



FIRST

Do No Harm

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Patient Care Assessment Division, Board of Registration in Medicine

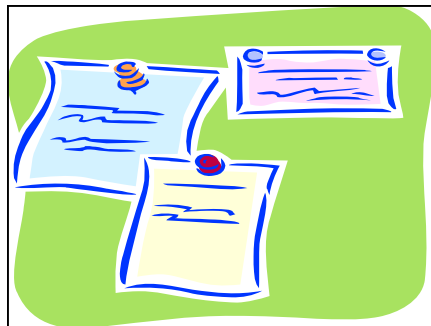
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The New Season for PCA

In March, the Board of Registration in Medicine will be releasing for public comment a draft of new regulations governing operations of the Board, including the PCA Program. This is the first significant revision of the Board's regulations in nearly twenty years.

Some of the major changes include creation of an administrative medicine license for physicians who have little direct clinical contact with patients, such as researchers; new reporting guidelines for the PCA Program; a new structure for the PCA Program; improvements for residency programs;

and changes to certain credentialing requirements. Other changes impact Board discipline for physicians who fail to respond to Board communications.



The proposed regulations will be posted on the Board's website by the end of March and a public hearing will

be held at the Board of Medicine's offices later this spring.

Notice of the hearing date will be posted on the Board's website and will also be in major newspaper publications. Details regarding the format for submitting testimony and how to submit written testimony will be on the website.

The entire administration has worked on these changes since last fall. We look forward to your input and hope that we will be able to achieve the goals of the Board and of the medical and patient safety communities. ✍

What We Do With What You Do

What does PCA "Do" with all the information sent in from health care facilities? This simple and honest question, raised at the first *PCA Patient and Training Session Workshop* (January 13, 2006), really caught the attention of the staff at the PCA Division. Thank you for asking.

The PCA Committee has recently finished a complete initial review of all acute care hospitals, including rehabilitation hospitals. This means that those of you reading this newsletter have been reviewed at least

once, and in fact, there are many facilities on their fourth Committee review.

The regulatory reports of each facility: the major incident reports, semi-annual and annual reports, are reviewed and analyzed for compliance with the elements of a qualified PCA Program. The information in these reports is the *aggregate* body of evidence that proves each facility has a robust and dedicated process, as required by PCA regulations. These regulations require that a healthcare

facility establish effective programs in quality assurance, risk management, peer review identification, prevention of substandard practice, maximization of patient care assessment and minimization of loss. That said, what do we do with the information we receive?

When it comes to Major Incident Reports, the following details from the report are entered into a database for Major Incident Reports: Name of facility, date of incident, location of incident, patient's date of birth, date of

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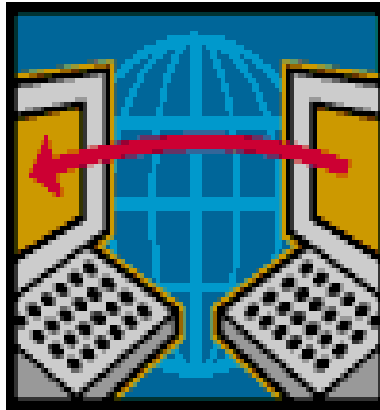
One Hospital's Success

Imagine this scenario: A patient is seen at 'Hospital A' after falling at home. She is seen in the Emergency Department and evaluated for neck pain. X-rays are done and the patient is sent home. Later that week, the patient returns to 'Hospital A' with numbness and weakness in her arms. She requests a transfer to 'Hospital B'. Following an evaluation at 'Hospital B', it is found that she has a fx cervical spine and is admitted and treated at 'Hospital B'. Over the course of these vents, there is no communication between 'Hospital A' and 'Hospital B', and 'Hospital A' is unaware of the patient's outcome. Was the cervical fracture missed at 'Hospital A'? Was there a problem with communication between the radiologist and the Emergency Department physician? An opportunity to correct a systemic problem and to make improvements in future patient care and safety may be missed in the absence of dialogue between the two facilities.

