OHCQ
Office of Health Care Quality

DEPARTMENT OF HEALTH & MENTAL HYGIENE

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Maryland Hospital Patient Safety Program

Annual Report

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Foreword & Executive Summary

I am pleased to present the Maryland Hospital Patient Safety Program 2006 Annual Report. During the program's second full year of implementation, the number of level 1 adverse events reported by hospitals to the Office of Health Care Quality (OHCQ) increased 16 % to 148. Falls continue to be the most frequently reported level 1 adverse event. The second most frequently reported category of event is death or serious disability associated with airway management, followed by suicide/attempted suicide (Appendix A). During FY06, 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 events does not necessarily mean that errors are occurring more frequently – we believe this represents outreach efforts by the OHCQ, as well as 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. Hospital 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 RCAs truly the product of a multidisciplinary team, and do they identify basic contributory causal factors? Or, are the RCAs 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 two 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 148 events reported in FY06, only one was 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 that 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

Maryland Hospital Patient Safety Program Analysis

Mandatory Reporting of Adverse Events

In FY05, the Department of Health and Mental Hygiene (the Department) Maryland Patient Safety Program received 145 reports of adverse events, of which 125 were determined to be level 1 adverse events.[1] In FY06, 168 possible level 1 adverse event reports were received and reviewed by the Department. After review, some adverse events were reclassified to a lower (or less serious) non-reportable level. Therefore, of the 168 possible level 1 adverse events initially reported, the Department and hospitals' staff concluded that 148 were actual level 1 adverse events. This corresponds to a 16% increase between FY05 and FY06 in the total number of reported events.

In FY06, 47 out of the 69 hospitals licensed in Maryland reported at least one level 1 adverse event. Since mandatory reporting began in March 2004, 54 Maryland hospitals have contacted the Department with the report of at least one level 1 adverse event. Six of the 15 hospitals that have not reported a level 1 adverse event have contacted the Department with reports of lower level, non-reportable events. The Department has and will continue to schedule Patient Safety Program surveys at hospitals that have not reported adverse events.

Table One: Total Level 1 Adverse Events Based on Hospital Capacity FY 2006

Hospital Size Number of Licensed Beds	Number of Hospitals	Number of Hospitals Reporting	Number of Level 1 Adverse Events
300 or more beds	12	12	47
200 – 300 beds	17	16	56
100 – 200 beds	19	14	36
Less than 100 beds	21	5	9
TOTALS	**69**	**47**	**148**

Inter-hospital comparability of event reporting is difficult. The licensed bed capacity of a hospital increases the frequency of reported adverse events (Table One). In addition, the complexity and number of patient interventions and interactions in an acute care hospital are higher than in special hospitals, therefore increasing the risk of an adverse event. Larger acute care hospitals also offer services that are frequently not available in smaller community hospitals.

Early trends indicate that patients in acute care hospitals are more likely to incur level 1 adverse events than patients in special hospitals (Table Two), but the events are just as likely to be fatal in either setting. In FY06, acute care hospitals reported 133 and special hospitals reported 15 level 1 adverse events, both with nearly 60% mortality. The reported adverse events that occur in psychiatric hospitals are frequently suicides or serious self injurious/mutilating actions. Chronic special hospitals also have frequent fatal events when caring for patients with artificial airways

[1] "Level 1 adverse event," as defined in COMAR 10.01.06.03(4), means an adverse event that results in death or serious disability.

who may or may not be ventilator dependent. These deaths frequently result from lack of effective and safe practices when caring for patients with artificial airways or fragile respiratory status. Therefore, despite the lower frequency of reported events from special hospitals, it is imperative that special hospitals focus on creating safe environments for their patients.

Table Two. Total Number of Level 1 Adverse Events Per Hospital Type FY06

Hospital Type	Total Number of Hospitals	Number of Hospitals Reporting	Number of Level 1 Events
Acute General	47	38	133
Special Hospital - Psychiatric	13	5	8
Special Hospital – Other	9	4	7
TOTALS	**69**	**47**	**148**

In FY06, nearly 60% of all hospital reported level 1 adverse events resulted in death, and approximately 40% required medical or surgical intervention (Appendix A). Outcomes of the medical or surgical interventions include loss of function (15 events), increased length of stay (18 events), and loss of organ or limb (3 events). Furthermore, fourteen patients required transfer to a facility that provided a higher level of care such as a trauma center or cardiac center.

A significant number of surgical adverse events occur during procedures that are considered routine or less risky. In FY06, 18 reported level 1 adverse events occurred in operating rooms (Table Three). Death and serious adverse outcomes have been reported subsequent to procedures such as D&Cs, hemorrhoidectomies, tonsillectomies, and laparoscopic procedures such as cholecystectomies.

