

FIRST

Do No Harm

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Quality and Patient Safety Division, Board of Registration in Medicine

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Use of Propofol in the Outpatient Setting

Erin M. Donovan, Director of Quality & Risk & Deborah Black-Pisick, RPH, Clinical Manager, Pharmacy Lowell General Hospital



Propofol, an intravenous sedative hypnotic agent used for the induction and maintenance of anesthesia and sedation, is being used with increasing frequency at Lowell General and other hospitals for sedation in the endoscopy setting. Reasons for this increase in use include faster onset of sedation, a more rapid recovery, little or no residual drowsiness

after awakening, no interference with GI motility, and increased patient and practitioner satisfaction. Propofol is highly lipid soluble, and has a much faster onset of action than does midazolam. It also has a very short plasma half life (1-4 minutes), compared with that of midazolam (30 minutes), allowing for rapid recovery without the amnesia sometimes associated with midazolam. The biggest risk associated with propofol is its narrow therapeutic index that may produce a deeper level of sedation than desired with a relatively small change in dose. In addition, unlike benzodiazepines, there is no reversal agent available for propofol, but the effects of even a higher than desired dose generally do not last for more than a few minutes. In addition, any adverse effect will be seen while the medication is being administered, unlike benzodiazepines, which due to active metabolites, may cause prolonged symptoms after the procedure.

Lowell General Hospital took a fresh look at safety practices surrounding the use of propofol in Endoscopy following an adverse case outcome. A 61 year old woman underwent a colonoscopy with propofol administered by an experienced CRNA. She was closely monitored throughout. Shortly after the procedure, she began to develop tachypnea and hypoxemia. Her condition continued to worsen and she was ultimately admitted to the ICU and intubated.

A close examination at this case revealed several issues. The patient was not a good historian and key elements of her past surgical and medical history had not been shared with her endoscopy team. She had multiple health-care providers in the outpatient setting. Our review prompted the team to reconsider the evaluation and clearance process for propofol patients.

Given the very low rate of serious occurrences in this outpatient setting, it also became clear, that there was no clear protocol for management of these patients once an adverse event occurred. Was the patient best managed under the Anesthesiologist or under the Gastroenterologist? Where should the patient continue to be treated? In Endoscopy or

PACU? What kind of support is available in the outpatient setting?

Members of the Anesthesiology and Gastroenterology departments met to evaluate our systems and improve the safety of our patients. The following practices were put into place:

- 1. Patients with an ASA class of III and above who require propofol sedation for their endoscopy procedure are now required to be seen in pre-screening by an Anesthesiologist. Pre-screening generally occurs two weeks ahead of the planned procedure. This allows the Anesthesiologist to evaluate the patient and triage the procedure to the appropriate site, whether that be Endoscopy or the OR.
- 2. All patients scheduled to receive propofol are required to arrive 1 $\frac{1}{2}$ hours before their procedure to be evaluated by an Anesthesiologist. This allows adequate time for the Anesthesiologist to gather a medical history and request and review blood tests, electrocardiograms, and radiology reports. Based on the anesthesiologist's evaluation of the patient, the procedure can be rescheduled to be performed in the OR suite.
- 3. Clear protocols were put into place for staff to access medical assistance following these types of procedures. The gastroenterologist was designated the primary provider responsible for the patient's continuing medical care. The scope of the hospital's internal Rapid Response Team areas was further broadened to include service to outpatient areas as needed.

In addition to Endoscopy, propofol is used in other outpatient locations for example, cardioversions in Cardiology and MRI sedations in Radiology. Block time was established in these areas for propofol cases. By scheduling set times, Anesthesiology was able to assign staff to actively assess and manage these patients as well as support the other units who rely on their services, including the main OR and Labor & Delivery.

These safety measures have proved beneficial to date. Patients undergo a much more thorough assessment and as a result several propofol cases have been shifted to the OR. Serious adverse incidents related to the use of propofol have been non-existent. These steps have provided a much safer environment for our patients and greater security for our staff.



