OHCQ
Office of Health Care Quality

DEPARTMENT OF HEALTH & MENTAL HYGIENE

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Maryland Hospital Patient Safety Program

Annual Report

Fiscal Year 2008

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Foreword

I am pleased to present the Maryland Hospital Patient Safety Program 2008 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. During the program's fourth full year of implementation, the number of Level 1 Adverse Events reported by hospitals to the OHCQ increased 8.3% to 182. Falls continue to be the most frequently reported Level 1 Adverse Event. This year, representatives of hospitals, OHCQ, and the non-profit Maryland Patient Safety Center collaborated to reduce patient falls using information derived from Maryland's Patient Safety Program. (See Analysis of types and causes of falls, attached as Appendix G.) A similar collaborative effort may be called for to respond to the serious outcomes caused by delays in treatment. Failure to recognize serious medical conditions and provide timely intervention has resulted in multiple serious outcomes and deaths in Maryland hospitals. (See Appendix B, Types and Numbers of Events Reported.)

The increase in the number of reported Level 1 Adverse Events does not necessarily mean that errors are occurring more frequently – we believe this represents outreach efforts by the OHCQ, and increased reporting by hospitals. 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 so that mistakes are caught before reaching the patient.

This report includes de-identified examples of errors reported. Hospitals staff have informed the OHCQ that it is helpful to review examples and ask, "Could this happen in my facility?" Hospital executives should take an active role in reviewing the root cause analysis (RCA) submitted by their facilities in response to a Level 1 Adverse Event. Are the RCA's truly the product of a multidisciplinary team, and do they identify basic contributory causal factors? Or, are the RCA's a paper exercise to meet the regulations, tending to focus on individual performance and not on processes or systems which may be deficient or broken?

In short, 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 182 Level 1 Adverse Events reported in FY08, only five were reported to OHCQ through other means such as complaints from the public. While we will continue to enforce the mandatory reporting requirements – and use our authority to fine hospitals which purposefully do not report – there is a more important goal than the exercise of event reporting. We firmly believe that the many hospitals which have worked hard to conduct serious and critical analysis of errors will see the results in improved patient care.

Finally, I would like to thank Renee Webster and Anne Jones, the heart and soul of OHCQ hospital patient safety activities.

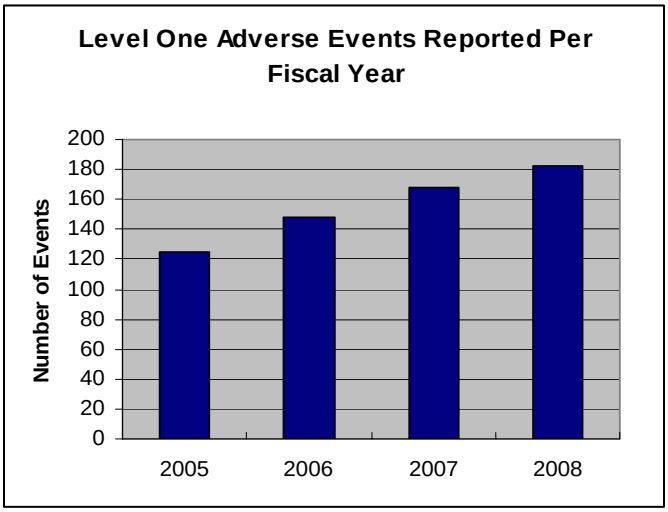
Wendy A. Kronmiller, Director

Maryland Hospital Patient Safety Program Analysis

MANDATORY REPORTING OF ADVERSE EVENTS

In Fiscal Year 2008, the Maryland Patient Safety Program received reports of 182 Level 1 Adverse Events[1] an 8.3 % increase over FY07. Since reporting began in March 2004, 623 Level 1 Adverse Events have been reported by Maryland hospitals. As noted in Table 1, reports continue to increase each year as the hospital staff become more familiar with reporting requirements.[2] Of the 69 licensed Maryland hospitals, 53 reported at least one Level 1 Adverse Event in FY08, a 20% increase in the number of reporting hospitals over FY07.

Table 1



As in previous years, the number and types of adverse events reported correlate with the hospital size (in licensed beds) and the complexity of the services provided. An overview of the types and sizes of hospitals licensed in Maryland is provided in Appendix A. Table 2 identifies the number of Level 1 Adverse Events reports received based on the size of the hospital.

[1] Level 1 Adverse Event means an unexpected occurrence related to an individual's medical treatment and not related to course of the patient's medical condition or underlying disease condition that results in death or serious disability. "Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual lasting more than 7 days or is still present at the time of discharge.

[2] Additionally, over the past four years more than 100 events were reported to the Department which were later determined not to be reportable Level 1 Adverse Events.

TABLE 2 FY 2008 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	14	14	63
200 – 300 beds	16	16	65
100 – 200 beds	19	15	44
Less than 100 beds	20	8	10
TOTALS	**69**	**53**	**182**

Large hospitals, those with more than 200 beds, reported 70% of the Level 1 Adverse events in FY08. Hospitals with 100 – 200 beds reported 44 Level 1 Adverse Events (24%) in FY08 while those with fewer than 100 beds reported only ten Level 1 Adverse Events (5%).

Acute care hospitals account for only 68% of all the licensed Maryland hospitals, but reported 168 (92 %) of the Level 1 Adverse Events in FY08. As noted in table 3, acute care hospitals historically have accounted for more than 90% percent of all the reports received. The number of reports from acute care hospitals is a reflection of the greater scope and complexity of services offered by these hospitals.

Thirteen Level 1 Adverse Events were reported in FY08 by six of the psychiatric hospitals. Three of Maryland's psychiatric hospitals are licensed for more than 300 beds. These hospitals accounted for 21 of the 35 Level 1 Adverse Events from psychiatric hospitals since reporting was mandated. Five of the eight special hospitals (chronic, rehabilitation and children's) reported eight Level 1 Adverse Events in FY08.

Table 3

HOSPITAL TYPE	TOTAL NUMBER OF HOSPITALS	NUMBER of HOSPITALS REPORTING IN FY 2008	LEVEL 1 ADVERSE EVENTS IN FY 2008	TOTAL NUMBER OF REPORTING HOSPITALS Since 7/1/2004	TOTAL LEVEL 1 ADVERSE EVENTS Since 7/1/2004
Acute General	**47**	**42 (89%)**	**168 (92%)**	**45(96%)**	**565 (91%)**
Special Hospital - Psychiatric	**13**	**6 (46%)**	**13 (7%)**	**8 (62%)**	**35 (5.6%)**
Special Hospital – Other *	**9**	**5 (56%)**	**8 (4%)**	**6 (66%)**	**23 (3.5%)**
TOTALS	**69**	**53 (76%)**	**182**	**59 (86%)**	**623**

In FY08, 42% of the reported adverse events resulted in death (39% in FY07, 58% in FY06). Patients required additional medical intervention as a result of the adverse event in 28% of the reported cases in FY 08. Twenty nine percent of the patients required surgery as a result of the adverse event.

Falls were the most frequently reported event in FY08 and 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 reported as it was in three of the last four fiscal years. Eighty-five percent of these patients who experienced delays in treatment subsequently died. Suicide attempts were successful in ten of the eleven reports

received. Many of the rarely reported adverse events such as hypoglycemic events, complications for ASA 1[3] patients and events related to vascular access devices also are generally fatal. Appendix C documents the number and types of Level 1 Adverse Events received in FY08 and the outcome of those events to the patient.

As noted in previous reports, most adverse events occurred in patient rooms on medical surgical floors. Eighty-two falls occurred in FY08, most of which occurred in inpatient rooms or their attached bathrooms. Level 1 Adverse Events are also highly likely to occur in critical care units, surgical suites and labor and delivery. (See Table 4)

Table 4
LOCATION OF LEVEL 1 ADVERSE EVENTS

Location of Events	Number of Events in FY2008	Number of Events in FY2007	Number of Events in FY2006	Number of Events in FY2005	Total Number of Events
Medical Surgical Units	82	75	54	47	258
Surgical Suites	16	22	18	20	76
Emergency Departments	17	17	19	11	64
Psychiatric Units	21	16	10	7	54
Critical Care Units	13	13	13	14	53
Labor & Delivery	11	8	9	9	37
Radiology Services (including interventional)	3	5	7	6	21
Rehabilitation	3	3	1	1	8
Outpatient	2	1	2	0	5
Cardiology	2	1	1	1	5
Pediatrics	2	0	3	1	6
Nursery	1	0	1	1	3
Ambulatory Care	0	0	1	0	1
Other	9	7	9	7	32
TOTALS	**182**	**168**	**148**	**125**	**623**

OHCQ's Patient Safety Program continues to classify the types of Level 1 Adverse Events using the National Quality Forum's "Never Events."[4] 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. Based upon patterns of events reported in Maryland, the Patient Safety Program has supplemented the NQF "Never Events" to include additional categories of adverse events that have frequently been reported. These additional classifications include:

- death and serious disability related to the use of anticoagulants,
- death and serious disability related to the failure to maintain a patient's airway,
- unanticipated fetal death or disability, and
- misdiagnosis.

[3] "ASA 1" is a physical status classification system used to identify a patient's anesthesia risk by the American Society of Anesthesiologists. An ASA 1 patient is a normal healthy patient.
[4] National Quality Forum. "Serious Reportable Events in Healthcare – A Consensus Report." Washington DC: National Quality Forum, 2002.

COMPLIANCE WITH REPORTING REQUIREMENTS

Over the years, the Department has been made aware of reportable adverse events which have gone unreported. Possible concerns about reporting include the Department's regulatory role as well as public disclosure. These concerns are unfounded. Unlike many states, Maryland regulations prevent the Department from citing deficiencies regarding the reported adverse events. COMAR 10.07.06 also contains safeguards to protect against public disclosure. Additionally the hospital should be conducting its patient safety activities under its medical review committee structure. The Office of Health Care Quality also has medical review protections for its activities related to patient safety. Because more hospitals reported events in FY08 than in any of the three previous years, it appears that hospitals continue to demonstrate an awareness of the reporting requirements and have developed confidence that the reports received by the Department will not result in public disclosure.

