OHCQ
Office of Health Care Quality

DEPARTMENT OF HEALTH & MENTAL HYGIENE

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Maryland Hospital Patient Safety Program

Annual Report

Fiscal Year 2005

MARYLAND

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Foreword

April 2006

I am pleased to present the first annual report on Maryland's Hospital Patient Safety Program. Over the first full fiscal year of the Program, Maryland hospitals reported 125 level 1 adverse events, of which over half resulted in patient death. Only three of these events were reported to the Office of Health Care Quality (OHCQ) as complaints from the public. Thus, the vast majority of these serious events would not have been known to OHCQ absent the Patient Safety Program. Falls, treatment delays, problems with airway management, and medication errors were the largest categories of reported events.

As a part of the Patient Safety Program and based on analysis of the events reported, the OHCQ: issued three "Clinical Alerts," coordinated hospital training on root cause analysis, conducted full-scale patient safety reviews of two hospitals, and issued two sets of deficiencies for inadequate internal quality systems which had failed to identify and assess level 1 adverse events.

The OHCQ continues to work with hospitals to implement and refine the Maryland Hospital Patient Safety Program. While our activities will remain largely educational and oriented towards sharing the information learned through hospital reporting, there will also be a firm regulatory response to hospitals that do not report obvious level 1 adverse events.

Clearly there is more work to be done in this important area. The Department of Health and Mental Hygiene has recently devoted additional personnel to the Hospital Patient Safety Program. The addition of these new patient safety nurses will enhance our ability in future years to work with hospitals to analyze error trends and rates with the mutual goal of enhancing patient safety.

I thank you for your continued support of the Office of Health Care Quality.

Very truly yours,

Wendy A. Kronmiller
Director

Background

In 1999, the Institute of Medicine (IOM) released the report, *To Err is Human*, in which it was asserted that health care in the United States is not as safe as it should be and that at least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented.[1] The IOM also released a second report in 2001, *Crossing the Quality Chasm*, which provided a strategic direction for the redesign of the health care delivery system. In response to growing public attention over the reports, numerous state legislatures and regulatory agencies instituted patient safety programs that recommend voluntary and/or required mandatory reporting of adverse events and near misses.[2]

At the time of the IOM reports, Maryland hospitals, under federal requirements, were only required to report deaths that occurred while a patient was in seclusion or restraint. In addition, state operated hospitals were required to report the death of any patient, regardless of the cause, to the Department.[3]

To address the growing concerns about patient safety in Maryland, the Maryland General Assembly passed the "Patients' Safety Act of 2001," which charged the Maryland Health Care Commission, in consultation with the Department of Health and Mental Hygiene (Department), with studying the feasibility of developing a system for reducing the incidence of preventable adverse medical events, including but not limited to a system of reporting such incidents.[4] To facilitate this request, the Patient Safety Coalition was established and recommended a three-prong approach that included 1) the creation of a Patient Safety Center, 2) development of systems within Maryland health care facilities to prevent adverse events and enhance patient safety, and 3) revising the Risk Management regulations.

A subcommittee, which included representation from the Department, the Maryland Hospital Association, malpractice carriers, hospitals, and the Maryland Society for Healthcare Risk Management[5], was formed to review and evaluate the Risk Management Regulations. Based on recommendations from the subcommittee, the Department promulgated new regulations to strengthen hospital accountability for certain adverse medical events that cause death or harm to patients and strengthen the internal reporting and evaluation systems. The regulations, effective March 15, 2004, implemented the Maryland Hospital Patient Safety Program[6], which includes:

- Establishment of an internal reporting and investigation system for adverse events[7] and near misses in a non-punitive environment;

[1] Institute of Medicine. To Err is Human.
[2] Maryland Health Care Commission. Final Report on the Study of Patient Safety in Maryland.
[3] Health General Article §5-805
[4] Maryland Health Care Commission. Final Report on the Study of Patient Safety in Maryland.
[5] List of Participants for the Subcommittee on Patient Safety Regulations can be found in the Maryland Health Care Commission's Final Report on the Study of Patient Safety in Maryland, Appendix H.
[6] Code of Maryland Regulations (COMAR) 10.07.06.
[7] "Adverse event," as defined in COMAR 10.01.06.03(2), means 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.

- Notification of families/patient when a patient has a negative outcome as a result of an adverse event;
- Performance of a root cause analysis[8] (RCA) for all level 1[9] and level 2[10] adverse events;
- Notification to the Department when a level 1 adverse event occurs;
- Submission of the RCA to the Department for review;
- Identification of a Patient Safety Designee/Coordinator; and
- Communication between hospitals when a hospital receives a victim of an adverse event after discharge from another hospital.

Maryland Hospital Patient Safety Program Analysis

Mandatory Reporting

In FY04, there were only six cases of hospital self-reported level 1 adverse events to the Department (Table One). After implementation of the Maryland Hospital Patient Safety Program, in FY05 the Department received and reviewed 145 possible level 1 adverse event reports. After review, some reports were classified a lower level (or less serious) adverse event and thus non-reportable. In a few cases, the adverse event was determined to be the result of a single health care practitioner's mishap and the Department verified that the case was properly reviewed by the hospital's peer review process. Also, in one case, an autopsy revealed that the death of the patient was the result of a medical condition and not the result of an adverse event. Of the 145 possible level 1 adverse events initially reported, the Department and hospitals' staff concluded that 125 were actual level 1 adverse events.[11] It is these 125 level 1 adverse events that make up the substance of this analysis.[12]

Table One. Hospital Self-Reported Level 1 Adverse Events to the Department FY04 & FY05

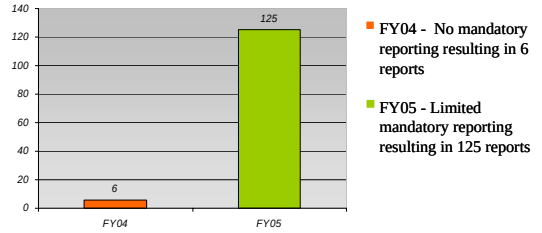
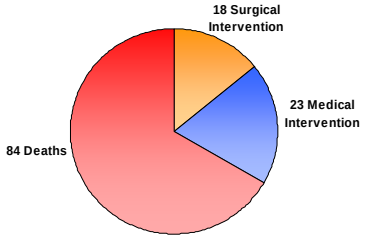


