



FIRST

Do No Harm

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Board of Registration in Medicine, Patient Care Assessment Division

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A New Beginning

Welcome to the first Patient Care Assessment (PCA) Division Newsletter. The PCA Division heard your requests to get more information about this program and about health care quality improvement measures, and we hope this quarterly newsletter will meet your need for timely and consistent communication of information. Included in each Newsletter will be various articles on issues such as health care system concerns, the outreach

efforts of the PCA Committee, as well as other tidbits of information. We are calling this newsletter



“First”, because as we all work to improve health care quality, reduce medical errors, and increase patient safety, the root of those

efforts stems from the mantra of health care, which is “First Do No Harm.” In addition to this newsletter, the PCA Committee is conducting task forces, managing research projects, implementing technology improvements and designing workshops—all for the purpose of being a resource to you. We hope these efforts will assist you in your endeavors and achievements, and we look forward to bringing you more Newsletters in the months ahead.●

Tumbles and Falls

In the past three years, the Board of Registration in Medicine Patient Care Assessment (PCA) Division received 101 Major Incident Reports of inpatient falls. There were 85 falls with severe injury and 16 falls that resulted in deaths. In several of the reports of deaths, the patients were receiving Coumadin or had a known coagulopathy and failed to receive an adequate and timely post-fall neurological assessment, delaying the diagnosis and intervention for intracranial bleed. The following

opportunity for improvement was noted from a review of these deaths: hospitals should have guidelines for post-fall assessment and monitoring, especially for the subgroup of patients with a coagulopathy or who are taking medications for anticoagulation.

Most of the hospitals where these Major Incidents occurred had protocols and policies for screening the patient at risk for fall, with detailed instructions for documentation and reporting of the fall. However, not all hospitals

had written guidelines for a post-fall clinical assessment and reassessment necessary for high-risk patients, such as those taking anticoagulation medications.

A timely, thorough post-fall evaluation can identify treatable complications and reduce the risk of subsequent falls. Examples of problems that may be evidenced through the post-fall assessment include: vital signs at variance from baseline; metabolic derangements; and cardiac arrhythmias.

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Meet the PCA Committee

The Massachusetts Board of Registration in Medicine, established in 1894, is the state government agency that licenses and regulates physicians in Massachusetts. It consists of seven members (5 physicians and 2 public members) appointed by the Governor to three-year terms. A member may serve only two consecutive terms.

Each member also serves on one or more Committees of the Board. There are five committees at the Board of Registration in Medicine: Complaint Committee, Licensing Committee, Acupuncture Committee, Data Repository Committee, and the Patient Care Assessment (PCA) Committee. The PCA Committee is comprised of eight members. Six members are physicians, one member represents the Board of Pharmacy and the other member represents the Board of Nursing. The Committee is currently searching for a public member.

The PCA Committee works with hospitals and other institutions to improve quality assurance and patient safety programs through the review of

certain types of reports submitted by the hospital. These reports describe adverse outcomes, full medical reviews of the incidents, and the corrective/preventative action plans of the facilities.

The Committee's mission is to prevent patient harm by strengthening medical quality assurance programs in all institutions. The PCA program concept has become a national model for health care excellence, as noted in the 1999 Institute of Medicine Report on the prevention of medical errors.

The current members of the Committee are Martin Crane MD (Ob/Gyn), Asha Wallace MD (Family Practitioner), Alice Coombs MD (Intensive Care, Anesthesiologist), John Herman MD (Psychiatrist), Dinesh Patel MD (Orthopedics), Hart Achenbach MD (General Medicine), Janet Dewan CRNA, Sophia Pasedis R.Ph. We are currently appointing new Nursing and Pharmacy Board representatives.

The PCA Committee meets once a month to review Major Incident Reports, Annual Reports and Semi-Annual Reports

submitted by Health Care Facilities, provide support services and make subsequent recommendations to improve care in individual facilities and in the health care system as a whole.

The PCA Committee members also visit health care facilities to provide information on the program. One item that the PCA Committee often clarifies is that the entire reporting and communication process with the PCA Division is confidential and non-punitive. It is not shared within the Board of Registration in Medicine nor it is shared with other agencies. The reports that go to PCA are separate and distinct from the types of reports that go to the Department of Public Health. This policy assures you that the adverse events that you report to us are kept confidential. The more reports we get, the more we learn and the more we can share with others to make improvements together. We already have a great and proven patient safety system in Massachusetts, let us make it work even better.●

The PCA Committee has created a Certificate of Recognition Program. Share with us your success stories or other innovations you have implemented to reduce medical errors. We would like to honor you and perhaps share your best practice with others.



