Addressing Opioid Warnings from The Joint Commission:
Unrecognized Opioid Induced Respiratory Depression and PCA Safety Checklist

Michael Wong, JD
Physician-Patient Alliance for Health & Safety
website: ppahs.org
email: mwong@ppahs.org
While opioid use is generally safe for most patients, opioid analgesics may be associated with adverse effects, the most serious effect being respiratory depression, which is generally preceded by sedation.”

Sentinel Event Alert #49 (August 8, 2012)

Failure to Rescue & Code Blue Statistics

- Fifty percent of Code Blue events involve patients receiving opioid analgesia.
- Unrecognized postoperative respiratory failure that results in cardiopulmonary arrest (CPA) is a daily occurrence at healthcare facilities across the United States.
- Since CPA results in death or anoxic brain injury in the majority of cases, these events have been termed “Failure to Rescue (FTR)”.
- FTR is the first and third most common patient safety-related adverse events affecting the Medicare population in U.S. hospitals, accounting for 113 events per 1,000 at-risk patient admissions.
Safety Checklist
Targeting PCA Use

PCA Pump Initiation, Refilling, or Programming Change

- Risk factors that increase risk of respiratory depression have been considered:
  - obesity
  - low body weight
  - concomitant medications (opioids and non-opioids) that potentiate sedative effect of opioid PCA
  - pre-existing conditions such as asthma, COPD, and sleep apnea
  - advanced age

- Pre-procedural cognitive assessment has determined patient is capable of participating in pain management (note: pediatric patients may not be suitable for PCA)

- Patient has been provided with information on proper patient use of PCA pump (other recipients of information -- family/visitors) and purpose of monitoring

- Two healthcare providers have independently double-checked:
  - patient's identification
  - all patient allergies are prominently on medication administration record (MAR)
  - drug selection and concentration confirmed as that which was prescribed
  - any necessary dose adjustments completed
  - PCA pump settings
  - line attachment to patient and tubing insertion into pump

- Patient is electronically monitored with both:
  - pulse oximetry and capnography

PCA Pump Check at Shift Change and Every Hour Since Last Assessment (Recommended)

- Patient satisfactorily assessed for:
  - level of pain
  - alertness
  - adequacy of ventilation

- PCA pump settings: verified

- Electronic monitoring verified:
  - pulse oximetry and capnography

- Patient assessment/condition has been added to flow chart documenting PCA dosing and monitoring

This checklist is not intended to be comprehensive. It is a short list of recommended steps to minimize adverse events and maximize patient safety and health outcomes.

Physician-Patient Alliance would like to thank the following healthcare professionals for their thoughts and input on this safety checklist:

- Dr. Christian Aipt (UCSF)
- Dr. James Barry (Vanderbilt)
- Dr. Art Boudreaux (University of Alabama)
- Dr. Brendan Carvalho (Stanford)
- Dr. Adam Collins (UCSF)
- Dr. Sandra Curry (Columbia)
- Dr. Rick Dutton (Anesthesia Quality Institute)
- Dr. Atul Gawande (Harvard)
- Dr. Mike Hawkins (CQH CI)
- Dr. Andrew Kofke (University of Pennsylvania)
- Dr. Elliot Koenze (Stanford)
- Audrey Kuntz, RN (Vanderbilt)
- Karen Rago, RN (UCSF)
- Dr. Rakesh Ramachandran (Cleveland Clinic)
- Dr. Adrienne Randolph (Harvard)
- Dr. Julius Pham (JHU)
- Dr. Peter Pronovost (JHU)
- Dr. Dan Saadler (Cleveland Clinic)
- Dr. John Williams (Society of Cardiovascular Anesthesiologists)

To view and download this Safety Checklist targeting PCA use, please click on the upper right hand link at the top of www.ppahs.org
Amanda Abbiehl

18-year old Amanda Abbiehl tragically died July 17, 2010.