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Don't Hesitate - Activate

Joyce Towle, RN, BS, BBA, Karen M Griswold, RN, MBA, and Jeffrey Rothschild, MD, MPH, Brigham and Women's Hospital

mong the recommendations for improving patient care by the Institute for Healthcare Improvement in the 2005 100K Lives Campaign, was the adoption of rapid response teams to provide earlier intervention to the decompensating patient.¹ In 2008, The Joint Commission included among their National Patient Safety Goals improved recognition and response to changes in a patient's condition.²

The Brigham and Women's Hospital (BWH) Rapid Response System (RRS) was implemented in 2009, and is available for adult patients on intermediate floors and newborns in well-baby nurseries or labor and delivery. The RRS provides frontline clinicians with a set of Early Warning Criteria, a set of clinical indicators including vital sign parameters, to assist the bedside clinician's assessment of changes in a patient's condition.

The RRS brings a multidisciplinary clinical team to the bedside within 10 minutes. The responding RRS clinicians for medical/surgical patients include physicians from the patient's primary service, a critical care nurse and a respiratory therapist. For post partum women, a specialized multidisciplinary team from Labor and Delivery responds, and for newborns, a pediatrician, NICU nurse and NICU respiratory therapist.

The BWH Rapid Response Committee tracks the utilization of the RRS and works closely with clinical leadership to evaluate outcomes and identify system improvements. The committee is comprised of the Medical Director of the Code Teams, the Cardiovascular Services Associate Chief Nurse, two Nurse Senior Consultants in Quality / Patient Safety and the Medical Director for Quality and Safety.

Due to the decentralized structure of the RRS system at BWH, it had been challenging for the RRS Committee to

gain frontline staff feedback. As a result, beginning in November 2010, the committee began facilitating multidisciplinary focus groups to solicit feedback from frontline staff as to how they perceived that the RRS was working well and also to identify areas for systems and patient care improvement. Focus group attendees included medical/ surgical and post partum nursing staff, respiratory therapy, resident and attending physicians, physician assistants and critical care nurses. Initial areas identified for improvement included:

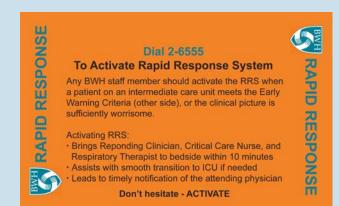
- ♦ The culture on some local units/clinical services did not fully support use of RRS;
- ♦ Educational programs for current and new house staff, physician assistants and nursing staff needed updating and consistency; and
- Lack of RRS awareness in some low use areas.

The RRS Committee created a comprehensive RRS awareness program to address these findings and improve RRS utilization. The program, Don't Hesitate – Activate, includes revised educational materials and programs; RRS badges that provide a bedside resource to Early Warning Criteria and activation procedure and can attach to ID tags (Figure 1); and posters that reinforce "Early Warning Criteria" and team composition. (Figure 2). The Don't Hesitate – Activate campaign is also featured as a recurring screen display on the hospital's public TV system, as part of the Safety Matters program (Figure 3).

Additional educational materials pertaining to the RRS, such as the RRS ID Tags, were incorporated into the orientation for incoming house staff, physician assistants and nursing staff.

In an ongoing effort to further evaluate the effective-

(Continued on page 3)



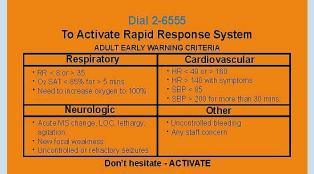


Figure 1

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Don't Hesitate - Activate continued...

ness of the Don't Hesitate - Activate awareness campaign, the RRS Committee began tracking potential missed opportunity for use of the RRS by reviewing transfers from intermediate units to the CCU and MICU in the spring of 2011. A retrospective review was implemented to identify instances where the patient's clinical status acutely deteriorated, meeting the RRS Early Warning Criteria prior to ICU transfer and neither the RRS nor Code Blue Teams were activated. These events have been termed 'unplanned transfers.' The use of RRS when patients begin to deteriorate can create a smoother and more efficient transfer to the ICU and in some instances prevents the need for ICU transfer as a result of earlier clinical interventions.

