

MANAGING RISK WITH PATIENT CONTROLLED ANALGESIA: RECENTLY RELEASED SAFETY CHECKLIST ADDRESSES JOINT COMMISSION CONCERNS OF OPIOID-RELATED ADVERSE EVENTS

By Michael Wong, JD

Using patient-controlled analgesia (PCA) pumps to help manage patients' pain has become accepted medical practice and is generally considered safe and effective. In its Sentinel Event Alert, "Safe Use of Opioids in Hospitals", The Joint Commission recommends the use of PCA to help avoid adverse events associated with the use of opioids.

However, in this very same Sentinel Event Alert, The Joint Commission also warns against the possibility of opioid-induced respiratory depression (OIRD):

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.

According to reports made to the Food and Drug Administration between 2005 and 2009,² more than 56,000 adverse events and 700 patient deaths were linked to patient-controlled analgesia (PCA) pumps. One out of 378 post-surgical patients are harmed or die from errors related to the patient-controlled pumps that help relieve pain after surgical procedures, such as knee or abdominal surgery.

Fifty percent of Code Blue events involve patients receiving opioid analgesia. Unrecognized postoperative respiratory failure that results in cardiopulmonary arrest is a daily occurrence at healthcare facilities across the United States. Since cardiopulmonary arrest often results in death or anoxic brain injury, these events have been termed "failure to rescue". Failure to rescue is the first and third most common cause of adverse events related to patient safety, accounting for 113 events per 1,000 at-risk patient admissions.³

As Dr. Robert Stoelting (President, Anesthesia Patient Safety Foundation) explains, "Clinically significant drug-induced respiratory depression (oxygenation and/or ventilation) in the postoperative period remains a serious patient safety risk that continues to be associated with significant morbidity and mortality."⁴

Developing and implementing standardized tools can help reduce the risk factors associated with over sedation and respiratory depression. As Dr. Ana Pujols McKee (Executive Vice President and Chief Medical Officer, The Joint Commission) says about the need for standards:

"The Joint Commission recognizes there is an opportunity to improve care for patients by improving the safety of opioid use in acute care settings given that data show opioids are among the top three drugs in which medication-related adverse events are reported. Opioids are necessary to prevent suffering, but there are risks related to potency, route of administration, and patient history. By engaging in a comprehensive approach to assessment, monitoring, and patient education, opioid overuse and associated harm can be prevented."

Healthcare facilities need to develop processes for safer opioid use of patient-controlled analgesia. To assist in that regard, below are discussed:

- Patient Stories of Opioid-Induced Respiratory Depression
- Veterans Health Administration Protocols and Forcing Function
- The ROI of Better Risk Management
- Managing Risk with the PCA Safety Checklist

Patient Stories of Opioid-Induced Respiratory Depression

Statistics do not reflect the tragedy and personal affect that adverse events and death have on patients, their families and healthcare providers.

Below discuss four patient stories to remind us of the human toll of opioid-related adverse events and the necessity of eliminating such events and of using tools and aids to help manage that risk.



11-Year-Old Leah Coufal

After being at her daughter's side for almost a day and a half, Lenore Alexander fell asleep exhausted in the hospital room only to awaken a short time later to find her daughter, Leah, dead.

Lenore 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.



18-Year-Old Amanda Abbiehl

Amanda Abbiehl was 18 years old when she died from an adverse event related to PCA. A high school senior, she was planning to attend college that fall.

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.



Grandmother Louise Batz

Louise Batz was a grandmother, looking forward to the birth of another grandchild. Her daughter of Louise shares 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 arrived on the general floor.



11-Year-Old Justin Micalizzi

Dale Ann Micalizzi describes the impact of the death of her son, Justin, 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.

Unfortunately, these patient deaths are not isolated incidents, but just four stories amongst hundreds and thousands of others.

Veterans Health Administration Protocols and Forcing Function

The U.S. Department of Veteran Affairs, National Center for Patient Safety (VHA), has conducted root cause analyses since 1999 to ensure the safe use of opioids. The VHA found that the error incidence rate of patient controlled analgesia (PCA) pumps was ten times higher than general-purpose pumps.

In an interview with the Physician-Patient Alliance for Health & Safety, Bryanne Patail (biomedical engineer, U.S. Department of Veterans Affairs, National Center for Patient Safety) describes what they found:

VHA has been conducting root cause analyses since 1999. In looking at infusion pumps, we found that more the 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!

To help prevent further PCA-related adverse events, the VHA put into place standard protocols and began continuously monitoring patients receiving opioids with capnography for adequacy of ventilation. Says Mr. Patail:

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.