Nonetheless, the Department staff continues to be concerned that the hospitals may not have effective internal reporting systems through which the hospital's administration learns of events occurring within their hospitals. Reporting of Level 1 Adverse Events to the Department is only one part of a hospital's Patient Safety Program; the most critical part of the regulations is the development of a Patient Safety Program within each hospital through which the hospital's administration obtains valuable information about adverse events and near misses[5]. These events and near misses can then be evaluated and corrective action taken to prevent the events from occurring again. Underreporting in all probability means that the Patient Safety Officer and administration do not have this information available. If all hospitals had effective internal reporting systems there is little doubt that more adverse events would be reported to Department.

One of the key factors that affect the numbers of events reported is the leadership of the hospital, in particular the Patient Safety Officer or designee. A change in the Patient Safety Officer can significantly change the number of events reported. The following anecdotes about two Maryland hospitals demonstrate how an effective patient safety director can drive the hospital's patient safety program:

- A large community hospital "A" reported one Adverse Event in the first three months of reporting in FY04. Four Adverse Events were reported in FY05 and the designated patient safety officer left that year. Only one event was reported in FY06. In FY07, the hospital hired a new Patient Safety Director. In FY07 and FY08, hospital A reported eight events and six events, respectively. Did hospital A suddenly become more unsafe or did the Patient Safety Director develop a more effective system to determine what was going on within the hospital? It is doubtful that these events began to occur after this individual was hired. A safer assumption is that this individual was able to obtain more information, not just for reportable events but for all events and near misses.

[5] "Near Miss" means a situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.

- A smaller community hospital "B" reported no events in FY04 and during most of FY 05. OHCQ conducted a survey of the hospital in FY05, and found that the hospital did not have an effective patient safety program. The hospital responded appropriately, educated staff, and began to examine what was happening in the hospital. The hospital also worked closely with the staff of OHCQ to make improvements in its program. The hospital reported fifteen events the second half of FY05, nine in FY06, and five in FY07. The Patient Safety Director left the position in late FY07. In FY08, hospital B has reported only one adverse event. Did hospital B make such significant improvements that only one adverse event occurred in FY08 or did hospital B lose the key staff that made its program effective over the previous two years?

There is no way to answer these questions with any certainty but if the hospital staff are not looking at what is occurring within their facility it will be impossible to find systems problems that may later result in a more serious and perhaps deadly medical error.

Few, if any, hospitals have an internal system that is 100% effective in recognizing Level 1 Adverse Events. Heightened awareness is especially important if the hospital wants to collect information on close calls or near misses. The patient safety literature consistently indicates that collecting data on near misses is imperative to identifying what went right as well as what went wrong in the processes of care.

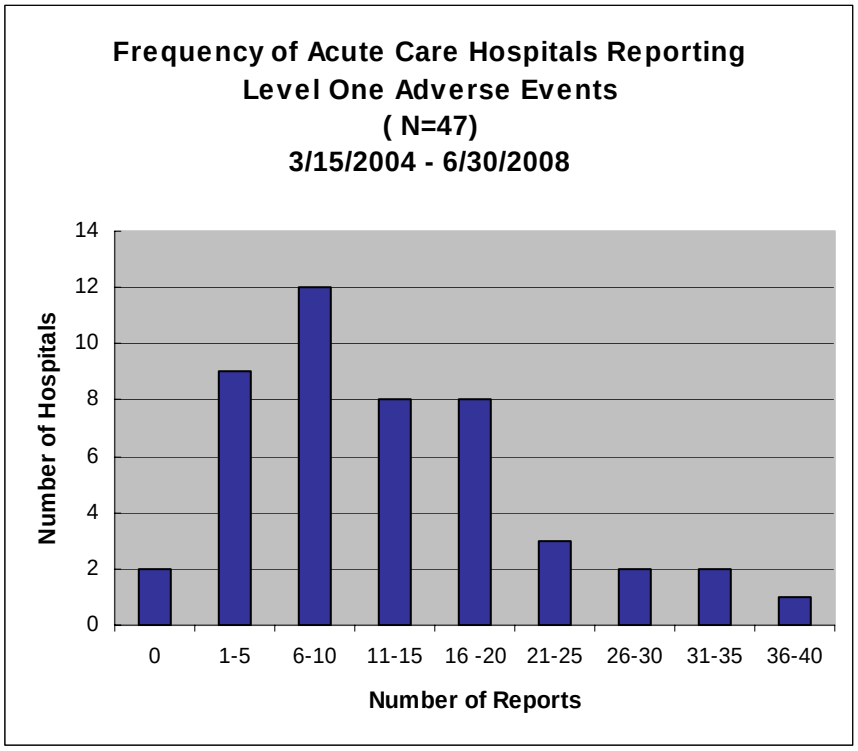
One barometer of hospital reporting may be to compare similar hospitals. Hospital Patient Safety Officers often query OHCQ staff as to whether their hospital reports too often or too seldom. There are concerns about how their hospital may compare to other hospitals. To provide some guidance to the hospitals, reports of Level 1 Adverse Events received since the program began on March 15, 2004 through FY08 were reviewed and collated. Table 5 groups hospitals by licensed beds and by types with the number of events for each hospital in each category and median number of reports received for each group since reporting began on March 15, 2004.

Table 5: Level 1 Adverse Events by Hospital Type & Size

	Number of Hospitals	Number of Adverse Events	Median Number of Adverse Events
Acute Care Hospitals with over 300 beds	12	217	20
Acute Care Hospitals 200-300 beds	15	222	14.5
Acute Care Hospitals 100-200 beds	12	116	8.5
Acute Care Hospitals Less Than 100 beds	8	36	2
Psychiatric Hospitals More Than 300 beds	3	23	9
Psychiatric Hospital Less than 150 beds	10	10	1
Other Special Hospitals	9	25	2

The data was further organized to demonstrate the frequency of reporting Level 1 Adverse Events by acute care hospitals in Table 6. Five acute care hospitals have each reported more than 26 Level 1 Adverse Events since March 15, 2004, averaging between six to nine reports per year. However, 23 acute care hospitals have reported less than three Level 1 Adverse Events per year. It should be noted that the data on both Table 5 and Table 6 do not include voluntary reports of events that were not classified as Level 1 Adverse Events.

Table 6



Similar comparisons revealed that seven of the 13 psychiatric hospitals each have reported between one to five events since reporting was mandated; one reported nine and another reported 11 events. Five of the nine other special hospitals/children's, rehabilitation and chronic) each reported between one and five Level 1 Adverse Events and one reported 13 Level 1 Adverse Events.

The Department continues to encourage hospital staff to use the algorithm developed by several hospital patient safety officers and risk managers and the staff of OHCQ. The Patient Safety Decision Tree can help hospitals identify Level 1 Adverse Events (Appendix E). Many hospitals have found this to be a helpful tool when trying to make difficult determinations about an event. However, if a hospital staff would prefer to discuss the event with OHCQ staff, we are always willing to assist. There is no penalty for contacting OHCQ to discuss an event that may not be a Level 1 Adverse Events.

REVIEW OF LEVEL 1 ADVERSE EVENTS

Falls

As in the previous three years, the most frequently reported adverse event were falls (46% of the FY08 reported events). Hospitals reported 81 falls in FY08. Twelve of the reported falls resulted in death and each of the remaining 69 events resulted in a fracture; some of which required surgical intervention. The increased reporting in FY08 was largely due to a greater awareness by hospitals that falls with fractures or head injuries were Level 1 Adverse Events.

In response, representatives of hospitals, OHCQ and the non-profit Maryland Patient Safety Center collaborated this year to develop protocols to prevent patient falls. Information derived from Maryland's program was used in developing these protocols and is cumulated in an informative analysis of types and causes of falls, attached as Appendix G. A similar collaborative effort may be called for to respond to the serious outcomes caused by delays in treatment. Failure to recognize serious medical conditions and provide timely intervention has resulted in multiple fatalities in Maryland hospitals. (See Appendix B, Types and Numbers of Events Reported.)

Suicides and Events in the Psychiatric Setting

In the inpatient psychiatric units and in freestanding psychiatric hospitals the types of reports of events received were:

- suicides and suicide attempts;
- assaults against self or others; and
- falls.

The most common reported occurrences in the psychiatric setting were suicides. There were 11 suicides or suicide attempts in FY08; nearly all occurring in the psychiatric hospitals or inpatient units in acute care hospitals. One suicide, an overdose of the patient's prescription medication, occurred in an emergency department while the patient was awaiting placement in an inpatient psychiatric bed. Another suicide involved a patient who eloped from an inpatient bed then purposely walked in front of a vehicle on a busy highway.

The remaining suicides involved hanging, strangulation, or asphyxia. Environmental risks accessible to the patients contributed to the suicides. These included sprinkler heads, accessible ventilation grids, a privacy curtain in a patient room that was sometimes served as a treatment room, light fixtures, patient gowns, shoe laces and sheets. One case involved a patient placing a trash bag over his head then using examining gloves to secure it tightly around his neck. While there were several suicides that took place early in the admission, suicide attempts reported to the Department were equally as likely in patients who had been hospitalized for days, even months; one occurred on the planned day of discharge. Unlike previous years when the more serious adverse events occurred in the large freestanding psychiatric hospitals, in FY08 eight of the eleven reported suicides occurred while patients were under the supervision of staff in psychiatric units in the acute care hospitals.

Falls were also reported for patients receiving inpatient psychiatric care. However, in the mental health setting, patients sustained fractures from falls as opposed to the more serious head injuries that often resulted in death in a medical surgical setting.