Types of Maryland Hospitals

Maryland regulation classifies hospitals in two groups - Acute Care and Special. Forty-seven hospitals are licensed as Acute Care and range in bed capacity from nine to 960 beds. All but one has an Emergency Department. Certain hospitals also provide specialized services such as trauma, burn and stroke care. However, not all hospitals offer services such as pediatrics, labor and delivery, and/or behavioral health. Several Acute Care general hospitals operate separate units that are dually licensed as either Chronic or Rehabilitation Special Hospitals.

Twenty-two Maryland 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 Psychiatric Special Hospitals range in size from 15 licensed to 639 licensed beds and seven are state operated. Three psychiatric hospitals serve only specific populations (children, forensics, clergy). Others may provide specialized services to specific populations such as treatment resistant patients and individuals with disabilities.
- Of the five Chronic Special Hospitals, four serve patients who are ventilator-dependent or have chronic respiratory problems. These hospitals range in size from 52 to 180 beds and two are State operated. While all provide some rehabilitation services, two of the hospitals are dually licensed as rehabilitation hospitals.
- There are two Rehabilitation Special Hospitals and two Children's Special Hospital. The children's and rehabilitation hospitals are smaller hospitals; the largest having 102 licensed beds, but all offer outpatient services.

Table Three. Location of Level 1 Adverse Event for FY 2006

Location of Events	Number of Events
Medical Surgical Units	54
Emergency Departments	19
Operating Rooms	18
Intensive Care Units	13
Psychiatric Units	10
Labor & Delivery	9
Radiology Services (including interventional)	7
Pediatrics	3
Outpatient	2
Rehabilitation	1
Nursery	1
Cardiology	1
Ambulatory Care	1
Other	9
TOTALS	**148**

The Department periodically adds classifications to its analysis as patterns and trends in reported level 1 adverse events occur. For example, in FY06, five out of seven level 1 adverse events classified as "Other" were determined to be hospital acquired infections. As a result, a hospital acquired infection classification will be added to the database in FY07. Appendix B includes definitions and examples of the types of adverse events reported.

In some cases, the only way to accurately determine cause of death is to perform an autopsy. For a variety of reasons, autopsies are decreasing nationwide and are performed in less than 12% of deaths in teaching hospitals and less than 4% in smaller, rural hospitals.[2] Data for FY06 reveals that only 20 autopsies were preformed out of the 88 reported level 1 adverse event deaths. While this number compares favorably with the nationwide average, an increase in autopsies preformed would provide valuable reporting information.

The Patient Safety Workgroup – Working with Hospitals to Refine the Reporting Process

In order to improve reporting and decrease the confusion about what type of events must be reported, in January 2006, the Department formed a workgroup composed of Department staff and hospital patient safety officers. The workgroup's primary task was to develop a tool to simplify the decision making process regarding what qualifies as level 1 adverse event. The workgroup developed a Patient Safety Decision Tree (Appendix C) for hospital staff to use when determining if an event qualifies as level 1.

The Patient Safety Workgroup has also addressed several other needs that were identified throughout the first 18 months of reporting. Hospitals expressed concern that performing a root cause analysis[3]

Case Review

A patient was admitted to a psychiatric special hospital on a Friday evening after two unsuccessful suicide attempts. The admitting nurse recognized that the patient was at risk for self harm, but did not put the patient on a one-to-one observation because of the nurse's perception that an unwritten budget policy did not allow for one-to-ones. The patient was depressed, gave his belongings away, and was actively hallucinating. A psychiatrist is on duty every weekend, but failed to see the patient or write admitting orders. Because the admitting nurse recognized that the patient was at risk for self harm, she was able to motivate the staff to keep a close eye on the patient and no suicide attempts were made over the weekend. On Monday morning, the nurse communicated her concerns to the on-coming staff. The patient was not seen by a psychiatrist or other mental health professional on Monday. That evening, when staff were busy with dinner, the patient went into the bathroom and hanged himself using a bed sheet knotted over the bathroom door. The patient was unconscious when staff found him. In this case, staff misunderstanding and complacency nearly had dire results.

[2] http://neoreviews.aappublications.org/cgi/content/extract/4/8/e207

[3] "Root cause analysis," as defined in COMAR 10.01.06.03(10), means a medical review committee process as defined under Health Occupations Article, §1-401, Annotated Code of Maryland, for identifying the basic contributing causal factors that underlie variations in performance associated with adverse events or near-misses.

