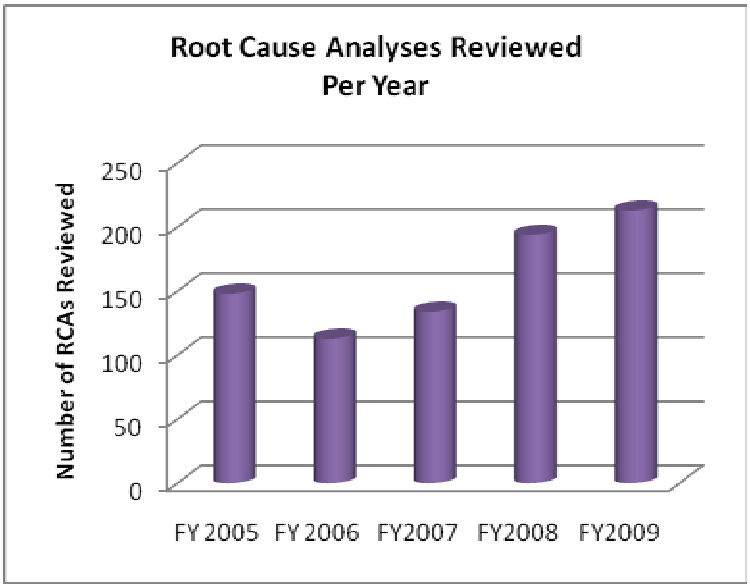


Table 7 indicates the number of RCAs reviewed each year since the program began. In FY09, hospitals submitted 205 root cause analyses to the Office of Health Care Quality. The staff of the OHCQ reviewed 213 root cause analyses during that time. The discrepancy represents several root cause analyses submitted but not reviewed in FY08 as well as voluntary root cause analyses submitted for events that were not Level 1 Adverse Events. The OHCQ continues to utilize the root cause analysis evaluation tool designed for that purpose. Since the

program began, 802 root cause analysis have been reviewed with feedback provided to the hospitals. Additionally over 90% of that feedback is provided within sixty days of the receipt of the RCA.

In FY07, OHCQ reported that nearly 50% of all RCAs were problematic. During FY08, the Office of Health Care Quality identified that 15 of the 194 RCAs reviewed did not meet the standards set in COMAR 10.07.06. Feedback was given to the hospitals using the root cause analysis evaluation tool. However, in FY09, when significant problems were noted in the submitted root cause analysis, deficiencies were cited and the hospital was required to submit a revised RCA and a plan of correction to address how future RCAs would be conducted. Formal deficiency statements were sent to hospitals for seven root cause analyses reviewed.

The overwhelming issue with the poorly constructed RCAs continues to be superficial analyses, which fails to reveal; 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 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 actual adverse event. Following are some examples of RCAs received over the past year, with discussion.

Root Cause Analysis Case No. 1:

In the description of the event, the RCA merely says "Patient admitted with chest pain. A myocardial infarction was ruled out. The patient experienced cardiac arrest a little over 48 hours after admission." The RCA failed to contain a timeline or explanation of the actual adverse event and did not explain what, if any, of this description was relevant. In addition, the outcome for the patient was not noted. If the RCA team cannot describe what happened in sufficient detail to allow identification of the causative and contributing factors, it will not be able to prevent a recurrence. If there truly was no preventable error, OHCQ will downgrade the event to not-reportable, but the hospital needs to provide evidence that the RCA team has examined the event and understood what happened.

Root Cause Analysis Case No. 2:

A very elderly patient had an outpatient laparoscopic surgery under general anesthesia. She was discharged from the recovery room when she met discharge criteria. She became unresponsive while being assisted into her daughter’s car and a Code Blue was called. She was taken to the ED and resuscitated and was eventually discharged after an inpatient stay. The RCA focused on the actions of the staff during the Code, which took place just outside the hospital doors. While conducting a Code outside of the hospital is dramatic, the more important contributing factors to the patient’s cardiac arrest were everything that happened before she arrested. Why was this patient with co-morbid conditions, including a recent untoward reaction to anesthesia, considered an appropriate candidate for outpatient surgery? There are multiple policy issues dealing with posting criteria, discharge criteria, individualized care planning, and

anesthesia supervision while in the recovery room that were not addressed by the RCA team. Peer review was also indicated in this case.