Other events reported in the psychiatric setting included a patient who injured himself during a behavioral incident and patient on patient assaults. In one case a patient injured himself while trying to elope by breaking up the furniture in his room, breaking the window with the pieces and jumping out the window, sustaining a fracture. In another, the patient kicked and broke the wired glass viewing window in the seclusion room sustaining a serious, debilitating laceration of a tendon.

Adverse Events in Chronic Hospitals

In past years the majority of the Adverse Events reported by chronic hospitals related to alarm failures with ventilator-dependent patients or other system problems related to their airway management. In FY08, only two Level 1 Adverse Events related to failure to protect patient's airway for ventilator-dependent patients were received by the Department. From the RCAs received over the past three years we have seen hospitals implement numerous changes to improve the management of ventilator-dependent patients. It is hoped that this is an indication that these changes have been effective. However, three of the reports received from chronic hospitals in FY08 were due to a delay in obtaining treatment for ventilator-dependent patients, who often have multiple co-morbidities and whose condition must be carefully monitored. In all three cases the failure to promptly respond to the patients' change in condition resulted in death.

Emergency Departments

Two years ago, the news media reported the case of a person who collapsed and died in the emergency department (ED) waiting room of a hospital in another state. While adverse events had been reported about delays in treatment in the ED, the Department had not received any similar incidents from Maryland hospitals. However, in FY08, eight reports related to delays in treatment and one report of failure to act in the ED were received. Some examples of ED events resulting in death include:

- An alcoholic patient presented to the ED and the physician diagnosed him with gastrointestinal bleeding. There were no beds available to admit the patient so he was held in the ED. Six hours and 12 poor hand-offs later, the patient died of hypo-volemic shock.

- A 44 year old patient presented to the ED with diabetic keto-acidosis at 7 AM. The ED physician decided to admit the patient to the care of the intensivist. The intensivist was delayed in coming to the ED and during that time the patient deteriorated. The patient died at midnight while still in the ED, due to the delay in treatment.

- An alcohol rehabilitation program dropped off a 42 year old patient to the ED. Ten minutes after arrival the patient was found unresponsive in the ED waiting room.

- A patient with a history of cerebral palsy, scoliosis, seizure disorder, and status post brain tumor and skin cancer presented to the ED with a distended abdomen at 2:46 AM. An x-ray revealed air in the peritoneum. Poor communication between the physician's assistant and the surgeon lead to the surgeon ordering a CT before taking the patient to the OR. The decision was made to take the patient to the OR but the patient coded while in transport to the OR and could not be resuscitated.

- A 9 year old was taken to the ED by her Spanish-speaking parents after falling from her bike. The child was treated for a minor laceration of her head and hand which was sutured. Although the child and her sibling spoke English, a nurse and registrar spoke Spanish to the family rather than obtaining a trained interpreter. The parents were given discharge instruction appropriate for a head injury but the instructions were in English. The child begun vomiting during the night so the parents returned to the ED with the child the next day. The child became unresponsive, coded and died of complications of the head injury.

- A 44 year old patient came to the ED with groin swelling and pain that had persisted for three days. The patient was examined by the physician's assistant who diagnosed the patient with an inguinal hernia. The physician's assistant made the decision to reduce the hernia under conscious sedation without consulting a surgeon or an ED Physician. The Physician's assistant was not privileged to perform the procedure. The procedure was successfully performed but 15 minutes later the patient became diaphoretic, hypotensive, and tachycardic. An EKG was performed which showed an anterior- lateral myocardial infarction. A cardiologist was consulted and the patient was taken to the cardiac catheterization lab where he arrested and died.

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 consent. The numbers of these events decreased in FY08, during which the Department received only three reports of retained foreign bodies. There were eight reported events in FY07 that involved wrong patient, wrong side surgeries or surgeries that were not consistent with the patient's consent in FY07 but only four in FY08.

Hospitals continue to report burns occurring to patients during surgical procedures; however, of the reports received in FY08, only one met the criteria of a Level 1 Adverse Event. Several hospitals, recognizing the serious potential of these events, voluntarily reported occurrences of burns even though the patients suffered only superficial burns with no lasting injuries.

Reports of death for ASA 1 patients, intra-operatively or immediately post operatively, remain low with only five cases since reporting began and one reported case in FY08.

Case Study: Wrong Patient Surgery
Adverse Events can take place across environments within hospitals, as demonstrated by the case of the two patients who presented to the ED with similar symptoms at the same time. The two patients, one female and one male, both had abdominal symptoms. The female was sent to radiology for a flat plate that showed a possible pneumoperitoneum (free air in the abdominal cavity). The radiologist informed the surgeon of the radiology results in passing. The surgeon went to the ED, saw the male patient who also had symptoms of acute abdomen. The surgeon took the male patient to surgery emergently, expecting to find a perforated colon but did not. In the interim, the ED staff determined that the wrong patient had been taken to surgery. Surgery was scheduled for the female patient but she died prior to the surgery. The male patient recovered. The female patient had been ill for some time prior to being sent to the ED so it could not be determined if the delay going to surgery caused her death. Besides the obvious hand off failures in this case, the surgical time out also failed.

Hospital Acquired Pressure Ulcers

The Department continues to receive few reports of hospital acquired pressure ulcers. The Departments anticipates that hospitals report all Stage 3 or Stage 4 pressure ulcers that were acquired by the patient while hospitalized. Pressure ulcers that progressed from Stage 2 to Stage 3 are excluded if the Stage 2 pressure ulcer was recognized upon admission.

In FY08, only one report of a hospital acquired Stage 3 or Stage 4 pressure ulcer was received. Hospital acquired pressure ulcers are among the most frequently reported to the Minnesota[6], Indiana[7] and New Jersey [8]reporting systems. It is difficult to understand why Maryland hospitals would not be expected to report similar numbers.

Healthcare Associated Infections

OHCQ has received only 14 reports of healthcare associated infections (HAI) – five were received in FY07 and again five were reported in FY08. Four of the five patients who acquired an infection in the hospital died as a result of the infection. However, it is highly unlikely that the five cases reported to OHCQ are the total number of HAIs that resulted in death or serious disability in Maryland hospitals.

In FY08, the Department promulgated regulations related to "Infection Prevention and Control" (COMAR 10.07.01.34). These regulations identify minimum standards that an effective infection prevention and control program must have, and incorporate compliance with the Maryland Patient Safety regulations (COMAR 10.07.06).[9] Data related to hospital acquired infections is to be reported internally to the hospitals' infection control programs. However, the Department has found that often hospitals do not link the hospital's patient safety program and

[6] Minnesota Department of Health. Adverse Health Events in Minnesota, Third Annual Report, Minnesota Department of Health, January 2007, page 9.
[7] Indiana Department of Health, Indiana Medical Error Reporting System, Preliminary Report for 2006, March 6, 2007, page 25.
[8] New Jersey Department of Health and Senior Services, Patient Safety Initiative 2007 Summary Report, December 2008, page 15.
[9] COMAR 10.07.01.34H states "The infection prevention and control program shall share data regarding health care associated infections with the hospital's designated patient safety officer. Healthcare associated infections that meet the definition of a Level I adverse event shall be reported to the Department and a root cause analysis submitted as required by COMAR 10.07.06.

its infection prevention and control program. Until hospitals establish a system to collect infection data into the patient safety program, hospitals will face impediments in evaluating the systems that contribute to hospital acquired infections.

There are additional barriers that contribute to the reporting infections. These include:

- The hospital may not know an infection occurred. The length of stay for most surgical patients is often less than three days. Infections take several days to develop and may not be present at the time of discharge. Therefore, treatment for hospital acquired infections may occur in the physician's office, a home health agency or another hospital.
- Despite hospitals' requests that these infections be reported through patient safety, infection control or risk management, physicians are reluctant to report for fear of the additional scrutiny of their practice by the medical staff and peer review process. Hospitals have a responsibility to educate physicians about the value of reporting in improving processes and systems within the hospitals.
- Laboratory results to confirm an infectious agent take several days to be completed. In that time the patient may be transferred or discharged, and the practitioners who cared for the patient have a new case load of patients.
- The acquisition of an infection can seldom be linked to a single event such as one staff who failed to wash their hands, as these breaks in process are often not witnessed.

Case Study: Healthcare Associated Infection
A 40 year-old patient came to the hospital for a CT (CAT scan) guided biopsy of her hip. She was diagnosed with an amyloid tumor. Post operatively she had a significant amount of bleeding. She returned to the hospital Emergency Department two weeks after discharge with copious drainage from her hip. The patient had lab tests performed and was admitted to an inpatient bed. She ran a fever over the next few days with a temperature as high as 103 degrees Fahrenheit. Despite this, the physician did not place the patient on antibiotics since he believed the drainage was from the tumor. The patient was found unresponsive and a code was called but she could not be resuscitated. The coordination of the patient's care was impacted by poor handoffs and the orthopedist leaving for vacation. Autopsy revealed the patient died of sepsis.

Medication Errors and Anticoagulants

Numerous studies indicate that nearly all patients experience a medication error or adverse drug reaction during hospitalization. However, 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 nine per year with eight in FY08. A review of the reporting reveals that while most cases occur to patients while hospitalized there is also a significant number of the reports received by the Department that occur post discharge due to poor medication reconciliation. The following two examples are representative of both inpatient and post discharge errors.

- An 80 year old patient was admitted from a nursing home for aspiration and was in respiratory failure. He was receiving IV fluids and had a propofol drip for sedation. When

the patient was moved from the ED to the inpatient unit the patient became hypotensive and dehydrated. The physician directed opening the IV fluids further. The nurse in error opened the propofol instead of the fluids. Of note, the IV bags were not labeled in accordance with hospital policy. The patient received 1 gram of propofol in 15 minutes and coded. The patient could not be resuscitated.

