FIRST

Do No Harm

Quality and Patient Safety Division, Massachusetts Board of Registration in Medicine

June, 2014 **REVISED EDITION**

IN THIS REVISED ISSUE:

Notice Concerning article in QPSD Newsletter - "Delirium Protocol at Steward Hospitals"

The lead article in this newsletter entitled "Delirium Protocol at Steward Hospitals" has been removed.

Below please find a message from the author, Dr. Harvey Kowaloff:

Regarding the recently published article concerning screening for delirium Steward Healthcare wishes to note the following: 'The protocol submitted for publication contained a previous version of the CAM (Confusion Assessment Method). Presently both the CAM assessment tool and the accompanying management protocol/ order set are being reviewed to incorporate the latest version of CAM. Once updated the protocol and associated tools will be published and circulated. We apologize for any confusion. Thank you.'

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SAFETY AND QUALITY REVIEW CORNER

UNEXPECTED INTRA-OP ARRHYTHMIA AND RESUSCITATION

The Event

A 6 month old male was scheduled for a circumcision in the OR under general anesthesia. The anesthesia attending was present for induction, assisted by an anesthesia resident. The patient was prepped and draped for a dorsal block right below the pubic bone above the base of the penis. Prior to injecting bupivacaine 0.25% as a penile block using 8 ml (1 ml/kg, the recommended dose), the urology attending drew back on the syringe to aspirate per protocol. There was no evidence of blood in the syringe and the medication was administered.

Immediately after administration of the bupivacaine the anesthesiologist noted a wide complex ventricular arrhythmia with a BP drop to 60/40. Epi 5 mcg was given, IV fluids were increased and a code was called. FiO2 increased to 100% with manual ventilation and the anesthetic gas was turned off. The patient maintained femoral and brachial pulses. Intralipids were administered at 1.5 ml/kg over 1 minute. The patient's hemodynamics remained stable. He was monitored overnight in the SICU as a precaution and discharged the following day.

Internal Review Findings and Action Plan

Review found that the patient received the appropriate dose for his age and weight. There was no error in technique during administration; the adverse reaction to bupivacaine is a known, rare complication of administering a penile block. The location of the block was in a vascular area. The urology attending is a senior faculty member who has performed this procedure numerous times. The complication was identified and addressed in a timely manner, per nationally accepted standard of care. The etiology of the cardiac arrhythmia was due to inadvertent intravascular administration or accelerated absorption in vascular tissue of 0.25% bupivacaine given as a local anesthetic.

Review with the anesthesia and urology services showed that there was not a common approach employed for administering a penile block. It was typically administered by the surgeon, not anesthesia. The review identified several different ways of administering a penile block; including doing half the block at the start of the procedure and half at the end; another approach is giving a reduced total dose.

The OR Governance Committee decided that a standardized approach was needed; they issued an alert to all surgeons, OR nurses, anesthesia staff, CRNAs and fellows immediately following this event. The alert (Bupivacaine Warning and Practice Change) specified the dosing practice, maximum volume bupivacaine for penile blocks (decreased from 1 cc/kg to 0.5 cc/kg), and changed from single dosing to two separate doses via the paramedian approach. Pharmacy developed an order set to support the practice change.

"STEWARD"SHIP IN RED BLOOD CELL TRANSFUSION PRACTICES

Justine Carr, MD Chief Medical Officer, Steward Health Care System

Steward Health Care System is comprised of 10 acute care hospitals that are integrated both clinically and electronically. Hospitals include Holy Family, Nashoba Valley, Merrimack Valley, Quincy Medical Center, Carney, St. Elizabeth's, Norwood, Good Samaritan Medical Center, Morton and Saint Anne's. The Intensive Care Units (ICUs) are integrated through a Tele-ICU program. In early 2013, the Steward Critical Care Enterprise group recognized that we were not top performers in red cell transfusion practices, based on a score card from Phillips Healthcare that compares eICU performance across the country. The Critical Care Enterprise Committee engaged the Steward Blood Bank Enterprise Committee for an evaluation of current practices.

