OHCQ
Office of Health Care Quality

DEPARTMENT OF HEALTH & MENTAL HYGIENE

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Maryland Hospital Patient Safety Program

Annual Report

Fiscal Year 2007

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Foreword

I am pleased to present the Maryland Hospital Patient Safety Program 2007 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 third full year of implementation, the number of level1 adverse events reported by hospitals to the Office of Health Care Quality (OHCQ) increased 13.5% to 168. Falls continue to be the most frequently reported level 1 adverse event. The second most frequent reported category of event is death or serious disability associated with airway management, followed by suicide/attempted suicide (Appendix B). During FY07, hospitals have indicated a significant increase in the notification of patients and families regarding level 1 adverse events.

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?

While it is difficult to illustrate trends with only three years of data, 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 168 level 1 adverse events reported in FY07, only three were reported to OHCQ through other means such as complaints.

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.

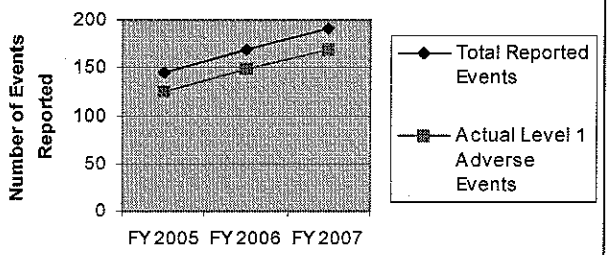
Very truly yours,

Wendy A. Kronmiller, Director

MANDATORY REPORTING OF ADVERSE EVENTS

The number of level 1 adverse event reports received in FY07 increased by 13.5%. Death or serious injury as a result of a fall was, again, the most frequently reported adverse event. Forty four hospitals reported 190 events in FY07 and, after review by hospitals or OHCQ, it was determined that 168 met criteria for level 1 adverse events. The number of reported events continues to increase. In FY05, the Department's Patient Safety Program staff received 145 reports of adverse events, of which 125 were determined to be true level 1 events. In FY06, 168 possible level 1 adverse event reports were received. As in previous years, discussion between OHCQ and hospital staff resulted in certain events being reclassified to a lower (or less serious) adverse event level, thus becoming non-reportable. (See Table 1)

Table 1
Total Reported Events in Relation to Level 1 Adverse Events



Despite the increase in the number of events reported in FY07, three fewer hospitals reported an adverse event than in the previous year, when forty seven hospitals reported adverse events. However, several hospitals which had not reported in the previous two years reported events in FY07. Since mandatory reporting began in March 15, 2004, fifty nine different hospitals have contacted the Department with the report of at least one actual level 1 adverse event. Hospital size, complexity, and hospital type continue to influence the number of adverse events reported by a hospital. An overview of the demographics of all Maryland hospitals is provided in Appendix A.

As in the previous years, large hospitals are more likely to report a level 1 adverse event than smaller hospitals. Hospitals with more than 200 licensed beds reported seventy three percent of the level 1 adverse events in FY07. Similarly, acute care hospitals reported ninety one percent of the level 1 adverse events in FY07 as opposed to the nine percent for the Special Hospitals. Since reporting to OHCQ was mandated in March of 2004, ninety two percent of the level 1 adverse events were received from acute care hospitals.

TABLE 2

FY 2007 LEVELONE ADVERSE EVENTS
BASED ON HOSPITAL CAPACITY

HOSPITAL SIZE NUMBER OF LICENSED BEDS	NUMBER OF HOSPITALS	NUMBER OF HOSPITALS REPORTING	NUMBER OF LEVEL1 EVENTS
300 or more beds	12	12	58
200 – 300 beds	18	15	64
100 – 200 beds	18	11	28
Less than 100 beds	21	6	18
TOTALS	**69**	**44**	**168**

Maryland's smaller hospitals tend to be "special hospitals," which do not perform surgical procedures or other interventions that are as complex or invasive as acute general hospitals.

In FY06, the data related to care provided in inpatient mental health settings indicated that the more serious events occurred in the psychiatric hospitals as opposed to the psychiatric units within acute general hospitals. However, this trend was not evident in the sixteen cases received in FY07. Of those cases, there were four level 1 adverse events that resulted in death; two in the acute hospitals with inpatient psychiatric units and two in psychiatric hospitals. Level 1 adverse events received that related to inpatient psychiatric care in FY07 included eight falls with fractures, two incidents of serious self injurious behaviors, two deaths from choking on food, two assaults, and two successful suicides.

Only five level 1 adverse events were reported by the State's chronic hospitals. Three of the five level 1 adverse events resulted in death, all related to ventilator dependent patients. Despite the lower frequency of reported level 1 adverse events from chronic hospitals, these hospitals must remain vigilant in management of ventilator dependent patients.

TABLE 3
TOTAL LEVEL 1 ADVERSE EVENTS PER HOSPITAL TYPE

HOSPITAL TYPE	TOTAL NUMBER OF HOSPITALS	NUMBER of HOSPITALS REPORTING IN FY 2007	LEVEL 1 EVENTS IN FY 2007	TOTAL NUMBER OF REPORTING HOSPITALS Since 7/1/2004	TOTAL LEVEL 1 EVENTS Since 7/1/2004
Acute General	47	36	153	45	404
Special Hospital - Psychiatric	13	5	10	8	22
Special Hospital – Other *	9	3	5	6	15
TOTALS	**69**	**44**	**168**	**59**	**441**

* Special Hospital –Other" include those special hospitals that are classified as chronic, children's or rehabilitation.

Thirty nine percent of the reported level 1 adverse events from all hospitals in FY07 resulted in death. This is a significant difference from FY06, when 58% of the level 1 adverse events resulted in death. Medical or surgical intervention was required for forty eight percent (48%) of the affected patients. Surgery was required in fifty nine cases, eight patients had an increased

length of stay in the hospital and eight required transfer to a facility that required a higher level of care such as a trauma or cardiac center. Twelve percent of the patients suffered loss of function (14) or loss of organ or limb (7) as a result of the level 1 adverse event. The most serious consequence has been assigned for each reported level 1 adverse event but it should be noted that patients may have been subject to more than one of these interventions after an adverse outcome. Appendix C documents the number and types of level 1 adverse events received in FY07 and the outcome of the level 1 adverse event to the patient.