Early results from this retrospective review of transfers demonstrate that in January 2011 there were 30 unplanned transfers and the number decreased to 18 in June 2011. Over the same 6-month time frame the rate of RRS activation prior to ICU transfer went from 14% to 32.7%, and unplanned transfers without activating RRS or the Code Blue Team has decreased by 20%.

Preliminary RRS utilization data indicate the Don't Hesitate – Activate may have increased awareness and utilization of the RRS. The monthly average for adult RRS activations for first 6 months of the campaign increased 38%, 50 to 69 events per month when compared to the same time period last year. The rates of RRS events increased from 18 per 1000 discharges in FY10 to 21.1 per 1000 discharges, to date in FY 2011. Multidisciplinary staff members who have

since attended focus groups, report a better understanding of the early warning criteria, and more consistently verbalize the improved patient care provided by calling RRS. This measurable improvement is helping the RRS Committee to push forward more efforts to advance recognition and response to changes in patient's condition throughout the hospital.

References

- Institute for Healthcare Improvement. 100,000 Lives Campaign. March 20, 2005; http://www.ihi.org/IHI/ Programs/Campaign/Campaign.htm.
- Institute for Healthcare Improvement. Getting Started Kit: Rapid Response Teams. http://www.ihi.org/NR/ rdonlyres/6541BE00-00BC-4AD8-A049-CD76EDE5F171/0/RRTHowtoGuide.doc. Accessed 19 January 2007, 2007.

Acknowledgements

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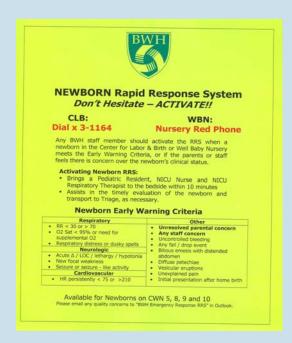


Figure 2



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An Interview with Edward Moore

President and CEO, Harrington Hospital



arrington Hospital CEO, Edward Moore, understands the challenges associated with driving cultural change in hospitals. With more than 30 years experience in health care management, Mr. Moore arrived at Harrington in 2007 and took steps to strengthen the institution's commitment to quality and patient safety. Taking advantage of an opportunity available through a VHA Foundation

grant, Mr. Moore visited the Palo Verde nuclear power plant in Arizona, and experienced, firsthand, how another high risk industry creates a culture of safety. The "take away message" from this trip was that safety and quality had to be imbedded in the mission of the hospital. With this goal in mind, Mr. Moore changed Harrington's committee structure to strengthen the role of its governing board, medical and administrative leaders in quality and patient safety. He also created a new leadership position - "Vice President for Quality and Patient Safety."

A Blue Cross Blue Shield grant provided an additional opportunity for fifteen members of the Harrington governing board, medical and administrative leadership team to spend a week at The Johns Hopkins Hospital, learning about Hopkins' quality and patient safety infrastructure. They returned to Harrington with tools to help them drive change at the hospital.

"Safety starts with attitude and emphasis from the CEO," stated Mr. Moore. He regularly engages in walk rounds, actively promotes a "blame free" quality culture, and is committed to "institutional learning" from near misses and medical errors. Mr. Moore cited examples of recent quality-driven changes: the focused effort on process improvement that significantly decreased Harrington's "door to balloon time" for cardiac patients; and the investment in UMass Memorial Healthcare e-ICU services to improve ICU care for Harrington's patients.

Mr. Moore expressed appreciation for the commitment of the entire hospital community to sustaining the culture of quality and patient safety at Harrington Hospital; and emphasized the important role that patients, their families, and the community play in these efforts.

The QPSD staff thanks Mr. Moore for his willingness to speak about his experiences for our newsletter.

"Cultural change happens slowly and it's iterative. Start with what you have that's good and build on it."