Tumbles and Falls

(Continued from page 1)

The PCA Division's efforts to locate a post-fall assessment tool for the inpatient setting (review of relevant society guidelines and medical literature) were unsuccessful. In "Quality Indicators for the Management and Prevention of Falls and Mobility Problems in Vulnerable Elders," Rubenstein notes that the basic fall evaluation includes the following components: 1) a history of fall circumstances, medications, acute or chronic medical problems, and mobility levels; 2) an examination of postural pulse and blood pressure, vision, gait and balance, and lower extremity joint function; 3) an assessment of basic neurological function, including mental status,

muscle strength, lower extremity peripheral nerves, proprioception, reflexes, tests of cortical, extrapyramidal, and cerebellar function; 4) an environmental assessment; and 5) a formulation summarizing diagnostic impressions and therapeutic recommendations. (*Ann Intern Med* 2001; 135:686-693)

The purpose of this Update is to strongly recommend that all hospitals review their existing fall policies to ensure that their guidelines include a comprehensive post-fall assessment with specific recommendations for follow-up, in the ED and outpatient unit, as well as the inpatient units. In addition, special attention should be paid to the anticoagulation medication list in a hospital's "Fall Risk

Assessment" protocols. Best practice in falls management ensures that the caregivers know: when an immediate medical evaluation is needed; the type of patient monitoring needed; the frequency of vital signs needed; and how to perform a skilled neurological assessment. Improvements in the process of care following patient falls should lead to improvement in patient outcomes.

Please contact the PCA Division if you have any questions or comments about this Update or if you need assistance in drafting a post-fall assessment protocol. The PCA Division has several literature references that can be accessed on the Board's website. ●

Workshop Opportunity

Starting this fall, the PCA Division staff will be holding PCA workshops. These workshops are designed to help you better the patient care assessment program at your facility. At a workshop, you will get a background of the Patient Care Assessment Program at the Board of Registration in Medicine. We will go over what we do and how we can assist you in your quality improvement activities.

Furthermore, we will review the types of quality assurance reports that your facility submits to the Patient Care Assessment Division.

We will provide examples and model reports to help you learn how to best analyze and report adverse events. From Semi-Annual and Annual Reports to the different types of Major Incident Reports, we will work with you, and provide you with, the

information and tools to make it easier for you to report and gather quality improvement information at your organization. Our goal is to be a resource for you as we all work to improve health care quality and reduce medical errors in the Commonwealth.

Workshops will be held at the Board of Registration in Medicine from 8:30 to 4:30 p.m. A list of available dates will be mailed during the month of October. ●



Special Points of Interest

- Visit the Board of Medicine website to view and download a copy of the 2005 PCA Annual Report and the 2005 Board of Registration in Medicine Annual Report
- Interested in Benchmark Data? See the Patient Care Assessment Link on the Board website for helpful information and articles
- Please share this Newsletter with others in your organization. To be on the “First” email list, please submit your name and email address to webmaster@state.ma.us and put in the subject line—Add to List.
- The Board Website is at www.massmedboard.org

Did You Know?

If you have a new PCA Coordinator, you must report the name to the PCA Division within 10 days of designation or replacement
243 CMR 3.06(2)

To electronically save your entries on the MIR form, first open the MIR Form in Adobe Acrobat Reader. Then you will be able to save your changes.

Bariatric Benchmarks

This article highlights the latest literature-based research information for management of complications post-bariatric surgery.* If you would like more information on the topic below, as well as the latest in the incidence and diagnosis of anastomotic leak after Laparoscopic Gastric Bypass (Lap GBP) and Gastrointestinal hemorrhage after Lap GBP, please go to the Patient Care Assessment link on the Board website. The references used below can be found in the “peri-operative bariatric surgery management” paper.

Immediate and Short Term Metabolic Complications following Bariatric Surgery

As the total number of weight loss surgeries increases, there are new concerns over uncommon metabolic complications in the

immediate postoperative period.

1. *Rhabdomyolysis*: This condition may be caused by unrelieved muscle pressure during surgery and is more common than previously thought. If creatinine kinase level rises over 5000 IU/L. clinical intervention should include fluid replacement, forced diuresis and alkalization of the urine.
2. *Wernicke’s Encephalopathy*: This condition is caused by severe thiamine deficiency and presents with ocular changes, ataxia, and mental confusion and can occur as early as two weeks post-op and as long as 13 years later. Early recognition and treatment with 100mg Thiamine q8hr can be successful.
3. *Vitamin A Deficiency*: One study of 170 patients showed an increase in this deficiency by 69% in 4 years. Long-term nutritional

monitoring is necessary after malabsorptive operations for morbid obesity.

4. *Acute Post Gastric Reduction Surgery Neuropathy (APGARS)*: The signs for this neuropathy include progressive vomiting, weakness and hyporeflexia. The diagnosis is made by an EMG showing polyneuropathy in the quadriceps. The treatment consists of nutritional supplements.