The Office of Health Care Quality has not mandated what type of form should be used by hospitals to conduct and report RCAs. However, one RCA form published by a popular accrediting organization and in use by many hospitals does not satisfy the requirements for RCAs contained in COMAR 10.07.06. If hospitals choose to use this form, they should be aware that OHCQ requires more evidence of analysis than that asked for in the form. For instance, the form asks for a check mark to indicate that "why" questions have been asked about a particular contributing factor. OHCQ requires evidence that the questioning process has been in depth enough to allow for identification or causative and contributing factors.

When RCA teams are comprised primarily of front-line staff, they focus on proximate causes and front-line fixes. In many of the poor RCAs reviewed by the OHCQ, the root causes are defined as a set of actions of one or two people. This approach makes it seem like all Adverse Events occur behind closed doors, in isolation, and untouched by whatever else is happening on the unit. We note that the issue of supervision is seldom raised in RCAs. Where are the nurse managers, charge nurses, and shift supervisors during the cascade of poor decisions being made by the practitioners at the bedside? Where are the service chiefs when the physician will not return a call or does not show up for the emergency C-section until it is too late? Where is the radiology supervisor when the radiology technician does not know how to gown and glove for intra-operative x-rays? Why is a PA-C consulting with another PA-C instead of the supervising physician when the patient has taken a turn for the worse? Supervision and accessing the chain of command are generic root causes that need to be addressed in the RCAs before meaningful change can occur in the hospital. Front-line staff may be reluctant to address these issues and may need assistance and reassurance by the facilitators of RCA meetings and by hospital leadership.

As part of the RCA process the hospital must develop an action plan to address the root cause of the adverse event. Consistent with other years, the hospitals were changing policies and procedures to address the root causes in 61% of the RCAs reviewed in FY09. Fifty six percent (56%) of the RCAs also indicated that education on the changed policies and procedures would be included. However, in 83% of the RCAs reviewed data collection and review was identified as a planned action, which may be an indication of the hospital's determination that planned actions must be measured and evaluated to determine if the actions taken were successful in correcting the root causes. Process and system changes were identified on 40% of the RCAs reviewed in FY09. Workload or staffing changes were made in 13% of the action plans. Six percent (6%) of the RCAs indicated that environmental changes were made as a result of an adverse event and 25% indicated that equipment modifications were made to prevent the reoccurrence of the adverse event. Twenty one percent (21%) of the RCAs indicated that the event would also be referred to the hospital's peer review system. In 33 of the 44 RCAs that identified peer review as an action, the hospital identified other required corrective actions in addition to peer review. The 213 RCAs reviewed in FY09 averaged 3 types of corrective actions per RCA. Appendix G includes the data for the types of actions taken for the recent and past fiscal years.

Measures of effectiveness 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 how effective a corrective action has been in remediating the set of circumstances that led to the adverse event. Completion of implementation is certainly something the hospital would want to track, but that is not a measure of effectiveness. Hospitals need to determine what the goal of the corrective action is, and how to measure that goal. What impact will this action have on the problematic process? Will this action eliminate or control the problem and how will we know? What is the goal for other patient undergoing this process? What do we expect from the staff and how will we ensure they are meeting our expectations? Even relatively weak actions like policy changes can be made more effective with frequent, random staff observations.

COMPLAINTS

The value of mandatory reporting continues to be exemplified by the absence of duplication between the complaints received by OHCQ's Hospital and HMO Quality Assurance Unit (the regulatory unit with jurisdiction over hospitals) and the Level 1 Adverse Events received by OHCQ's Patient Safety Program. The Department received 416 hospital quality of care complaints during FY09. Even with a 25% increase in the number of complaints received by OHCQ over FY08, only three complaints were received about Level 1 Adverse Events. Since March 2004, 826 Level 1 Adverse Events have been reported by Maryland hospitals. In that same period 1,805 hospital complaints were received by the OHCQ. Only 18 Level 1 Adverse Events were also received as a complaint since reporting began in March of 2004. Most patients or families affected by serious adverse events do not file complaints about those events. Mandatory reporting and review of RCAs provides another avenue for the Department to evaluate how hospitals are providing care. The data obtained from the complaint process has little relevance to the number and type of adverse events occurring in Maryland hospitals.