Table Two. Summary of Level 1 Adverse Event Outcomes



Eighty-four of the 125 level 1 adverse events resulted in death while 24 required medical intervention and 18

[8] "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.
[9] "Level 1 adverse event," as defined in COMAR 10.01.06.03(4), means an adverse event that results in death or serious disability.
[10] "Level 2 adverse event," as defined in COMAR 10.01.06.03(5), means an adverse event that requires a medical intervention to prevent death or serious disability.
[11] To dispel any lingering confusion as to what constitutes a level 1 adverse event, the Department continues to work with hospital representatives to provide examples and clarify definitions.
[12] In only three instances did the patient or a family member file a complaint with the Department and two out of the three complaints resulted in deficiencies being cited to the hospital involved.

required surgical intervention (Table Two). Both interventions, medical and surgical, resulted in an increased length of stay in the hospital for the patients involved. Falls were the most frequently reported level 1 adverse event (24%) with 12 of the falls resulting in death and 11 requiring medical intervention.[13] Often, the patients who fell were on anticoagulants and suffered a subdural hematoma or a subarachnoid hemorrhage as a result of a head injury.

While the elderly were most frequently the victims of falls, reported deaths due to the failure to maintain a patient's airway more frequently occurred with younger patients. The Department received 13 reports (10%) of failure to maintain a patient's airway; nine of which resulted in death. In one case, a young male sustained a severe traumatic injury to the face and was taken to the Emergency Department. The patient was admitted to the inpatient surgical unit, for five hours, while awaiting surgery. In route to the operating room, his airway occluded from massive swelling and there was no resuscitation equipment readily available. The patient died. In a second case, a young male patient, who was morbidly obese, was having an elective surgical procedure. The procedure was performed under local anesthesia and the patient was placed in a knee to chest position. When the patient experienced difficulty breathing, the anesthesiologist informed the surgeon and requested that the patient be repositioned. The surgeon refused to turn the patient over, stating that he only needed to do a few more stitches to complete the surgery. The patient then went into respiratory arrest and suffered permanent neurological damage.

Hospital reports indicate that more than half of all level 1 adverse events occur in the in-patient medical surgical units (38%) and operating rooms (16%) with all other hospital locations accounting for the remaining 46% of the reported events (Table Three).

Table Three. Location s in Hospitals of Level 1 Adverse Events

Location	# of Events
Medical/Surgical Units	47
Operating Rooms	20
Critical Care Units	14
Emergency Departments	11
Labor and Delivery	9
Psychiatry	7
Radiology	6
Other	11
Total	**125**

The Department received level 1 adverse event reports from 43 of the 69 Maryland hospitals. In addition, six hospitals[14] had contacted the Department with reports of adverse events that were determined not to be subject to the mandatory reporting requirements.[15] Almost 95% of the level 1 adverse events reported were received from acute care hospitals. Ten (21%) of the 48 total acute care hospitals located in Maryland had accounted for more than half of the level 1 adverse events reported.[16]

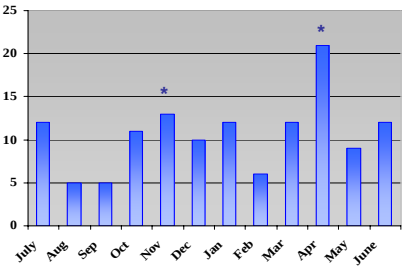
Table Four. Number of Level 1 Adverse Events by Hospital Type

Type of Hospital	# of Hospitals	# of Hospitals Reporting an Adverse Event	# of Reports of Level 1 Adverse Events
Acute General Hospitals	48	38	118
Special Hospital - Psychiatric	13	4	4
Other Special Hospitals	8	1	3
Total	**69**	**43**	**125**

[13] See Appendix A for the categories of level 1 adverse events, FY05.
[14] These six hospitals are not included in table four as reporting an adverse event.
[15] (COMAR) 10.07.06.
[16] Reports of deaths received from State operated psychiatric hospitals required by Health General Article § 5-805 are not included in these totals unless the death met the definition of a level 1adverse event.

On average, the Department received 10 level 1 adverse event reports per month, with increased reporting in the months following Department presentations to hospital quality improvement/risk management staff (Table Seven). The Department receives adverse event reports from the hospital's patient safety designees, risk managers, or performance improvement staff and over half of the reports are via telephone. Hospitals may also submit reports to the Department via fax, email, and in writing.[17]

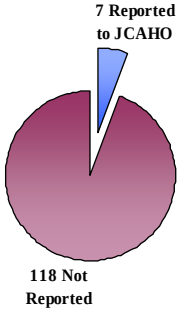
Table Five. Number of Level 1 Adverse Events Reported by Month, FY 2005



Notifying Patients and/or Families of Adverse Events and Inter-Hospital Notification

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.[18] However, hospitals indicated that notification to the patient or family member of an unanticipated outcome had occurred in only 46 of the 125 level 1 adverse events. In some cases, the hospital patient safety staff was not aware whether the physician had informed the patient or appropriate family member of the adverse event or even if the physician intended to inform them.

Table Six. Level 1 Adverse Events Reported to JCAHO

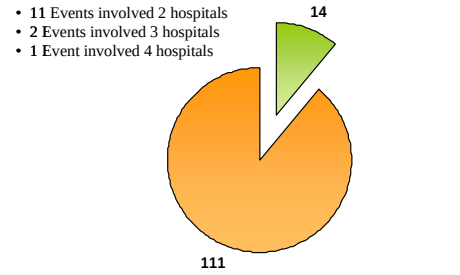


Of the 125 level 1 adverse events reported to the Department in FY05, only seven[19] were also reported to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)[20] (Table Six). Hospitals are encouraged to report sentinel events[21] to JCAHO, but reporting is not mandatory. JCAHO does expect accredited organizations to identify and respond appropriately to all sentinel events. Appropriate response includes conducting a timely, thorough, and credible root cause analysis, implementing improvements to reduce risk, and monitoring the effectiveness of those improvements.