(RCA) for every reported level 1 adverse event fall was cumbersome and difficult to complete due to the frequency of falls. As a result, hospitals with multiple falls over a short period of time are now afforded the opportunity to perform an aggregate RCA, i.e., reviewing multiple falls in one RCA. One Maryland hospital that experienced six level 1 adverse event falls over a short period of time submitted an aggregate RCA. As a result of the lessons learned through the aggregate RCA, the hospital has since made sweeping changes in fall protocols, and now reports a substantial decrease in the number of falls. Other hospitals have elected to review each fall on a case by case basis. In addition, the Department, working with the Patient Safety Workgroup, developed a short form for submitting RCAs regarding falls (Appendix D) which is a viable alternative to completing a full RCA for each and every fall.

Additionally, the Department, with the assistance of the Patient Safety Workgroup, developed a standardized reporting form to request a change in classification of a reported adverse event (Appendix F). In some instances after reporting an event, a hospital may receive additional information about an event that requires a downgrade in the event level. Occasionally, autopsy results reveal that a level 1 adverse event is non-reportable, or that the death occurred due to an underlying health condition which was not the result of a preventable error. For instance, a fall resulting in death initially seems to be a level 1 adverse event, but the death may actually turn out to have been caused by a massive stroke.

Case Review

A patient was taken to the operating room for a common minor surgical procedure. The surgeon preferred to use two different solutions during surgery, one for injection and one for topical use. Because no other surgeon in the hospital used this particular set-up, the scrub personnel were not as familiar with the surgeon's use of these solutions. The solutions were labeled in accordance with hospital policy. As the surgeon switched back and forth between the solutions, the scrub tech became confused and the patient received at least one injection of the topical medication. The patient suffered a permanent loss of function and could possibly require an organ transplant. In this case, the lack of standardization of processes in the operating room and the non-evidence based nature of the surgeon's preferences had a near-fatal outcome.

Notifying Patients and/or Families and JCAHO of Adverse Events

The Maryland Hospital Patient Safety Program and Maryland regulations require hospitals to notify a patient, or if appropriate, a patient's family member, whenever an outcome of care differs significantly from an anticipated outcome.[4] In FY06, hospitals reported notification to the patient or family member of an unanticipated outcome had occurred in 131 (89%) of the 148 level 1 adverse events. This is a significant improvement from FY05 when hospitals reported that families notification occurred in only 46 (37%) of the 125 level 1 adverse events.

Of the level 1 adverse events reported to the Department in FY06, only six were also reported to the Joint Commission on Accreditation of Healthcare Organizations[5] (JCAHO). While JCAHO

[4] COMAR 10.07.06.11(F)

[5] Joint Commission on Accreditation of Healthcare Organizations is the nation's oldest and largest accrediting body for health care organizations. *http://www.jcaho.org*.

requests hospitals to voluntarily report sentinel events,[6] it does require 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. During JCAHO's triennial surveys and when conducting complaint investigations, JCAHO staff review and critique the RCAs for sentinel events. Maryland does not have a statutory requirement that hospitals report adverse events to JCAHO.

Root Cause Analyses

Root cause analyses[7] (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 hospital review human factors, processes and systems, and underlying cause and effect. The hospital is also to identify risks and contributing factors for recurrence, and determine what improvements in systems or processes are needed.

During the first year of the Program's implementation, the Department examined how to best review the RCAs submitted by hospitals, and developed a review tool to ensure the RCAs comport with regulations. During the second year, the Department has worked to develop a consistently objective review process. Using the tool developed in year one, all RCAs are reviewed by a nurse surveyor who presents a selection of the RCAs, based on the failure of the RCA to meet standards, the egregiousness and urgency of the event, or any indications of a trend forming, to the Patient Safety Committee.[8]

If the RCA is incomplete or inadequate, the Department will make recommendations and request that the hospital resubmit the RCA, provide additional information about how the RCA team came to its conclusion, or meet with the Department. The Department provides a great deal of formal and informal feedback to the hospitals regarding adverse events and RCAs.

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[6] Sentinel events subject to JCAHO reporting are those that have resulted in unanticipated death or major permanent loss of function not related to the patient's illness or underlying condition or if the event is one of the following (even if the outcome was not death or major permanent loss of function): 1)suicide of a patient in a setting where around-the-clock care was received or within 72 hours of discharge; 2) Abduction of a patient, 3) discharge of an infant to the wrong family, 4) rape, 5)hemolytic transfusion reaction involving major blood group incompatibilities, 6) surgery on the wrong individual or wrong body part, 7) Unintended retention of a foreign object in an individual after surgery or other procedure, or 8) delivery of radiotherapy to the wrong body region.