Clinical Alerts

Based on the information obtained from the review of the events and the root cause analyses, OHCQ has developed and distributed hospital Clinical Alerts. It is hoped that the experience of a hospital or several hospitals disseminated through the Clinical Alerts will prevent the recurrence of the event in another hospital and will enable the office to share "Best Practices." Five Clinical Alerts were released in FY09:

- "IV Promethazine Injuries"
- "Preventing Retained Foreign Bodies"
- "It Takes a Village: Anticipating and Managing Medication Side Effects"
- "Hospital Acquired Pressure Ulcers"
- "Transdermal Fentanyl Safety"

IV Promethazine Injuries was released in the fall of 2008. In follow-up, the FDA recently changed the warnings on Promethazine to caution against using the IV route for administration.

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[6] 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, OHCQ Patient Safety Program staff continued 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.

Five Years Later

It has been more than five years since the implementation of the Maryland Patient Safety Program on March 15, 2004. The program started with minimal resources and the commitment of OHCQ staff to create a partnership with Maryland hospitals that went beyond the traditional regulator/regulated roles. Skeptics said that an effective program could not work in a regulatory agency. Clearly, that has presented challenges over the past five years but that challenge has not been the impediment many expected. While the Department believes there is still under reporting, most Maryland hospitals have embraced both the spirit and the letter of the legislation and are trying to make health care safer for all patients.

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

Staff of the Office of Health Care Quality has been afforded the opportunity to participate in workgroups and learning exchanges sponsored by NASHP (National Association of State Healthcare Policy), AHRQ (Agency for Healthcare Research and Quality), and NQF (National Quality Forum). OHCQ has presented information on the Maryland program at 2008 AHFSA (Association of Health Facility Survey Agencies) Annual Conference and at the 2008 Centers for Medicare and Medicaid Services Leadership Conference and for the AHRQ VA (Veterans Administration) Patient Safety Improvement Corp training in 2005 and in 2006. The Department has also provided educational programs to many local professional organizations on the topic of patient safety and remains contributors to the Maryland Patient Safety Center's activities.

In 2003, when the hospital leadership met with the staff of the Office of Healthcare Quality to draft the regulations, the hospitals requested that the event information received by OHCQ be shared with the hospitals. They suggested the feedback be an integral part of the program. After five years, OHCQ believes that this request has been fulfilled and will continue to look for new opportunities for open dialogue and discussion.

Feedback has been provided in a variety of ways. Each year, OHCQ publishes this Annual Report with a summary of the types and numbers of adverse events reported, as well as any trends or patterns noted throughout that year. Since the program inception, the Department has used the information from the RCAs and event reports to develop Clinical Alerts and other transmittals. These Clinical Alerts are publically available and have been shared with the hospitals and other health care providers to educate and possibly prevent the recurrence of some of these very egregious events.

Each year the Department has also been pleased to present information on the events and RCAs at the annual Maryland Patient Safety Conference. As previously mentioned, OHCQ has developed data and information from the reports to provide information to the Maryland Patient Safety Center for its training programs and collaboratives.

OHCQ recognizes that some of the most valuable feedback has occurred despite our limited resources. Since there are limited funds to provide a sophisticated computer program that would allow hospitals to electronically submit their reports, most hospitals contact OHCQ directly. While this may not be the most efficient reporting system, the discussions with hospital staff have provided valuable insight to the OHCQ staff about how the hospitals handle these events and the exchange has provided additional education to hospitals.

OHCQ has also communicated to hospitals in reference to every RCA submitted to the Department over the past five years. Written correspondence, onsite visits, phone calls, a completed root cause analysis evaluation tool or, in a few cases, deficiency statements are shared with the hospitals for the purpose of refining the RCAs and to ensure that the most effective corrective actions are implemented.