Marc Rubin, MD Presenter, QPS Conference Engaging Physicians in Quality and Patient Safety

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QPSD Conference "Engaging Physicians in Health Care Facility Patient Safety and Quality Programs" Held June 3rd in Worcester

The Quality and Patient Safety Division (QPSD) held a half-day conference in Worcester on June 3rd. The conference focused on physician culture in hospitals with respect to quality improvement and patient safety programs. Discussion topics included: the development of systems to ensure physician participation in the quality and safety efforts at hospitals; methods for involving physicians in unexpected event identification and analysis; organizational structure for medical staff peer review; and non-punitive policy development and confidentiality.

The faculty included: Dr. Leslie G. Selbovitz, Senior Vice President and Chief Medical Officer, Newton Wellesley Hospital; Dr. Kathy Jenkins, Senior Vice President, Chief Safety and Quality Officer, Children's Hospital Boston; and Dr. Marc Rubin, Chair, Department of Surgery, North Shore Medical Center.

The QPSD is pleased to be co-sponsoring a conference on September 8th, entitled "Gain Full Value From Your Root Cause Investigations," with the Massachusetts Hospital Association, the Medical Society for Healthcare Risk Management and the Massachusetts Medical Society. The conference will be held in Marlborough at the Courtyard Marriot.

Registration closes on August 26th. Information can be found on the home page of the Board's website: www.mass.gov/massmedboard.

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Guidance for Hospitals Performing Mastectomy with Immediate Breast Reconstruction

QPSD Issues the Report of the Expert Panel to Review Breast Reconstruction following Mastectomy

In June 2010, prompted by Safety and Quality Review reports describing complications associated with breast reconstruction, the QPSD convened an expert panel to investigate how health care facilities and providers can improve the treatment and overall experience of women who are faced with decisions about mastectomy and breast reconstruction. The Panel membership included patient representatives, and experts in the fields of breast surgical oncology, plastic surgery, radiation oncology, infectious diseases, epidemiology, medical oncology, nursing, and social work. Members also included hospital surgical department chairs, experts in quality and patient safety, surgical data collection experts and a representative from the Massachusetts Cancer Registry.

This Panel recently completed its work and the QPSD released its final report on June 30, 2011. The report discusses current practice in breast reconstruction and includes consensus statements and recommendations for patient education, perioperative care and further research.

The Panel's recommendations include:

(1) Promotion of a process for informed consent, in which the patient and her physician are "partners" when making decisions about treatment, based on both the best available scientific evidence and the patient's values and expectations.

- (2) Careful consideration of those "risk factors" that might place the patient at a higher risk for breast reconstruction complications. For example, patients who need radiation therapy have a higher risk of complications. Obesity and a smoking history may also influence the success of the patient's outcome.
- (3) The need for an aggressive response when patients develop signs of infection during the postoperative period, which includes antibiotic therapy and may include the removal of the implant.
- (4) Recognition of the need for a collaborative effort by Massachusetts hospitals to develop a system for collecting uniform breast reconstruction data, which can then be used to develop evidence based standards of care for these procedures.

The work of the Panel will be ongoing in a number of ways. A concerted effort is being made to improve data collection statewide so that hospitals can revise and improve recommendations based on prospectively collected data. The group is also working toward developing a tool to be used by patients to better understand their options and how to best choose a provider and procedure. All CEOs, CMOs and PCA Coordinators were emailed a copy of the report. If you did not receive the report, please let us know. The report is also available at the QPS Division website: http://www.mass.gov/Eeohhs2/docs/borim/breast-reconstruction-report.pdf.

News from QPSD Mortality Review Project

Thank you for submitting the information requested by QPSD concerning your mortality review program. We will keep you advised on the progress of our reviews of your responses. Please continue to submit your mortality data and analysis to the QPSD in your Semi-Annual Reports.

Here are examples of initiatives three hospitals (two acute care and one long term care) have taken in response to their mortality review findings: (1) implementation of multidisciplinary rounds in the ICU after identifying opportunities to improve communication between services; (2) implementation of palliative care committee to review end of life care issues; and (3) revisions to "advance care plans" and enhancement of patient and family education on end of life treatment issues.