The VHA attributes much of the success of its efforts to the introduction of a “forcing function”, which means that the PCA pump will pause when the capnography monitor senses patient deterioration in ventilation. Mr Patail explains further:

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.

The ROI of Better Risk Management

Using this forcing function by integrating capnography monitoring into PCA pumps has been demonstrated by St. Joseph/Candler Hospitals in Savannah, Georgia, to eliminate adverse events. St. Joseph/Candler are two of the oldest continuously operating hospitals in the US.

As discussed in the article “Clinical Experience with Capnography Monitoring for PCA Patients”, Ray R. Maddox, PharmD and Carolyn K. Williams, BSPHarm of St. Joseph/Candler describe how their hospitals have been able to become “event free” by instituting protocols and the forcing function of capnography monitoring in the PCA pumps they use.

Detecting at the earliest possible time that onset of respiratory depression, which can lead to death, is critical and has great benefit for hospital staff and their ability to provide optimal care and see more patients. Report Mr. Maddox and Ms. Williams:

At each shift, the respiratory status of PCA patients is assessed by a therapist. The assessment includes an evaluation of the recorded trend analysis of RR, EtCO2 waveforms, and any pulse oximetry results. Nurses consult respiratory therapists to assist with the assessment at any time during the shift when alarms indicate potential patient respiratory distress. Early identification of respiratory depression allows respiratory therapy to intervene before a patient's condition becomes serious, which saves time, helps increase the likelihood of a positive outcome, and allows existing staff to oversee more patients.

Moreover, although a human life should never be measured in dollars and cents, St. Joseph/Candler calculated that their decision made great financial sense:

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

Managing Risk with the PCA Safety Checklist

The Physician-Patient Alliance for Health & Safety, with the advice of a group of nineteen renowned physicians and nurses, recently released a PCA Safety Checklist to help healthcare professionals reduce the number of adverse events involving PCA pumps. This concise checklist reminds caregivers of the essential steps needed to be taken to initiate PCA with a patient and to continue to assess that patient's use of PCA.

Below are discussed the five steps to initiate PCA.

Step 1: Patient Risk Factors

The first step ensures that patient risk factors have been considered, such as obesity, low body weight, advanced age, and pre-existing conditions (asthma, COPD, and sleep apnea):

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

However, it should be noted that this is not a recommendation to risk stratify. For example, a recent study published in the British Journal of Anesthesia found that anesthetists and surgeons failed to identify significant numbers of patients with pre-existing obstructive sleep apnea and symptomatic undiagnosed OSA. This step is just a guide for identifying higher risk patients.

Steps 2 & 3: Patient Suitability

Steps 2 and 3 of the PCA Safety Checklist ask whether the patient is a suitable candidate:

- **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 use of PCA pump (other recipients of information-family/visitors) and purpose of monitoring**

In The Joint Commission sentinel event alert, we are reminded to make sure that the patient is aware of a number of factors:¹¹

- The various generic and brand names, formulations, and routes of administration of opioids in order to prevent confusion and reduce the accidental duplication of opioid prescriptions;
- The principal risks and side effects of opioids, including the likelihood of constipation, and the risk of falls, nausea and vomiting;
- The impact of opioid therapy on psychomotor and cognitive function (which may affect driving and work safety);
- The potential for serious interactions with alcohol and other central nervous system depressants;

- The potential risks of tolerance, addiction, physical dependency, and withdrawal symptoms associated with opioid therapy.
- The specific dangers as a result of the potentiating effects when opioids are used in combination, such as oral and transdermal (fentanyl patches).
- The safe and secure storage of opioid analgesics in the home.

Step 4: PCA Pump Double-Checked

Step 4 of the PCA Safety Checklist reminds caregivers of the necessity of double-checking to make sure that the pump has been programmed correctly:

- **Two healthcare providers have independently double-checked:**
 - **patient's identification**
 - **all patient allergies appear 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**

The Joint Commission reminds us that more than 50% of errors are related to medication type errors. That's why a double check is necessary.

Step 5: Continuously Electronically Monitor Patients

The final step is to monitor the patient continuously with pulse oximetry for oxygenation and capnography for adequacy of ventilation:

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

As noted by The Joint Commission, 29% of adverse opioid events are due to inadequate monitoring.

Managing Risk With Patient-Controlled Analgesia

Use of patient-controlled analgesia to manage patients' pain is accepted medical practice and is generally considered safe and effective.

Unfortunately, the statistics and the tragic patient stories noted above remind us that without proper protocols and technology in place (such as, using a PCA with integrated capnography), adverse events and patient deaths may occur.

