

**California Hospital Engagement Network**

# **ADE Webinar Series**

**May 7, 2013**

**Preventing Opioid-Related Adverse Events:  
Patient Stories and Best Practices**

Speakers:

L. Alexander, D. Fox, M. Loflin, M. Parmenter, M. Wong

# Introduction

- Lenore Alexander, *Mothers Against Medical Errors*
- Debra Fox, *Wesley Medical Center*
- Malinda Loflin, *Oklahoma City VA Medical Center*
- Dr. Mark Parmenter, *Scripps Health System*
- Michael Wong, *Physician-Patient Alliance for Health & Safety (PPAHS)*



# Leah's Legacy



# Leah's Legacy



# Leah's Story

## [Leah's Story](#)

<http://www.strikingly.com/leahs-legacy#2>

# Leah's Law

Continuous electronic monitoring of all  
post-operative patients receiving  
opioids

# Leah's Four Essentials for Safety:

All Patients and Families Need To Know

1. Ensure patients/families are provided information on proper use of the PCA pump, so they understand:
  - Pump delivers a powerful narcotic
  - No PCA by proxy



# Leah's Four Essentials for Safety:

All Patients and Families Need To Know

2. Make sure patients/families understand why they must be monitored for safety reasons:
  - oximetry on finger
  - capnography cannula on nose

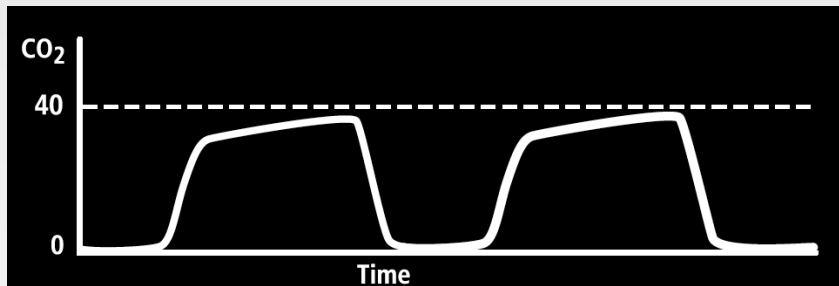




# Leah's Four Essentials for Safety:

All Patients and Families Need To Know

3. Save yourself some trouble and educate patients and families about monitor readouts.



Normal waveform



- Normal blood oxygen saturation level = 94% to 99%.
- Mild respiratory diseases= 90% or above.  
Supplementary oxygen needed = less than 90%

# Leah's Four Essentials for Safety:

All Patients and Families Need To Know

4. Why alarms sound and what to do when they do sound.



Example of Patient Surveillance Monitoring Equipment  
(shown that used by Wesley Medical Center, Hattiesburg, MS)



**A Nurse's Perspective on Whether  
Nursing Spot Checks are a  
Sufficient Patient Safety Measure**



# Intermittent Checks

For my Dad, Intermittent Checks FAILED



# Robert Goode

- Devoted Son
- Loving and Faithful Husband
- Nurturing Father
- Wonderful Grandpa
- Enjoyed fishing, traveling, and spending time with family
- Near retirement (63 years old; 9 months to retire from Tinker AFB; worked as civilian 40+ years)



# Condition

- Hiatal Hernia -- part of stomach sticks upward into the chest, through opening in diaphragm
- Surgery Decision -- having difficulty eating
- Heart Problems -- pacemaker (clearance for surgery from cardiologist)
- Sleep Apnea requiring CPAP

# Surgery

- Standard Procedure: Laparoscopic Nissen Fundoplication
- Everything went well
- No complications

# Recovery

- Transferred to general med-surg unit
- Within day after surgery, walking the halls and feeling great
- Looking forward to going home next day



# Post-Operative Orders

- Morphine PCA Pump
- Supplemental Oxygen
- However ... History of sleep apnea and used CPAP at home.
- Not electronically monitored

# Deterioration Timeline

<u>Timeline</u>	<u>Event</u>
0500	<ul style="list-style-type: none"><li>• Found Unresponsive Code Blue Initiated</li><li>• Placed On Vent, Pressors, and Anti-arrhythmics</li><li>• Transferred to a Larger Facility</li></ul>
0740	<ul style="list-style-type: none"><li>• DIC – Bleeding From Mouth and Nose</li><li>• Blood Products Given</li><li>• Multi-System Organ Failure</li><li>• EEG – Minimal Brain Stem Activity</li><li>• Hypothermic- Body Temp 93 Degrees</li><li>• Maxed Out on Pressors and Anti-arrhythmics</li><li>• Continues to Bleed From Mouth, Nose, and IV Sites</li><li>• Having Multiple Runs of V-TACH</li><li>• Decision Made to Stop Resuscitative Measures</li></ul>
1715	<ul style="list-style-type: none"><li>• Pronounced Dead</li><li>• Cause of Death: Anoxic Brain Injury</li></ul>

# Deterioration Timeline

- What are the odds of detecting deterioration?
- Dad's room at the end of hall, furthest away from nurses' station

# Standard of Care

- Standard of care: nursing spot checks
- Lippincott Manual of Nursing Practice:  
Respiratory Rate, Sedation Score and SpO2  
every 1 hour x 12 hours, then  
every 2 hours x 12 hours, then  
every 4 hours until dose increase or  
discontinuation.