- A patient who was on Lipitor was seen in a hospital's ophthalmology clinic for a fungal eye infection. The patient was prescribed an oral anti-fungal medication, Voriconazole, as well as Voriconazole eye drops. The prescriptions were not written for a specific number of days so the medications were taken indefinitely. In accordance with the literature the patient should have had a liver function test when placed on this medication. No baseline or periodic liver function tests were performed. About ten weeks after going to the clinic and the beginning the medication regimen, the patient began to suffer gastrointestinal problems and also noticed that she was jaundiced. The patient returned to the clinic and her liver function was tested. She was diagnosed with liver failure and was referred to a transplant center for a liver transplant three months after beginning the medication. She also went into renal failure from hyperbilirubinemia. She developed aplastic anemia from the immune suppression post transplant for which she continues to receive therapy.

In the first year of reporting the Department determined that there were significant number of medication errors related to anticoagulant medication and as a result these events are counted separately from the other medication errors. Two Clinical Alerts have been written addressing these issues, available on the Office of Health Care Quality website at www.dhmh.state.md.us/ohcq/regulated_programs/h_alerts.htm?id=. Despite this, three reports of deaths or serious disability associated with anti-coagulation medication were received in FY08. Below are two examples of anticoagulation events from FY08:

- A patient was admitted for a total knee replacement. The surgery went well and post operatively the patient had an epidural patient-controlled analgesic (inserted into the spinal canal). The hospital's pathway for patient controlled epidural analgesics clearly stated "No Lovenox." However, the Pathway for a total knee replacement stated that Lovenox was to be given to prevent post surgical blood clots. The patient received a dose of Lovenox on the first post surgical day and developed an epidural hematoma with paralysis. The patient was taken back to surgery the following day to drain the hematoma. The patient regained some movement prior to discharge to a rehabilitation facility.

- A patient came to ED with cerebral palsy and chronic obstructive pulmonary disease. She was ordered Riapro, an anticoagulant with a long half-life and no reversal agent. This medication was not on the hospital's standard acute myocardial infarction protocol but was ordered by the cardiologist. Nurse calculated the dose appropriately at 37.5 mg. but then administered 37.5 cc. of Riapro instead of 37.5 mg. The patient received a dose of the anticoagulant medication ten times the dose ordered by the physician. The patient developed a pulmonary hemorrhage and exsanguinated.

NOTIFYING PATIENTS AND/OR FAMILIES AND THE JOINT COMMISSION OF ADVERSE EVENTS

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. Of the 182 Level 1 Adverse Events reported, hospitals indicated that the required notification was made in 166 cases or 91 %. This is a slight decrease from FY07 when hospitals indicated that notification to the patient or family member of an unanticipated outcome had occurred in 158 of the 168 Level 1 adverse events (94%). Both years are a significant improvement from FY05 when hospitals reported that families were notified in only 46 of the 125 Level 1 adverse events (37%). In the sixteen cases where no notification was reported, the hospital either had no permanent address or the reporter was not aware if the physician had made the notification to the family. Hospitals continue to prefer that the physician has this difficult and very sensitive discussion since the physician has the relationship with the patient. As in previous years, there is no way to determine the quality or extent of these discussions with the patient and/ or their families.

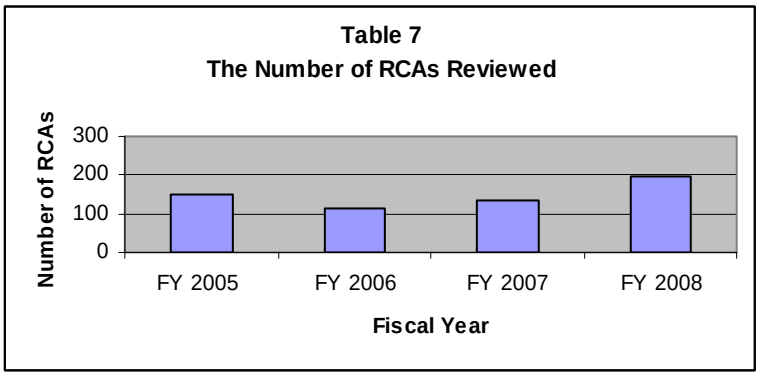
As in FY07, in FY08 hospitals reported only two Level 1 Adverse Events to The Joint Commission as sentinel events.[10] Reporting events to The Joint Commission is not mandatory. It should be noted that some hospitals indicated that the decision to report to The Joint Commission had not been made at the time the event reported to the Department. The Joint Commission requires its accredited hospitals to identify all sentinel events including conducting a timely, thorough, and credible root cause analysis, implementing corrective action to reduce risk and monitoring the effectiveness of those actions. During their triennial surveys and during complaint investigations, surveyors from The Joint Commission will review and critique selected RCAs for sentinel events. There is no Maryland statutory or regulatory requirement that hospitals report to The Joint Commission.

ROOT CAUSE ANALYSES

"Root causes" are defined by the Maryland Patient Safety Program regulations 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 fixed. Root cause analyses (RCA) should focus primarily on systems and processes, not individual performance, and seek to determine not only the "what" of the event but the "why" as well. 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 or processes are needed.

[10] A "Sentinel" event is an unexpected occurrence involving the death or serious physical or psychological injury or the risk thereof." Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which the reoccurrence would carry a significant chance of serious adverse outcome.

In addition to the 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. Most programs administered either by state agencies or independent patient safety organizations require the hospitals to answer a series of questions related to the corrections made as a result of the event. Maryland requires a full analysis with identification of the root causes, the action plan, the outcome measures and implementation which must then be submitted to the Department for review. 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. Table 7 indicates the number of RCAs reviewed each year since the program began.



The Maryland Patient Safety Program reviews the root cause analysis using the evaluation tool designed for that purpose. In FY08, 194 RCAs were reviewed by the Department's clinical staff in consultation. Since the program began, 589 root cause analysis were reviewed and feedback provided to the hospitals. With the addition of staff at OHCQ, the RCAs are now being reviewed in a timelier manner.

In FY07 we reported that nearly 50% of all RCAs were problematic in some way. 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 and they are being monitored for trends in the submitted RCAs that may require additional intervention.

When they receive incomplete or inadequate RCAs, the OHCQ Patient Safety staff will make recommendations using the RCA evaluation tool developed by OHCQ and may request the hospital to resubmit the RCA or provide additional information about how the RCA team came to its conclusion. If the hospital repeatedly submits poor RCAs or similar events continue to occur, the OHCQ has met with hospital staff, including members of the Medical Staff and in some cases deficiencies have been cited. Over the first four years of the Patient Safety Program, the OHCQ has provided a great deal of formal and informal feedback to the hospitals regarding their events and RCAs.

The overwhelming issue with the poor RCAs was the superficial analyses failing to uncover anything other than first level or proximate causes for the events. Many of the RCAs reviewed

mentioned that "why" questions had been asked, but no answers were given and the corrective action did not reflect an in-depth level of analysis. Following are some examples of RCAs received over the past year, with discussion.

Root Cause Analysis Case No. 1:

A young adult with a history of congenital intestinal abnormalities was admitted through the Emergency Department (ED) with several days of nausea/vomiting and weight loss. General surgeon and gastrointestinal consults were completed and the work-up revealed a large duodenal (upper GI) obstruction. A nasogastric tube was not inserted for continued vomiting until day four, and the patient was not taken to surgery until day seven. Prior to surgery, the anesthesia provider allowed a student to insert the endo-tracheal tube. The tube entered the esophagus. The certified registered nurse anesthetist (CRNA) immediately reinserted the tube into the trachea. Post-op, the patient developed pneumonitis, aspiration pneumonia, and respiratory failure.

Root causes as identified in RCA:

1. Human error.

Action items:

1. Patient's nurse is now responsible for notifying the anesthesia provider about any changes in patient condition.
2. Students will not practice intubation on patients with complicated medical histories.

Discussion:

1. Blaming the CRNA and the student ignores the medical management of this patient. The RCA does not explain why the patient did not have a NG tube inserted for four days and why he was not taken to surgery for seven days, with a known duodenal obstruction.
2. The RCA assumes that he aspirated because of the attempted intubation. Isn't it at least as likely that he aspirated at some point over the seven days before surgery? Cause and effect were not established.
3. Since the RCA does not uncover any other possible causes of the bad outcome, the action items do not go deep enough, and focus only on nursing. Why is the communication of patient status only one-way, from the RN to the MD? What about the responsibilities of the physicians?
4. No outcomes or measures of success were provided.

Root Cause Analysis Case No. 2:

A very elderly patient underwent an outpatient, ambulatory surgery laparoscopic cholecystectomy. A week prior to this procedure, he had had a severe hypotensive episode following a diagnostic test done under anesthesia and nearly arrested. The patient was discharged several hours after the lap cholecystectomy even though he had had another severe hypotensive episode in the PACU. As he was being assisted into his daughter's car by the nurse, he arrested. He was resuscitated, taken to the ED and then back to the operating room. He spent several days in the hospital and was discharged to a long-term care facility.

Root causes identified in the RCA:

1. Authority gradient made the PACU RN reluctant to question the surgeon about the discharge, and discharged the patient when he technically met the discharge criteria.

Action items:

1. Surgical peer review.
2. Discussion and training for nursing staff regarding chain of command and authority gradient issues
3. Assess adequacy of equipment/policies regarding codes in public areas.

Response/Discussion:

1. RCA did not address appropriateness of criteria and patient selection for ambulatory surgery.
2. RCA did not address what seem to be serious supervision issues. Where is the nursing management in the PACU who should be aware of patients like this and assisting the nurses with patient management and physician communication issues? Who is in charge of medical management of the patients in the PACU? Is it anesthesia or the surgeon?
3. Root causes do not go deep enough and do not address latent issues that could affect patients in other areas.
4. Much of RCA focused on the code process at the front door. This would seem to be a side issue, since the process worked in this case, even though the nurses involved in the code had several complaints.