[17] An initial Report of Event Form is available on the Department's Web site at *www.dhmh.md.gov/ohcq/*.
[18] COMAR 10.07.06.01(H)
[19] Thee of the seven level 1 adverse events reported to the Department were suicides.
[20] Joint Commission on Accreditation of Healthcare Organizations is the nation's oldest and largest accrediting body for health care organizations. *http://www.jcaho.org*.
[21] Sentinel events subject to 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.

The Maryland Hospital Patient Safety Program and regulations also require inter-hospital communication. When a hospital admits a patient with a condition resulting from a level 1 or level 2 adverse event that the hospital perceives may be related to care that was provided at another Maryland hospital, the admitting hospital must notify the appropriate medical review committee at the hospital where the adverse event allegedly occurred.[22] In FY05, there were 14 reported adverse events where more than one hospital cared for the patient involved and in one case, four hospitals were involved (Table Seven).

Table Seven. Number of Events Involving More than One Hospital



Root Cause Analyses

Root cause analysis (RCA) focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future.[23] A RCA may also determine, after analysis, that no such improvement opportunities exist.

Initially, there was confusion among some hospital staff about how to conduct a RCA. Even when hospitals attempted, through voluntary internal mechanisms, to assess the problems that resulted in a patient's unexpected injury and/or death, the tendency was to find a person, often a nurse, to blame for the adverse event. There was little consideration about what processes and systems in the hospital might be deficient or how to prevent the same adverse event from happening again.

Physicians historically have used the "peer review" process, which keeps their review of an adverse event apart from the hospital review. Peer review results were usually disclosed only to the hospital's senior officials and there was often no coordinated effort to collectively review the hospital findings and peer reviews.

Moreover, neither the Department nor any other governmental agency had the authority to ensure that hospitals were truly looking at systems of care and quantitating findings. Patterns of deficient systems and processes within each hospital and among all Maryland hospitals were not easily recognizable. Many of the same problems occurred within most or all hospitals, yet there was no dissemination of information so that the overall quality of patient care in Maryland could improve.

During the first year of the Program's implementation, the Department looked at how to best review the RCAs submitted by hospitals. The Department, working closely with hospital staff and other agencies, revised the RCA review process several times with the goal of providing meaningful feedback.

[22] COMAR 10.07.06.12
[23] Joint Commission on Accreditation of Healthcare Organizations. *http://www.jcaho.org*.

In addition, Department staff received training from several sources, including a three-week training session through the Agency for Health Care Research and Quality/Veterans Administration sponsored Patient Safety Improvement Corp (PSIC). One of the projects completed by Department staff and hospital partners in the PSIC training was the development of a root cause analysis evaluation tool. The evaluation tool was used and revised several times by Department staff to ensure that it was a functional tool that provided a consistent and thorough review of submitted RCAs.[24]

When a Maryland hospital submits a RCA to the Department, it is evaluated for regulatory[25] compliance by a nurse surveyor using the RCA evaluation tool. The nurse surveyor rates each element of the RCA by marking it as either "Met" or "Not Met." The surveyor may also include comments to support his/her decisions.

Weekly, the OHCQ Patient Safety Committee[26] meets to review a selection of the submitted RCAs. If a RCA is incomplete or has not provided adequate feedback, including changes to hospital policy or procedure to prevent the reoccurrence of the level 1 adverse event, the Committee will make recommendations and request that the hospital resubmit the RCA. In FY05, 95 RCAs were received, of which 80 were reviewed and closed.

In lieu of citing regulatory deficiencies to the hospital, the Department, as indicated above, provides recommendations and feedback on submitted RCAs. This is done so hospitals will become familiar with the expectations of the Department and the proper way to utilize the RCA process. The Department also engages in open communication with hospital staff to discuss areas of a RCA that are deficient, share patient quality of care concerns, and to gather additional information.

In many of the RCAs reviewed, the Department noted similar problems. These include:

- *Failure to investigate and find the root cause(s).* Hospital staff frequently stopped asking "why" before they reached the true root cause. For example, a patient who had a procedure that required injection of a dye was discharged from the hospital and subsequently went into renal failure. The RCA focused on the hospital's failure to inform the patient to delay taking one of her regular medications for several days. The RCA never considered that the dye used for the procedure is often implicated in renal failure and was more likely to have been the cause.

[24] See Appendix B for the root cause analysis evaluation tool.
[25] COMAR 10.07.06
[26] 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, Physician Advisor, Chief Nurse, Patient Safety Nurse Surveyor, and the Assistant Director for Hospitals, Laboratories, and Patient Safety.

- *Failure to develop an appropriate corrective action plan[27] to address the root cause(s).* Often RCAs indicated that staff would be retrained or in some cases disciplined as the corrective action plan. The intent of the regulations is to determine what systems changes may be implemented to prevent the reoccurrence of a level 1 adverse event. The Department is looking for process changes that will result in safer patient outcomes. Examples include process breakdowns when patients are "handed off" from one group of professionals to another, when medications are stored and prepared, standardization of equipment to minimize staff confusion, and medical record prompts to alert staff of potential safety problems.

- *Failure to develop and monitor outcome measures to determine if the corrective action plans have been effective in correcting the root cause(s).* Hospitals frequently have difficulty trying to measure the results of their corrective action plans. For example, rather than focusing solely on the number of training sessions, hospitals would benefit by focusing on whether such interventions had impact on behavior and outcomes.

Hospital Patient Safety Plans

During the summer of 2004, the Department requested all 69 Maryland hospitals to submit patient safety plans in accordance with the new regulations. The quality and depth of the plans varied significantly. In addition, hospitals were experiencing some difficulty in attempting to blend the requirements for voluntary reporting under the Joint Commission on Accreditation of Health Care Organizations' (JCAHO)[28] standards and the requirements of Maryland's new regulations. All hospitals that submitted patient safety plans which were found not to meet regulatory requirements, were asked to resubmit plans with corrections or additions.