UNDER-REPORTING

All states with reporting requirements, including Maryland, have experienced under-reporting. Under-reporting may be due to several factors. Fear of retribution and fear of public disclosure may be the primary reasons for not reporting adverse events to State regulatory agencies.

In Maryland, COMAR 10.07.06 provides protections that prevent the Department from routinely citing deficiencies regarding the reported adverse events. COMAR 10.07.06 also contains safeguards to protect against public disclosure. The regulations establish medical review status for activities conducted under the authority of a hospital's Patient Safety Committee and the law provides Medical Review Committee protections to the activities conducted by the Office of Health Care Quality. Based on these protections, there should be no motivation for Maryland hospitals to willfully fail to report a level 1 adverse event to the Department. In fact, Health General Article 19-304 establishes civil money penalties for failure to report a level 1 adverse event.

In most cases where Department staff have identified an unreported level 1 adverse event, our investigation found that the hospitals had reviewed the case and believed it to be a level 2 adverse event[1]. The majority of these events have been falls with fractures. The hospitals mistakenly believed that after the fractured bone was set or surgically repaired that the patient was no longer disabled and did not meet the criteria for a level 1 event[2].

Hospitals frequently report that the term "serious disability" in the definition of a level 1 adverse event is confusing. Hospitals indicate that a serious disability would be permanent or last longer than the seven days identified in the definition. Hospital staff rationalize that once an injury is stabilized through medical or surgical intervention the disability no longer exists. Staff fail to consider the impact the disability has made even temporarily on the patient's length of stay in the hospital, the patient's need for post hospitalization care such as skilled nursing care or rehabilitation, the patient's ability to ambulate with mobility assistance such as a wheelchair or crutches, or the patient's ability to function independently. One example is the patient who

[1] COMAR 10.07.06.02 B(5) defines level 2 adverse event as an adverse event that requires medical intervention to prevent death or serious disability

[2] COMAR 10.07.06.02B defines a level 1 adverse event as an unexpected occurrence related to an individual's medical treatment and not related to the natural course of the patient's illness or underlying disease condition that results in death or serious disability. Serious disability is further defined in COMAR 10.07.06.02 B(11) as "a physical or mental impairment that substantially limits one or more of the major life activities of an individual and lasts more than seven days or is still present at the time of discharge."

sustained a fracture of the cervical vertebrae during the course of staff intervention for an aggressive behavioral incident. The fracture was surgically repaired and the patient was required to wear an external fixation device to stabilize the neck for several weeks. The hospital believed that because the patient was readmitted four days after the injury occurred and was not paralyzed, the event was not reportable. This kind of confusion was evident in another event in which a patient fell and broke his neck. He required transfer to a tertiary care center, underwent stabilizing surgery, and wore a halo neck brace for several months. Although this event clearly meets the criteria for a level 1 adverse event, the hospital erroneously categorized it as level 2 adverse events because the patient had not been paralyzed. We believe that there will be little excuse for these erroneous interpretations as the reporting process matures.

OHCQ staff also noted through complaint and regulatory activities another subset of level 1 adverse events that are not reported. These events are not internally reported to the hospital administration. The Patient Safety Officer and administration do not learn of an event, which the hospital should have reported in accordance with COMAR 10.07.06. These events include a case of a retained foreign body in which the physician was working with the plaintiff's attorneys and did not report the event to the hospital until the plaintiffs included the hospital in the lawsuit.

Hospitals also rationalize that some events need not be reported because the sustained injury is a known risk of the procedure or is consistent with the natural course of the patient's underlying condition. One hospital felt that a fall resulting in death of a person with dementia was not reportable since patients with dementia are known to be at risk for falling. This rationale is also used as a reason for not reporting surgical wound infections. When asked why an infection was not reported, the hospital explained that infections are a risk for all surgeries therefore if the patient acquires an infection at the surgical site it was a known risk and not reportable. These assumptions prevent hospitals from looking at their systems and taking actions to prevent the recurrence of these very serious events.

OHCQ has attempted to assist hospitals in identifying a level 1 adverse event. In FY06, staff from several hospitals and OHCQ developed an algorithm, the Patient Safety Decision Tree, for hospitals to use when reviewing an adverse event. (Appendix E) Additionally, hospital staff can feel free to call and discuss an event with an OHCQ staff member who will assist the hospital in its decision making process.

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 close calls is vital to identifying what went right as well as what went wrong in processes of care.

CATEGORIES OF LEVEL 1 ADVERSE EVENTS

Hospital reporting systems are highly effective in capturing certain high profile categories of events, including post-surgical retention of foreign bodies and wrong site/wrong procedure

surgeries. While Department staff believe that the reports of level 1 adverse events received are a fraction of the actual number of level 1 adverse events, we believe that hospitals report these high profile events.

Case Study - Increase in wrong site surgeries and retained foreign bodies

During the first two years of reporting, wrong site surgeries and retained foreign bodies had been reported infrequently. OHCQ has received only one wrong site surgery from March 15, 2004 to June 30, 2006. It had been our expectation that The Joint Commission National Patient Safety Goal to standardize procedures to prevent wrong site surgeries had been effective. However, in FY07, eight wrong site or wrong procedure surgeries were reported.

Another disturbing increase in reporting was noted with incidents of post-surgical retained foreign bodies. In the first two years of reporting, six events were reported to OHCQ. In FY07, there were six more reported adverse events involving retained foreign bodies. The common threads identified in the RCAs for these events are a lack of attention to equipment counts during the cases, and a failure to follow up on inconsistent counts. In one case, the final count was incorrect and the staff called for x-rays to be done while the patient was in the operating room (OR). The radiology personnel did not know how to do intra-operative x-rays. Eventually, it became dangerous to keep the patient under anesthesia and the patient went to the recovery room and required another surgery to remove the foreign body.