Review of the literature demonstrated the continued emergence of evidence supporting a more restrictive transfusion practice, reducing both morbidity and mortality in matched cohorts for reasons beyond transmission of viruses. RBC transfusions have been shown to cause an increase in serious complications including postoperative infection rates, ventilator-acquired pneumonia, central line sepsis, ICU and hospital length of stay, as well as short term and long term mortality rates.

A study of existing Steward Hospital practice in red blood cell (RBC) transfusions revealed significant variability across hospitals, such that one third to one half of first RBC transfusions were initiated for hematocrits greater than 25%. In addition, there was two-fold variability in the rate of transfusion of medical/surgical patients. The Critical Care and Blood Bank Enterprise groups proposed hardwiring clinical decision support in the electronic health record to drive alignment with published guidelines from the American Association of Blood Banks (AABB). (*Annals of Internal Medicine*, *2012;157:49)*

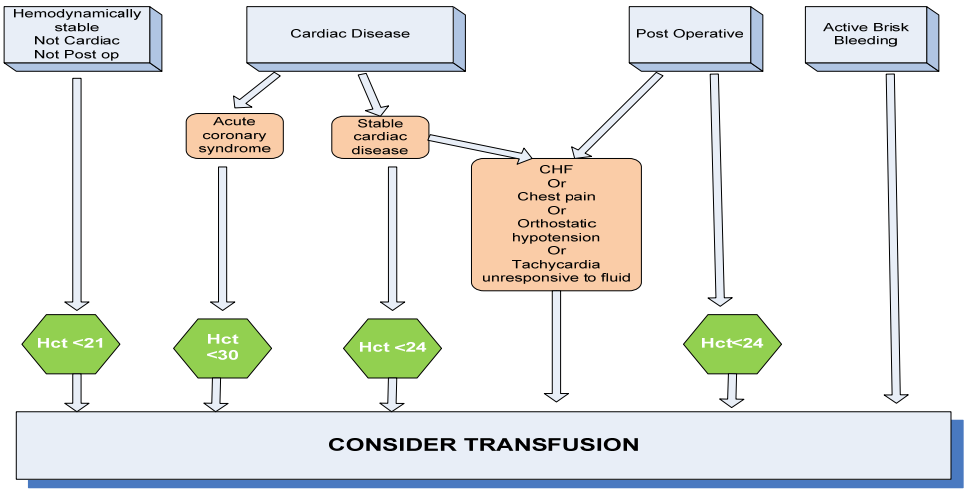

Figure 1 AABB RBC Transfusion Guidelines

Working with hospital Vice Presidents of Medical Affairs and Information Systems staff, the Meditech 6.0 platform has been redesigned to push information to the ordering clinician that includes the most recent hematocrit. If the hematocrit is >21%, the clinician needs to indicate which of the evidence-based indications is present. If none, the choice "other" is selected.

Implementation began with a pilot at Norwood Hospital, introduced by the Medical Director of the Blood Bank who recounted not only the evidence for restrictive transfusion, but also his own experience as a multi-transfusion recipient at another hospital after a serious bicycle accident. Data was provided showing both the rate of transfusion, as well as the percentage of first transfusions occurring in the following categories: <21%, 21-24.9%, 25-28.9% and ≥29%. Computer-based training (with CME credit) on the evidence for restrictive transfusion was also provided and discussions were held with hospital Medical Executive Committees. An immediate reduction in RBC transfusion was seen, seemingly resulting from the real time clinical decision support.

With a few modifications made after the pilot, the program was rolled-out to all 10 acute hospitals over a 4 month timeframe. Compared to a year ago, we now transfuse 30% fewer red cells (units transfused per medical/surgical discharge). We also have fewer transfusions initiated for hematocrits greater than 25%. Performance reports are generated monthly for each hospital, including lists of transfusions which occurred for "other" indications, affording an opportunity for targeted clinician education where needed.