[7] "Root cause analysis," as defined in COMAR 10.01.06.03(10), means a medical review committee process as defined under Health Occupations Article, §1-401, Annotated Code of Maryland, for identifying the basic contributing causal factors that underlie variations in performance associated with adverse events or near-misses.

[8] The Patient Safety Committee is an internal committee comprised of Department of Health and Mental Hygiene Office of Health Care Quality staff that includes the Medical Director, Chief Nurse, Patient Safety Nurse Surveyor, and the Assistant Director for Hospitals, Laboratories, and Patient Safety. See Appendix H for committee listing.

RCAs submitted to the Department continue to be problematic. Many RCAs do not go deep enough, either in the analysis or the corrective actions. Hospitals still have a tendency to find a person, often a nurse, to blame for the adverse event, and, at times the patient or family is blamed. Many hospitals have difficulty considering that processes and systems might be deficient or broken and that failure, not the individual's performance, must be addressed to prevent the same adverse event from recurring.

In many of the RCAs reviewed, the Department noted similar problems. The most frequent include:

- *Failure to investigate and find the root cause(s).* Hospital staff conducting the RCA often stopped asking "why" before they reached the true root cause. For example, a hospital reported a case of a woman who had a planned abdominal surgery. In the weeks following the surgery, she continued to complain to her physician that she was experiencing nausea, diarrhea, and other gastrointestinal problems. Her physician referred her to a gastroenterologist, but two months after the surgery and before she went to the appointment with the specialist, she returned to the hospital with severe gastrointestinal symptoms. After further diagnostic work up, it was determined that the patient had a retained sponge from her previous surgery that had caused the erosion of a section of her intestines. A review of the RCA revealed that the hospital identified the following root causes: surgical staff did not follow standard surgical count procedures; surgical staff did not complete the count sheet; and surgical staff competencies were not regularly evaluated. The RCA did not delve any deeper to determine why policies and standard procedures were not followed. What were the conditions that allowed or even encouraged these kinds of work-arounds? What were the expectations for supervision and accountability? Before RCA teams give in to the easy tendency to "blame and shame," they need to ask, "Is this the last health provider who will make this mistake?"
- *Failure to develop an appropriate corrective action plan*[9]*to address the root cause(s).* Often RCAs indicate that staff would be retrained or in some cases disciplined as the corrective action plan. The intent of the regulations is to focus hospitals on the system faults that underlie level 1 adverse events. Appendix G identifies what actions have been implemented by hospitals according to RCAs. Data reviewed from RCAs submitted during the first 15 months of the program indicate that the most frequent plan of action identified was changes in policies and procedures and training. Improved processes were identified in 42% of the RCAs reviewed in FY06. Only 10% of the RCAs submitted in the first 15 months of mandatory reporting identified process improvement in the corrective action plan. Process improvement is a stronger action that is more likely to drive change and prevent a recurrence.

[9] "Action plan," as defined in COMAR 10.01.06.02(B)(1), means a 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 and specific measure; and title of responsible individual to monitor implementation and effectiveness.

Additionally, the data indicate that hospitals are responding to adverse events in FY06 by addressing staff and workload changes 31% of the time, versus 18% as reported during the first 15 months of the program. This does not mean that hospitals are throwing people at a problem, but that they are trying to work smarter with the staff they have. While these data are a sign that some hospitals understand the need for stronger actions as a result of an adverse event, further improvement and compliance is needed.

- *Timeliness of hospital intervention.* An additional problem with action plans submitted by the hospitals is the length of time required to fully implement the corrective actions for identified unsafe practices. The hospitals sometimes fail to recognize the urgency and the need to promptly implement corrective measures to prevent another serious or life threatening event from recurring. Corrective measures that involve capital investment or structural changes may take some time, however, straightforward changes, like revising a form, should be implemented within a reasonable timeframe.

- *Failure to develop outcome measures to determine if the corrective action plans have been effective in correcting the root cause(s).* According to the RCAs reviewed, hospitals frequently have difficulty trying to measure the results of corrective actions. For example, an outcome measure will state "100% of the surgical staff will attend training on the new surgical count procedure within 60 days." While this can be effective in determining how many staff attended an in-service, it does not reflect whether the procedure change has been effective in improving safety. Effective change cannot be determined unless the process is measured. Instead the hospital could state that "thirty surgeries will be audited each month until 100% compliance with the new surgical count procedure is maintained for three consecutive months." If the hospital's audit determines there is continued non-compliance with a policy or procedure, the hospital should review and revise the policy or procedure as appropriate.