Many hospitals have self reported non-Level 1 Adverse Events in recognition of the seriousness of system level problems that may exist in their facilities and for assistance to avoid a more serious outcome in the future. As previously mentioned, burns that occur in the OR are

often not Level 1 Adverse Events but many hospitals report these events when they occur even if the injuries are minor. 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.

In this tenth year since publication of the Institute of Medicines report "To Err Is Human" it is difficult to determine if national patient safety activities have made a difference. OHCQ has asked that question about the Maryland Patient Safety Program as well. While it is difficult to claim that hundreds of patients have been saved or that the hospitals are now delivering 100 percent safe care, there are two examples where improvements were identified that may be related to the Maryland Patient Safety Program:

- OHCQ staff wrote and distributed a Clinical Alert based on a trend of serious injuries to patients related to the use of Phenergan intravenously entitled "IV Promethazine Injuries" in the Fall of 2008. Multiple hospitals reported to OHCQ that they were removing IV Phenergan from their formularies after reading the alert. It was not until September 2009 that the FDA put out an alert regarding IV Phenergan. There is no way to measure if this action may have prevented the injury to another patient.

- A hospital that treated chronic ventilator dependent patients reported nine Level 1 Adverse Events between April 13, 2004 and March 1, 2007. Six of the involved patients died when they became disconnected from their ventilators without staff hearing the alarms. The hospital submitted RCAs that addressed multiple changes after the first four events. However, after the last two patients died, the hospital acquired new ventilators, and determined that all ventilator dependent patients should be placed on continual pulse oximetry. For more than two years this hospital has reported no additional airway or ventilator related events.

Hospitals expressed some concern following the development of regulations regarding the confidentiality of the reports and RCAs once they were received by OHCQ. Despite public information requests, OHCQ has not released any hospital specific data or specific event data. OHCQ has fulfilled our regulatory mandate to respect the protections provided to hospital and patient specific events yet still provide information for educational purposes.

OHCQ is pleased with the increased number of hospitals who are reporting their notification of Level 1 Adverse Events to affected patients/families. We commend the hospitals for improvements in the quality of their RCAs over the last five years. We hope that this process and the products of the RCAs are being utilized by hospitals to improve patient care.

Future Plans

As previously noted, hospitals report that the sharing of information is valuable to their education. Information sharing provides hospitals with the opportunity to review systems and procedures and make proactive changes to prevent recurring adverse events. Clinical Alerts developed by the staff of the Department have proven to be an effective tool to disseminate information to hospitals and other health care providers. The Department intends to continue providing Clinical Alerts in the upcoming fiscal year. Additional plans for the dissemination of information include:

- Research and publish best practices for commonly occurring Level 1 Adverse Events;
- Continue to support the collaboratives sponsored by the Maryland Patient Safety Center;
- Identify 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
- Continue participation in the educational offerings provided by the Maryland Patient Safety Center.

OHCQ remains focused on determining the best methods to review RCAs, performing activities to support the improvement of the hospitals patient safety programs and encouraging hospitals to report Level 1 Adverse Events. For the future, the Department plans on further analysis and use of the data accumulated to date. We are continually challenged to identify trends in events and corrective actions while attaching meaning to the data.

The Hospital Patient Safety Program regulations mandate the reporting of Level 1 Adverse Events and Health General Article §19-304 allows OHCQ to collect civil money penalties from hospitals that fail to report such events. As patient safety reviews are conducted, OHCQ will, when appropriate, cite deficiencies and advise the Secretary of the Department of Health and Mental Hygiene when the application of the civil money penalty is required.

Appendices

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 has an Emergency Department. Certain hospitals also provide specialized services such as trauma, burn and stroke care. However, not all hospitals offer certain other services, such as pediatrics, labor and delivery and/or behavioral health. Several acute general hospitals also operate separate units that are dually licensed as Special Hospitals, either Chronic or Rehabilitation types.

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

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.

