



FIRST

Do No Harm

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Patient Care Assessment Division, Board of Registration in Medicine

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Advocating for Patients

Everyday we receive stories from health care advocates having experienced medical mishaps during medical care. If they are subject to unexpected adverse events, then the general public most surely is experiencing similar events.

We consistently receive phone calls, emails or letters from physicians, hospital executives, and patient care coordinators stating that they believe their quality assurance program does not need to be independently monitored. They argue that they have evidenced-based policies and

procedures and a deep commitment to patient safety and medical error reduction. While we have come a long way since the 1999 Institute of Medicine report, more work needs to be done to improve patient safety. These facilities are working hard, but patients are still at risk due to medical mistakes. Hospitals should be looking for ways to ensure provider competency, proper delivery of medical care, adherence to standards of care and more. Physicians and hospitals need to support reporting of events so that information can be

gathered; allowing us all to learn from these events and to disseminate this learning to others. The PCA Division is a reporting entity that is confidential and non-punitive in order to collect, analyze, and distribute information and knowledge to health care facilities so that all facets of the health care system are engaged, working together and learning. This newsletter is about providing information on how to better improve safety and increase quality. Twenty years ago the Legislature entrusted this mission to us. So let's do it and save another life.

Conscious Sedation—Where, When and How?

Conscious Sedation, now routinely performed in hospitals, was not so "routine" back in 1994 when the Medical Board's PCA Committee convened a task force to review the evidenced-based standards applicable to the performance of these procedures. Conscious sedation involves the administration of moderate sedation and analgesia to allow for patient comfort during a procedure. At that time, the PCA Committee was concerned that not enough was being done to assure that conscious sedation was being

administered safely in hospitals. The work of the 1994 task force led to the issuance of "Patient Care Assessment Guidelines for Intravenous Conscious Sedation."*

Today, with the expansion of surgical procedures outside of the controlled operating room setting and the proliferation of invasive diagnostic procedures, conscious sedation is being performed in a variety of locations, both inpatient and outpatient, throughout health care facilities. Appropriate and uniform policies and procedures should govern

administration of conscious sedation, regardless of where these procedures are performed.

The Board's Conscious Sedation Guidelines, developed by PCA, describe the basic elements for safe and effective conscious sedation that remain applicable today, such as the need for appropriate drugs, doses and techniques; training supervision and credentialing of involved practitioners; patient selection criteria; patient monitoring requirements; and

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Change in Command

Effective July 2006, Dr. Martin Crane will be stepping down as Chair of the PCA Committee. Dr. Crane has served as Chair of the Committee since 2003 and is commended for his dedication, commitment to and vision for the Patient Care Assessment Program.

Dr. John Herman will be assuming the role as Chair of the Patient Care Assessment Committee. John B. Herman grew up in Wisconsin and graduated from the University of Wisconsin Medical School in 1980. His medical internship was at Brown University Medical School and his residency in Psychiatry at Massachusetts General Hospital, which he completed in 1984.

Dr. Herman is Director of Clinical Services in the Department of Psychiatry at MGH. He also serves as

Medical Director for Partners HealthCare Employee Assistance Program. In 2002, Massachusetts Governor Mitt Romney appointed Dr. Herman to the Commonwealth's Board of Registration in Medicine.

Dr. Herman is past President of the American Association of Directors of Psychiatry Residency Training. He is a Distinguished Fellow of the American Psychiatric Association. Following his residency at MGH, Dr. Herman joined the staff of the MGH Psychopharmacology and Addiction clinics where he remains in active practice.

Until 2003, for 14 years Dr. Herman directed the department's nationally renowned continuing education program, Harvard Medical School's most successful post-graduate educational offering.

Between 1991-2000, he was Director of Psychiatry Residency Training at MGH. His primary interest is in addressing the gap between the quality of mental health care delivery in the community and rapidly accelerating advances in psychiatric practice. Consequently, he focuses his teaching efforts on primary care clinicians.

Dr. Herman has lectured to primary care audiences across the United States and internationally. Currently, he is co-editor (with Ted Sterne, MD) of the popular **MGH Guide to Primary Care Psychiatry** (McGraw Hill, 1998, 2003). Dr. Herman looks forward to working with health care facilities, physicians and other health care quality improvement leaders to advance health care quality. ~

Health Care Recognition

Award of Excellence for Outstanding Performance

~Mercy Medical Center~

For their implementation of the IHI Rapid Response Team Initiative that resulted in the education of staff, the collection and tracking of data, decreased transfers to critical care and increased patient safety.



Examples of Reporting

Many facilities struggle with the analysis of adverse events. At times, the Patient Care Assessment Division receives reports that have minimal to non-existent root cause analysis of adverse events.

Often those facilities ask us what we are looking for. A good analogy is a standard high school math class. When taking a test or submitting homework, the math teacher looks not only for the correct numerical answer to each question, but also wants to know how the student got this answer. The teacher wants to see the equation and the process. This process also applies to the PCA Division.

We are not only looking for your final answer of what went wrong, but rather how you reached that conclusion. What things did you look

at, or what policies did you rewrite or implement? That is what the PCA Division asks for and looks for on your health care facility reviews.