5. *Immobilization Hypercalcemia*: Critically ill bariatric patients may be at increased risk for this disorder. The recommendation is to monitor the calcium levels in those with complicated courses and periods of immobilization. Pamidronate infusions have been used to resolve hypercalcemia.

*Source: Gastroenterology Clinics of North America, March 2005



Regulation Review

PCA regulations require that health care facilities submit an annual summary analysis of patient complaints and disposition in its Annual Report.*

Here is why the PCA Division requires this data. The PCA regulations require that a health care facility establish effective programs in quality assurance, risk management, peer review, identification and prevention of substandard practice, maximization of patient care assessment and minimization of loss.* When a patient or family makes a complaint about the health care facility's services or encounters with staff, the facility's ability to respond to the complaint, investigate the complaint, and take an action to address any problems identified is a mirror of the quality improvement and patient safety culture that exists at that facility. The PCA Division is interested in the components of this complaint process. How your complaints are processed is one measure of the effectiveness of your facility's PCA Program.

Both the reason for a complaint and the response by the health care facility to the complaint provide evidence of the ability of the facility to identify problems and take effective action to improve

systems and practitioner performance. Unlike the health care facility's internal reporting system that is designed to capture outlier data, the patient complaint system is external and usually reported retrospectively following the care.

The PCA Committee has reviewed Annual Reports from sixty-nine health care facilities and has found that most facilities submit the breakdown of complaints, but fail to provide an analysis of the data collected. Merely indicating the number of complaints received does not provide evidence that your facility is using that information as an opportunity for improvement.

Here are two examples of the type of complaint data analysis that we would like to see in the Annual Reports.

1. A health care facility found that 48% of its patient complaint totals were related to patient encounters in its Emergency Department (ED). An analysis of the individual complaints showed that the majority of complaints were due to the ED wait time. The facility was unable to reduce the ED wait time until significant resources in capital were allotted to ED expansion. In the interim, the facility used the data to identify

other measures to assist patients who may be subject to extended waits in the ED, based upon their triage assignments. These efforts led to the creation of a patient advocate position specifically for the ED.

2. A health care facility received a patient complaint about being left alone following her exam in the radiology department. The health care facility reviewed the radiology waiting area and noted it was somewhat remote from the radiology reception area and lacked a patient call bell. Having no other available space for a waiting area closer to the radiology exam rooms, the health care facility assigned a monitor to the waiting area and also placed a call bell in an accessible location.

Use patient complaint data not only to address the individual complainant's concerns, but also to identify global opportunities for improvement. Submission of your facility's analysis of this data in the Annual Report, along with a description of the opportunities for improvement identified, will reassure the PCA Committee that your facility has an appropriate system for managing patient complaints and is committed to identifying opportunities to improve patient care. ●



To Report or Not Report

Every *First* Newsletter will contain a section called “To Report or Not Report”. This section is designed to assist you on whether or not you should report certain adverse events.

Everyone has difficulties determining whether an adverse event falls under a Type 4 Major incident as defined in the PCA regulations.* This section will help you understand the analytical process and patient safety analysis that should be conducted in anticipation for reporting Type 4 events.

Specifically, each article will feature a case example and an analysis on why or why not that case should be reported under the PCA regulations. We hope this will be helpful. If you ever have questions on whether a case should be reported, feel free to contact the PCA Division staff for assistance. Thank you again for your commitment to patient safety.

Example

A seventy-six year-old patient sustained a large retroperitoneal hemorrhage following cardiac catheterization and expired. The Hospital determined that it was an adverse outcome associated with a cardiac catheterization. The potential complication was noted appropriately on the Informed Consent and the hospital stated no corrective measures were needed.

Does this event meet the Type 4 Reporting Criteria, which is defined as “a death or major impairment of bodily function that was not ordinarily expected as a result of the patient’s condition on presentation?”

The first question is whether the case has a death or major impairment. This case does have a death, so it meets part of the Type 4 definition. The second question whether the death was ordinarily expected. In this case the answer is no because the patient died

secondary to a usually non-fatal complication.

Although hemorrhage is a recognized complication of this procedure, a thorough review of the events surrounding the procedure is needed before the hospital can state that this was an adverse outcome of procedure that did not need corrective measures or reporting to PCA.

Reporting the event does not indicate that the patient received less than adequate care. Conducting a review and reporting the findings will be described and will act as supporting documentation for the conclusion of the reviewers that this incident was a “rare but recognized potential adverse outcome of the procedure.”

This case will be expanded in future newsletters to address the review for the cause of the hematoma, how to include complication data and attending follow-up.●

*243 CMR 3.12

Thanks to All for Submitting Responses to the Weight Loss Surgery Survey last Spring. We are working with the Betsy Lehman Center to compile the results and provide you with aggregate feedback on the survey results later this fall. Thanks again for your support.