Surgical case data compiled in FY07 was so compelling in this area that the staff of OHCQ developed a Clinical Alert which is available at www.dhmh.state.md.us/ohcq/.

Despite two Clinical Alerts regarding medication safety issues with anticoagulant medications there were seven reported level 1 adverse events associated with anticoagulants in FY07 (six in the previous two fiscal years). Anticoagulants continue to be a class of medication that requires careful use and monitoring.

Since the beginning of reporting, the Department has identified two areas where under-reporting was particularly problematic—hospital acquired stage III and stage IV pressure ulcers and health care associated infections. In FY07, there were four reports of hospital acquired stage III or IV pressure ulcers. There were no reports of hospital acquired pressure ulcers in previous years. Hospital acquired pressure ulcers are the most frequently reported adverse events in the Minnesota[3] and Indiana[4] reporting systems.

[3] Minnesota Department of Health. Adverse Health Events in Minnesota, Third Annual Report, Minnesota Department of Health, January 2007, page 9.

[4] Indiana Department of Health, Indiana Medical Error Reporting System, Preliminary Report for 2006, March 6, 2007, page 25.

Case Study - Pressure Ulcers

One of the reported cases involved a 53 year-old patient who had a total knee replacement. The patient experienced numbness from epidural anesthesia requiring her to be bed-bound for 24 hours. The patient developed a blister on the inner buttock by the second post operative day. When discharged, she had open blisters and an indurated buttock. The patient returned to the hospital six days after surgery with a Stage IV pressure ulcer. Two other cases involved anti-embolism stockings or boots that were not removed while the patients were in the hospital. When the stockings or boots were removed at home, the patients were found to have developed Stage III or IV pressure sores on their heels.

OHCQ has received only nine reports of healthcare associated infections (HAI) – five were received in FY07. All five reported cases in FY07 resulted in the death of the patient. However, it is unlikely that the five cases reported to OHCQ are the total number of HAIs that resulted in death or serious disability in Maryland hospitals.

One barrier to reporting infections is that the hospital may not know an infection occurred. The length of stay for most surgical patients is short and the discharged patient who develops a surgical wound infection post discharge may be treated through the physician's office, a home health agency or another hospital. While hospitals encourage their medical staff to report infections that occur in discharged surgical patients, the hospital is dependent on the physician's willingness to report. Therefore, hospital staff where the surgery or procedure was performed may never know that the patient acquired an infection.

Some examples of reported healthcare associated infections demonstrate the difficulty hospitals have reporting HAIs. In one case, positive culture reports for Staphylococcus aureus were not received from the laboratory until after the patient was discharged to a Veterans' Administration facility. Six days after discharge the patient was readmitted to the acute care hospital with sepsis and died. In another case, a male patient had genito-urinary surgery; he returned to the hospital five days after the procedure with gangrene of the scrotum. A patient had a C-section; nine days after the surgery the patient returned to the Emergency Department (ED) with necrotizing fasciitis. In the latter two cases the hospitals might argue that the infections were not due to their care but to the post surgery wound care.

Traditionally, infection control practitioners within hospitals collected data and reported it to the hospital leadership. In a recent meeting with infection control directors from several Maryland hospitals, OHCQ found that the infection control directors were not aware of the mandatory reporting requirements for level 1 adverse events. As a result of that discussion, OHCQ staff will establish a dialogue with the local Association for Professionals in Infection Control and Epidemiology (APIC) chapter to educate Infection Control professionals about Patient Safety and the reporting requirements. OHCQ staff will also begin focusing on Infection Control data during OHCQ's regulatory and Patient Safety activities to determine if hospitals have effective processes to review infections in the context of patient safety.

A listing of the types and numbers of reported level 1 adverse events per year can be found at Appendix B **The most frequently reported event in FY07 continues to be patient falls**. There were 55 patient falls reported to the Department; most of which occurred in patient rooms. As a result, the most frequent location within the hospital where level 1 adverse events occur is the inpatient room on a medical or surgical unit. Level 1 adverse events are 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 FY2007	Number of Events in FY2006	Number of Events in FY2005	Total Number of Events
Medical Surgical Units	75	54	47	176
Surgical Suites	22	18	20	60
Emergency Departments	17	19	11	47
Psychiatric Units	16	10	7	33
Critical Care Units	13	13	14	40
Labor & Delivery	8	9	9	26
Radiology Services (including interventional)	5	7	6	18
Rehabilitation	3	1	1	5
Outpatient	1	2	0	3
Cardiology	1	1	1	3
Pediatrics	0	3	1	4
Nursery	0	1	1	2
Ambulatory Care	0	1	0	1
Other	7	9	7	23
TOTALS	**168**	**148**	**125**	**441**

OHCQ's Patient Safety Program continues to classify the types of level 1 adverse events using the National Quality Forum's "Never Events."[5] This is a nationally known classification of events used by several state reporting systems as their criteria for reporting. Since it is nationally recognized, it enables OHCQ to compare its data with those state reporting systems. Due to the broader scope of our definition of a level 1 adverse event and trends and patterns of reported events, the list of categories has been expanded several times to 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. In FY07, OHCQ added a separate category to its database to capture healthcare- associated infections that result in death or serious disability.

The Department's data for FY06 revealed twenty autopsies done for eighty eight deaths reported as level 1 adverse events. There were twelve autopsies (18 %) for sixty six deaths reported in FY07. Autopsies can provide an invaluable opportunity to learn more about the cause of death.

[5] National Quality Forum. "Serious Reportable Events in Healthcare – A Consensus Report." Washington DC:National Quality Forum ; 2002

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. In FY07, 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%). This is 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 ten cases where no notification was reported, hospitals reported that the patients had no permanent address.

Of the level 1 adverse events reported to OHCQ in FY07, only two were also reported to The Joint Commission. In some cases, the hospitals informed OHCQ that the decision to notify The Joint Commission had not yet been made. The Joint Commission asks its hospitals to voluntarily report sentinel events.[6] The Joint Commission requires its accredited hospitals to identify and respond appropriately to all sentinel events including conducting a timely, thorough, and credible root cause analysis, implementing improvements to reduce risk, and monitoring the effectiveness of those improvements. Surveyors from The Joint Commission will review and critique the RCAs for sentinel events during its complaint investigations and triennial surveys. There is no Maryland statutory or regulatory requirement that hospitals report to The Joint Commission.