Here is another example. “On a sunny day, Timmy went to the park.” If this was a Major Incident Report, the PCA Division would want to know, as should the health care facility reporting the information, details such as when was the sunny day? How did Timmy get to the park? Why was Timmy going to the park?

So a better Major Incident Report would state: “On a sunny Friday in July 2006, around 2pm in the afternoon, Timmy rode his red bike to the Pleasant Valley Park. He was meeting his friends Mike and Stephen, so they could prepare for a school science project about the solar system, which was due the next day.”

Another question often raised is: How do you know what to put in the story?” The simplest explanation is to put in relevant details. Describe what Timmy was wearing if it was relevant; for example, if Timmy suffered heat stroke or if Timmy’s pant leg got caught in the spokes of the bike wheel and suffered severe injury.

PCA is looking for a story and not an investigatory finding alone. We hope that these examples will explain what we are looking for a little better, but the PCA Division continues to hold training sessions if you would like more information on our program, or to receive help with your reports.

We are also always available by phone to confidentially answer any questions you may have or to hypothetically discuss a case at your facility. ☺

Conscious Sedation (Continued)

availability of emergency support services. Since the issuance of the PCA Guidelines, conscious sedation standards have been further defined and improved, and facilities should refer to the American Society of Anesthesiologist’s guidelines and standards.* Conscious Sedation is now more commonly referred to as ‘Moderate Sedation’.

Take time to review your facility’s conscious sedation policies and make sure that they are up to date. Make sure you know the locations where

conscious sedation is being administered at your facility. Are candidates for conscious sedation being appropriately evaluated, so as to exclude those patients who may be a high risk due to underlying systemic disease? Are services and all departments uniformly and consistently following applicable drug dosage and monitoring policies? Do all services and departments have the necessary equipment for safe monitoring of patients during these procedures? Is the hospital able to

provide the necessary emergency support should complications arise in any of the locations where conscious sedation is administered? Do you have an ongoing process for monitoring compliance with your facility’s conscious sedation policies? Make sure you can answer “yes” to all of these questions. Knowing “where, when and how” will go a long way toward assuring a safe environment for patients receiving conscious sedation. ☺

*PCA Guidelines: www.massmedboard.org/pca/pca_intravenous.shtm,

*ASA Standards & Guidelines: www.asahq.org/publicationsAndServices/sgstoc.htm



Hydromorphone Advisory

The Board's Patient Care Assessment Committee has reviewed 15 Major Incident Reports describing adverse patient outcomes associated with the administration of intravenous hydromorphone.

Based on our review of these cases, we have noted the following concerns: (1) hospital staff did not have available information on the equianalgesic dosing of morphine and hydromorphone; and (2) respiratory depression went unrecognized following both patient-controlled analgesia and single bolus dosing of hydromorphone.

We noted that none of the patients were monitored with O₂ saturations or telemetry. Four deaths occurred after bolus dosing of 2-4 mg of hydromorphone, with repeats of 1-4 mg; one death occurred after the patient, who was receiving hydromorphone via epidural, was

given lorazepam for restlessness; and one death occurred after hydromorphone and morphine were both given to the patient within a short time period.

These concerns are not new to health care facilities. The *Institute for Safe Medical Practices* issued a Medication Safety Alert in July 2004 that addressed the potential for adverse events from "mix-ups" when hydromorphone 2 mg was accidentally substituted for morphine 2 mg.

The alert contained several recommendations to reduce the chance of "mix-ups" including: limiting access to the stock of the drug; ensuring that each drug is stocked in a different strength (for example 2 mg hydromorphone and 4 mg morphine); requiring an independent double check prior to administering IV narcotic doses; educating staff on the differences between the two narcotics;

and implementing policies that specify the scope, frequency and duration of monitoring when patients are receiving parenteral narcotics.

Please review your facility's ordering practices for hydromorphone dosing. Assure that your facility has appropriate policies and procedures for monitoring patients who are receiving parenteral analgesia, and that those policies and procedures are being followed by your facility's health care providers.

Please review the root causes of events and "near misses" from oversedation with hydromorphone and other narcotics, and based on this review, implement change wherever an opportunity for remediation is identified. PCA will be issuing a detailed advisory on this issue later this month. If you have any questions about this topic please contact your PCA Division representative. ~

The Need for PCA

As Donald Berwick (et al) stated in the *BMJ—Quality and Safety in Health Care* (8/2005), the primary goal of improvement is to change performance. Berwick also stated that it was unfortunate that scholarly accounts of the methods, experiences, and results of most medical quality improvement work are not published. Thus depriving staff of the opportunity and incentive to clarify thinking, slowing dissemination of established

improvements, inhibiting discovery of innovations, and compromising the ethical obligation to return valuable information to the public.

Berwick had many thoughts as to the reasons for this failure, but ultimately suggested that medical quality improvement will not reach its full potential unless accurate and transparent reports of improvement work are published frequently and widely. The PCA Division is currently

working with the Harvard School of Public Health to publish aggregate data from the classification of PCA reports. This analysis shows that PCA is making a difference in medical error reporting and changing the thinking regarding the quality landscape in the Commonwealth. In 1986, the Legislature entrusted us with the mission of improving quality of care, and this data will document the effectiveness of the program. ~



Regulations Update

The Board of Registration in Medicine is currently proposing revisions to its regulations. The proposed regulations have been drafted through three public hearings, and the proposals are currently being reviewed by various state agencies.