It was also noted that some hospitals either had not reported level 1 adverse events or reported very few. Among the reasons for this breakdown is the lack of ability in the hospital internal information systems to identify level 1 adverse events, as well as the inability of the hospital quality systems to effectively coordinate inquiry fact-finding, conclusions, and monitoring. Some hospital quality systems are based on the principle of simply finding someone to blame rather than looking at the internal systems and procedures that could prevent staff from making an error which results in patient harm. Because of this, the Department selected two hospitals for a thorough onsite review of patient safety programs. In each review, the Department cited deficiencies and required both hospitals to submit a Plan of Correction. The Department found that one hospital had failed to identify several level 1 adverse events because the events were never reported to the hospital's quality, risk, or patient safety staff. The other hospital had identified level 1 adverse events that were discussed in various committees, but the committees did not forward the events to the hospital's quality, risk, or patient safety staff for further review. As a result of the review findings, the Department is making on-site Patient Safety Program reviews an integral part of Patient Safety oversight.

[27] "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.
[28] Joint Commission on Accreditation of Health Care Organizations. *http://www.jcaho.org*.

The Hospital Patient Safety Program regulations encourage hospital dissemination of information regarding level 1 adverse events by protecting the confidentiality of the RCA and any other medical review committee information submitted as a part of the Program.[29] Therefore, there is no incentive for a hospital to knowingly not submit a level 1 adverse event.

Clinical Alerts

To disseminate important information, including trends and patterns, obtained through the RCA reviews, the Department has released several clinical alerts.[30] Since falls were the most frequently reported level 1 adverse event in FY05, the Department released the clinical alert "*Falls in Maryland Hospitals*."[31] Some of the findings published in this clinical alert include that the majority of falls occurred in patients over 60 years of age and that at seven of the 20 cases reviewed were patients who were on fall precautions. Other clinical alerts include "*Potassium, Still a Dangerous Drug*,"[32] which discusses medical errors related to potassium administration and "*OHCQ Review of Two Root Cause Analysis: Are You Looking as Hard as You Might?*,"[33] which discusses how a more in-depth RCA review may have yielded different results.

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 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. [34]

The Department fully supports the activities of the Maryland Patient Safety Center and regularly attends training workshops sponsored by the Center. In particular, the OHCQ Patient Safety Unit staff attend each Root Cause Analysis training workshop, which allows the participants, as well as the presenter, to inquire about the Department's Hospital Patient Safety Program.

[29] However, if the Department receives a complaint alleging a level 1 adverse event, the Department will accept the RCA as a hospital's internal investigation but can still cite the hospital with deficiencies for any regulatory violation arising from OHCQ's independent investigation of the complaint. COMAR 10.07.06.09(C) & (D).
[30] Clinical alerts are posted on the Department's Web site at *www.dhmh.md.gov/ohcq/alerts/alerts*.
[31] See Appendix C for the "Falls" clinical alert.
[32] See Appendix D for the "Potassium" clinical alert.
[33] See Appendix E for the "OHCQ Review of Two RCAs" clinical alert.
[34] Maryland Patient Safety Center. *www.marylandpatientsafety.org*.

In the Fall of 2004, the Department asked Dr. William Minogue, Director of the Patient Safety Center, to join with OHCQ staff as part of a second Maryland team at the VA/AHRQ sponsored Patient Safety Improvement training workshop. It is anticipated that this collaboration will continue to improve patient safety initiatives in Maryland.

Future Plans

The FY06 budget includes 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. However, as a separate unit, there will be a "firewall" between the regulatory oversight of the hospitals and the patient safety activities. In several other states, the regulatory and patient safety units operate separately with the belief that hospitals will more freely report a level 1 adverse event when the structure of the unit reinforces legal requirements that the report will not be used against licensure or certification status.

With the additional staff, the Department the will be able to perform a more comprehensive review of RCAs, in comparison with other submitted RCAs, and provide feedback to the hospitals on a much more timely basis. The Department intends to analyze level 1 adverse event patterns and trends occurring statewide as well as within individual hospitals. Also, an onsite Hospital Patient Safety Plan review schedule will be established to ensure that every hospital's program is reviewed.

A key component in any private or public Patient Safety Program is the sharing of information. Information sharing provides hospitals with the opportunity to review systems and procedures and make changes to prevent the same adverse event from occurring again. 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. Additional plans for the dissemination of information include:

- Development of a "Patient Safety" page on the Department Web site;
- Research best practices for commonly occurring level 1 adverse events;
- Information sharing via email to all patient safety coordinators; and
- Continued participation in the educational offerings provided by the Maryland Patient Safety Center.[35]

Inter-departmental information sharing is fostering new relationships. The Patient Safety Review Committee and the Department's Center for Maternal and Child Health[36] work together to review RCAs related to negative outcomes in obstetrics and neonatology. The Center for Maternal and Child Health's expertise in these areas has forged new ways to use data to improve serious public health issues such as fetal mortality. The establishment of other inter-departmental relationships is an aim for the Patient Safety Committee for the upcoming fiscal year.

[35]Maryland Patient Safety Center. *www.marylandpatientsafety.org*.
[36] Center for Maternal and Child Health. *www.fha.state.md.us/mch/*.

In addition to staffing, 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 has focused on determining the best methods to review RCAs and encouraging hospitals to report level 1 adverse events. The Hospital Patient Safety Program regulations[37] 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.

Conclusions

Maryland hospitals and OHCQ staff have spent significant time working together to determine how to improve the safety of patients. Throughout FY05, the Department received adverse event reports which verified that the lives of many Marylanders are harmed or lost because of preventable mishaps. Even well trained and well-intentioned individuals err, particularly when systems in which they work do not support their efforts. Mandatory event reporting and review of RCAs provides the Department with insight into each hospital's internal quality oversight program as well as providing the hospitals with a methodology to determine how they are ranking compared to sister institutions around the entire state and, eventually, the country. While errors will always occur, even in the best of circumstances, many of the level 1 adverse events reported are largely preventable if Maryland hospitals focus primarily on systems and processes, not individual performance.

The greatest challenge presented by the Maryland Hospital Patient Safety Program is to positively answer the question as to whether these efforts can truly make a difference in the protection of patients against adverse, serious, and frequently preventable errors. The answer to this question will take continued time and resources. In the meantime, the Department looks forward to continued involvement with the Maryland Patient Safety Program as well as the continued interest and cooperation of Maryland hospitals and their staff.