Hospital Complaints from the Public

Outside of the Patient Safety Program, the Department continues to receive and review complaints from the public. The Department received 339 quality of care complaints during FY06. Of these complaints, only one was also reported as an adverse event by the hospital. Since reporting began in March 2004, 348 adverse events were reported by Maryland hospitals and over 650 hospital complaints were received by the Department. Only five adverse events were also received as complaints and investigated using the usual complaint resolution process. This emphasizes the value of mandatory reporting. The Department would not know the scope of adverse events if it relied solely on complaint data.

Hospital Patient Safety Plans

When the Patient Safety regulations were implemented in 2004, all hospitals submitted patient safety plans in accordance with the COMAR 10.07.06.14 (A). While the Department has not mandated that hospital staff revise and resubmit their plans on a regular basis, hospitals are

required to resubmit the plans when the plan is revised. Hospitals that have made revisions have submitted the revised plans and have received feedback from the Department. Revisions made by the hospitals during FY06 reflect a better understanding of the Patient Safety regulations.

Clinical Alerts

To disseminate important information, including trends and patterns obtained through the RCA reviews, the Department has released several Clinical Alerts.[10] Clinical Alerts are disseminated to hospitals with the intention of preventing the recurrence of the same type of event in a different hospital. The most recent Clinical Alert currently under development is "Alarm Complacency and Patient Safety," discussing patient events resulting from hospital staff failure to hear or address alarms in a noisy, busy environment.

As part of the continued development and expansion of the Department's Patient Safety Unit, it is anticipated that reviews of the RCAs will provide further information that can be used to develop Clinical Alerts and other educational materials on a regular basis.

Maryland Patient Safety Center

The Maryland Patient Safety Center (MPSC) is not part of the Department, but 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.[11]

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

- Representation on the MPSC Advisory Board;
- Representation on the MPSC Education Committee;
- Regular attendance at training workshops sponsored by MPSC; and
- Attendance when requested at the MPSC Patient Safety Directors' meetings.

In addition to the Department staff attending the RCA training sessions at the MPSC, the Patient Safety Unit has provided de-identified RCAs and other data for the MPSC RCA training classes which will assist in the development of curriculum that will further drive improvements in crafting root cause analyses.

[10] Clinical alerts are posted on the Department's Web site at *www.dhmh.md.gov/ohcq/alerts/alerts*.
[11] Maryland Patient Safety Center. *www.marylandpatientsafety.org*.

Observations and Questions

Despite continuing challenges posed to the Department in mining data, possible underreporting of level 1 events by hospitals and the poor quality of some of the submitted RCAs, the Patient Safety Committee feels that the efforts of all those working to improve safety in Maryland hospitals is beginning to bear fruit. Hospital patient safety staff appear more comfortable reporting serious adverse events and sharing details of cases with the Department. The majority of hospitals seem to be embracing the need to critically examine all adverse events, and the idea of changing to a "culture of patient safety" does not seem so far out of reach.

The main question we are not yet able to confidently answer is the real impact of the work we are all doing together in protecting patients against adverse, serious and frequently preventable events. The fact that there was a 16% increase in the reporting of actual level 1 adverse events from FY05 to FY06 might be interpreted as improvement in the quality of reporting, or perhaps that more adverse events are actually occurring. Other questions remain:

- Falls continue, for the second year in a row, to be the most frequent level 1 adverse event reported. As the age of hospitalized patients increases, and the number of medications taken by patients increases, it is expected that falls will continue to be a major issue for some time to come. Moreover, patients who are placed on "fall precautions" do not seem to fare any better than those not on such precautions. Why is that and what can be done to decrease falls as a major cause of reported level 1 adverse events?

- There appears to be more risk for a level 1 adverse event occurring to a patient in a psychiatric facility located in a specialty hospital than in an acute hospital. Why is this so? Is it related to the shorter length of stay in an acute hospital, or to differences in the type of hospital? The same questions can be asked about patients with chronic respiratory problems; many of the errors reported involve the management of ventilators.

- While there was improvement in the percentage of cases in which the patient or family was notified of a level 1 adverse event, why is it that in 10% of the cases the patient or family is not notified?

The questions being discussed in Maryland are quite similar to those being debated nationally. In 1999, the Institute of Medicine (IOM) released the report, *To Err is Human*, in which brought the issue of hospital patient safety to the forefront nationally, as well as in Maryland (National Academy Press, Washington, DC). The Department is following closely the work that has been done since then. Recently, a coalition of health care purchasers, quality groups, and government agencies, working with the National Quality Forum, the leading government advisory body on health care quality measurement and standards, have agreed to endorse a single set of 30 Safe Practices, which all hospitals should implement to prevent death and injury (Wall Street Journal, Nov. 6, 2006). We will incorporate this work and these Safe Practices as we move forward.