ROOT CAUSE ANALYSES

Unique to the Maryland Patient Safety Program is the requirement that hospitals submit a root cause analysis to OHCQ for each reported level 1 adverse event. Many states have mandatory reporting but few receive the hospital's root cause analysis. Some states, particularly those with computerized systems, require 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. 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 Hospital Patient Safety Program 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) 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

[6] 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.

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.

If OHCQ receives an incomplete or inadequate RCA, the OHCQ Patient Safety nurse 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. When repeated, poor RCAs have been received or similar events continue to occur, the OHCQ has met with hospital staff, including members of the Medical Staff. Over the first three years of the Patient Safety Report, the OHCQ has provided a great deal of formal and informal feedback to the hospitals regarding their events and RCAs.

Hospitals still have a tendency to find a person, often a nurse, to blame for the adverse event. In FY07, 10 % of the RCAs indicated that disciplinary action was taken against one or more employees as a result of a level 1 adverse event and 3% of the RCAs indicated that professional staff were referred to a licensing board. While individual staff performance may have played a role in these reported events, the root cause analysis will not be effective if the team stopped at the point of blame. It seems easy to find one person to blame for an error; however, real change occurs only when hospitals investigate further. There have been RCAs where the hospital has placed blame on the family or patient, and not looked at its own systems that allowed the error to occur. Many hospitals still have difficulty considering that processes and systems in the hospital might be deficient or broken, and that systems failure, not the individual's performance, must be changed to prevent the same adverse event from recurring.

In FY07, 21% percent of the RCAs indicated that the hospital had referred the event through the Medical Staff Peer Review process. 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.

OHCQ's review of RCAs reveals 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 front line staff who are analyzing the adverse events. If the RCA group believes that the hospital leadership is not invested in fixing systemic problems, they 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. On a systems-based approach to analyzing and solving problems, the hospital Board of Directors should also interact with and receive education regarding patient safety guidelines and activities. To really invest in patient safety, leadership must be involved.

Almost half of the RCAs submitted to the Department were determined to be problematic in at least one area. RCAs often do not delve deep enough, either in the analysis or the corrective

actions. Through review of the RCAs the Department continues to note these areas to be the predominant weaknesses:

- *Failure to investigate and find the root cause(s).* Hospital staff identify a problem area but do not delve deep enough to find the root cause. To find the true root cause, it is imperative that hospital staff continue to ask "why" until the root cause becomes apparent, even if that answer is uncomfortable to the hospital.

- *Failure to develop an appropriate corrective action plan[7] to address the root cause(s).* The most common action plan was to educate staff (67% of the reviewed RCAs). In many cases this is actually re-educating individuals who are highly educated and trained, and who make errors despite their education and training. The second most frequently reported action plan was a change in policy and procedures (in 51 % of the RCAs reviewed). Changing policies and procedures and training staff are considered to be "weak" actions and do not address the system and process changes that must be made to prevent highly trained professionals from repeating the same error.

  OHCQ expects hospitals to take stronger actions; such as process and system changes that will result in safer patient care over the long term. Appendix F "Recommended Hierarchy of Actions" taken from the training materials of the Veterans' Administration National Patient Safety Center classifies the actions as weak to stronger and can be used as guidance for RCA teams when developing action plans. [8] Appendix G identifies actions implemented by hospitals, according to their RCA. Action plans in RCAs reviewed during FY06 identified these stronger actions more frequently than in the first fifteen months of the Patient Safety Program, unfortunately, this pattern did not continue in FY07. Process improvement was an identified action in 34 % of the reviewed RCAs in FY07. Workload changes were identified in 13 % of the action plans. Environmental changes (3%) and equipment modifications (17%) were other stronger actions planned on reviewed RCAs. While the decrease in the number of stronger actions is disappointing, it is hoped that this pattern will not continue. OHCQ staff will continue to reinforce the need to look for systems changes. 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.

  The VA provides additional guidance to its root cause analysis teams when determining what is or isn't an appropriate action. Teams are instructed to ask if the actions will meet the following criteria:

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[7] "Action plan," as defined in COMAR 10.07.06.02(B)(1), as an written document that includes: specific measures to correct problems or areas of concern, specific measures to address areas of system improvement, time frames for implementation of specific measure, and title of individual responsible for monitoring implementation and effectiveness.

[8] Root Cause Analysis Tools. Department of Veterans Affairs, National Center for Patient Safety, Version: August 2002.

- Do the actions address the root cause and contributing factors?
- Are the actions specific and concrete?
- Can a "cold" reader understand the actions and implement them?
- Were the process holders consulted for input into the actions?
- Will the actions be tested or simulated prior to implementation if feasible?[9]

Once the hospital has identified the root cause of a level 1 adverse event it must take prompt decisive actions to prevent its recurrence. Too often the submitted action plans will not be implemented for months after the event occurred. While changes that involve capital investment or structural changes may take quite a while, there is no reason for simpler changes, like a change in a form, to take many months. In some cases, the hospitals are waiting months for the approval of a system change by the Governing Board or Medical Staff. The hospitals sometime fail to recognize the urgency and the need to promptly implement corrective measures to prevent another serious or life threatening event from recurring.

- *Failure to develop outcome measures to determine if the corrective action plans have been effective in correcting the root cause(s).* Hospitals often find it difficult to identify methodology to measure if their action plan was effective. An outcome measure should state *"Falls assessments will be performed for 100% of all patients admitted who are over age 65"* as opposed to how many staff will be trained on the falls assessment tool. The outcome must then be measured to determine if it was effective. The results should be stated using a numerator and denominator. If the hospital's audit determines there are continued problems with non compliance with a procedure, the hospital should review and revise the outcome measure.