In his recent presentation at a patient safety conference,¹² Dr. Robert Stoelting estimated that 13 million patients will use PCA each year. The incidence of opioid-induced respiratory depression ranges from 16% to 5.2%. This means that each year up to 676,000 patients using PCA will experience opioid-induced respiratory depression. This number excludes other forms of opioid administration.

Fortunately, as the experience of St. Joseph/Candler has demonstrated, PCA adverse events can be reduced, if not eliminated, and putting into place proper risk management and patient safety measures can provide a significant return on investment.

Hospitals and healthcare professionals are, therefore, encouraged to use the PCA Safety Checklist as a tool to use to assist with this risk management and reduction.¹³

¹ The Joint Commission Sentinel Event Alert, Issue 49, August 8, 2012

http://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf

² Advanced Society in Medical Instrumentation, "Infusing Patients Safety: Priority Issues from the AAMI/FDA Infusion Device Summit (October 2011)

http://www.aami.org/publications/summits/AAMI_FDA_Summit_Report.pdf

³ Overdyk FJ, et. al., "Continuous Oximetry/Capnometry Monitoring Reveals Frequent Desaturation and Bradypnea During Patient-Controlled Analgesia"

Anesth Analg 2007; 105: 412-8 http://jivmedicscorner.com/Anaesth-Post_Anesth_Management_files/Desaturation%20and%20PCA.pdf

⁴ "Post-Surgical Patients Require Better Monitoring":

<http://ppahs.org/2011/08/09/post-surgical-patients-require-better-monitoring-for-improved-patient-safety-anesthesia-patient-safety-foundation-guidelines-recommend-using-capnography-and-oximetry-to-continuously-monitor-patients/>

⁵ For Amanda's story, see <http://promisetoamanda.org/about-amanda/>

⁶ For Louise's story, see <http://ppahs.org/2012/01/13/guest-post-monitoring-can-prevent-errors-with-patient-controlled-analgesia/>

⁷ For Justin's story, see <http://ppahs.org/2011/08/18/would-monitoring-have-saved-justin-micalizzi/>

⁸ The author has been contacted by five other families whose loved ones have died from opioid-induced respiratory depression during the gathering of information for and writing this article.

⁹ http://www.apsf.org/newsletters/pdf/winter_2012.pdf

¹⁰ <http://ppahs.org/2012/07/17/physician-patient-alliance-for-health-safety-announces-new-expert-checklist-for-facilitating-safety-of-hospital-based-intravenous-patient-controlled-anesthesia-pumps/>

¹¹ Perhaps an easier short hand version of this are the PPAHS four essentials to

patient safety: <http://www.beckersasc.com/asc-quality-infection-control/4-essentials-for-patient-controlled-analgesia-pump-safety.html>

¹² <http://www.patientsafetysummit.org/2013/>

¹³ The PCA Safety Checklist can be downloaded as a static pdf or a checkable word document from www.ppahs.org



Michael Wong, JD is a recognized healthcare and patient safety expert. He has been at the forefront in driving practical solutions that reduce healthcare costs, decrease medical errors, and improve patient health outcomes. He has been particularly active in these areas that most affect patient safety:

- Improving patient adherence (i.e. helping patients to take their medications as prescribed by their physicians)
- Enhancing patient access to healthcare
- Reducing medical errors

Wong is the driving force behind the Physician-Patient Alliance for Health & Safety (PPAHS), an advocacy group of physicians,

patient advocates, and healthcare organizations. Supporters of and commenters for PPAHS include some of the most highly respected physicians and healthcare organizations, including The Joint Commission, Anesthesia Patient Safety Foundation, Anesthesia Quality Institute, Johns Hopkins School of Medicine, Harvard Medical School, Stanford University School of Medicine, and Cleveland Clinic.

Together with a renowned group of health experts (including Dr. Peter Pronovost of Johns Hopkins who developed the central IV line checklist and Dr. Atul Gawande of Harvard who created the surgical checklist with the WHO), Wong helped develop a concise checklist that reminds caregivers of the essential steps needed to be taken to initiate Patient-Controlled Analgesia (PCA) with a patient and to continue to assess that patient's use of PCA. More than 56,000 adverse events and 700 patient deaths were linked to PCA pumps in reports to the Food and Drug Administration (FDA) between 2005 and 2009.

In recognition of his efforts to improve patient safety, Wong is a founding member of the American Board of Patient Safety, a recently created board to certify and recertify physicians in patient safety through the American Board of Physician Specialties, one of the United States's main recognized physician multi-specialty certifying bodies.

A graduate of Johns Hopkins University and a former practicing attorney, Wong is on the editorial board of the Journal of Patient Compliance (JPC), the only peer reviewed journal devoted to helping patient's take their medication as physician recommended. Published in London, England, JPC looks into the ideal way in which patient compliance could be enhanced.