For consideration: Why exclude "DNR" or terminal patients from your mortality review? Valuable lessons can be learned from reviews of their hospitalization, and findings can lead to improvement in the quality of "end of life" care.



Ambulatory Surgical Center Reporting Update

On July 8, 2011, notification of the Patient Care Assessment (PCA) regulatory reporting requirements was sent to all Licensed Ambulatory Surgical Centers (ASCs). To assist ASCs, the QPSD section of the Board of Medicine website, www.mass.gov/massmedboard/qps has been updated with a separate link for "Licensed Ambulatory Surgical Centers and Clinics."

The QPSD staff will present a two hour Workshop designed to assist ASCs in fulfilling the reporting requirements. The Workshop will be offered three times on different dates to accommodate ASC staff members. The history of the Board's oversight, the confidentiality and benefits of reporting will be discussed. The Workshops are scheduled on Thursday afternoons from 3pm to 5pm: Wakefield, August 25, 2011; Shrewsbury, September 15, 2011; and Brockton, September 22, 2011. The registration forms were included in the notification packet.

The QPSD thanks the ASCs that submitted a response to our request for their "contact" information. It will allow us to contact ASC representatives directly with important advisories and updates. The contact information forms are located on the website for download.

Safety and Quality Review (SQR) reporting is an important component of the requirements for ASCs. SQRs target

four types of unexpected events for which reporting is required. The types of events relevant to ASCs include (1) an unexpected death in the course of, or resulting from an elective ambulatory procedure; (2) wrong site procedure; and (3) death or major or permanent impairment of bodily function not ordinarily expected as a result of the patient's condition on presentation. More information and reporting forms can be found on the website.

ASC Patient Care Assessment (PCA) Plans can be submitted at any time, but are due by December 31, 2011. The PCA Plan is evidence of a facility specific program for risk identification, analysis, and prevention, incorporating quality assessment, peer review, and program improvement with governance and executive level involvement. It will describe the Quality and Patient Safety Program in place for each ASC. For QPSD approval, the PCA Plan must include the Plan "Elements" as set forth at Chapter 243 of the Code of Massachusetts regulations, sections 3.01-3.16. The website link contains information on the elements required for inclusion.

We look forward to the opportunity of assisting ASCs and meeting as many representatives as possible at the upcoming Workshops. Please call the QPSD for Workshop signup forms or other assistance (781-876-8296).

Quality and Patient Safety Division (QPSD) Notes

Writing with an additional suggestion in follow-up to the QPSD Interventional Radiology Advisory, Dr. Donald Bachman, an Interventional Radiologist at Metrowest Medical Center, noted the need for caution when performing biopsies with needles that advance under spring loaded force as the biopsy is performed. The purpose of this type of needle is to avoid movement of the target lesion away from the needle tip. However, this type of needle has potential to extend into a critical adjacent structure, such as an artery. Careful consideration should be given to "needle choice" when planning for biopsy, as needles without a spring-loaded mechanism may be safer for some procedures. The QPSD Interventional Radiology Advisory was sent to all hospitals in July. It is posted on the QPSD website: www.mass.gov/massmedboard/qps.

The QPSD reviewed two recent cases involving delayed diagnosis of gastrointestinal bleeding in patients who were post-op elective (non-gastrointestinal) surgery. Please ensure that providers are educated about the need to carefully evaluate abdominal symptoms, changes in vital signs, and declining hemoglobin and hematocrit. Care plans should alert providers to patients who have medical histories that include ASA or NSAID (non-steroidal anti-inflammatory drug) use or have prior histories of gastric ulcers. Postoperative nursing protocols should include criteria for hemoccult testing and guidance for when to contact the surgeon.

Potential for error may occur during hand surgery when the hand is turned from one position to another, obscuring the site marking. One hospital addressed this concern by adding an additional time-out and new site marking when the hand is repositioned.