The result of this improvement is greater ***Steward***ship in the care of our patients and resources by:

- ♦Aligning with evidence-based guidelines.
- ♦Reducing patient harm from unnecessary transfusions.
- ♦Limiting unnecessary use of a scarce resource.
- ♦Reducing expenditure on red blood cells across Steward.

IMPROVING PCA SAFETY

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Patient Controlled Analgesia (PCA) devices are a common mechanism for delivering opioids to patients suffering from moderate to severe pain when oral and bolus administrations of opioids do not provide adequate relief. Utilizing PCA regimens for pain management is a complex process that involves assessing the patient's baseline clinical status and risk criteria. These factors impact the ordering decisions around PCA dosing, device lock out interval and nurse administered rescue doses.

During routine reviews of our hospital's Rapid Response System (RRS) events, a trend of respiratory depression triggered events was noted involving patients who were receiving opioids via PCA. These were adverse patient events that were not easily identified prior to the initiation of a RRS with its systematic event reviews. After case reviews by our Safety and Risk Management departments, a hospital-wide multidisciplinary task force was commissioned to examine these events and our practice. The primary charge of this task force was to develop and implement a new series of computerized prescriber order entry (CPOE) PCA order set templates embedded with advanced clinical decision support, and to evaluate and revise the routine monitoring parameters for these patients.

CPOE has been in place at BWH since 1993, including templates for ordering PCA medication regimens. The templates were used by a wide range of providers and patient needs ranging from surgeons caring for routine post operative patients to palliative care specialists writing regimens for hospice and complex pain patients. The options for medications and dosing parameters were broad to accommodate all potential patients, and in a few cases, we found were no longer in line with current recommendations. There also were no guardrails or decision supports offered to the prescribing clinicians for dosing patients who were at higher risk for complications; such as patients over age 65, those with a history of sleep apnea, or opioid naive.

The PCA task force used available data, expert opinion and recommendations from the Anesthesia Patient Safety Foundation[1], American Society for Pain Management Nursing[2], Centers for Medicare & Medicaid Services, The Joint Commission[3] and the Institute for Safe Medication Practices[4] to determine that for improved safety, multiple PCA templates with varied dosing strategies should be created. The major recommendations were to individualize the dose and infusion rate of opioid while considering the unique aspects of each patient's history and physical status, and to make continuous monitoring of oxygenation (i.e., pulse oximetry) the routine rather than the exception. The group created a simple series of questions around the patient's health and medication history (figures 1 and 2) that drives the CPOE system to determine the safest template for each patient's needs.