Root Cause Analysis Case No. 3:

An elderly patient went blind in one eye after developing a healthcare-associated infection (HAI) following cataract surgery.

Root causes identified in the RCA: None

Action Items:

1. Develop protocols to aid decision making.

Response/Discussion:

1. The narrative description of this event did explain what made this a Level 1 Adverse Event. No cause and effect were established. A bad outcome does not necessarily mean that a preventable medical error occurred. The RCA did not explain if the standard of care was met or if the patient was mismanaged. There was insufficient explanation about the medical management of the patient and no identification of a root cause or even what adverse event happened.
2. The initial report of the adverse event said that there was a delay in contacting a retinal specialist, but the RCA did not mention this at all.
3. The RCA was very narrowly focused on this ophthalmic event and did not identify if the same sort of circumstances could lead to bad outcomes in other types of patients.
4. Developing protocols to aid decision making will probably improve care but may not address the root cause of this event. If an appropriately deep analysis has taken place, the

action items will be fairly generic, and apply to more hospital processes than those involved in the specific event.

5. No outcomes or measures of success were identified.

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. Where are the nurse managers, charge nurses, and shift supervisors during the cascade of poor decisions being made by the nurse at the bedside? Where are the service chiefs when the physician will not return a call or does not show up for the emergency Caesarean-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 (physician assistant) 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 any meaningful change can occur. Front-line staff may be reluctant to address these issues and may need assistance and reassurance by the facilitators of RCA meetings.

In analyzing the RCAs received by the OHCQ, it has become apparent that many of the hospitals that consistently fail to identify root causes lack leadership involvement. It is almost impossible to fix serious, systemic problems without the backing and active involvement of management. It is often a front line staff who analyzes the adverse events. If the RCA group believes that the hospital leadership is not invested in fixing systemic problems, the team may not look very deep to identify the causes of adverse events. In the adverse events noted above, the lack of depth in the root causes shows a focus on individuals, rather than the systems that are actually at fault. It is far easier to blame individuals than to identify and fix often long-standing processes. Hospital leadership needs to do more than pay lip service to patient safety. They need to focus on, and focus the staff on, a systems-based approach to analyzing and solving problems. Since hospital boards of directors are ultimately responsible for the operation of the hospitals, they too may need education regarding patient safety goals and activities.

Once root causes of an event are determined, the hospital must develop an action plan in response. The most common corrective action taken by hospitals in FY08 was formal education to staff (62% of the 194 RCAs reviewed). In many cases this coincided with a change in policy and procedures (58%). Changing policies and procedures and training staff although often required are not generally considered the strongest action to be taken unless they are addressing systemic issues identified by the RCA. Process and system changes which are stronger actions were addressed on 30% of the RCAs reviewed. Workload changes were identified in 13% of the action plans. Six percent of the RCAs indicated that environmental changes were made as a result of an adverse event and 23% indicated that equipment modifications were made to prevent the reoccurrence of the adverse event. Data tracking and trending was noted as an action on 61% of the RCAs reviewed. This indicates a better understanding on the part of the hospitals of the need to monitor the effectiveness of the actions that they have developed. The 194 RCAs reviewed in FY08 averaged 2.9 types of corrective actions per RCA. Appendix F includes the data for the types of actions taken for the recent and past fiscal year.

Forty seven RCAs (24%) identified peer review as the corrective action; OHCQ staffs were pleased to note that in all but 10 cases where peer review was identified as the action, additional corrections were also planned. While an individual practitioner may need to be held accountable for an event, in most cases there was a broken process or system that allowed the practitioner to make the error. While adverse events have historically been reviewed solely through the peer review process, this process alone does not reveal the process and systems problems resulting in medical errors. Peer review results are often disclosed only to the hospital's senior officials and there is no coordinated effort to collectively review the hospital's findings. Peer review can make the analysis process appear secretive and punitive. Additionally, in FY08, 2 % of the RCAs indicated that disciplinary action was taken against one or more employees as a result of a Level 1 Adverse Event. This is a significant decrease from FY07 when 10% of the RCAs indicated that staffs were disciplined. Hospitals should determine what level of professional accountability is consistent with safe practice and identify processes that encourage staff to do the right thing and impede them from doing the wrong thing.

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 399 hospital quality of care complaints during FY08. Of these complaints, only five were also reported as Level 1 Adverse Events. Three of these five reports were received from State operated facilities that are also mandated to report all deaths to the OHCQ for investigation. From March 2004, when mandatory reporting began, and the end of FY08, a total of 732 adverse events and near misses have been reported by Maryland hospitals; over 1,389 hospital complaints were received over this time, and only 13 events "overlapped."

These data indicate that victims of the most egregious events or their families usually do not file complaints with the Department. They may elect not to take any action against the hospital, or they may proceed directly to attorneys. Sometimes, they may not have been aware that they had been victims of a serious adverse event. It is hoped that through the information obtained through mandatory reporting, the Department will be able to make informed decisions about how we regulate and evaluate hospitals. This demonstrates the value of mandatory reporting, since we would have no idea of the scope of adverse events if we relied solely on complaint data.

HOSPITAL PATIENT SAFETY PLANS

When the Patient Safety Program regulations were implemented in 2004, all hospitals submitted patient safety plans in accordance with the COMAR 10.07.06.14(A). After more than four years since the passage of the regulations the hospitals have learned what has been effective process in their institutions and what has been ineffective. Hospitals are encouraged to review and revise their Patient Safety Programs. Revisions made by the hospitals reflect a better understanding of the regulations and process.

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." Two Clinical Alerts have been developed based on the review of RCAs and Adverse Events in FY08:

- Retained Foreign Bodies
- IV Promethazine

Clinical Alerts can be obtained at www.dhmh.state.md.us/ohcq/

Maryland Patient Safety Center

The Maryland Patient Safety Center[11] 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 attendance at 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.

In addition, OHCQ Patient Safety Unit staff has provided 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 developing root cause analyses.

Observations

Despite continuing challenges posed by data mining, possible under-reporting of Level 1 Adverse Events by hospitals, and the quality (or lack thereof) of some of the RCAs, the Patient Safety staff of the Office of Health Care Quality believe that the Patient Safety Program is very important to the citizens of Maryland. Unlike voluntary reporting systems, our program forces hospitals to recognize and monitor adverse events that are happening in the facilities. The Patient Safety Program has created a dialogue between hospitals and the Department regarding serious

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

errors which are not revealed through complaint investigations and review of the triennial reports of The Joint Commission used as the basis to license hospitals. Adverse events and details of these events would not be known without mandatory reporting. Additionally, many hospitals voluntarily contact OHCQ with reports of Level 2 and 3 Adverse Events[12] and near misses when they believe the event is representative of a unique or significant error. The increased number of reports to OHCQ reveals that most hospitals understand the value of analyzing adverse events and near misses and are attempting to develop and implement processes and systems to prevent the recurrence of medical errors.

Because of the number of fatalities associated with delays in treatment, hospitals (and their patients) may benefit from focusing on events in this area. Failure to recognize serious medical conditions and provide timely intervention has resulted in multiple fatalities. While patient falls are statistically less likely to result in fatality, falls have significant impact on health care costs due to the required surgeries to repair the fractures, increased lengths of stay, required rehabilitation including in some cases post discharge skilled nursing home care. Therefore, OHCQ is pleased to have been a part of the Maryland Patient Safety Center initiatives to reduce the numbers and severity of falls in Maryland hospitals. See, "I Only Had my Back Turned for a Second," analysis of falls data prepared by Anne Jones, RN, of the Patient Safety Program, attached as Appendix G.

We are pleased to note the continued high percentage of hospitals reporting that patients/families are notified of Level 1 Adverse Events, and are also pleased to note improvements in the quality of many RCAs received. We hope that this process and the products of the analyses are being used by hospitals to improve patient care.

Future Plans

Hospitals report that the sharing of information is valuable to their learning. Information sharing provides hospitals with the opportunity to review systems and procedures and make proactive changes to prevent the adverse event from recurring. 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;
- Develop a process to include the review of quality indicator information;
- 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;

[12] COMAR 10.07.06.02 B defines Level 2 adverse event as an adverse event that requires medical intervention to prevent death or serious disability and Level 3 as an adverse event that does not result in death or serious disability and does not require medical intervention to prevent death or serious disability.

- Identify trends and patterns of poor RCAs submitted by specific hospitals;
- Develop quarterly “lessons learned” from the reports received and post to the web page; 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, we plan on further analysis and use of the data accumulated thus far. We are continually challenged to identify trends in events and corrective actions and 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

In order to better understand the data obtained through the Maryland Patient Safety Program, we feel that a review of the regulatory classification of Maryland hospitals would be of use, especially given the differences in bed capacity and available services from year to year.