- The 13 Special Hospitals-Psychiatric range in size from 15 licensed beds to 639 beds.
  - Seven of these hospitals are State operated.
  - Three psychiatric hospitals serve only specific populations (children, forensics, and clergy).
- 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.
  - Two are operated by the State of Maryland. While all provide some rehabilitation services, two of the hospitals are dually licensed as rehabilitation hospitals.
- There are two Special Hospitals-Rehabilitation and two Special Hospitals - Children. The latter are also dually licensed as rehabilitation hospitals. The children's and rehabilitation hospitals have less than 102 beds and all offer outpatient services.

Appendix B: TYPES OF EVENTS

Type of Event	FY 2004 [7]	FY 2005	FY 2006	FY 2007	FY 2008	FY09	Totals
Death or serious disability associated with a fall	3	27	46	56	83	98	**313**
Death or serious disability associated with a delay in treatment	1	12	9	24	20	16	**82**
Death or serious disability associated with airway management	3	11	15	7	7	6	**49**
Suicide or attempted suicide resulting in serious disability	1	6	10	5	11	8	**41**
Death or serious disability associated with medication error	0	11	8	10	8	2	**39**
Unanticipated complication of treatment	2	5	9	5	2	7	**30**
Unanticipated fetal death or injury	0	3	7	5	9	3	**27**
Misdiagnosis	7	6	5	2	2	3	**25**
Death or serious injury of patient or staff associated with health care acquired infections	0	0	2	7	5	9	**23**
Malfunctioning device	1	3	5	5	4	2	**20**
Surgical procedure not consistent with consent/ wrong patient / wrong body part	1	1	2	7	4	3	**18**
Post-surgical retention of foreign body	0	3	1	6	3	6	**19**
Unanticipated intra-op or immediate post-op death	0	6	5	1	3	3	**18**
Death or serious disability associated with the use of anticoagulants	1	3	2	6	3	2	**17**
Death or serious disability associated with the use of a vascular access device	1	6	3	2	2	2	**16**
Stage III or IV pressure ulcers acquired after admission	0	0	0	4	1	9	**14**
Death or serious disability associated with a staff member's failure to act	0	2	3	2	2	1	**10**
Maternal death or serious disability associated with Labor & Delivery	1	2	0	2	2	1	**8**
Death or serious disability associated with hypoglycemia	0	2	1	1	1	2	**7**
Death or serious injury resulting from physical/sexual assault occurring within or on hospitals grounds	0	0	2	2	2	0	**6**
Intra-op or post-op death in ASA 1 patient	2	0	1	1	1	1	**6**
Death or serious disability associated with the use of restraints seclusion, or side rails	0	1	1	1	1	0	**4**
Death or serious disability resulting from an intravascular air embolism	0	2	2	0	1	0	**5**
Death or serious disability associated with a burn that occurred in a hospital	0	0	0	3	1	1	**5**
Hemolytic reaction to ABO incompatible blood products	0	0	1	1	0	0	**3**
Death or serious disability resulting from a contaminated drug, device or biologic	0	1	0	0	0	0	**1**
Other	0	2	5	3	5	4	**19**
Totals	**24**	**116**	**145**	**168**	**183**	**190**	**826**

[7] Mandatory reporting did not begin until March 15, 2004.