Some of the Major Incident Reports that come in to the PCA Division are from tertiary care centers, where the sickest patients have been transferred by smaller hospitals, or where a patient is seen at more than one hospital for the same complaint. Was the original facility aware of the patient outcome as reported to us by the subsequent facility? In many cases, we have contacted the original hospital to discuss the patient outcome and

determine whether or not they investigated the occurrence and took corrective action at their facilities. While many facilities communicate outcomes back to the referring hospital, this does not consistently occur.

The PCA Committee had requested a description from one Massachusetts hospital of their process to review outcomes of patients transferred to tertiary care facilities. The Hospital, in its reply, stated that HIPAA made systematic



outcome review very difficult. Either the Hospital or the tertiary care facilities was interpreting HIPAA restrictively, as well as allowances for such activities as peer review, inherent in tracking the appropriateness of transfers.

The PCA Committee suggested that the Hospital and its partner tertiary care facilities meet and eliminate the unnecessary barriers to sharing of appropriate information. Systematic feedback from the tertiary care facilities is the preferred method

for peer review regarding transfers.

The majority of patients from the smaller Hospital were transferred to two or three tertiary care centers. The Hospital established a Memorandum of Understanding (MOU) with the tertiary care centers, which included language that protects patient confidentiality, yet allows the sharing of information to ensure appropriateness of transfer and pre-transfer treatment. The Hospital approved a policy and form letter to send to all tertiary care facilities on the appropriateness of transfer and pre-transfer treatment. A MOU may also be useful in eliminating HIPAA barriers with the Medical Examiner's office. It may enable a review of previously unavailable autopsy reports.

The Board of Registration in Medicine PCA Committee appreciates the strong commitment to improving patient care shown by this facility in implementing this MOU. We were particularly impressed with the efforts the Hospital made to enable the sharing of information between facilities following a patient transfer, in order to assure the appropriateness of transfer and other aspects of the patient's care.

We encourage all facilities to look at their transfer policies to see what improvements can be made in their patient safety processes. Much can be learned by collecting and analyzing this data, and implementing policies as a result.☺



PCA Goes to School

The PCA Division is now enrolling participants in its Patient Care Assessment Quality and Patient Safety Training sessions. These workshops are designed to help you maximize the results of the Patient Care Assessment program at your facility. At a training session, 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 to you, the information and tools to make it easier for you to report and gather quality improvement information at your organization. This program is designed for anyone in your organization who is involved in patient safety or quality improvement activities.

The PCA Division is offering these training sessions at no cost. However, the training sessions are on a first-come first-served basis and are limited to twenty participants per session.

The training sessions will be held at the Board of Registration in Medicine from 8:30 to 4:30 p.m. Parking is nearby and the Board of Medicine is easily accessible by public transportation.

The remaining dates for the training sessions are May 18, June 22, and July 13. These classes fill up quickly, so to enroll, please fill out a form. Forms have been mailed to all PCA Coordinators and the brochure is available on the Board's website. These training sessions are meant to be positive, collaborative processes, and we hope that you will find it, and will help it, be a valuable event. ☺

Inaugural Board of Medicine Newsletter

The Board of Registration in Medicine has issued its inaugural issue of the Board Newsletter. Each calendar quarter, the Board of Medicine will publish a newsletter called "Newsbrief" with useful news and information, answers to your questions, legal and regulatory updates, and notice of any new Board

programs or initiatives of which you should be aware.

A copy of the Board's newsletter will be available on the Board website. The Winter edition of the newsletter is currently available and features topics such as how to avoid consumer complaints, how to be a bedside advocate volunteer, the new HIPAA

requirement, physician urban myths, and much more.

Between PCA's newsletter "First" and the Board's newsletter "Newsbrief", we hope you find helpful resources for your entire medical and professional staff. Please contact us with any suggestions for future content. ☺

To directly receive an e-copy of this newsletter, please send an email with your name and organization to First@dph.state.ma.us, with the words "Add me to the email list"



Special Points of Interest

- Benchmarking information is available on the Board of Medicine website. At the Home page, please click on “Patient Care Assessment”, then click on “Benchmarking”. The “Benchmarking” page will link you to information relative to Perioperative Bariatric Surgery Management, Colonoscopy, and Sepsis. The links will be updated periodically.