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 but the changes are relatively small. 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 to 639 licensed beds. Seven of these hospitals are State operated. Three psychiatric hospitals serve only specific populations (children, forensics, and clergy). Others may provide specialized services to specific populations such as treatment-resistant patients and individuals with disabilities.
- 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 and Numbers of Level 1 Adverse Events

Type of Level 1 Adverse Events	FY 2004 [13]	FY 2005	FY 2006	FY 2007	FY 2008	Totals
Death or serious disability associated with a fall	2	30	46	55	82	215
Death or serious disability associated with a delay in treatment	1	16	9	22	20	68
Death or serious disability associated with airway management	3	13	18	9	7	50
Death or serious disability associated with medication error	0	11	8	9	8	36
Suicide or attempted suicide resulting in serious disability	1	4	11	4	11	31
Unanticipated complication of treatment	2	6	9	4	2	23
Unanticipated fetal death or injury	0	3	6	5	9	23
Other	0	6	6	4	5	21
Malfunctioning device	1	3	5	4	4	17
Misdiagnosis	3	5	5	2	1	16
Surgical procedure not consistent with consent/ wrong patient	1	1	2	8	4	16
Unanticipated intra-op or immediate post-op death	0	5	5	2	3	15
Death or serious disability associated with the use of a vascular access device	1	6	3	2	2	14
Post-surgical retention of foreign body	0	4	1	6	3	14
Death or serious disability associated with the use of anticoagulants	1	1	2	6	3	13
Death or serious disability associated with a staff member's failure to act	0	2	3	4	2	11
Death or serious injury of patient or staff associated with health care acquired infections	0	0	1	5	5	11
Maternal death or serious disability associated with Labor & Delivery	1	3	0	2	2	8
Death or serious injury of patient resulting from physical/sexual assault occurring within or on hospitals grounds	0	0	2	2	3	6
Stage III or IV pressure ulcers acquired after admission	0	0	0	4	1	5
Death or serious disability associated with the use of restraints seclusion, or side rails	0	1	1	2	1	5
Death or serious disability resulting from an intravascular air embolism	0	2	2	0	1	5
Death or serious disability associated with hypoglycemia	0	2	1	1	1	5
Intra-op or post-op death in ASA 1 patient	2	0	1	1	1	5
Death or serious disability associated with a burn that occurred in a hospital	0	0	0	3	1	4
Hemolytic reaction to ABO incompatible blood products	0	0	0	1	0	1
Totals	**19**	**125**	**148**	**168**	**182**	**642**

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

Appendix C

TYPES OF EVENTS AND SUBSEQUENT OUTCOMES - FY 2008

Type of Event	Loss of limb/ function	Surgical Intervention	Medical Intervention	Death	Total
Death or serious disability associated with a fall	9	46	15	12	**82**
Death or serious disability associated with a delay in treatment	3			17	**20**
Suicide or attempted suicide resulting in serious disability			1	10	**11**
Unanticipated fetal death or injury	3		1	5	**9**
Death or serious disability associated with medication error	3		2	3	**8**
Death or serious disability associated with airway management	2		2	3	**7**
Other	2	1		3	**5**
Death or serious injury of patient or staff associated with health care acquired infections		1		4	**5**
Malfunctioning device			1	3	**4**
Surgical procedure/body part not consistent with consent	1	1		1	***4***
Death or serious disability associated with the use of anticoagulants	1			2	**3**
Post-surgical retention of foreign body		3			**3**
Unanticipated intra-op or immediate post-op death				3	**3**
Death or serious injury of patient resulting from physical/sexual assault occurring within or on hospitals grounds			2	1	**3**
Death or serious disability associated with a staff member's failure to act				2	**2**
Unanticipated complication of treatment				2	**2**
Maternal death or serious disability associated with Labor & Delivery				2	**2**
Death or serious disability associated with the use of a vascular access device				2	**2**
Stage 3 or 4 pressure ulcers acquired after admission			1		**1**
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				1	**1**
Misdiagnosis				1	**1**
Intra-op or post-op death in ASA 1 patient				1	**1**
Death or serious disability associated with hypoglycemia				1	**1**
Death or serious disability as a result of an intravascular air embolism	1				**1**
Totals	**25**	**53**	**26**	**78**	**182**

Appendix D

DEFINITIONS AND EXAMPLES OF ADVERSE EVENTS

Death or serious disability associated with airway management includes cases in which a patient needs an artificial airway (an endotracheal intubation) and, for whatever reason, the hospital staffs were incapable of inserting the airway. This category also includes the mismanagement of chronic hospital patients who have tracheotomies and may or may not be ventilator dependent.

An example of this type of event is the patient who choked on peanut butter. The staffs were unable to insert an airway and the patient died.

An unanticipated complication of treatment is an event in which a patient develops a complication that happens so infrequently that it is completely unexpected. This complication is not related to the natural progression of the patient's illness. It is typically very difficult to "prove" that the complication was, or was not, the result of an error.

An example of an unanticipated complication of treatment is a patient who developed necrotizing fasciitis (the so-called flesh eating disease) following a relatively minor laparoscopic procedure. This patient required extensive surgery and transfer to a higher level of care.

A delay in treatment frequently turns fatal through a cascade of poor decisions and bad judgment on the part of many people, and a lack of supportive hospital systems. These events frequently occur in the emergency department or on the medical -surgical floor, when a patient has a sudden change in condition that is not responded to in a timely and effective manor.

An example of this is the case of the patient who started having a heart attack two days after surgery. He was on a medical-surgical floor. Neither the nurses nor the physician exhibited any urgency in caring for the patient. He was not started on oxygen, he was not given aspirin or nitroglycerin, and he was not moved to the Intensive Care Unit. He was also left alone as the nurse copied his chart for a transfer to another hospital. The patient suffered a fatal cardiac arrest two hours after he had started complaining of chest pain. This particular hospital has a rapid response team charged with evaluating and starting treatment on these types of patients, but apparently neither the physician nor any of the staff on this patient's unit were aware of its existence.

Death or serious disability associated with the use of a vascular access device frequently involves angiogram procedures in a radiology lab. Death results from unnoticed internal bleeding when a large blood vessel is inadvertently punctured. Puncturing a vessel is a known complication of these types of procedures, but the reports indicate that hospitals have not done a good job educating their staff about recognizing and reacting to this very serious condition.

For instance, a machine in the OR that was to be used for suction had the ability to be set up to pump out as well as suction. This resulted in a patient's death when air was forced into his vasculature. The machine should not have been designed with interchangeable connections.

Anticoagulants have been broken out from other medication errors because the causes of the errors are multi-factorial and the results are so dramatic.

For instance, a patient came in to the hospital with a large blood clot in one of the veins in his leg. He was started on a clot-busting drug. Because the patient also had liver disease, his coagulation blood tests were abnormal. These abnormal results were not reported to the physician, so the patient continued to receive the anticoagulants until he had a large bleed in his head and died.

Death or serious disability associated with a staff person's failure to act refers to the failure of one or more staff persons, who have a duty to act based on hospital policy and/or their licensing requirements, to take action in the face of a change in a patient's condition.

For instance, a patient died at a Special Hospital-Chronic when four nurses stood around her bed trying to determine if she had a pulse, rather than calling 911, or getting the automatic external defibrillator to see if she actually had a pulse.

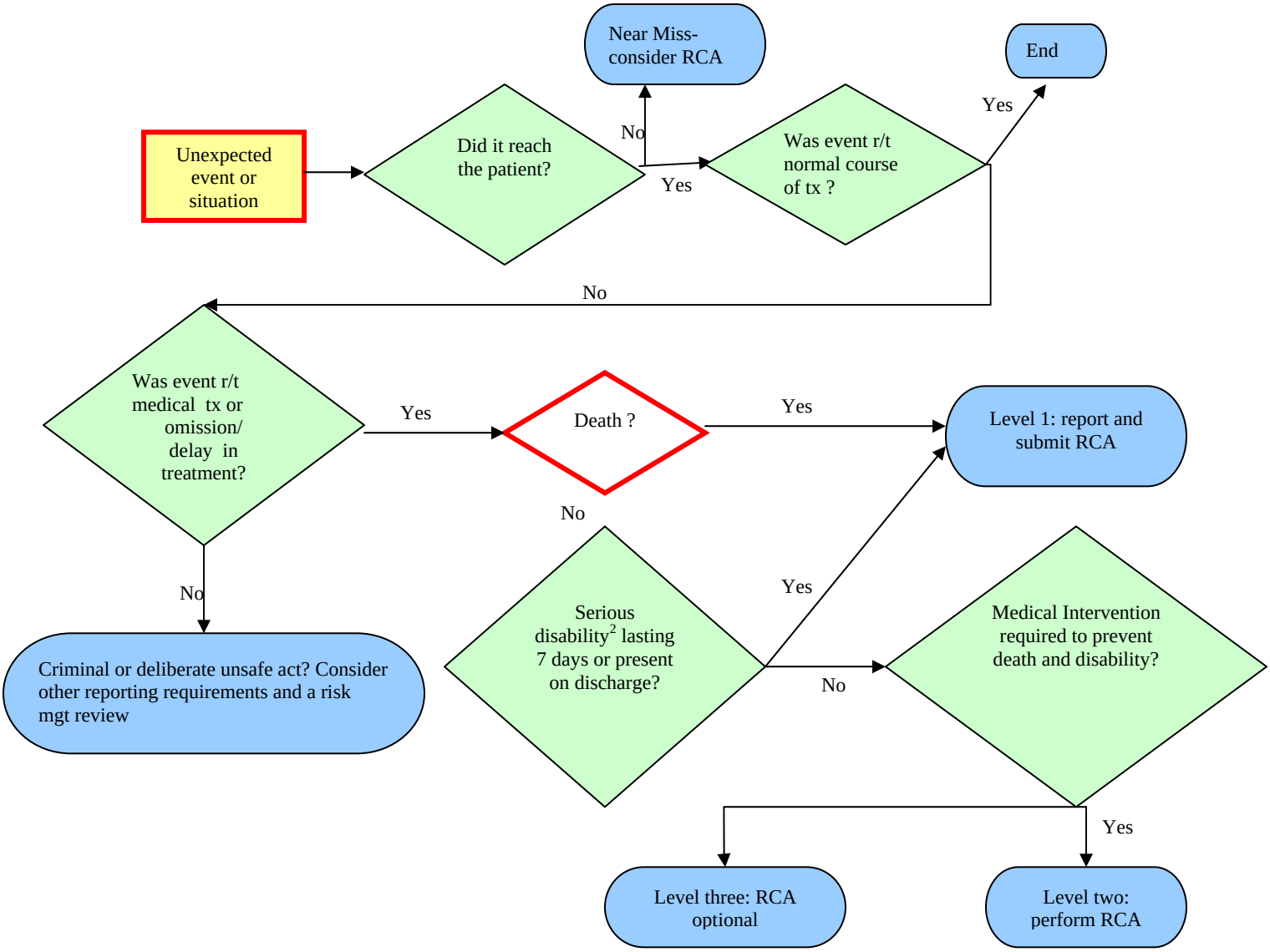
An intravascular air embolism occurs whenever air, instead of liquid, is injected into an IV. The injection of even a small amount of air can put the heart into a frequently fatal dysrhythmia. If the volume of air is enough, death ensues.