Appendix C: TYPES OF EVENTS AND SUBSEQUENT OUTCOMES - FY09

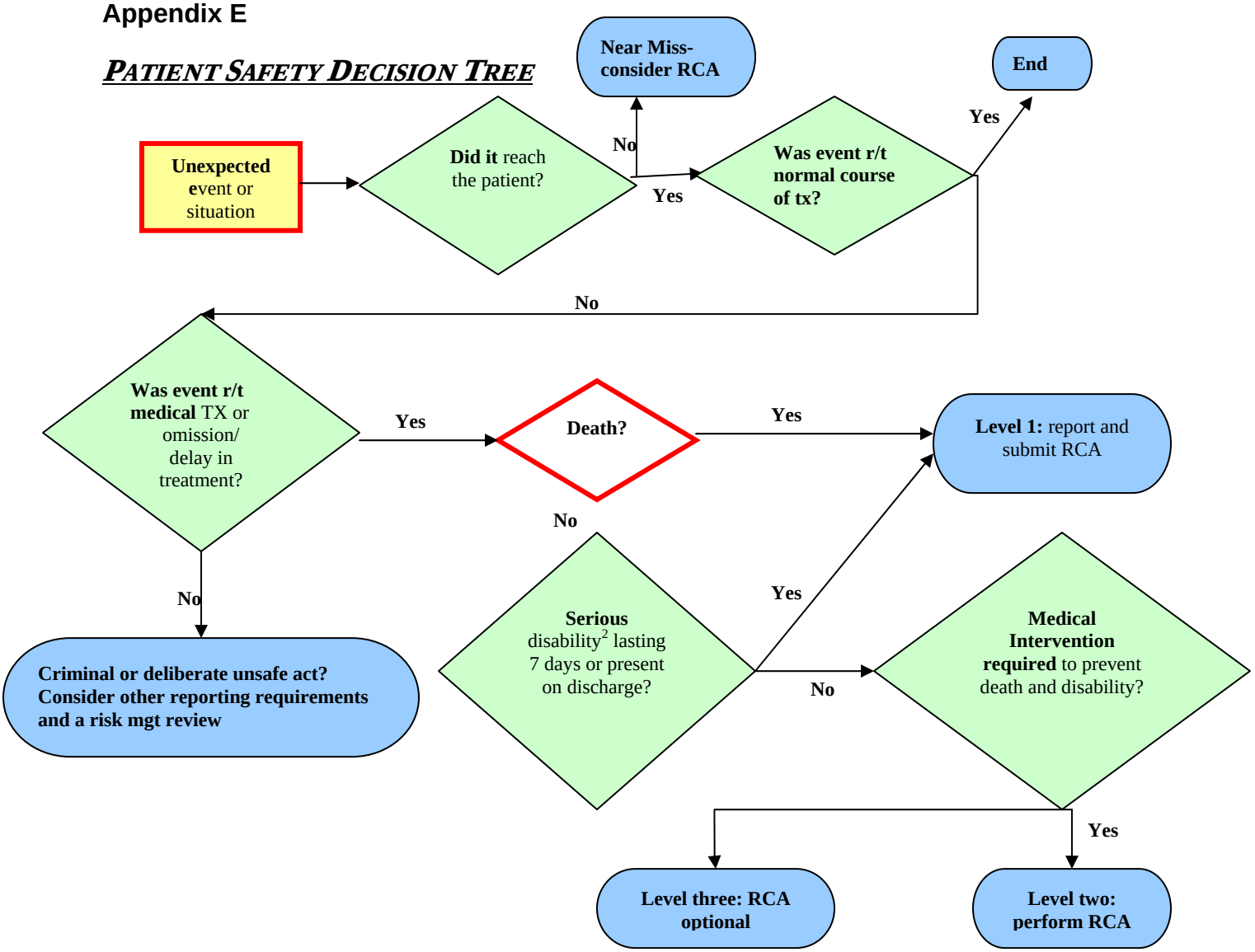
Type of Event	Loss of limb/ function	Surgical Intervention	Medical Intervention	Death	Total
Death or serious disability associated with a fall	0	56	28	14	**98**
Death or serious disability associated with a delay in treatment	1	1	5	9	**16**
Suicide or attempted suicide resulting in serious disability			1	7	**8**
Unanticipated fetal death or injury				3	**3**
Death or serious disability associated with medication error			1	1	**2**
Death or serious disability associated with airway management			1	5	**6**
Other	1			3	**4**
Death or serious injury of patient or staff associated with health care acquired infections			2	7	**9**
Malfunctioning device		1	1		**2**
Surgical procedure/body part not consistent with consent		3			**3**
Death or serious disability associated with the use of anticoagulants		1		1	**2**
Post-surgical retention of foreign body		5		1	**6**
Unanticipated intra-op or immediate post-op death				3	**3**
Death or serious injury of patient resulting from physical/sexual assault or abuse occurring within or on hospitals grounds			1		**1**
Death or serious disability associated with a staff member's failure to act				1	**1**
Unanticipated complication of treatment	1		2	4	**7**
Maternal death or serious disability associated with Labor & Delivery				1	**1**
Death or serious disability associated with the use of a vascular access device		1		1	**2**
Stage 3 or 4 pressure ulcers acquired after admission		2	7		**9**
Death or serious disability associated with a burn that occurred in a hospital			1		**1**
Death or serious disability associated with the use of restraints seclusion, or side rails					**0**
Misdiagnosis			1	2	**3**
Intra-op or post-op death in ASA 1 patient				1	**1**
Death or serious disability associated with hypoglycemia			1	1	**2**
Death or serious disability as a result of an intravascular air embolism					**0**
Totals	**3**	**70**	**52**	**65**	**190**