The Massachusetts Board of Registration in Medicine, of which the PCA Division is a part, plans to hold a formal comment period and hearing later this summer.

However, it is concerning to the PCA Division that some leading organizations with a public commitment to patient safety have many misconceptions about the PCA Division, the PCA Program, or the current PCA regulations proposals.

While the Board of Registration in Medicine is still modifying the provision of its regulations, here is a summary of the proposed changes to the PCA regulations.

The regulations would create two separate committees at the Board of Registration in Medicine to enable the Board to carry out its patient safety functions. One committee (Patient Care Oversight Committee) would be a public committee that would oversee the Patient Care Assessment Plans for health care facilities and the reports and advisory committees created to provide information to the public. The other committee (Quality Improvement Committee) would be a private committee that would confidentially review adverse event

reports. This proposed change is to balance the need for public transparency and to maintain the PCA's mission to provide confidentiality for peer review information, tracking trends, and lesson learning.

The definition of "Health Care Facility" and "Clinic" is modified. The proposed definition expands the types of facilities that would be required to report to the Quality Improvement and Patient Care Oversight Assessment Committees. This definition change reflects case law and legislative intent enabling the PCA Division to oversee the practice of medicine wherever it occurs.

The section on reporting of Patient Care Assessment Plans, and amendments, updates, and written instructions regarding the Plans, has been updated. The proposed changes would require filing of PCA Plans every three years for formal approval by the Patient Care Oversight Committee. The Patient Care Oversight Committee would have the authority to annually issue a list of facilities that do not have a Qualified Patient Care Assessment Plan in their facility.

PCA Coordinators would be required to provide the details of the facilities' internal incident reporting system to health care providers employed, credentialed or associated at said facility, rather than to employees only. The providers would

now be required to have more hours of patient safety training.

Under the proposed changes to the annual report, information about terminated full licensees would go to the Data Repository rather than to PCA. The annual report would not contain information about the PCA Plan as that would go to the Patient Care Committee.

Another significant change is the elimination of the four types of major incidents currently used for reporting. In its place are two proposed categories of reports: National Quality Forum Never Events* and unexpected occurrences. All health care facilities would have to report on any of 27 events listed in this section. In addition to these 27 events, facilities would be required to report any other unexpected occurrence related to system or process deficiencies or health care provider concerns leading to death or major and enduring loss of function for a recipient of health care services. Aggregate reports would be issued every year and, starting in 2010, a list of facilities and the number and type of Never Events would be annually released to the public. However, the root cause analysis and the occurrence reports would remain confidential. Balancing the continuing confidentiality with aggregate disclosure may lessen the need for total disclosure as advocated by other federal and state governmental bodies.

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Regulations Update Continued

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This Never Event reporting requirement is not necessarily new. PCA already receives Incident Reports that are Never Events. Having regulations specifically requiring Never Event reporting is the result of hospitals wanting clearer reporting requirements and national standards for patient care quality, and research on PCA data shows that more Never Event reports are submitted to PCA due to confidentiality protections.

Changes are also proposed to the types of reports that physician offices must submit to the PCA Division. In the Type 2 category of events that must be reported to the Quality Improvement Committee, physician offices must report any adverse event resulting from the use of intravenous,

intramuscular sedation/analgesia, general anesthesia, or major conduction blockade. The report would be filed directly with the Quality Improvement Committee unless the licensee has an affiliation



with a health care facility. In such a case, the licensee would report to the health care facility and the health care facility would have to report to the Quality Improvement Committee.

Some of the previous sections have

been moved to other areas of the regulations. Additions to note include the ability of the Committees to fine, audit and request information from health care facilities pursuant to the Board's statutory authority. Due process for fines is located in this section, as well as the ability to seek extension of due dates for reports.

All in all, there are several changes to the PCA regulations, but each change is the result of research, analysis, studies, and individual meetings with stakeholders and patient safety experts. The PCA Division and PCA Committee is reviewing comments to the proposals and we look forward to working with everyone to improve health care quality in the Commonwealth. ☺

*www.qualityforum.org

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

An Update

With the growing number of requests for peer review information, many health care facilities are perplexed over what adverse event reporting information has confidential peer review protections. We are not in the position to provide legal advice, so you may wish to consult your facilities' legal counsel if you have

questions. However, we are able to clarify that the PCA Division has the statutory and regulatory authority to ensure confidential, non-discoverable, and peer review safeguards of reported information.

Lastly, the PCA Division and PCA Committee support the creation of the Cost Containment Counsel in the

Executive Office of Health and Human Services. This Council's creation is located in Section 3 of Chapter 58 of the Acts of 2006* PCA believes that this entity will be a perfect accompaniment to its work. Saving lives and saving costs can be achieved harmoniously, and we look forward to working with this new program. ☺

*(www.mass.gov/legis).