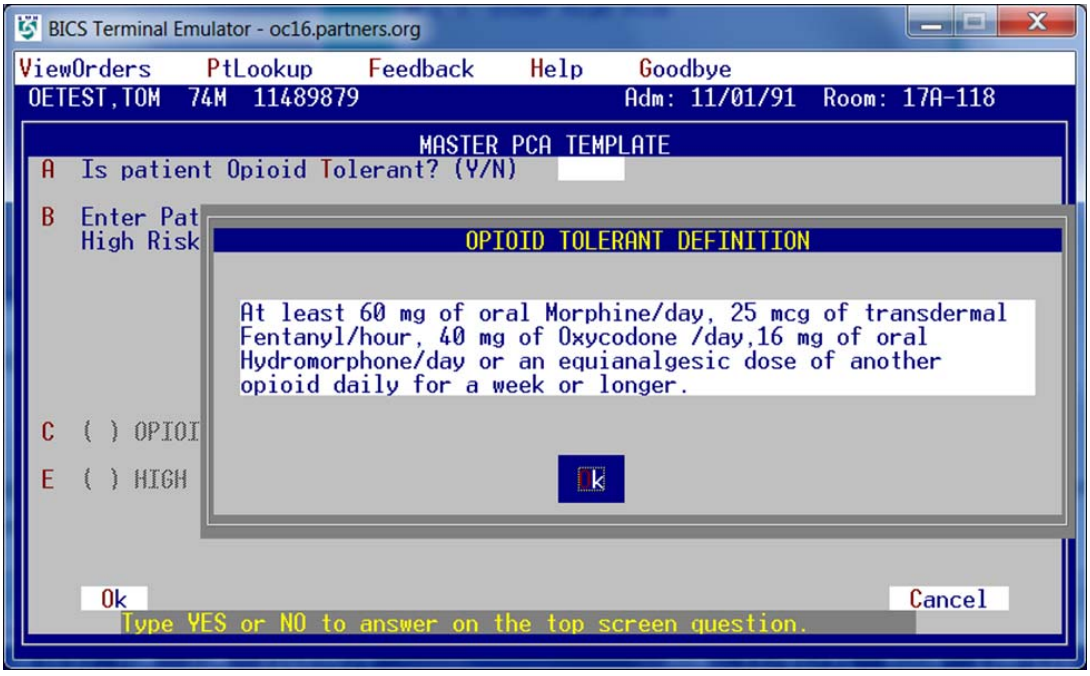

Figure 1: Definition of Opioid tolerance provided to ordering clinicians to help guide them in appropriate template selection.

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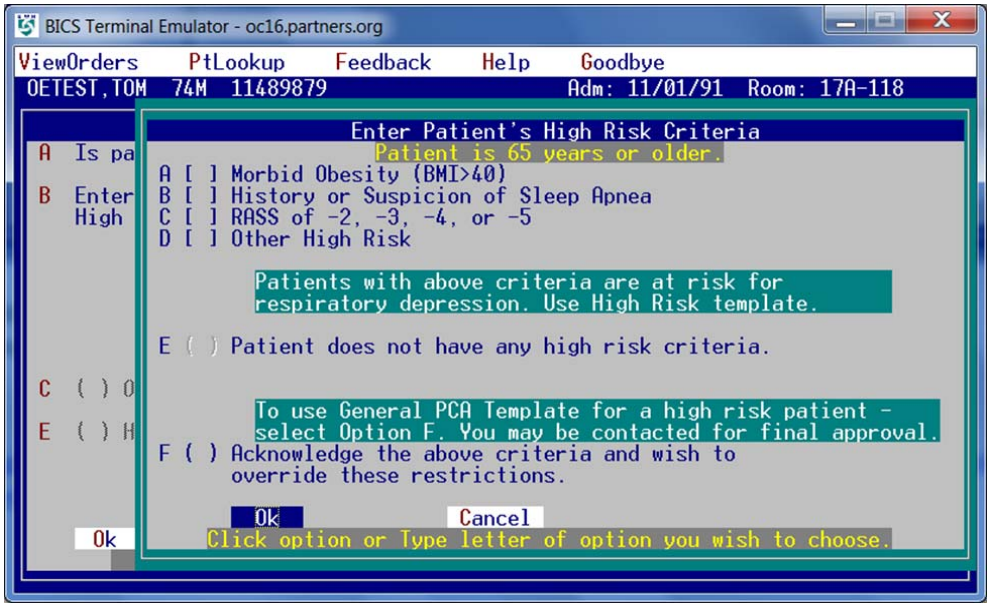

Figure 2: High risk criteria provided to ordering clinicians to help guide them in appropriate template selection.

This decision support applies specific patient characteristics including age, prior opioid use, and baseline high risk criteria for over-sedation, in the algorithmic selection of four PCA templates: Opioid Tolerant, Pain & Palliative Care, General, and High Risk (Figure 3). Each of these templates has embedded clinical decision support of PCA parameter defaults, minimums, maximums and allowable incremental values. There is no continuous dose option on the High Risk PCA template. Once the provider completes the short questionnaire describing the patient, decision support embedded in CPOE then provides the appropriate template. Only certain providers (Pain Service or Palliative Care) have access to order using the Opioid-tolerant or Palliative Care templates, which allow for larger bolus doses and higher continuous doses of medication.