Appendix D: TYPES OF EVENTS AND SUBSEQUENT OUTCOMES 3/15/04 - 6/30/09

Type of Event	Loss of limb/ function	Surgical Intervention	Medical Intervention	Death	Total
Death or serious disability associated with falls	12	178	68	55	**313**
Death or serious disability associated with a delay in treatment	9	4	3	66	**82**
Death or serious disability associated with airway management	3		3	43	**49**
Suicide or attempted suicide resulting in serious disability	1		6	34	**41**
Death or serious disability associated with medication error	4	2	7	26	**39**
Unanticipated complication of treatment	3	4	6	17	**30**
Unanticipated fetal death or injury	3		4	20	**27**
Misdiagnosis	3	4	4	14	**25**
Death or serious injury of patient or staff associated with health care acquired infections		2	3	18	**23**
Malfunctioning device	2	2	3	13	**20**
Post-surgical retention of foreign body		17		2	**19**
Unanticipated intra-op or immediate post-op death				18	**18**
Surgical procedure/body part not consistent with consent/wrong patient	4	12		1	***17***
Death or serious disability associated with the use of anticoagulants	2	1		14	**17**
Death or serious disability associated with the use of a vascular access device		1		15	**16**
Stage 3 or4 pressure ulcers acquired after admission	1	4	9		**14**
Death or serious disability associated with a staff member's failure to act	1			9	**10**
Maternal death or serious disability associated with Labor & Delivery		2	1	5	**8**
Death or serious injury resulting from physical/sexual assault or abuse			6	1	**7**
Death or serious disability associated with hypoglycemia	1		2	4	**7**
Death or serious disability associated with a burn that occurred in a hospital			5		**5**
Intra-op or post-op death in ASA 1 patient			1	5	**6**
Death or serious disability associated with the use of restraints seclusion, or side rails	1	1	1	1	**4**
Death or serious disability as a result of an intravascular air embolism	1			4	**5**
Death or serious disability resulting from hemolytic reaction to ABO incompatible blood products			1	2	**3**
Death or serious disability resulting from a contaminated drug or biological				1	**1**
Other	3	1	2	13	**19**
Totals	**53**	**236**	**135**	**402**	**826**

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?

[1] 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

PLANS OF ACTION IDENTIFIED IN ROOT CAUSE ANALYSIS

Percentages of the RCAs Identifying This Action

	FY 2004 FY 2005 (N=148)	FY 2006 (N=113)	FY 2007 (N=134)	FY08 (N=194)	FY09 (N=213)
Change In Policy/procedures	79%	71%	51%	58%	61%
Formal education	79%	70%	67%	62%	56%
Disciplinary actions	4%	2%	10%	2%	3%
Process improvement	10%	42%	34%	30%	40%
Equipment Modifications	31%	27%	17%	23%	25%
Environmental Changes	11%	9 %	3%	6%	6%
Workload/Staffing Changes	18%	31%	13%	15%	13%
Referral to Professional Board	0%	0%	3 %	0.5%	0%
Data Tracking/Trending	36%	42%	35%	61%	83%
Reported to FDA	1%	2%	2%	1%	1%
Peer Review	12 %	14 %	21%	24%	21%

**Hospitals took an average of 2.9 actions on each RCA.*

Appendix G

Short RCA for Reviewing Hospital-acquired Stage III/IV Pressure Ulcers

Hospital Name:	Event #

Note: All hospital-acquired Stage III/IV pressure ulcers or deep tissue injury (DTI) must be reported in accordance with the requirements of 10.07.06. This form may be used in lieu of a root cause analysis.

