Reducing Healthcare Costs While Improving Patient Health Outcomes and Safety: Checklist and Case Studies in Making Patient-Controlled Analgesia (PCA) Safer

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

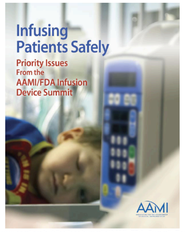
Justin's mother, Dale Ann Micalizzi, describes the impact his death had on her family:

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://onlinelibrary.wiley.com/doi/10.1111/j.1460-9592.2010.03513.x/full

PCA Adverse Events: How Often Do They Occur?

More than 56,000 adverse events and 700 patient deaths linked to PCA pumps (reports filed with the FDA between 2005 and 2009)



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

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/

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)

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

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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About PPAHS

Physician-Patient Alliance for Health & Safety (PPAHS) is an advocacy group devoted to improving patient health and safety. PPAHS is composed of physicians, patients, individuals, and organizations

Improving health and safety involves many facets:

- Innovative technology to provide for necessary monitoring of patient vital signs. For example, as the Wall Street Journal proclaimed in its story about Howard Snitzer "A little known device is shaking conventional wisdom for reviving people who suffer sudden cardiac arrest: People may be able to go much longer without a pulse than the 20 minutes previously believed."
- Health Care Providers who must make critical live-saving decisions, such as anesthesiologists who, as the American Society of Anesthesiologists says, "are responsible for administering anesthesia to relieve pain and for managing vital life functions, including breathing, heart rhythm and blood pressure, during surgery. After surgery, they maintain the patient in a comfortable state during the recovery and are involved in the provision of critical care medicine in the intensive care unit."
- Information on what works and how it enhances patient health and safety.

5 Tips on How to Improve Patient Safety With the Help of Technology

#1 Focus on what is right for the patient.

#2 Don't be mired in the way things "have always been done." Let technology help you in caring for patients.

#3 Realize that any new technology or technique may have unintended changes to daily routine, but remember that this is better than having an adverse event.

#4 Ensure changes help caregivers better manage their own daily work days.

#5 Get closer to the patient.

For a complete copy of this article, please see:
http://www.beckershospitalreview.com/quality/5-tips-on-how-to-improve-patient-safety-with-the-help-of-technology.html

Cases Studies: Hospitals That Have Reduced PCA Adverse Events

UNITED STATES DEPARTMENT OF VETERANS AFFAIRS

60% Reduction in PCA Adverse Events

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 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!

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

PCA pump with integrated capnography like that used at St. Joseph/Candler Hospitals (Savannah, Georgia)

St. Joseph's/Candler Hospitals (SJ/C) in Savannah, Georgia calculated that their initiative to redcuce 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.

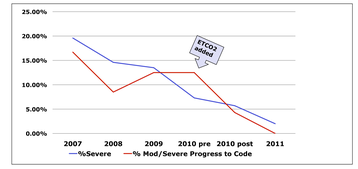
Since using "smart" PCA pumps with integrated capnography, SJ/C has been "error-free". As they report in their article, "Excellent Return on Investment with Capnography Monitoring" in the recent edition of the APSF Newsletter, these changes averted 450 highest-risk IV medication errors and respiratory monitoring helped avert at least 35 PCA-related undesirable events.
http://www.apsf.org/newsletters/pdf/winter_2012.pdf

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.



Opioid ADRs By Severity	2007	2008	2009	2010 Pre-ETCO2	2010 Post-ETCO2	2011 Jan – June
% Mild	47.8%	36%	35%	41.5%	56.6%	59%
% Moderate	32.6%	49%	51.5%	51.2%	37.7%	38%
% Severe	19.6%	14.6%	13.5%	7.3%	5.7%	2%
% Mod/Severe progressing to Code Blue	16.7%	8.5%	12.5%	12.5%	4.3%	0%