Key process improvements were to increase the frequency of nursing pain assessments to every 2 hours, require that respiratory assessments include both quality and rate, and to improve our monitoring safety by placing these patients on centralized continuous oxygen saturation monitoring instead of bedside or spot-check monitors. This requirement required capital investment by the institution in new centralized monitoring equipment and training of nursing staff before the new order sets could roll out. Nursing education also focused on early interventions for managing declining trends detected with improved patient assessment.

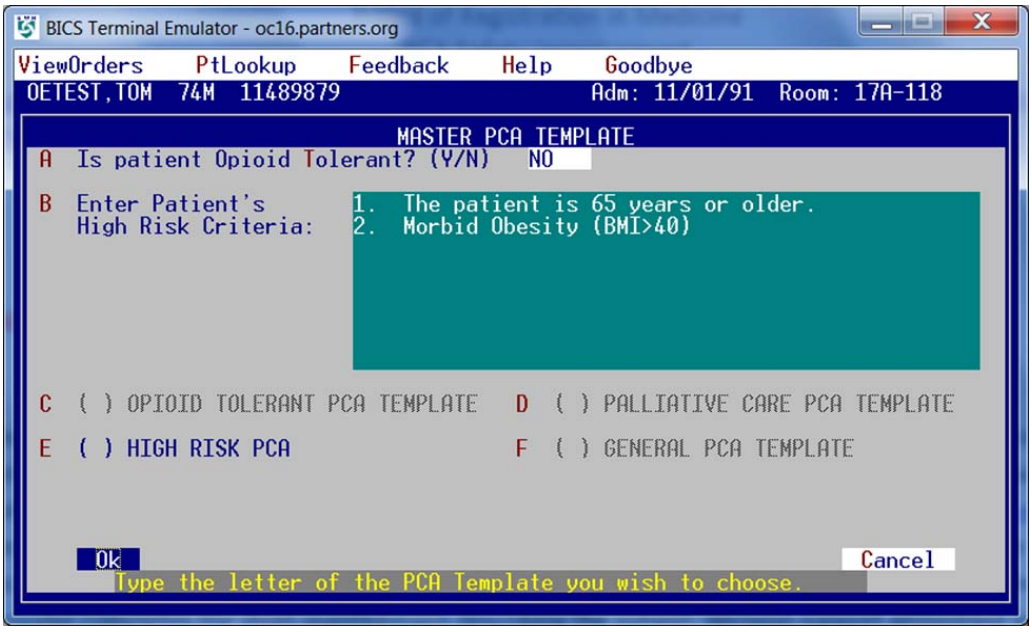

Figure 3: Example of PCA template choices offered for a patient with high-risk criteria (note: "grayed-out" options not available to select).

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The new CPOE templates and revised policy went into effect at the end of June 2013, after significant trend assessment, planning, developing, testing and implementing improvements to the CPOE system, capital equipment purchases and required staff training. We have been gratified to see that our RRS event rates related to oversedation while using PCA since the implementation of our revised templates and monitoring protocols have decreased significantly (*figure 4*).

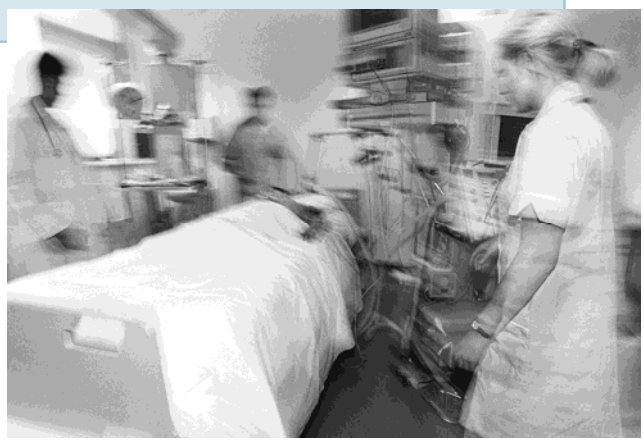
Calendar Year	# of Oversedation related RRS events
2011	23
2012	38
2013 Jan-Jun	15
2013 Jul- Dec	1