Please provide the following:

1. **Patient date of birth:**
2. **Patient sex:**
3. **Patient admit date:**
4. **Patient admitting diagnosis:**
5. **Patient secondary diagnoses:**
6. **Functional status changes during hospitalization?**
7. **Was family notified?**
8. **Does physician documentation reflect awareness of skin condition?**

9. Functional and cognitive contributory or causal factors:

	Present on Admission	Y	N	Root Cause	Contr. Factor
a.	**Compromised level of consciousness**				
b.	**Inability to eat or enteral feedings**				
c.	**Restricted mobility**				
d.	**Incontinence- bowel, bladder**				
e.	**Peripheral vascular disease**				
f.	**Impaired sensory perception**				
g.	**Diabetes mellitus**				
h.	**Obesity or cachexia**				
i.	**Sepsis or multi-system organ failure**				
j.	**Hypoperfusion state**				
k.	**Chronic end-stage disease such as liver, heart, lung, or kidney.**				
l.	**Immunosuppressive diseases**				
m.	**Hip fracture and/or spinal cord injury**				
n.	**Dehydration and/or malnutrition**				

10. Did communication breakdown contribute to the development and/or worsening of the pressure ulcer to DTI or Stage III/IV?

		Y	N	Root Cause	Contr. Factor
a.	**Staff to staff**				
	1. Nutritional consult requested prior to progression to Stage III/IV				
	2. Wound nurse consult requested on identification of Stage III				
	3. PT/OT consult regarding mobility				
b.	**Staff to/from patient**				
c.	**Staff to/from family/other**				
d.	**Evidence of MD involvement with assessment/treatment plan?**				

11. Medical Treatment and Medications

	During hospitalization	**Y**	**N**	**Root Cause**	**Contr. Factor**
a.	**Antidepressant medication**				
b.	**Sleeping medication**				
c.	**Pain medication**				
d.	**Immunosuppressive medication**				
e.	**Steroids**				
f.	**Radiation***				
g.	**Chemotherapy***				
h.	**Renal dialysis***				
i.	**Multivitamin / Mineral supplements (if deficiency confirmed or suspected)**				
j.	**Bed rest ordered Total days Total hours**				
k.	**Operative procedure >/= to 4 hours.**				
l.	**Nuclear Medicine/MRI imaging obtained**				
m.	**Restraints**				
n.	**Other (describe):**				

* - Also includes treatments prior to admission

12. Interventions:

	Interventions	Y	N	Root Cause	Contr. Factor
a.	**Identified as high risk for hospital-acquired pressure ulcer on admission?**				
b.	**Preventive measures implemented with high risk score?**				
c.	**Did care plan address these issues?**				
d.	**Complete skin inspection documented daily (minimally).**				
e.	**Intake and output monitored.**				
f.	**Nutritional needs met?**				
g.	**Evidence of turning every two hours (minimally) while in bed.**				
h.	**Patient turned minimally 40° to reduce pressure on sacrum**				
i.	**Evidence ROM exercises twice per day and mobilization as tolerated?**				
j.	**Urinary and/or fecal incontinence evaluated and managed prior to skin breakdown.**				
k.	**Head of bed elevated no higher than 30° unless medically required.**				
l.	**Other**				

13. What happened? Include date of identification presence/progression of hospital-acquired pressure ulcer, findings of skin assessments, and interventions implemented prior to progression/development of DTI or Stage III/IV pressure ulcer during hospitalization. Please also briefly discuss any failures of interventions and treatment once pressure ulcer was identified. What is patient's prognosis?

Contributing Factor(s) Discussion

Root Cause(s) Discussion

14. Patient-specific care plan changes after DTI/Stage III/IV pressure ulcer identified

15. Organizational Corrective Actions/Monitoring/Responsible Party

Immediate Actions

After Case Review Actions

16. Compliance Monitoring