Baystate Franklin Medical Center reports that its Patient and Family Advisory Council (PFAC) provided feedback that led to changes in processes for surgery discharge instructions, operation of the inpatient bed and selection of television programs. "The PFAC is supporting the hospital in its work to improve service excellence."

FIRST

Safety and Quality Review Corner

Case Description

A 68 year old female had an uneventful elective total knee arthroplasty. She was started on the hospital's post-operative deep vein thrombosis (DVT) prophylaxis protocol, which called for a target INR of 1.8 using warfarin, to be maintained for 4 to 6 weeks post-op. The patient's INR values were 1.01, 1.05 and 1.03 on PODs #1-3. She was discharged on POD #3 with instructions to take warfarin 5 mg daily, with follow-up INR testing twice weekly. On POD #6 the patient was readmitted with an acute bilateral pulmonary embolism (PE).

Hospital Response

This hospital engaged its orthopedic service in the review and reported the following findings and actions.

- ◆ The orthopedic service had been using an evidence based pathway for Total Joint Arthroplasty (TJR) management for 10 years.
- Review of overall complication rate, LOS and other quality data indicated excellent outcomes for TJR procedures and did not identify any trends or outliers. There were two other occurrences of PE/DVT in the prior two years.
- ♦ <u>All</u> TJR cases were analyzed and reviewers identified a failure to achieve target INR prior to discharge or at follow up in 20% of the patients.
- There was no measurable difference between surgeons in "likelihood to achieve target INR," and the protocol had been fully adopted by all orthopedic surgeons.
- ♦ The orthopedic service had previously decided against using enoxaparin or heparin as a bridge in the early post op period before target INR was reached.

Based on the above-findings, a "Performance Improvement Team" was convened to improve coagulation for TJR patients, with a goal to achieve the target INR more efficiently and reliably. At the time of the report they were considering options: (1) add enoxaparin bridging to a warfarin protocol, coordinated through the anticoagulation clinic; or (2) abandon warfarin and migrate to a protocol based solely on enoxaparin administered for 4-6 weeks commencing on POD #1.

Here are some examples of cases reported to the QPSD as "Type 4" events.

- Stent thrombosis related to inadequate anticoagulation
- Misplacement of PICC line
- Severe bleeding post tPA infusion
- Cerebral edema following elective total hip replacement
- Stroke during epicardial ablation
- Delay in diagnosis of anastomotic leak following bowel surgery
- Newborn sepsis and respiratory failure
- Delay in diagnosis of lung cancer
- Retained foreign body following hysteoscopic transcervical sterilization

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HELP QPSD SHARE YOUR IMPORTANT QUALITY INITIATIVES

Please circulate this newsletter! We depend on the PCA Coordinators to ensure that the QPSD newsletter is circulated to their staff, and also to health care facility leadership, including members of the health care facility's governing board.

We are updating our mailing list. Watch for our email requesting contact information for your Chief Quality Officers and other health care facility leaders.

Please send articles! If you would like to write an article about one of your successful quality programs, please let us know.

Don't forget to register for the Root Cause Analysis Workshop on September 8th. CEUs and CMEs will be offered. Information is available at the Board's website: www.mass.gov/massmedboard.

QPSD Workshops for Ambulatory Surgical Centers will be offered on August 25th, September 15th and 22nd. Call the QPSD for details: (781) 876-8296.

CONTACT THE QPSD

To be added to the QPSD Newsletter and advisory mailing list, update hospital contact information, submit an article, request an SQR form, or obtain additional information, contact QPSD: Jennifer.Sadowski@state.ma.us or (781) 876-8296.

Send mail to Massachusetts Board of Registration in Medicine, QPS Division, 200 Harvard Mill Square, Suite 330, Wakefield, MA 01880.

The Quality and Patient Safety Division newsletter, FIRST Do No Harm, is a vehicle for sharing quality and patient safety initiatives of Massachusetts healthcare facilities and the work of the Board's Quality and Patient Safety Division and Committee. Publication of this newsletter does not constitute an endorsement by the Board of any studies or practices described in the newsletter and none should be inferred.