National Exposure

As other States begin to develop patient safety programs, Maryland has been recognized as a resource on a national level. The Maryland Patient Safety Program's activities on a national level include:

- In October 2006, a presentation to the National Quality Forum regarding the types and numbers of level 1 adverse events received over the first 18 months of the program.

- In May 2005, Maryland participated in a meeting conducted by the National Academy for State Health Policy (NASHP) to identify mechanisms to improve reporting and data dissemination. The resulting report, *Maximizing the Use of State Adverse Event Data to Improve Patient Safety*, was published in October 2005 by NASHP.

- In January 2006, the Maryland Patient Safety Program presented the webcast *How States are Using Adverse Event Data to Improve Patient Safety*. The webcast was sponsored by NASHP and the Commonwealth Fund.

- The Maryland Root Cause Analysis Tool was presented in 2004 to the Agency for Healthcare Research and Quality and Veteran's Administration Patient Safety Improvement Corp (PSIC). Maryland has been asked to present its project to the PSIC training session in both 2005 and 2006.

Future Plans

A key component in any private or public Patient Safety Program is sharing information. Information sharing provides hospitals with the opportunity to review systems and procedures and make proactive changes to prevent the adverse event from recurring. Dissemination of information, in the form of Clinical Alerts, has proven to be a valuable tool, and the Department intends to increase the number of Clinical Alerts in the upcoming fiscal year. Additionally, the Department will:

- 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 where Clinical Alerts and other information would be posted;
- Develop quarterly lessons learned from the received reports and post to the web page;
- Continue information sharing via email to all patient safety coordinators; and
- Continue participation in the educational offerings provided by the Maryland Patient Safety Center.

In addition, information technology is needed to improve the analysis of RCAs. The current database limits the Department's ability to identify trends and patterns of level 1 adverse events. The Department is exploring the possibility of expanding the current data base program or obtaining software with the capability of providing more robust and useful data.

During the first fiscal year of implementation, the Department focused on determining the best methods to review RCAs and encouraging hospitals to report level 1 adverse event. Future plans include better analysis and use of data accumulated. The Department is continually challenged with making useful comparisons between hospitals, identifying trends in events and corrective actions, and attaching meaning to the data.

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

Appendices

Appendix A: Types of Events and Subsequent Intervention

Type of Event	Surgical Intervention	Medical Intervention	Death	Total
Death or serious disability associated with a fall	28	7	11	46
Death or serious disability associated with airway management		2	16	18
Suicide or attempted suicide resulting in serious disability		4	7	11
Unanticipated complication of treatment	3		6	9
Death or serious disability associated with a delay in treatment			9	9
Death or serious disability associated with medication error	1	1	6	8
Other	4		3	7
Unanticipated fetal death or injury		1	5	6
Unanticipated intra-op or immediate post-op death			5	5
Misdiagnosis	3		2	5
Malfunctioning device			5	5
Death or serious disability associated with the use of a vascular access device			3	3
Death or serious disability associated with a staff member's failure to act			3	3
Death or serious disability associated with the use of anticoagulants			2	2
Intravascular air embolism			2	2
Surgical procedure not consistent with consent	2			2
Sexual assault of a patient within or on the grounds of a facility		1		1
Post-surgical retention of foreign body	1			1
Death or serious injury of patient or staff resulting from physical assault occurring within or on the grounds of a facility		1		1
Death or serious disability associated with the use of restraints, seclusion, or side rails			1	1
Death or serious disability associated with hypoglycemia			1	1
Hemolytic blood reaction due to administration of ABO-incompatible blood or blood products		1		1
Intra-op or post-op death in ASA 1 patient			1	1
Total	**42**	**18**	**88**	**148**

Appendix B: 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.

Malfunctioning devices accounted for five deaths in FY06. These were most often associated with poor design that set the users up for fatal errors.

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.