Unanticipated intra-operative death and the death of an ASA patient are similar except that the unanticipated intra-operative or immediately post-operative death occurs in people that are not categorized as ASA 1. (The American Society of Anesthesiologists (ASA) classification 1 is a normal healthy patient who is expected to come through surgery without problems).

An example of the death of an ASA 1 patient is the 30 year old woman with no risk factors who died within a few hours of a laparoscopic cholecystectomy (gallbladder removal). An autopsy revealed that she had massive unnoticed hemorrhage from the internal operative site. Another example of an unanticipated intra-op or immediately post-op death in a non-ASA 1 patient is the case of an elderly patient with many co-morbidities who went into a coma after a small dose of an anesthetic that she had had before. She never regained consciousness and died.

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)	FY2008 (N=194)
Change In Policy/procedures	79%	71%	51%	58%
Formal education	79%	70%	67%	62%
Disciplinary actions	4%	2%	10%	2%
Process improvement	10%	42%	34%	30%
Equipment Modifications	31%	27%	17%	23%
Environmental Changes	11%	9 %	3%	6%
Workload/Staffing Changes	18%	31%	13%	15%
Referral to Professional Board	0%	0%	3 %	0.5%
Data Tracking/Trending	36%	42%	35%	61%
Reported to FDA	1%	2%	2%	1%
Peer Review	12 %	14 %	21%	24%

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

Appendix G

A Review of Falls Data Extracted from RCAs and Adverse Event Reports Received by the Office of Health Care Quality

The Maryland Patient Safety Center (MPSC), Delmarva Foundation, and the Hospital Association (MHA) and OHCQ worked together to develop a pilot with the goal of reducing both the number and the severity of falls in three care arenas: acute care, long-term care, and home health. The group started off by agreeing on a definition of a fall which was the definition provided by the National Database of Nursing Quality Indicators (NDNQI): A fall is any unplanned descent from a higher level to the ground or floor. The National Database of Nursing Quality Indicators (NDNQI®) is a proprietary database of the American Nurses Association. The database collects and evaluates unit-specific nurse-sensitive data from hospitals in the United States. Participating facilities receive unit-level comparative data reports to use for quality improvement purposes. We further decided that a fall with injury meant any injury, no matter how minor. The injury question would be a yes/no question, with no mechanism for assigning severity.

Members of the group went to the Minnesota Patient Safety Center and toured a hospital in Minnesota that has a fall rate near zero. Other members had a conference call with the head of the Veteran's Administration's fall prevention project in Florida. These meetings led to the adoption of a roadmap similar to the form Minnesota uses. The road map is divided into two sections; the SAFE section contains facility-wide activities such as data collection, education, and improving the overall safety climate. The FALLS portion contains patient-specific interventions such as screening, linked interventions, post-fall debriefing, and providing a safe environment. Each section is supported by a selection of evidence-based tools and recommendations.

The workgroup split into three subcommittees; acute care, long-term care, and home health. Each subcommittee was tasked with developing the site-specific roadmap and compiling evidence-based tools. OHCQ provided data to the group regarding the causes of Level 1 falls in acute care. While this information was fairly subjective and not scientific, it provided an opportunity for the group to discuss the events to assist in the development of recommendations. The goal of the roadmap work was to develop a non-prescriptive toolkit that would be implemented in whole or in part during the eight month pilot by the participating facilities. The facilities would report just three metrics a month: Number of falls per 1000/patient days, number of injuries, and number of days without falls.

> Ten hospitals, 10 long-term care facilities, and five home health agencies were recruited to take part in the pilot. Because the pilot requires the commitment of resources and personnel, the agreement to take part had to be signed off by the facility CEO or administrator. The participating facilities encompass all geographic areas of Maryland and all sizes of facilities. The notebooks containing the toolkits and roadmaps were disseminated in the middle of October 2008 and a "webinar" with all of the participants was held on Tuesday, October 28.

The staff from Delmarva and the MHA has created a web site for the project that has all of the toolkits and links to the tools. Each facility will assign a point person to enter data on a private page on the site. The project manager (from Delmarva) will be compiling the data and reporting to the group as well as having frequent phone conversations with the participating facilities. Most of the questions from the participants in the webinar had to do with data collection. The group had assistance from a statistician at MHA to clarify what and how we were going to measure change. The participants were to provide baseline data by the end of November that is supposed to reflect the past six months, and then report on the three metrics monthly.

The data will be collected over an eight month period ending with an outcomes congress on June 16, 2009. The group hopes to be able to provide a tested set of tools to all providers in the State of Maryland.

"I Only Had my Back Turned for a Second"

There were 220 Level 1 falls reported to the Office of Health Care Quality from 3/15/04 to 7/30/08. What follows is an attempt to assign root causes to the falls. In most cases, the assessment of the cause(s) coincides with the hospitals'; in some cases, it does not. Since falls are usually multi-factorial, the total number of identified causes does not equal the number of reported falls. The categories of causation are identified below but are based only on what was reported by the hospitals and may not represent all factors leading up to the fall.

1. Four side rails refer to patients who have climbed over four rails and fallen. In one case, the hospital was unable to determine who had put up all the rails. In another case, the nurse felt that four side rails provided more safety than two.

2. Over-reliance on sitters: In one case, the sitter was sitting right next to the bed but was engrossed in her laptop when the patient climbed out the other side of the bed and fell.

3. Laxatives and diuretics: In one case, an 84 year old had been given two doses of Lasix within two hours just before change of shift. He fell when no one came to assist him to the bathroom.

4. Eight of the falls reportedly happened to patients within 24 hours after transfer from the ICU into a medical surgical bed.

5. Assisted and witnessed falls accounted for another nine falls with serious injury. Several of these patients are bariatric patients who could not be managed by the available staff. A few of these occurred with physical therapists in attendance.

6. Eleven patients who were on fall precautions fell after being left alone in the bathroom or while on the bedside commode.

7. Poor communication and hand-offs contributed to at least 13 falls. In one case, the CNA was late for her shift and did not hear the report that the patient was now on bed rest. In more than one case, the hand-off between nursing and transportation staff did not include information about the patient's fall risk.

8. Fourteen patients fell within a few hours of surgery. Several of these occurred in the same-day surgery or outpatient post anesthesia care unit setting as the patients were coming out of anesthesia and preparing to go home.

9. At least fifteen patients had personal or bed alarms that were not replaced upon return to bed, or had been removed by the patient. One hospital replaced most of their beds with beds with built-in alarms but the nursing staff felt like they had not had enough training to use them safely and did not use them. One hospital replaced their beds with beds with

built-in alarms. The control panel had a green light on it when the alarm was off. Staff thought this meant the alarm was on.

10. Environmental factors contributed to at least fifteen falls with serious injury. These include the patient who slipped on a tile floor while walking with a cane. It also includes the patients who fell on wet floors or tripped over equipment. One hospital found out the hard way that the bed alarm and the call-bell canceled each other out. This category also includes two patient who climbed out windows, and one patient who ran from the ED and fell off the ledge of the parking garage.

11. Sixteen of the falls were reported from outpatient areas in the hospital as well as EDs and radiology suites. Many hospitals found out that their hospital-wide efforts at curbing falls had not penetrated into the ED, Radiology, and Outpatient departments.

12. Ambien, sedation, pain medication: A significant number of reported falls happened to patients who had recent medication changes, or who had gotten one-time doses of sedation or hypnotics. The drug Ambien was specifically mentioned in eight of these cases. One hospital took Ambien off their formulary and another hospital set up their pharmacy system to flag all orders for high risk medications for their elderly patients. Other drugs mentioned were Restoril and Ativan.

13. Inadequate falls precautions: Also known as “magnet failure” for the lack of protective ability of the magnets that are put on the doors of the rooms indicating fall risk. Non-slip socks, a magnet, toileting rounds every two hours, and beds close to the nursing station were not enough to protect at least 25 patients.

14. Over-reliance on family help and the patient’s mental status: The patient agreeing to not get up without help was cited as a contributing factor to at least 25 falls. Families add their own unique contributions to the falls data: One 95 year-old patient was found on the floor one morning after her son-in-law got her up to a chair in the middle of the night so he could sleep in her bed. One daughter told the staff that her mother would fall if they did not get a sitter. She agreed to stay for the hour it would take to get one, then left after ten minutes without saying anything to anybody.

15. Twenty-seven of the reported falls occurred after changes in the patient’s physical or mental status failed to trigger a reassessment of fall risk. Most of these cases involved a change in mental status brought on by the unfamiliar environment and/or medication changes, including sedation and acute delirium. One elderly woman who fell had been in the hospital for two weeks with multiple medication and status changes. She had only been assessed for fall risk at admission. Several of these patients fell after invasive procedures involving sedation and or anesthesia. The increased risk was not recognized by the staff.

16. The majority of cases were falls reported in patients who had had no falls precautions implemented, despite what seem like glaring risks. Some of these patients (six) had simply not had a fall risk assessment done, others had been assessed as at risk but had had

no interventions put into place. Patients who had not been assessed as at risk included several patients who had been admitted through the EDs with recent falls. One patient had a sitter ordered for the medical surgical floor, but then was left alone in the ED waiting for a bed. Two patients fell after acquiring new sensory deficits (blindness) from progressive disease states. One patient fell after forgetting that his leg had just been amputated. One patient had been identified as being at risk, had no interventions, and a staff person who was unaware of the risk told the patient to get up and walk. Besides mental status changes, other admitting diagnoses that should have triggered falls precautions include suspected CVAs and TIAs, seizures, metabolic derangements leading to weakness and delirium, and anemic/hypoxic states.