- *Failure to perform an applicable literature search.* Several hospitals have asked about the requirement under 10.07.06.06D(2) to consider relevant literature. Often the mechanism of injury is clear and does not require further research. However, we would strongly suggest that hospitals conduct a literature search into best practices for preventing or controlling the problematic process. Most hospitals clearly need help with identifying and implementing effective interventions. As noted, the most prevalent actions continue to be education and policy changes. If those interventions actually worked, we should be the safest state in the nation, but the patient safety literature consistently verifies that policy changes do little, and re-education is seen as a punishment by competent caregivers. Most hospitals also need help identifying effective ways to measure the success or failure of any intervention.

The following cases are examples of the types of problems noted in the RCAs reviewed by the Department:

❖ ***RCA No. 1*** *– A patient with deep vein thrombosis (DVTs) admitted to the hospital and put on anticoagulation with Heparin and Urokinase infusions. A critical Fibrinogen value was*

[9] Ibid.

called to nurse by the lab. Nurse was immediately called to assist another patient and forgot to call the physician about the critical value. The patient continued on anticoagulation for another eight hours until the vascular surgeon noticed the critical value. The patient developed an intracranial hemorrhage which worsened over the next few days until she died.

Root causes as identified in RCA: Human error; the nurse took the critical results and failed to pass the results onto the physician.

- Hospital's Action Items:

1. Educate physicians to provide current and legible contact information so the nurse can reach them with critical results.
2. Intensive Care Unit pre-printed order sheet will be changed to allow space for physician to add contact information.
3. Nurses will be reminded to check status of patients.
4. RCA mentions discussion surrounding the issue of single person notification, but then facility elected to keep this system because it had been safe in the past.

- Discussion:

1. A process cannot be judged to be inherently safe just because nothing bad has happened in the past. To leave the responsibility on the nurse alone to notify the physician does not fix the root cause of this adverse event.

2. The Action Items are not robust. The facility already has a partially electronic medical record. Why implement an information technology modification that allows the physician contact information without improving more of the lab notification process? Why can't notification be made automatically? Can the lab notification system by linked to e-mail, log-in, or text message to a cell phone?

- ***RCA Case No. 2*** *– An elderly, somewhat confused man came to the Emergency Department with right upper quadrant pain, nausea and vomiting. An ultrasound was done in the Emergency Department that showed gall bladder polyps. The patient was admitted. A HIDA scan was done the next day which showed "non-visualized gall bladder" with suspected acute cholycystitis. The patient was taken to surgery for a laparoscopic cholecystectomy. No gall bladder was found. Later investigation revealed that the gall bladder had been removed more than 20 years previously.*

- Root causes identified in the RCA: The only root cause identified was the patient's lack of knowledge regarding previous surgery.

- Hospital's Action Items:

1. Surgical peer review for surgeon.
2. Considered requiring a flat plate before an abdominal ultrasound. The facility elected to not do this because a flat plate was not required in order to interpret the ultrasound

- Discussion:

1. The patient should not be blamed unless everything possible has been done to protect the patient. This could not have been the first patient who is a poor historian, and it surely won't be the last. What will the hospital do with other patients like this?

2. If a flat plate x-ray is not required in order to interpret the ultrasound, what about requiring one before any abdominal surgery? This is the third case reported to the OHCQ where a confused patient has been found gall bladder free during laparoscopic cholecystectomy. A flat plate would identify surgical clips and any other anomalies prior to surgery, and could be considered part of the standard work-up.

3. Root cause does not go deep enough. Analysis seems to have stopped once the patient was identified as the root cause. There was a three-week delay between the first diagnosis and the lap cholecystectomy to allow the patient's coagulation status to return to normal. What happened during this time? Was the pre-operative assessment adequate? Did anyone ask the patient's family if he had had any previous surgeries? Did any other cause for the patient's symptoms suggest itself during this time?

❖ ***RCA Case No. 3:*** *A very confused patient who was in a restraint bed was able to break the bed and fall out. The nurse notified the Physician Assistant (PA), who ordered an x-ray. The hip x-ray was suspicious for a fractured hip, but the PA did not pass this on to the attending physician. The results were also in the computer system, but apparently no one noticed. No one reported the fall as an adverse event; so no one in hospital management knew about the event. It was more than a month later, after more diagnostics were done for the patient's continued complaints of pain that it was discovered the patient had a fractured hip.*

- Root causes identified in the RCA: No root causes were identified.

- Hospital's Action Items:
  1. Counseled the PA
  2. Reminded the radiology department and nursing staff of their responsibilities.

- Discussion:
  1. Since no root causes were identified, it was hard to determine if a thorough analysis had taken place.

  2. According to the report, this fall occurred in the afternoon. How was it that no one else knew about it but one nurse and the PA? What is the supervision of the nursing staff and PAs? Has the facility done enough of an analysis to determine if the same lack of reporting and follow through is happening with other events? Does management know how the staff feel about creating and maintaining a safe environment?

  3. Corrective actions are insufficient to address the two issues of unreported events and lack of follow up on test results. What other action items can be implemented that do

not rely on memory? For instance, is there a way that positive results entered into the computer would automatically generate an e-mail to the ordering provider? And obviously, the facility needs to identify the underlying causes for failure to follow the event reporting policy.

- ***Case No. 4*** *– A delusional, agitated patient was brought to the Emergency Department by police on an emergency petition for evaluation after assaulting several people in the community. He was initially restrained in the Emergency Department, but later became calm and cooperative and was released from the restraints. He agreed to a voluntary admission. Upon admission to the behavioral health unit, he became highly agitated and assaulted a nurse. Other patients intervened and pulled the patient off the nurse. He was eventually sedated and sent to another hospital. The nurse suffered severe facial injuries.*

  - Root causes identified in the RCA: None

  - Hospital's Action Items:
    1. Establish transfer protocol to address thorough evaluation by Emergency Department and improve hand-offs.
    2. Develop improved hand-off form.