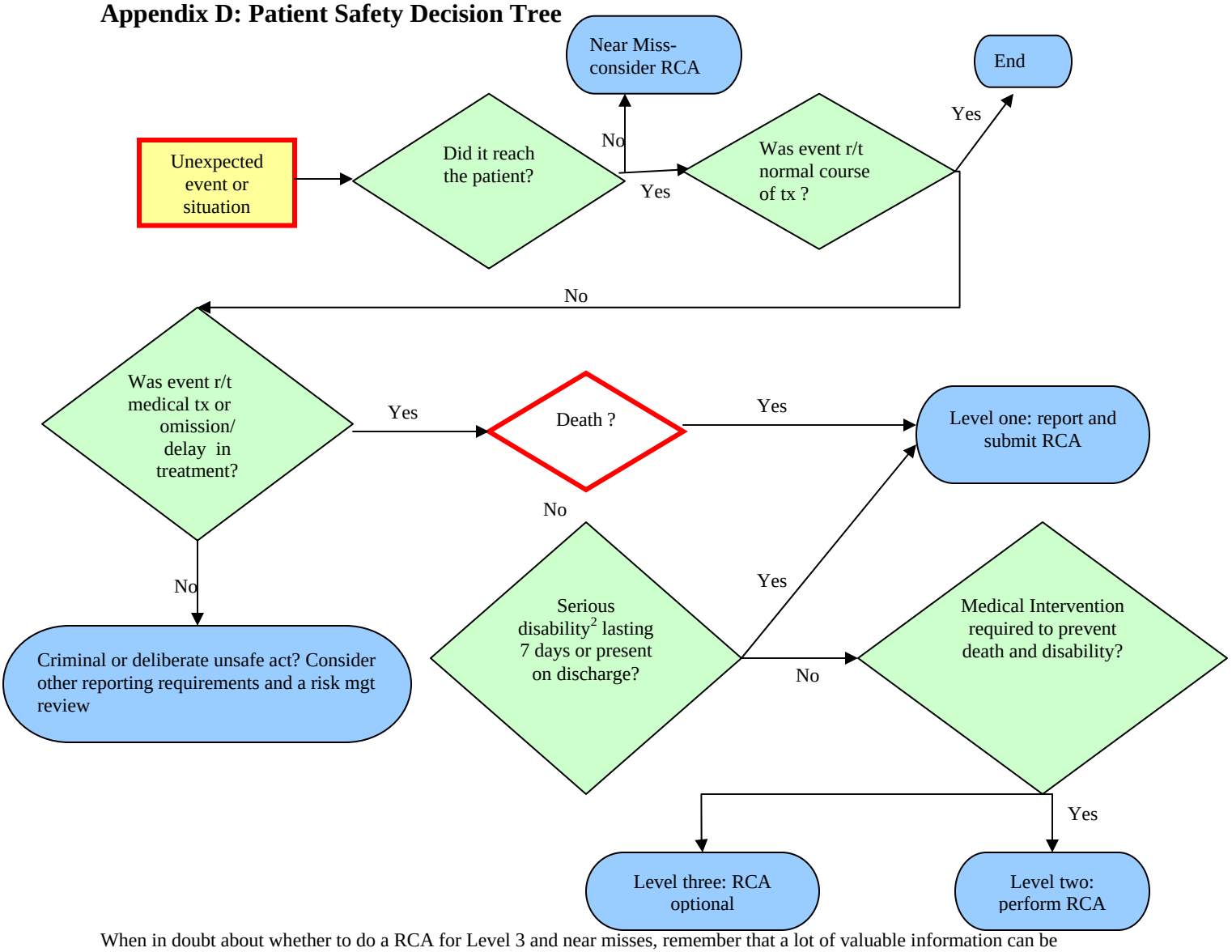
Unanticipated intra-operative death and the death of an ASA patient are similar except that the unanticipated intra-operative or immediately post-operative death occurs in people that are not categorized as ASA 1. (The American Society of Anesthesiologists (ASA) classification 1 is a normal healthy patient who is expected to come through anesthesia 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 C: Total Number and Type of Level 1 Adverse Events Since Program Inception

77	5D. Death or serious disability associated with a fall
32	4L. Death or serious disability associated with airway management
25	4K. Death or serious disability associated with a delay in treatment
19	4A. Death or serious disability associated with medication error
19	3C. Suicide or attempted suicide resulting in serious disability
19	4J. Misdiagnosis
17	4N. Unanticipated complication of treatment
11	1F. Unanticipated intra-op or immediate post-op death
10	2E. Death or serious disability associated with the use of a vascular access device
10	4M. Unanticipated neonatal death or injury
9	2B. Malfunctioning device
9	6G. Other
7	4I. Death or serious disability associated with the use of anticoagulants
5	4H. Death or serious disability associated with a staff member's failure to act
4	1D. Post-surgical retention of foreign body
4	2C. Intravascular air embolism
3	4C. Maternal death or serious injury associated with labor or delivery
3	1C. Surgical procedure not consistent with consent
3	1E. Intra-op or post-op death in ASA 1 patient
3	4D. Death or serious disability associated with hypoglycemia
2	4B. Hemolytic blood reaction due to administration of ABO-incompatible blood or blood products
2	5E. Death or serious disability associated with the use of restraints, seclusion, or side rails
2	6C. Sexual assault of a patient within or on the grounds of a facility
1	1A. Body part not consistent with consent
1	2A. Contaminated drug, device, or biologic
1	6D. Death or serious injury of patient or staff resulting from physical assault occurring within or on the grounds of a facility
0	5C. Death or serious disability associated with a burn that occurred in a healthcare facility
298	**TOTAL EVENTS**