Guidelines on Performance Data

In early February 2006, the PCA Committee issued guidelines for the collection, analysis and reporting of Performance Data.

When you submit an Major Incident Report to PCA Division, one of the requests you may receive back from us is for additional (de-identified) information about the individual credentialed practitioners involved in the event. We do not ask this in order to identify the practitioner(s) involved, but to assure that your facility, as part of the investigation, has made an assessment of the practitioner’s performance.

The PCA Committee wants to be sure that your facility ensures that its professional staff is competent and meeting applicable patient care standards. The information submitted in the Major Incident Reports is de-identified and absolutely confidential; nothing is shared with the public or with the other divisions at the Board of Registration in Medicine.

We understand that there is great variety in the size of facilities within

Massachusetts and in the available resources to be used in analyzing practitioner performance. Based on the PCA’s review of more than 1,000 Major Incident Reports over the past two years, and in an effort to clarify what information PCA feels is most critical, the PCA Committee created guidelines for the collection, analysis



and reporting of performance data that may be of interest to facilities.

Summarized, these guidelines are: (1) a brief description of the practitioner’s education, training, experience, board certification; (2) a description of the criteria that are used to assess the practitioner(s)

performance (this will depend on the specialty of the practitioner); (3) an analysis of the practitioner’s performance, as measured by applicable criteria, for the three years prior to the incident. This should include: a numerator (practitioner data) and denominator (department/service data), and rate per year (relevant to the analysis of the case); (4) a comparison of the practitioner’s data to internal benchmarks (the department or service) and external benchmarks (and source); (5) whether or not this practitioner was involved in other MIRs (briefly describe), and any other performance issues that may be relevant to the analysis. For example, did the practitioner meet applicable performance based credentialing/recredentialing requirements?; and (6) an assessment of whether any corrective actions or performance improvement measures are necessary (further education, training, monitoring). You will be receiving a this guideline by mail and it is available on the website. ☺



What We Do With What You Do (continued)

(Continued from page 1)

admission, facility staff involved in the incident (de-identified), type of report (I-IV), Basis Codes, narrative, investigation, and corrective actions.

The new database currently has nearly 3000 reports. When there is a suspicion that an adverse event may show a trend (e.g., deaths following gastric bypass and maternal deaths), the database is searched by text or by the Basis Codes. That aggregate information is reviewed and becomes the basis of a PCA Advisory or Alert for the Commonwealth, (in the same fashion that JCAHO alerts are derived from information received via Sentinel Event Reports).

For example, when one facility reports a “rare event” following colonoscopy, there is a good chance that PCA has received the same type of incident from several other healthcare institutions across the Commonwealth. The detail in each report is looked at for trends. Those trends can then be shared with all healthcare facilities in a PCA Advisory or Alert to improve patient safety.

Another example is patient falls. Every facility has a formal process to review patient falls. However, aggregate review of fall data received by PCA indicates that the severity of the outcome, after a fall, is often related to the process in place at the facility for post-fall assessment and intervention. PCA has reviewed many

Fall Prevention and Assessment Policies that completely address fall risk, assessment and reporting of the fall. However, these policies do not address the expectations required in post-fall observation of the patient. This finding was shared in the December PCA Newsletter “*First, Do No Harm.*”

At the present time, the PCA Committee is reviewing reports where there is concern that a delay in the diagnosis of septic symptomatology has led to major morbidity or mortality. Every facility has identified this issue as a concern, yet very few are able to recommend a corrective action beyond “staff education.”

The Rapid Response Teams have been an instrumental action in decreasing the level of morbidity. Every Hospital continues to struggle with the means to prevent a crisis and ensure early intervention. It is the goal of the PCA Division to put together an Advisory with the findings from the review of multiple medical records and Major Incident Report reviews attributed to a delay in the recognition of the signs and symptoms of sepsis. Then the PCA will share these findings with facilities that have not found a way to ensure early intervention.