Amanda’s parents talk about the fears all parents have for their children:

As parents of a teenage daughter, our worst fears were that our daughter would become pregnant, take drugs, or drink and drive. Never did we imagine that our daughter would go into a hospital with an infection, be hooked to a patient-controlled analgesia (PCA) pump to manage her pain, and never come out alive; but this is exactly what happened.

As Amanda’s father asks:

It isn’t standard practice to monitor patients with Capnography. However, if Amanda’s CO2 level had been monitored, wouldn’t this have alerted her caregivers so her life could have been saved?

For Amanda’s story, please see:
http://promisetoamanda.org/?page_id=32

Louise Batz

Louise’s daughter, Laura Batz Townsend, tells what happened to her mother:

My Mom, Louise Batz, died from a preventable medical error after recovering knee surgery. Mom went into the hospital for knee replacement surgery ...

This was not emergency surgery. She had planned the surgery so she would have enough time to heal and be ready to welcome the arrival of her fourth grandchild ...

Like a lot of patients after surgery, my Mom was on patient-controlled analgesia (PCA) to manage her pain. Sadly for my Mom, she was not monitored continuously by pulse oximetry for oxygenation or capnography for ventilation once she arrive on the general floor.

For the complete article on Louise, please see:
Leah Katherine Coufal

Lenore Alexander (active member of Mothers Against Medical Errors) recalls the incidents leading to her daughter’s death:

When I brought Leah to Cedars-Sinai hospital in Los Angeles that Friday morning, she was a healthy 11-year-old girl. She was scheduled to have elective surgery to repair a condition called pectus carinatum, which required the opening of her chest. The epidural anesthesia used during the operation had been left in place to manage her postoperative pain.

Would real-time monitoring have saved Leah?

That is one of the many questions that I have asked myself every day since I found my daughter, Leah, dead in her hospital bed.

The answer is yes, it would have.

For Lenore’s article on her daughter, please see:
http://ppahs.org/2012/02/01/guest-post-yes-real-time-monitoring-would-have-saved-leah-2/

Justin Micalizzi

Justin’s mother, Dale Ann Micalizzi, describes the impact his death had on her family:

My son was on a stretcher in the hall being wheeled away by the trauma team to the ambulance, after his cardiac arrest in the operating room. They would not let us ride along. I had broken my promise not to leave him already. My husband’s promise that he would be fine was also broken. Our pain and guilt over these broken promises have eased only minimally over the ensuing years ... The pain of seeing my child in this condition was unfathomable. I left his room as the team attempted to revive him over and over again. I could not watch. I rocked back and forth while kneeling down outside his room. I remember a group of residents being briefed on the case, and one of them wanting to comfort me, but sadly turning away. I remember his dark hair and eyes looking down at me. Many years later, tears stream down my face, as if this happened yesterday.

For the complete article on Justin, please see:
More than 56,000 adverse events and 700 patient deaths linked to PCA pumps (reports filed with the FDA between 2005 and 2009)


4,500 Adverse Events in 6 Years

Over the six-year period from June 2004 to May 2010, data collected by Pennsylvania Patient Safety Authority revealed that there were approximately 4,500 reports associated with PCA pumps.


Three Times as Likely to Result in Injury or Death

FDA's Manufacturer and User Device Experience (MAUDE) database demonstrates that PCA-related device events are three times as likely to result in injury or death as reports of device events involving general-purpose infusion pumps.


PCA Errors: Just the Tip of the Iceberg

“PCA errors certainly occur, both in programming and in delivery, but any published estimate is likely to be only the tip of the iceberg.”

Dr Richard Dutton
Executive Director
Anesthesia Quality Institute
Bryanne Patail, biomedical engineer at the U.S. Department of Veterans Affairs, National Center for Patient Safety, discusses patient-controlled analgesia (PCA) pumps and what the Veterans Health Administration has done to reduce errors and improve patient safety. This interview was conducted with Michael Wong of the Physician-Patient Alliance for Health & Safety.

Q: What concerns do you have with PCA pumps?