[37] COMAR 10.07.06

Appendices

Appendix A

Categories of Level 1 Events in FY 2005

Categories of Level 1 Events in FY 2005

CATEGORIES OF EVENTS	Surgical Intervention	Medical Intervention	Death	Total
Falls	7	11	12	30
Treatment delay	1		15[38]	16
Airway management		4	9	13
Medication errors	1	1	9	11
Complications		1	5	6
Death /disability associated with the use of a vascular access device			6	6
Unanticipated intra-operative or immediately post operative death			5	5
Misdiagnosis		1	4	5
Post surgical retention of a foreign body	4			4
Suicide or attempted suicide			4	4
Maternal death/injury	1	1	1	3
Fetal death/injury			3	3
Malfunctioning devices	1	1	1	3
Intravascular air embolism			2	2
Hypoglycemic event		1	1	2
Staff member failure to act			2	2
Restraint related death	1			1
Blood transfusion reaction			1	1
Anticoagulation			1	1
Surgical procedure not consistent with consent	1			1
Other	1	2	3	6
TOTALS	**18**	**23**	**84**	**125**

[38] In once case, medical intervention occurred but still resulted in death.

Appendix B

Root Cause Analysis Evaluation Tool

Root Cause Analysis Evaluation Tool

Hospital: **OHCQ Case Number:** **Date of Event:**

Thank you for submitting the RCA to the adverse event identified above to the Office of Health Care Quality. Staff of the Office of Health Care Quality have reviewed the submitted RCA and have evaluated its compliance with COMAR 10.07.06, Hospital Patient Safety Programs. All elements are scored as meeting or not meeting the requirements of 10.07.06. Our evaluation of your RCA is intended to provide guidance on completeness, give positive feedback, and offer cues in areas where it appears the RCA team may have experienced some difficulty in crafting entries. The comments and scores provided should be used to evaluate and improve the hospital's RCA process.

This evaluation is based on the information contained in the documents submitted to OHCQ and the hospital's compliance with COMAR 10.07.06. It does not constitute an endorsement or agreement with the substance of either your findings or your action items. If you would like to discuss our findings, you may contact this office at (410) 402-8016.

	Element (All elements are required)	**Guidelines**	**OHCQ Score**	**Comments**
1	*Categorization Score- Must be present*	*Indicate which level (according to COMAR 10.07.06)*	*Met/Not Met*	
		Level 1--An adverse event that results in death or serious disability.		
		Level 2--An adverse event that requires medical intervention to prevent death or serious disability.		
		Level 3--An adverse event that does not result in death or serious disability and does not require medical intervention to prevent death or serious disability.		
		Near Miss - a situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.		
2	*Multi-disciplinary RCA team COMAR 10.07.06.06A*	*List participants by title. Some participants but not necessarily all should have a knowledge of the processes or systems being analyzed.*	*Met/Not Met*	
3	*Brief description of event*	*Include details of event, date, day of week and time event occurred, and the area/service involved. Include timeline if appropriate.*	*Met/Not Met*	
		Has a similar event occurred in the facility in the past? Look at previous outcomes to determine if actions were effective.		
4	*Diagram or narrative analysis of cause and effect 10.07.06.06C*	*Identify which was used and identify whether diagram indicated process as it actually worked (or did not work) during adverse event, or if diagram indicates process as it should work. No need to include diagram with RCA submission.*		
5	*Analysis of all available resources 10.07.06.06C 4*	*Has RCA team looked at all medical records, policies and procedures, maintenance logs, committee minutes, etc., necessary to identify all factors relevant to event. Have all pertinent staff been interviewed?*		
	Analysis of cause and effect through: 10.07.06.06C 3			
6	*Analysis of human factors 10.07.06.06C 1*	*Includes communication, training, competencies, staffing, and fatigue/scheduling*		
7	*Analysis of equipment and environment 10.07.06.06C 1*	*Includes availability of needed equipment, equipment performance and maintenance, and identification of uncontrollable environmental factors*		

8	Analysis of policies and procedures 10.07.06.06C 3	Includes identification of barriers to compliance with P&Ps		
9	Identification of risks and possible contributing factors 10.07.06.06C 4	Include possible barriers to identifying, reporting, and responding to risks. Identify if risks or possible contributing factors to this adverse event continue to exist at the time of the RCA, or if all risks and contributing factors were eliminated in the immediate aftermath of the adverse event.		
10	Analysis of related processes and systems 10.07.06.06C 2	Identify if risks or possible contributing factors may affect other areas/processes in the hospital.		
11	Clearly identified Root Cause contributing factors 10.07.06.06C 4	List as many as applicable. Must (1) clearly show cause and effect,		
		(2) be specific and accurate, avoid negative and vague words like wrong, bad, careless, etc		
		(3) identify the preceding cause(s) of human error, identify systems vs. people issues, avoid blame		
		(4) identify the preceding cause(s) of relevant procedure violations, identify normal operating procedures vs. ideal (as per policy).		
12	Identify corrective action 10.07.06.02B	Must include specific measures to correct problems or areas of concern and specific measures to address areas of system improvement		
		Actions can be defined as stronger, intermediate, or weaker actions and can be classified as controlling, eliminating, or accepting the root cause or risk. Identify mechanisms to compensate for uncontrollable environmental factors. Stronger actions include architectural/physical plant changes, tangible involvement & action by leadership, simplifying the process, standardizing equipment or processes, and/or implementing a new device that's had usability testing performed. Intermediate actions include checklists, cognitive aids, staffing changes, readbacks, enhanced documentation and communications, software enhancements/modifications, elimination of look- and sound-alikes, and eliminating or reducing distractions.		
		Weaker actions include redundancy/double checks, warnings and labels, new procedures/ memorandum/ policy, training, and additional study and analysis. Wherever possible, develop actions that do not rely on the memories of staff members.		
13	10.07.06.02B	Time frames for implementing specific measures.		
14	10.07.06.02B	Title of person responsible for implementation and effectiveness.		
15	Outcome measures 10.07.06.05A 5	Must be more than a restatement of the actions. Must be quantifiable with defined numerators, denominators, and thresholds. Set realistic and achievable thresholds for performance. Include any physical/operational changes to be implemented.		