  - Discussion:
    1. Even though no root causes were identified, it was apparent that several system failures contributed to this event. There was only two staff present on the unit covering four patients prior to the admission of this patient. This might have been an adequate number of staff for four non-violent patients, but did anyone think about the staffing level before the decision was made to admit this particular patient? During the assault, the other staff person dialed "0" to get help, rather then the facility's emergency number, which was five digits. This caused a delay in the response of security personnel. It also turned out that all of the "panic buttons" in the unit rang at the nursing station, not at Security. In a panic situation, is it reasonable to expect someone to remember to dial five digits? Most people will just dial "0," despite all education to the contrary. This is not the first adverse event reported to OHCQ in which dialing the wrong emergency number delayed help. There must be a way to compensate for this common behavior. Might it also be a good idea to notify Security staff before transferring a violent patient between units?

    2. The analysis also revealed that the psychiatrist who admitted the patient had not been told about the patient's assaultive behavior and positive toxicology screen. The patient had been evaluated by another mental health professional in the Emergency Department and for some reason, critical information about his behavior had not been provided to the unit.

    3. The manager of the unit was the only person who had been trained on the prevention and management of aggressive behavior. That is all the more reason to critically evaluate the appropriateness of admissions.

4. The action items were only suggestions. No concrete actions had been identified.

BEST PRACTICES

After reviewing over 500 RCAs since the start of mandatory reporting, OHCQ has begun compiling an informal list of best, or at least better, actions that hospitals have implemented in the aftermath of adverse events. We will continue to let hospitals know about innovative interventions as they come to our attention.

For example, when a hospital identified that ventilator alarms could not be heard through Intensive Care Unit room doors closed for respiratory isolation, hospital staff immediately bought several baby monitors to use in the rooms with the receivers in the hall, until a structural solution could be achieved.

Some of the more innovative fall precautions we have seen include the use of bright red non-slip slippers for patients at risk, to alert everyone who sees them that the patient is a fall risk. One hospital started doing finger-stick glucose checks on all diabetics who fall, to determine if there is a correlation between blood sugar and falling.

After an injection of Lovenox was given too close to the abdominal mid-line, and inadvertently into an artery, causing a massive intra-abdominal wall hemorrhage leading to death, one hospital changed its practice to require Lovenox be given in the "love handles" only.

COMPLAINTS

The value of mandatory reporting is 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 Unit. The Department received 316 quality of care complaints during FY07. Of these complaints, only three were also reported as a level 1 adverse event by a hospital. From March 2004, when mandatory reporting began, and the end of FY07, a total of 550 adverse events have been reported by Maryland hospitals; over 966 hospital complaints were received over this time, only eight events "overlapped."

This data indicates that victims of the most egregious events or their families usually do not file complaints with the Department. These families and patients may proceed directly to attorneys to litigate the most serious events. Sometimes, they may not have been aware that they had been victims of a serious adverse event. To exemplify this, prior to mandatory reporting only once was OHCQ made aware of a retained foreign body during a surgical case. The hospital voluntarily reported the event to this office when they learned that the media had been contacted by the patient's attorney. However, since mandatory reporting began, hospitals have reported twelve cases of retained foreign bodies to OHCQ. It is hoped that through the information obtained through mandatory reporting, the Department will be able to make informed decisions about how to 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 OHCQ regulations were implemented in 2004, all hospitals submitted their patient safety plans in accordance with the COMAR 10.07.06.14 (A). While OHCQ has not mandated that hospital staff revise and resubmit their plans on a regular basis, hospitals that have revised or updated their plans submit the plans to OHCQ for review and approval. 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. Three Clinical Alerts have been developed based on the review of RCAs and adverse Events in FY07:

- Medication Reconciliation Error Between a Hospital and a Long-Term Care Facility;
- Wrong Site Procedures and Retained Foreign Bodies: Why are They Still Happening in Maryland? ; and
- An Unnecessary Distraction: Vendors in the OR.

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

Maryland Patient Safety Center

The Maryland Patient Safety Center [10] 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;
- Representation on the MPSC Education Committee;

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

- Regular attendance at training workshops sponsored by MPSC; and
- Attendance when requested at the MPSC Patient Safety Directors' meetings.

In addition, OHCQ Patient Safety Unit staff has provided de-identified 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 crafting root cause analyses.

Observations

It is impossible to eliminate all errors in people-intensive processes. However, hospitals cannot continue to tolerate processes that do not catch mistakes before they reach the patient, or that do not minimize the harm to a patient if an adverse event should occur.

Despite continuing challenges posed by data mining, possible under-reporting of level 1 events by hospitals, and the quality (or lack thereof) of many of the RCAs, the Patient Safety staff of the Office of Health Care Quality believes that the Patient Safety Program is important. It forces hospitals to recognize and monitor adverse events that are happening in Maryland hospitals. The Patient Safety Program has created a dialogue between hospitals and the Department regarding serious errors. OHCQ is becoming aware of events and details of events that it otherwise would not have known. Hospitals understand the value of critically examining adverse events and near misses and are attempting, although many times unsuccessfully, to develop and implement processes and systems to prevent the recurrence of a critical error.

The fact that there was a 13.5% increase in the reporting of actual level 1 Adverse Events from FY06 to FY07 continues to indicate that hospitals are becoming more comfortable with recognizing and reporting events. Also, the fact that several hospitals which had previously not reported events participated in the program in FY07 is an indication that more hospitals are critically looking at the care being provided. However, about 10% of the hospitals that had previously reported did not report even one level 1 adverse event in FY07. Are these hospitals safer, or have internal systems to identify events failed?

Special Hospitals, while only reporting 15 level 1, events have a death rate of fifty per cent for the cases reported, as compared to thirty nine per cent for all hospitals. Suicides in psychiatric hospitals and alarm failures related to ventilator care are the major causes of these deaths.

As in the previous two years, falls continue to be the most frequently reported level 1 adverse event. As hospital patients age and the number of prescribed medications increase, it is expected that falls will continue to lead for years to come. A Clinical Alert was written in 2006 describing hospital experience with falls, with causative factors. We are pleased that significantly fewer patients who fell in a Maryland hospital died as a result of their injuries in FY07 (three of the fifty five reported falls). It is hoped that this may be an indication that hospitals have become more diligent in assessing those patients most likely to die as a result of a fall (patients on anticoagulants) and implementing falls precautions. However, even after identification and

repair, a fracture in an elderly patient will likely lead to lengthy disability and often death. Falls have significant impact on health care costs from the required surgeries to repair the fractures, increased lengths of stay, required rehabilitation and often post discharge skilled nursing home care. Despite the impact of falls on healthcare, RCAs reviewed indicate that some hospitals believe that little can be done to reduce the numbers or severity of falls.