Appendix D: 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 DIC 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 E: Short RCA for Reviewing Patient Falls

Hospital Name:	Event #

All falls resulting in a Level 1 injury (death or serious disability lasting seven days or present on discharge) must be reported in accordance with the requirements of 10.07.06. This form may be used in lieu of a root cause analysis.

Please report the following:

1.	**Patient date of birth:**				
2.	**Patient sex:**				
3.	**Patient admit date:**				
4.	**Patient admitting diagnoses:**				
5.	**Event day, date, time:**				
6.	**Number of routine medications:**				
		Yes	**No**		
7.	**Was event witnessed?**				
8.	**Was family notified?**				
9.	**Was physician notified?**				
10.	**Functional and cognitive contributory or causal factors:**	**Yes**	**No**	**Root Cause**	**Contr. Factor**
a.	Pt. assessed as fall risk				
b.	Appropriate interventions in place				
c.	Recent change in meds				
d.	Incontinent or foley				
e.	Dependant for ADLs				
f.	Gait or balance limitations				
g.	Need for assistive devices				
h.	Confusion or memory deficits				
i.	Sedated or on pain meds				
j.	Related medical conditions				
k.	Did care plan address these issues?				

Short RCA for Reviewing Patient Falls

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11. Did communication breakdown contribute to fall?	Yes	No	Root Cause	Contr. Factor
a. Staff to staff				
b. Staff to/from patient				
c. Staff to/from family/other				
d. Physician to/from patient/staff				
e. Patient/family education				
12. Environmental factors:	**Yes**	**No**	**Root Cause**	**Contr. Factor**
a. Use of restraints				
b. Use of protective devices				
c. Adequate footwear				
d. Bed side rails (specify number):				
e. Floor condition				
f. Physical obstacles				
g. Adequate personnel				
h. Adequate lighting				
i. Bed/wheelchair locked				
j. Equipment failure				
k. Bed alarm in use				
l. Fall during transfer				
m. Other (specify):				
13. What happened, including description of injury?				
14. Patient-specific care plan changes:				
15. Facility post-fall actions:				

Appendix F: Request to Change the Classification of a Reported Adverse Event

COMAR 10.07.06 requires that a level 1 adverse events be reported to the Office of Health Care Quality within 5 days of the hospital becoming aware of the event. In order to comply with this requirement, hospitals may report an event prior to having the necessary information to determine if the event qualified as a level 1 adverse event. If further investigation by the hospital has uncovered information that changes the status of an event previously reported to the Office of Health Care Quality as a level 1 adverse event, hospitals may request a change in the status of an event by completing this form and submitting it to the Office of Health Care Quality, Hospitals, Laboratories and Patient Safety Unit, Spring Grove Center, Bland Bryant Building, 55 Wade Avenue, Catonsville, Maryland 21228, FAX (410) 402-8167.

1. OHCQ event number:
2. Date reported:
3. Initial level classification:
4. Change requested by:
5. Phone number:
6. Requested new classification:
7. Rationale for change:
8. If the hospital believes that peer review is the only appropriate response to this event, please answer the following questions:

   a. Was the standard of care met?

   b. Did the organization look for underlying system issues such as communication, work environment and availability of information?

   c. Were the actions immediately preceding the adverse event under the sole control of the provider(s)?

   d. Have you observed a trend with this (or these) provider(s)?

Staff of the Office of Health Care Quality will notify the Hospital's Patient Safety Director or designee by phone if additional information is needed.

Appendix G: Plans of Action Identified in Root Cause Analysis

Proposed Action	**% RCAs Identifying This Action** ***3/15/2005 – 6/30/2005***	**% RCAs Identifying This Action** ***FY 2006***
Change In Policy/procedures	79%	71%
Formal education	79%	70%
Disciplinary actions	4%	2%
Process improvement	10%	42%
Equipment Modifications	31%	27%
Environmental Changes	11%	9%
Workload/Staffing Changes	18%	31%
Referral to Professional Board	0%	0%
Data Tracking/Trending	36%	42%
Reported to FDA	1%	2%
Peer Review	12%	14%

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

Appendix H: The Office of Health Care Quality Patient Safety Committee Member List

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