		Must measure impact on the root cause or adverse event. Measure effectiveness of actions, not steps in process to implement actions. For instance: Falls assessment will occur on 100% of patients admitted from nursing homes…, not: A falls assessment tool will be developed by..., staff will be trained by ..., etc.		
16	*Feedback to staff 10.07.06.06E*	*The hospital shall provide feedback including changes to hospital policy or procedure resulting from the RCA to hospital employees and staff who were involved in the event or who could benefit from the feedback.*		
17	*Leadership concurrence for corrective actions 10.07.06.03B 3*	*Leadership concurrence for corrective actions. Identify by job title/date. If this is through the committee structure, identify committee.*		
18	*Relevant literature considered 10.07.06.06D 2*	*List relevant literature considered*		
	For Office of Health Care Quality use only			
	Date event reported to Office of Health Care Quality			
	Date of RCA			
	Link to Adverse Event report #			
	Office of Health Care Quality recommendations for follow-up			
	Medical Director Review			

Appendix C

Clinical Alert
"*Falls in Maryland Hospitals*"

Clinical Alert

Volume 3, Number 1
Spring 2005

Maryland Department of Health and Mental Hygiene
Office of Health Care Quality
Spring Grove Center
55 Wade Avenue
Catonsville, MD 21228
410-402-8004

Patient Safety Clinical Alert No. 1, March 2005

Falls in Maryland Hospitals

Since March 15, 2005, twenty falls resulting in death or serious disability have been reported to the Office of Health Care Quality (OHCQ). Half of these falls were fatal, most from traumatic brain injury, specifically subdural hematomas. Fourteen of the falls were associated with patient confusion or other mental status changes. These cases are representative of the nature of the cases in Maryland hospitals, but probably under-represent the number of serious falls occurring in hospitals. A review of these cases shows strong correlation with the known risk factors listed below, and suggests the need for better assessment and more effective fall reduction strategies.

Falls are a serious public health problem among older adults. One Australian study determined that 38% of all hospital incidents involve falls.[1] According to statistics compiled by the Center for Disease Control and Prevention (CDC), as many as 75% of nursing home residents and nearly 35% of seniors living in the community fall each year.[2] A literature search reveals little information regarding falls in US hospitals. Falls, wherever they occur, are the leading cause of death by injury in those 65 and older, and are the underlying cause of many traumatic brain injury fatalities.

Risk Factors

Age: Age has been associated with an increased risk of falling in most studies and correlates with a high mortality from falls. In the US, the elderly represent 12% of the population but account for 75% of the deaths from falls. One British study showed rates of falling for women at 9% for age 65 to 74; 13% for ages 75 to 84; and 17% for age 85 and older. Rates for males are slightly lower, at 4%, 9%, and 7% respectively.[3] Age related conditions predisposing patients to fall include cardiac arrhythmias, TIAs, stroke, dementing illnesses, orthostatic hypotension, visual or auditory impairments, and dehydration. In addition, a fall may be the presenting symptom of a serious acute illness, for instance, when the hypoxemia of impending respiratory failure causes agitation and confusion, leading to patient injury. ***Maryland Findings:*** *All but four of the falls reported to OHCQ occurred in patients over 60, and all of the fatalities were in patients over 65.*

Mental status: Alteration in mental status is strongly correlated with falls risk. Confused, sedated, or otherwise cognitively impaired patients do not realize their own limitations, cannot interpret their environment appropriately, and cannot remember or follow directions. ***Maryland Findings***: *14 of the people who fell that were reported to the OHCQ were noted to have mental status changes.* The mental status changes were either present on admission or occurred during the admission. Surprisingly, known mental status changes or cognitive impairment was not necessarily correlated with assessment of fall risk or being on fall precautions. For instance,

Continued

one patient fell when he went to the bathroom unattended after having a procedure involving conscious sedation. This patient was neither reassessed for the risk of falling nor assumed to be at a higher risk for falling after the procedure. Two patients who were reported to OHCQ were so confused they pulled out large venous access catheters and then had unwitnessed falls associated with hemorrhage. Two other patients had acute mental status changes associated with their disease processes that caused hallucinations leading them to jump out windows.

Co-morbidities: The presence of co-morbidities as a risk factor for falls is not captured by all risk assessment tools but clearly needs to be considered. Having multiple co-morbidities also leads to prolonged hospital stays—another risk factor for falling. Frailty and deconditioning increases with length-of-stay. While this information is not always reported to us, at least three of the patients who fell had been in the hospital for seven days or longer. ***Maryland Findings:*** *19 of the 20 patients who fell had two or more serious co-morbidities.* These chronic and acute disease states included coagulopathies, cancer, end-stage renal disease with dialysis, arthritis and other diseases that lead to weakness and difficulties with balance and gait. In particular, patients need to be assessed for the presence of coagulopathies and the use of anticoagulants. While a prolonged bleeding time is not necessarily predictive of falling, it is associated with a high mortality. *In fact, of the ten patients reported to OHCQ who died after falling, seven had coagulopathies and died of subdural hematomas.*

Two other patient characteristics are not reported to the OHCQ, but are associated with high risk for falling. These are incontinence and polypharmacy.

Incontinence: One study determined that the risk of falling for patients who are incontinent is 12 times higher than for those who are continent.[4] Besides the urgency and frequency involved with incontinence, there may be other self-care deficits that are indicative of weakness and general debility or deconditioning.

Polypharmacy: Polypharmacy is another aspect not always captured by falls risk assessments. Many medications cause weakness or mental status changes, contributing to falls. Drugs that may increase the risk of falling include sedative/hypnotics, anxiolytics, narcotics, benzodiazepines, tricyclic antidepressants, antihypertensives, cardiac medications, corticosteroids, hypoglycemics, NSAIDs, and any medication likely to affect balance. In addition, the initiation of a new drug therapy in the previous two weeks has also been associated with an increased risk of falling for elderly patients.[5] This describes most hospitalized elderly. Polypharmacy is to be expected in the presence of co-morbidities and should be considered as part of a thorough risk assessment.