We are pleased to identify one area of these regulations that has been highly effective; according to reports received from the hospitals, ninety four per cent of the patients or their families were informed after an adverse event occurred in FY07. While we do not know the extent and quality of that notification, it is a significant increase from the previous years' reports.

Future Plans

The OHCQ FY06 budget included three additional positions for the Patient Safety Unit. The Patient Safety Unit staff, as well as the hospital regulatory staff, report to the Office of Health Care Quality's Assistant Director of Hospitals, Laboratories, and Patient Safety. Resignations and difficulty in recruiting nurses with strong hospital experience have made filling these positions difficult. Once hired it has been difficult to retain nurses more than a few months before they are recruited to positions with higher compensation. Due to the difficulty in hiring qualified nurses and attrition, one nurse continues to perform intake of adverse events, the review of the RCAs and analysis of the data. Once additional staff are hired and trained, the activities of the Patient Safety Program can be expanded and RCA reviews will be completed in a timelier manner.

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;
- Develop a Patient Safety page on the Office of Health Care Quality website;
- Develop quarterly "lessons learned" from the reports received and post to the web page;
- 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
- Continued participation in the educational offerings provided by the Maryland Patient Safety Center.

In addition to staffing, information technology is needed to improve the analysis of RCAs. The current database limits OHCQ's ability to identify trends and patterns of level 1 adverse events.

OHCQ is exploring the possibility of obtaining a grant to expand the current data base program or obtain software with the capability of providing more robust and useful data.

OHCQ remains focused on determining the best methods to review RCAs and encouraging hospitals to report level 1 adverse events. For the future, we plan on better 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.

The main question we are not able to answer is whether these patient safety efforts will truly make a difference in protecting patients against adverse, serious, and frequently preventable errors. Is patient care in Maryland hospitals getting safer? The answer to this question will take continued time and resources. In the meantime, OHCQ looks forward to the continued interest and cooperation of Maryland hospitals and their staff.

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 thirteen 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 are smaller hospitals; the largest having 102 licensed beds, but all offer outpatient services.

Appendix B
TYPES OF EVENTS

Type of Event	3/15/04 to 6/30/04	FY 2005	FY 2006	FY 2007	Totals
Death or serious disability associated with a fall	2	30	46	55	133
Death or serious disability associated with a delay in treatment	1	16	9	22	48
Death or serious disability associated with airway management	3	13	18	9	43
Death or serious disability associated with medication error	0	11	8	9	28
Unanticipated complication of treatment	2	6	9	4	21
Suicide or attempted suicide resulting in serious disability	1	4	11	4	20
Other	0	6	6	4	16
Misdiagnosis	3	5	5	2	15
Unanticipated fetal death or injury	0	3	6	5	14
Malfunctioning device	1	3	5	4	13
Unanticipated intra-op or immediate post-op death	0	5	5	2	12
Surgical procedure not consistent with consent	1	1	2	8	12
Death or serious disability associated with the use of a vascular access device	1	6	3	2	12
Post-surgical retention of foreign body	0	4	1	6	11
Death or serious disability associated with the use of anticoagulants	1	1	2	6	10
Death or serious disability associated with a staff member's failure to act	0	2	3	4	9
Maternal death or serious disability associated with Labor & Delivery	1	3	0	2	6
Death or serious injury of patient or staff associated with health care acquired infections	0	0	1	5	6
Stage III or IV pressure ulcers acquired after admission	0	0	0	4	4
Death or serious injury of patient resulting from physical/sexual assault occurring within or on hospitals grounds	0	0	2	2	4
Death or serious disability associated with the use of restraints seclusion, or side rails	0	1	1	2	4
Death or serious disability resulting from an intravascular air embolism	0	2	2	0	4
Death or serious disability associated with hypoglycemia	0	2	1	1	4
Intra-op or post-op death in ASA 1 patient	2	0	1	1	4
Death or serious disability associated with a burn that occurred in a hospital	0	0	0	3	3
Hemolytic reaction to ABO incompatible blood products	0	0	0	1	1
Totals	**19**	**125**	**148**	**168**	**460**

Appendix C

TYPES OF EVENTS AND SUBSEQUENT OUTCOMES - FY 2007

Type of Event	Loss of limb/ function	Surgical Intervention	Medical Intervention	Death	Total
Death or serious disability associated with a fall	3	42	7	3	55
Death or serious disability associated with a delay in treatment	4	2	2	14	22
Death or serious disability associated with airway management	1			7	9
Death or serious disability associated with medication error	1		2	6	9
Surgical procedure not consistent with consent	2	6			8
Death or serious disability associated with the use of anticoagulants				6	6
Post-surgical retention of foreign body		5		1	6
Unanticipated fetal death or injury	1		2	3	5
Death or serious injury of patient or staff associated with health care acquired infections				5	5
Malfunctioning device	2			3	5
Death or serious disability associated with a staff member's failure to act	1			3	4
Suicide or attempted suicide resulting in serious disability			1	3	4
Unanticipated complication of treatment	1		2	2	4
Stage 3 or 4 pressure ulcers acquired after admission	1	2	1		4
Other		1		3	4
Death or serious disability associated with a burn that occurred in a hospital			3		3
Unanticipated intra-op or immediate post-op death				2	2
Misdiagnosis	2				2
Death or serious injury of patient resulting from physical/sexual assault occurring within or on hospitals grounds			2		2
Death or serious disability associated with the use of a vascular access device				2	2
Death or serious disability associated with the use of restraints seclusion, or side rails	1			1	2
Maternal death or serious disability associated with Labor & Delivery		1		1	2
Intra-op or post-op death in ASA 1 patient				1	1
Death or serious disability associated with hypoglycemia	1				1
Hemolytic blood reaction due to administration of ABO incompatible blood products				1	1
Totals	**21**	**59**	**22**	**66**	**168**

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 staff are incapable of inserting the airway. This category also includes the mismanagement of chronic hospital patients who have tracheostomies and may or may not be ventilator dependent.