Other items of note:

- Forty-three of the 220 falls were fatal. Forty of these patients died from intracranial bleeding. One patient went into DIC, one died of internal bleeding, and one bled out after pulling a large bore IV out during the fall.

- Three patients fell and were able to get back into bed without alerting the staff. They were later found with injuries and confessed to having fallen.

- At least six of these reports involved patients who fell more than twice in the hospital. One patient fell, the nurse went to call the physician for a restraint order, and the patient fell again. Another patient fell in the ED, had an order for a sitter written that was missed on arrival to the medical surgical floor, then fell again. The second fall occurred at a time when the staffing was low and did not allow for a sitter. The patient subsequently fell a third time, all within 24 hours of arrival to the hospital. After the third fall, the staff decided to take turns sitting with the patient until a sitter arrived. Multiple falls seem to be a clear indication that inadequate fall precautions have been implemented.

- According to the reports, restraints rarely prevent falls, yet they are often the first alternative staff think of when a patient falls.

- Forty-four patients fell out of bed or off the ED stretcher or X-ray table. The rest fell while ambulating—whether they were supposed to be ambulating or not.

- Low staffing was mentioned in only three of the fall reports.

- Only three of the reported falls could truly be said to be the patient's fault. These were alert, oriented patients who refused to use assistive devices and, in at least one case, refused to follow directions given by staff who were engaged in helping the patient.

- Several ideas presented themselves during the analysis of these data. More hand rails and grab bars in hospital bathrooms and rooms, especially on the path from the bed to the bathroom, may be an effective tool for patients who lose their balance while ambulating

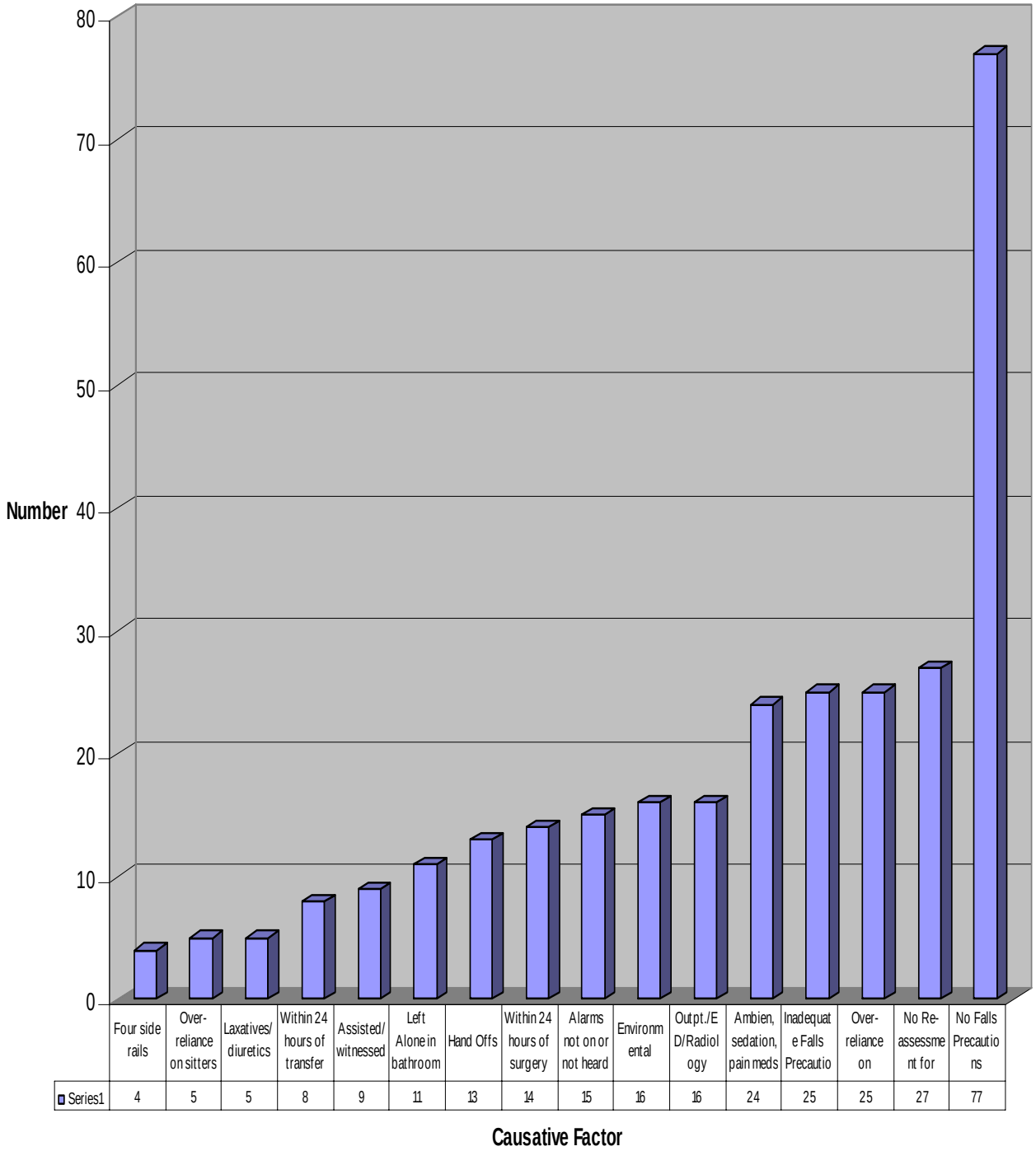
and who cannot, or will not wait for help. At the least, the rails would provide a handhold while the patient is lowering herself to the floor.

- The reports to the Office of Health Care Quality about falls rarely mention testing orthostatics.

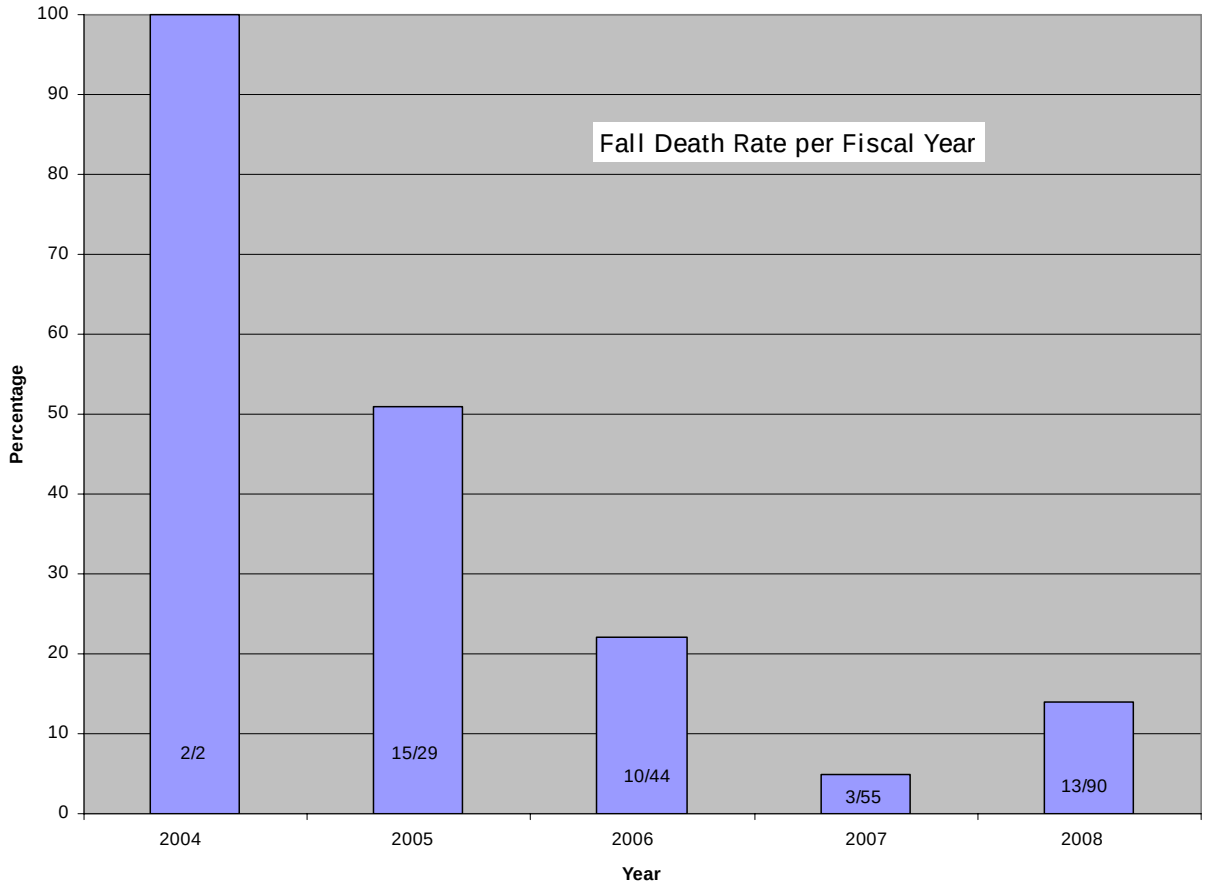
- Many elderly female patients in hospitals are less than five feet tall. Hospital may want to offer pediatric-sized gowns to more petite patients so they don't trip over the gown.

** It should be noted that this information has been extracted from the reports and RCAs received by OHCQ and is only as good and complete as the information provided by the hospitals.*

Causative Factors for Falls



Percentage of Falls Resulting in Death Per Fiscal Year



Number of Reported Falls per Age Group