Interventions

Falls Risk Assessment: At least seven of the 20 patients who fell were on falls precautions. Another seven patients should have been on falls precautions based on mental or physical status changes that occurred in the hospital, but were not. These changes included being on narcotics, medication regimen changes, confusion, and sedation following procedures. The falls assessment is normally done only on admission. This may miss some important new information as the patient's condition changes. The falls risk assessment needs to be a multi-dimensional assessment of causes and consequences.[6] As stated above, polypharmacy, length of time in the hospital, age, and presence of co-morbidities are patient characteristics associated with fall risk. Falls risk assessment should be done on a routine basis while in the hospital and should be done with any change in the patient's condition. One patient who was not on falls precautions fell twice—the second time just a few minutes after the first while the nurse was attempting to get a restraint order. Another patient was on falls precautions and had a sitter ordered which could not be provided due to short staffing. The patient fell and died. One of the patients who should have been on falls precautions (for escalating narcotic use) and

Continued

was not, fell three times in 12 hours and fractured her hip on the third fall. In this case, a sitter had been ordered after the second fall, but the order was missed for several hours and then could not be implemented due to staffing constraints.

Most of the falls precautions incorporate increased vigilance by staff, moving the patient to a room closer to the nurse's station, and reducing the amount of environmental hazards. These were ineffective and/or inadequate interventions in the falls reported to this office. For instance, two patients who fell did so after procedures done off the unit. In both cases, the transporters who brought them back to the rooms were not aware of the falls precautions and failed to notify the staff that the patients were back in bed. While hospitals may not feel free to post large signs at the bedside about a patient's condition due to HIPAA, they must develop a system for alerting all staff to each patient's care issues.

The Veteran's Administration has developed a very extensive Falls Toolkit[7] which takes an interdisciplinary approach to falls prevention. Interventions included in the Toolkit include:

- Assessing risk on admission and at regular intervals.
- Fully engaging patient and family in prevention activities.
- Placing both side rails up on the patient's weaker side, thus encouraging the patient to exit the bed on his or her stronger side.
- Ambulating as early and as frequently as possible.
- Every 1, 2, or 3 hour comfort and toileting rounds, depending on the needs of the patient.
- PT consult for balance, strength, and exercise program.
- Patients at high risk may be placed on a concave mattress and may have an absorbent, non-slip mat placed on the floor next to the side they exit.
- Use of bedside commodes.
- Pharmacy review of medications.

Another resource for fall prevention strategies is the American Medical Directors Association (AMDA), which, along with the American Health Care Association (AHCA), published clinical practice guidelines[6] for understanding fall risk and reducing the severity of injury and the rate of falls. AMDA recommends having a minimum set of universal precautions, then individualizing interventions based on risk assessment. Most hospitals have universal precautions, such as keeping beds in the low position and reducing environmental hazards, but if the events reported to this office are any indication, the individualized interventions lack effectiveness for a variety of reasons. Hospitals may have to define what "high risk" means based on the patient population of each unit.

While the Office of Health Care Quality is not advocating that every hospital in Maryland follow the VA or the AMDA model, these resources contain many useful suggestions and "outside the box" ideas that may help your hospital decrease the rate and staggering cost, in dollars and lives, of patient falls. While not every fall warrants a root cause analysis, the Office of Health Care Quality recommends that hospitals quickly analyze individual falls for correctable issues and closely monitor fall rates in the aggregate.

1. Evans et al, *Falls in Acute Hospitals: A Systematic Review*, The Joanna Briggs Institute for Evidence Based Nursing and Midwifery, 1998
2. *http://www.cdc.gov/ncipc/factsheet/fallcost.htm*, 2000
3. *http://www.official-documents.co.uk/documents/deps/doh/survey01/nfa/nfa11.htm*, 2003
4. Stevenson et al, *Falls Risk Factors in an Acute Care Setting*, Canadian Journal of Nursing Research, 1998
5. *http://www.aafp.org/afp/2000401/2159.html*, 2000
6. *Falls and Fall Risks*, Clinical Practice Guideline, American Medical Directors Association, 1998
7. *http://www.patientsafety.gov/SafetyTopics/fallstoolkit/index.html, 2004*

Clinical Alert

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Appendix D

Clinical Alert
"*Potassium: Still a Very Dangerous Drug*"

Clinical Alert

Volume 3, Number 2
Fall 2005

Maryland Department of Health and Mental Hygiene
Office of Health Care Quality
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Potassium: Still a Very Dangerous Drug

As required by Health-General Article, §19-304, Annotated Code of Maryland, the Office of Health Care Quality receives Root Cause Analyses (RCAs) from all Maryland hospitals for any adverse event resulting in death or serious disability. From July 1, 2004 through June 30, 2005, OHCQ received and reviewed over 100 RCAs.

These sad events are almost always of a kind that could happen in any hospital. Thus, OHCQ is aware of the potential teaching value of certain events. Periodically, the OHCQ distributes a description of an event to all Maryland hospitals to initiate a dialogue within the hospital. Please distribute this alert to appropriate staff.

The Case

A middle-aged patient was admitted to a hospital for persistent nausea and diarrhea. Because of dehydration, the patient was administered intravenous fluid with potassium at a rate of 150 cc/hr. On admission, the physician ordered a serum potassium and it was 3.5 mEq/L. Fluids (with the potassium) were continued for the next 48 hours because of persistence of nausea. On the second day after admission, the serum potassium rose to 4.8 mEq/l.

On the third hospital day, the patient appeared much improved; however, a serum potassium drawn by the laboratory early in the morning was reported to the floor via phone from the laboratory as 7.1mEq/l (normal = 3.5 – 6.5 mEq/l). When this result was given to the nurse, the laboratory technician opined that the specimen was "contaminated." A repeat STAT test was ordered. The repeat specimen was drawn at 8:30 a.m. and was logged into the laboratory at 10:00 a.m. At 10:00 a.m., the physician discontinued the IV fluid that contained potassium. At 11:22 a.m., the floor was notified that the potassium was 8.3 mEq/l. At 11:52 a.m., more than 3 hours after the first blood result was known, the patient lost consciousness and coded. The attending physician arrived during the resuscitation effort. The patient was pronounced dead about 5 hours after the code occurred.

Discussion

A number of systems failed in this unfortunate case. If this incident occurred in your hospital, what questions would you ask? Have you looked at this issue recently to prevent any similar occurrence?