An example of this type of event is the patient who choked on peanut butter. The staff 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.

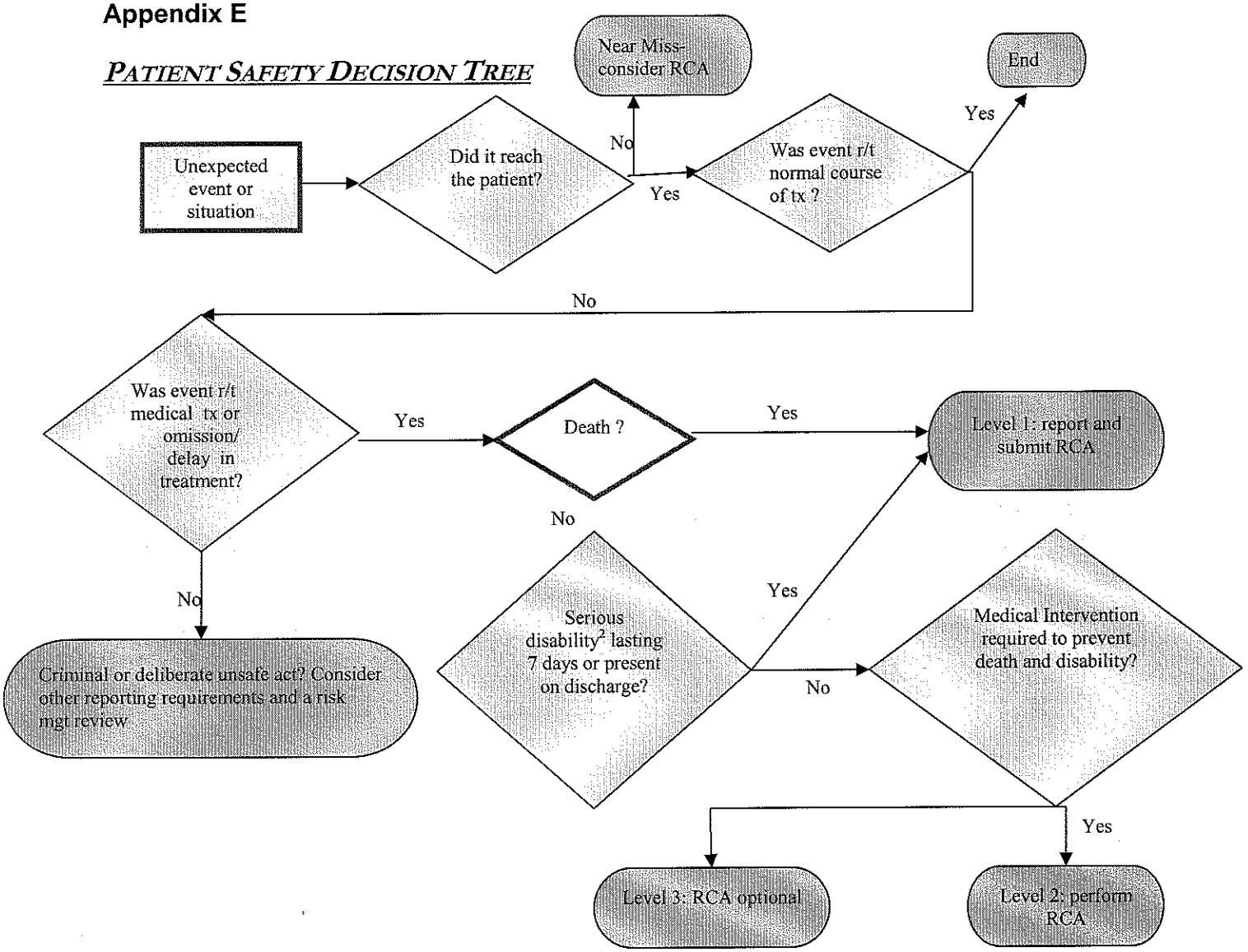
An intravascular air embolism occurs whenever air, instead of liquid, is injected into an IV. The injection of even a small amount of air can put the heart into a frequently fatal dysrhythmia. If the volume of air is enough, death ensues.

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 incident).

An example is 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

Veterans Administration National Patient Safety Center

Actions

Stronger Actions:

Architectural / physical plant changes
Tangible involvement & action by leadership in support of patient safety
Simplify the process and remove unnecessary steps
Standardize on equipment or process or care maps
New device with usability testing before purchasing

Intermediate Actions:

Checklist / cognitive aid
Increase in staffing/decrease in workload
Read back
Enhanced documentation / communication
Software enhancements / modifications
Eliminate look and sound-a-likes
Eliminate / reduce distractions (sterile medical environment)

Weaker Actions:

Redundancy / double checks
Warnings and labels
New procedure / memorandum / policy
Training
Additional study / analysis

Appendix G

PLANS OF ACTION IDENTIFIED IN ROOT CAUSE ANALYSIS

TYPE OF PROPOSED ACTION	PERCENTAGE OF 148 RCAs IDENTIFYING THIS ACTION 3/15/2005 – 6/30/2005	PERCENTAGE OF 113 RCAS IDENTIFYING THIS ACTION FY 2006	PERCENTAGE Of 134 RCAs IDENTIFYING THIS ACTION FY2007
Change In Policy/procedures	79 %	71 %	51 %
Formal education	79 %	70 %	67 %
Disciplinary actions	4 %	2 %	10 %
Process improvement	10 %	42 %	34 %
Equipment Modifications	31 %	27 %	17 %
Environmental Changes	11 %	9 %	3 %
Workload/Staffing Changes	18 %	31 %	13 %
Referral to Professional Board	0	0	3 %
Data Tracking/Trending	36 %	42 %	35 %
Reported to FDA	1 %	2 %	2 %
Peer Review	12 %	14 %	21%

**Hospitals may have taken multiple actions on one RCA.*