Figure 4

References:
1. Stoelting RK, Weinger MB. Dangers of postoperative opioids - is there a cure? APSF Newsletter. Summer 2009; 24(2): 25-26.
2. Jarzyna D, Jungquist CR, Pasero C, et al. American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression. Pain Management Nursing. 2011; 12 (3): 118-45.
3. The Joint Commission. Safe use of opioids in hospitals. Sentinel Event Alert. 2012; 49: 1-5.ISMP. Fatal PCA adverse events continue to happen…better patient monitoring is essential to prevent harm.
4. ISMP Medication Safety Alert. 2013; 18 (11): 1-3.

MAINTAINING SITUATIONAL AWARENESS IN BAYSTATE'S CARDIAC ICU

A team of researchers at Baystate Medical Center developed a computerized system to assimilate pertinent real-time and historical patient data and present it in a user-oriented, clinically relevant form in Baystate's cardiac intensive care unit. The display is projected continuously above each patient's bed and allows the provider team to simultaneously speak with a patient while reviewing all pertinent laboratory values, vital signs, ventilator settings, intake and output, hemodynamics, and vasoactive drug dosages, with trends shown in a graphic format. *Engelman DT, et al. Maintaining situational awareness in a cardiac intensive care unit. J Thorac Cardiovasc Surg. 2014: Mar 147(3): 1105-6.*



One hospital reported success with the following initiatives:

- *A CPOE filter was developed for inpatients undergoing CT with contrast, to improve identification of allergies and renal impairment. This has dramatically improved the detection of these potential contraindications to contrast and the filter is being extended to the system used by ED physicians, as well.*
- *The Pharmacy is now tracking physician compliance with standardized order sets for pain medication, insulin, warfarin and heparin. The data is provided to the appropriate chiefs, resident directors and lead PAs for their follow-up with practitioners.*

NOTICE TO HEALTH CARE FACILITIES THAT PERFORM UTERINE POWER MORCELLATION

The FDA issued a Safety Communication discouraging the use of laparoscopic power morcellation for hysterectomy and myomectomy and urges health care providers to inform patients of all treatment options: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm

Please review your current practices with regard to the use of laparoscopic power morcellation for hysterectomy and myomectomy, as well as your informed consent guidelines for these procedures.

Cases involving patients who undergo laparoscopic uterine power morcellation, with subsequent diagnosis of uterine sarcoma, are considered by the QPS Division to be "Type 4" reportable events under PCA regulations, 243 CMR 3.08.

Quality and Patient Safety Division Notes

- The QPSD recently circulated an *Advisory on Suicide Risk Assessment in the Emergency Department*. A link to the Advisory is at: http://www.mass.gov/eohhs/docs/borim/physicians/pca-notifications/suicide-risk-assessment.pdf.
- *Are the cases involving patient harm discussed at Morbidity and Mortality conferences also being reported into the hospital's internal incident reporting system?* Please review your internal incident reporting policies and remind providers of their affirmative duty to report injuries and incidents to their health care facility's PCA Coordinator. 243 CMR 3.07 (3).
- The following article should be of interest to health care facilities performing robotic surgery: Larson, JA, et al. *Application of Surgical Safety Standards to Robotic Surgery: Five Principles of Ethics for Nonmaleficence*. J Am Coll Surg. 2014 Feb; 218(2):290-3.
- *Reminder*: Annual written notice of the requirements and rights under the "Peer Report" law, MGL c. 112, 5F, must be given by a health care facility to both its employed and credentialed health care providers. 243 CMR 3.11 (1). Information about the Peer Report law is available at the Board's website: http://www.mass.gov/eohhs/gov/departments/borim/physicans/mandated-reporting/peer-rpts/.

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.

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