Bryanne Patail: As I reported at the AAMI/FDA Infusion Device Summit (pdf), VHA has been conducting root cause analyses since 1999. In looking at infusion pumps, we found that more than 13 percent (129 in all) involved two types of infusion pumps. Of these 129 events, 60 related to general-purpose pumps and 69 to PCA pumps. In other words, more than 50 percent of these events involved PCA pumps — roughly a 50/50 split between general-purpose and PCA pumps. However, there are about 10 times as many general-purpose pumps in use across the VA system than PCA pumps. This suggests that incidents with PCA pumps are about 10 times more than with general-purpose pumps. That’s significant!

Q: What did VHA do about this high PCA pump incidence rate?

BP: One action that VHA has taken to address this high error incident rate is to use a PCA pump that has an integrated end tidal CO2 monitor or capnograph. A capnograph measures in real-time the adequacy of ventilation. Using this technology could prevent more than 60 percent of adverse events related to PCA pumps. In addition, we developed a standard protocol that looks at the other key issues that need to be addressed for safe use of PCA pumps: human factors (communication, training, fatigue and scheduling); the environment and equipment, rules, policies and procedures, and barriers and controls.

Q: From your experience, what would you recommend to other healthcare providers to reduce their PCA-related errors?

BP: Use of PCA pumps is a process, and improving that process is an area that involves many stakeholders. In looking at fixes, they can be categorized as strong, intermediate or weak fixes. The strongest fix for PCA pumps is a forcing function, such as an integrated end tidal CO2 monitor that will pause the pump if a possible over infusion occurred. So, healthcare providers should first look at these strong fixes. There they will see the most impact on reducing errors and improving patient safety.

Thank you to Becker’s Clinical Quality & Infection Control for publishing this interview and for this reprint.
The ROI of Safer PCA: Eliminating Adverse Events and Improving Patient Safety While Reducing Costs

St. Joseph’s/Candler Hospitals (SJ/C) in Savannah, Georgia calculated that their initiative to reduce PCA adverse events made great financial sense:

• $4 million -- estimated potential expenses averted (not including potential litigation costs)
• $2.5 million -- 5-year return on investment

SJ/C are two of the oldest continuously operating hospitals in the US. About 10 years ago, SJ/C had three opioid-related events with patient-controlled analgesia (PCA) with serious outcomes over a two-year period.

Since using “smart” PCA pumps with integrated capnography, SJ/C has been “error-free”. As they report in their article, “Excellent Return on Investment with Capnography Monitoring” in the recent edition of the APSF Newsletter, these changes averted 450 highest-risk IV medication errors and respiratory monitoring helped avert at least 35 PCA-related undesirable events.


Achieving Zero Code Blues: Wesley Medical Center (Wichita, Kansas)
Debra Fox, MBA, RRT-NPS & Mark Wencel, MD
Poster presentation at: AARC International Congress (November 2011 in Tampa FL)

Prior to implementing capnography monitoring in 2010, 12.5% of moderate-to-severe patients progressed to Code Blue. After implementing end-tidal CO2 monitoring, that rate fell to 4.3% and then 0% in 2011.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>% Mild</td>
<td>47.8%</td>
<td>36%</td>
<td>35%</td>
<td>41.5%</td>
<td>56.6%</td>
<td>59%</td>
</tr>
<tr>
<td>% Moderate</td>
<td>32.6%</td>
<td>49%</td>
<td>51.5%</td>
<td>51.2%</td>
<td>37.7%</td>
<td>38%</td>
</tr>
<tr>
<td>% Severe</td>
<td>18.6%</td>
<td>14.6%</td>
<td>13.5%</td>
<td>7.3%</td>
<td>5.7%</td>
<td>2%</td>
</tr>
<tr>
<td>% Mod/Severe progressing to Code Blue</td>
<td>16.7%</td>
<td>8.5%</td>
<td>12.5%</td>
<td>12.5%</td>
<td>4.3%</td>
<td>0%</td>
</tr>
</tbody>
</table>