OHCQ staff discussed this case at length and asked the following questions:

1. When an IV infusion containing potassium is given to a patient over several days, should an automatic stop order be instituted pending an assessment?

2. When the nursing staff receives a lab result showing hyperkalemia, what is the hospital's protocol to ensure an immediate assessment of the patient and any appropriate intervention?

3. If the nurse, physician or lab technician believes that a specimen is contaminated, should this "assumption" change the vigilance that is exerted by staff insofar as the continued IV infusion is concerned?

4. When a life-threatening laboratory value is found, should the laboratory call the attending physician as well as the nurse? This procedure might apply with hyperkalemia and hypoglycemia,

Continued

Potassium: Still a Very Dangerous Drug *Continued*

and other tests as determined by the hospital medical staff.

5. Is there a procedure to handle STAT tests? Is this procedure audited to determine appropriate response times, including the length of time for the specimen to be obtained and length of time for the result to be transmitted?

6. Is there a protocol for a nurse to call a physician, such as a house physician or a rapid response team, if there is not an appropriate response by the attending physician regarding a dangerous laboratory value, or any other life-threatening situation? Is laboratory and nursing staff performance in dealing with STAT situations periodically audited?

7. Does the laboratory document show how quickly it returns stat values, and to whom? Is there an audit of how these values are acted upon?

8. Is the list of "panic" lab values reviewed periodically and updated?

How would your hospital fare in dealing with a patient like this one, receiving a potentially dangerous drug while there is laboratory evidence of a potentially serious problem?

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Appendix E

Clinical Alert
"OHCQ Review of Two Root Cause Analyses: Are You Looking as Hard as You Might?"

Clinical Alert

Volume 3, Number 3
Fall 2005

Maryland Department of Health and Mental Hygiene
Office of Health Care Quality
Spring Grove Center
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OHCQ Review of Two Root Cause Analyses: Are You Looking as Hard as You Might?

Identification of a Level 1 adverse event and reporting it, both internally to the hospital staff and to the Office of Health Care Quality (OHCQ), is only the beginning of an effective patient safety program. What is critical is the ability of the hospital to fully evaluate an event, find its root cause, identify any systems failures, and put mechanisms in place to prevent a reoccurrence.

Occasionally however, the investigative phase of an adverse event illustrates the failure of a hospital to look beyond the immediate and apparent breakdown to find real inadequacies of systems that should be protecting patients. We find two areas where decisions must be made especially quickly and where systems' failures to avoid human errors can have a devastating impact on patients. This is the Emergency Room and the Operating Room. Two recent Root Cause Analyses (RCA) received by OHCQ illustrate this point.

Emergency Room Case

A 40-year old patient presented to the emergency room complaining of sore throat, cough, weakness and nasal congestion. After treatment, lasting 10 hours, the patient was discharged, only to return to the emergency room 5 hours later in acute respiratory distress. The patient developed respiratory failure, hypoxia, and septic shock. After a second 9-hour stay in the emergency room, the patient was transferred to the intensive care unit and died the next day.

During the first emergency room visit, the patient received 5 liters of fluid and 2 doses of insulin. In the RCA the patient is described as dehydrated, tachycardiac, and hyperglycemic with a blood sugar of 275. The white blood cell count was normal but the differential indicated possible sepsis. No blood or urine cultures were obtained on the first visit.

The RCA, under "human factors" stated, quite simply, that the physician who sent the patient home after the first emergency room visit made a poor judgment call. There were no other factors identified that could have been responsible for, or even contributed to, this unfortunate outcome. The RCA noted that the physician was well trained with no previously described poor outcomes. The identified root cause was "misinterpretation of information." Corrective action was to be measured by "The physician will not develop a trend of clinical misinterpretation."

Comment; Wachter and Shojania in their book **Internal Bleeding** [1] write that the "RCA attempts to write a 'second story' about the actions that led to error -- to look past the obvious, sharp end scapegoats and find the other culprits, however deeply they may be embedded in the system or lost in the labyrinth of procedures and traditions." The RCA described above does not do this. Rather it found only an experienced and well trained physician who misjudged the degree of illness in a patient who was under his/her care for 10 hours in an emergency room. The physician appears to have worked entirely alone. There was apparently no supporting staff to advise the physician nor was there any concurrent quality oversight system in place to back up the physician.

Can we expect that education and counseling of this physician and watching him/her for further mistakes will correct the

Continued

problems in this emergency room? Are there steps that the hospital could take to make other members of the team in the emergency room more involved in assisting in the management of this patient? Could policies be written that ensure that under certain circumstances, such as when patients receive certain kinds of treatment, or when patients spend certain periods of time in the emergency room pending a decision, another physician be asked to provide another opinion. Was the emergency room physician simply too busy to closely follow his/her patient? What outcome measurements might be used to determine whether complicated patients are being adequately managed prior to discharge?

Operating Room Case

Case No. 2 involved a patient who was status-post a motor vehicle accident and who was taken to the operating room for a tracheostomy. While in the operating room, there was a small fire associated with the use of electrocautery in the presence of oxygen. It turned out that there was an unwritten practice in the hospital for the surgeon to indicate to the anesthesiologist, either verbally or non-verbally, when he or she was about to use the cautery so the percentage of oxygen being delivered to the patient could be decreased. In this event, a fellow, who was operating with the surgeon, was unaware of the unwritten practice and so did not indicate to the anesthesiologist that he was about to use the cautery.

The RCA focused on the lack of communication between the fellow and the anesthesiologist, and the education and information needs of non-attending physicians. As one of its action items, the RCA proposed an initiative to educate patients on steps they can take to avoid operating room fires.

Rather than focus on codifying and improving unwritten practice standards, this hospital chose to blame the fellow for failure to adhere to an unwritten practice that the fellow had no knowledge of. The RCA also seeks to spread the blame to a class of people who are least at fault in operating room fires -- patients!

If you have comments on how you would handle these two cases, please email Joseph Berman, MD at *jberman@dhmh.state.md.us.* We will post comments (please tell us if you want your name released) on our OHCQ website so that we all might share experiences and solution. We are all trying to learn together.

[1]Wachter, M. and Shojania, K. *Internal Bleeding*. Rugged Land, NY, 2004, p 46.

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