With regard to Semi-Annual and Annual Reports, the information in these reports is a window into the

quality improvement process at each facility. These reports that come to PCA are varied in size, from three pages to fifty pages, and in an array of styles, from a professionally bound report to a simple memo.

PCA is looking for four measures of quality in the semi-annual report: the indicators chosen to monitor the quality of care; the manner in which the data is presented for each indicator; the facility's' analysis of that data; and what, if any, actions the facility has taken to improve patient care, based on this analysis.

In the annual report, PCA is looking at three categories of the information: the process for handling patient complaints, the facility's' analysis of the data, and any action taken to improve patient care and safety as a result of the this process.

The PCA Committee analyzes the information and compares it to available benchmark data (the Board has a Medical Librarian continuously compiling and updating benchmark data on common adverse events), and an evaluation is made as to the effectiveness of the quality improvement program. The Committee reviews the outcome, and identifies areas for remediation and other actions to improve patient care. This assessment is shared with the healthcare facility in the Health Care Facility Review and a dialogue is open between the facility and PCA. ☺



A Focus on Type 3 Reports

The PCA Division revised its definition of a “Major Incident” in 1999, when the current definition of a Type 3 Major Incident was instituted. A Type 3 Major Incident is “an invasive diagnostic procedure or surgical intervention performed on the wrong organ, extremity, or body part.”*

Since the reporting of such incidents has been mandatory since 1986, the number of Type 3 Major Incident Reports received from 2003-2005 has fluctuated very little, though the total number of MIRs received in each of these years has increased dramatically. Indeed, the issue of wrong-site surgery has been a topic of discussion for years, as evidenced by a 1998 JCAHO Sentinel Event Alert entitled “Lessons Learned: Wrong Site Surgery” (Issue 6: August 28, 1998; www.jcaho.org). The numbers of Major Incident Reports and Type 3 MIRs from 2003-2005 are listed in the chart below.

Out of the twenty-five Type 3 Major Incident Reports received in 2005, twenty-one were reports of wrong-site surgeries or biopsies. The remaining four reports concerned anesthesia delivered to the wrong site

prior to surgery, which is, in itself, invasive. In these four cases, the mistaken site was corrected before surgery was performed.

Root causes analyses of these incidents reveal that the primary reason for wrong-site surgery is unclear, inconsistent, or non-existent protocols for Site-and-Side Marking and Time-outs. Other concerns include communication between health care personnel, patient identification, and correct identification of the surgical site (in the case of spinal procedures). Additionally, six of the reports demonstrate concern with individual physicians; all six of these cases were among the twenty-one cases of surgery or biopsy. These cases resulted in monitoring, re-educating and counseling the practitioners in question. In one of these cases, the PCA recommended a letter be placed in the physician’s file.

The Corrective Action Plans for the majority of these cases were well-considered and appropriate. Most common were the implementation of new protocols or the revision of existing protocols. The most frequent

policy adaptations are as follows:

- Implementation of new, or revision of current, “Site-and-Side” protocol (6 cases)
- Implementation of new, or revision of current, “Time Out” protocol (4 cases)
- Implementation of a “Time-Out” protocol in the pre-operative area to prevent anesthesia to the wrong site (2 cases)
- Creation of a new policy requiring X-rays be performed after the placement of site markers, in the case of spinal surgeries (2 cases)
- Other protocol revisions, including scheduling for invasive procedures, as well as patient identification (4 cases)

In conclusion, the occurrences of wrong-site surgery can be reduced or even eliminated through effective written protocols. If such protocols are in place, compliance must be monitored and enforced in order to prevent mistakes by individual non-compliant practitioners. With these systems in place, it will be possible to eliminate the phenomenon of wrong-site surgery. * 243 CMR 3.08(2)(1)

	2003	2004	2005
Total MIRs	466	637	809
Type 3 MIRs	22	23	25