# Patient Safety Checklist Addresses Opioid Warnings from Joint Commission

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Physician-Patient Alliance
for Health & Safety (PPAHS)
www.ppahs.org

## Introduction

***"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)*
*www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf*

## Background: The Problem

**A Common Fatal Pathway for "Non-Fatal" Conditions**

- **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)".

Frank Overdyk, Michael Da Vita, Chris Pasero,
"Postoperative Opioid-Induced Respiratory Depression:
Current Challenges and New Developments in Patient Monitoring"
Anesthesiology News (October 2012)
www.anesthesiologynews.com/download/SR1221_WM.pdf

- **FTR is the first and third most common patient safety-related adverse events** affecting the Medicare population in U.S. hospitals
- This accounts for 113 events per 1,000 at-risk patient admissions.

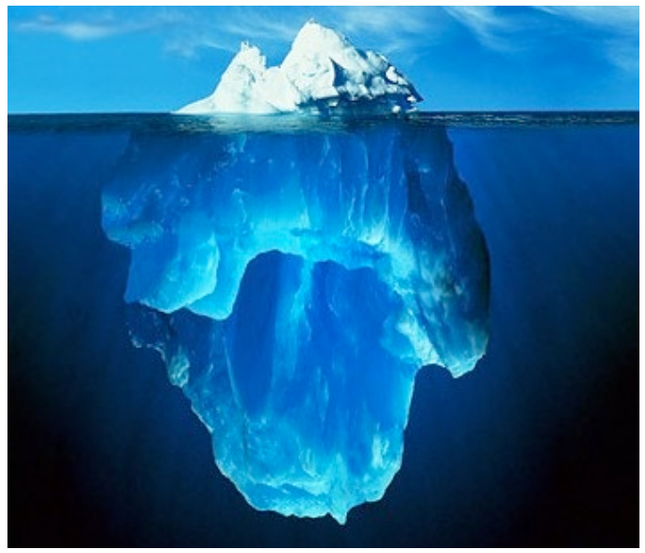
Health Grades
"The Sixth Annual HealthGrades Patient Safety in American Hospitals Study"
www.healthgrades.com/business/img/PatientSafetyInAmericanHospitalsStudy2009.pdf

## PCA Adverse Events: How Often Do They Occur?

- **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.
- 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.

Association for the Advancement of Medical Instrumentation (AAMI),
"Infusing Patients Safely: Priority Issues from the AAMI/FDA Infusion Device Summit"
www.aami.org/publications/summits/AAMI_FDA_Summit_Report.pdf

## 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

## 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.
http://ppahs.org/2012/03/20/physician-patient-alliance-for-health-safety-hospitals-need-to-address-pca-pump-patient-safety/

## 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.
http://ppahs.org/2012/03/20/physician-patient-alliance-for-health-safety-hospitals-need-to-address-pca-pump-patient-safety/

# Faces of Tragedy:
# PCA-Related Patient Deaths


## 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

## 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/

## 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:
http://ppahs.org/2012/01/13/guest-post-monitoring-can-prevent-errors-with-patient-controlled-analgesia/

## 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:
http://ppahs.org/2011/08/18/would-monitoring-have-saved-justin-micalizzi/

## 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 (opiates and non-opiates) that potentiate sedative effect of opiate 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 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**
- ☐ **Patient is electronically monitored with both:**
  - **pulse oximetry and**
  - **capnography**

## Expert Opinion

**Frank Federico, RPh**
**(Patient Safety Advisory Group at The Joint Commission and executive director at the Institute for Healthcare Improvement):**

*"Use and adherence with standardized processes for eligible patients leads to better clinical outcomes. The PPAHS PCA checklist lays out essential steps to be taken to initiate patient-controlled analgesia (PCA) with a patient and to continue to assess that patient's use of PCA. Following these steps will help to increase patient safety and save lives."*

**Ana Pujols McKee, MD**
**(executive vice president and chief medical officer, The Joint Commission):**

*"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."*

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***Characteristics of patients who are at higher risk for oversedation and respiratory depression***

- Sleep apnea or sleep disorder diagnosis
- Morbid obesity with high risk of sleep apnea
- Snoring
- Older age; risk is
  - 2.8 times higher for individuals aged 61-70
  - 5.4 times higher for age 71-80
  - 8.7 times higher for those over age 80
- No recent opioid use
- Post-surgery, particularly if upper abdominal or thoracic surgery
- Increased opioid dose requirement6 or opioid habituation
- Longer length of time receiving general anesthesia during surgery
- Receiving other sedating drugs, such as benzodiazepines, antihistamines, diphenhydramine, sedatives, or other central nervous system depressants
- Preexisting pulmonary or cardiac disease or dysfunction or major organ failure5
- Thoracic or other surgical incisions that may impair breathing

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*Educate and provide written instructions to patients who are on opioids (and to the patient's family or caregiver) about:*

- *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.*

*References*


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Opioid Adverse Events (The Joint Commission Sentinel Event Database (2004-2011):
- 47% - wrong dose medication errors
- 11% - inc. excessive dosing, medication interactions and adverse drug reactions

*References*
- *The Joint Commission, Sentinel Event Alert #49 (August 8, 2012)*

The Joint Commission Sentinel Event Database (2004-2011)
- *29% adverse drug events - improper monitoring of the patient*

*Dr. Robert Stoelting (President, Anesthesia Patient Safety Foundation*
- *"As many as 50% of of PCA adverse events could be prevented with effective monitoring"*

## 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 sheet/ 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.**

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