# Standard of Care

**Table 6: Nursing Assessment Event & Frequency Guidelines for PCA Monitoring**

Cognitive Opioid Tolerance	Pain	Sedation	Respiratory			
			Rate	Quality	SPO2	ETCO2
Baseline	X	X	X	X	X	X
Initiation OR Change in Drug*	X	X	X	X	X	X
Q15 min x 1 hr						
Q1 hr x 4 hrs						
Then Q2hrs						
Dose Change OR Bolus	X	X	X	X	X	X
Q1 hr x 4 hrs						
Then Q2hrs						
Event OR Deterioration	X	X	X	X	X	X
Q15 min x 1 hr						
Q1 hr x 4 hrs						
Then Q2hrs						
Hand-offs/Shift change*	X	X	X	X	X	X

\* Independent check

# The Prevailing Standard

- 2-4 Hour Nurse Checks
- Intermittent Checks are NOT Sufficient

## Anesthesia Patient Safety Foundation

**Robert Stoelting, MD (president):**

*“the conclusions and recommendations of APSE are that intermittent ‘spot checks’ of oxygenation (pulse oximetry) are not adequate for reliability recognizing clinically significant evolving drug-induced respiratory depression in the post-operative period.”*

<http://ppahs.org/2013/02/07/update-on-cms-proposedquality-measure-on-pca-patient-safety/>

## Institute for Safe Medication Practices (ISMP)

**Mathew Grisinger(Director, Error Reporting Programs):**

*“One reason why it (periodic spot checks by caregivers and pulse oximetry) is not effective is that a ‘periodic check’ and pulse oximetry would only catch an error, not prevent the error.”*

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

# Value of Continuous Electronic Monitoring

## Nurses' Electronic Aid

- Continuous Pulse Oximetry
  - O2 Saturation
- Capnography
  - EtCO2 monitoring

Supplements 2-4 Checks

# Value of Continuous Electronic Monitoring

***Julianna Morath, RN, MS  
(chief quality & safety officer,  
Vanderbilt University Medical Center)***

*“Human vigilance is required but insufficient, continuous electronic monitoring needs to be there to support and back up nurses, and allow them to visit a patient while monitors are continuously assessing other patients for various physiological parameters (such as, oxygenation with pulse oximeter and adequacy of ventilation with capnography).”*





# **Lessons Learned from Implementing the San Diego Patient Safety Council Toolkit**



# Burning Platform

- August 2012 Joint Commission alert issued
- Focus on safe use of opioids in hospitals
  - Assess & Stratify patients
  - Team approach to management
  - Monitoring
  - Technology
  - Education

# San Diego Patient Safety Taskforce PCA Toolkit

## San Diego PCA Task Force *A Community Endeavor*



UNIVERSITY of CALIFORNIA, SAN DIEGO  
MEDICAL CENTER



PALOMAR  
POMERADO  
HEALTH

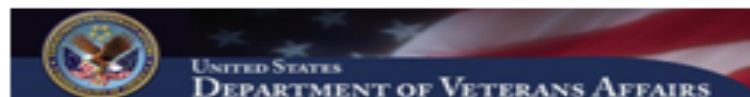
SHARP

San Diego Hospice  
& Palliative Care



Tri-City Medical Center

ALVARADO HOSPITAL



“Never doubt that a small group of thoughtful, committed citizens can change the world (*especially with lunch and a great facilitator*). Indeed it is the only thing that ever has.”  
- **Margaret Mead**

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# San Diego Patient Safety Taskforce PCA Toolkit

- Created by multidisciplinary clinicians across San Diego County
  - Received the 2009 ISMP Cheers award for PCA toolkit
  - 2013 recipient of the AAMI & Becton Dickinson Patient Safety Award
- Assessment of literature and identification of best practices
- Targeted to management of opioid naïve patient population
- Recommendations for orders, dataset, technology and monitoring
- Available at:  
<http://www.carefusion.com/safety-clinical-excellence/medication-safety/patient-safety-council.aspx>

# Orders

- Single vs. multiple drugs on an order form
- Patient stratification
  - Comorbidities, sensitivity
  - Opioid tolerance – definition and MD education
  - Opioid Tolerant Patients – different management
- ***Opioid tolerant*** – “Patients who have been taking, for a week or longer, at least 60mg of Morphine daily, or at least 30mg of oral oxycodone daily, or at least 8mg of oral hydromorphone daily, or an equianalgesic dose of another opioid.”  
- FDA

*Remaining challenge:*

- *How to link patient’s assessment of opioid tolerance to the proper orders and products*

# Orders

- Require stratification by MD upfront
- Mimic the way drugs appear in the pump layout/entry
- True PCA vs Basal/PCA
- Directions for nursing on dosing changes and assessment
- Directed assessment and initial response
- Directed collaboration with pharmacy
- Monitoring – ETCO<sub>2</sub>

# Smart Pump Dataset

- Number of Drugs/Concentrations
- Limit custom concentrations
  - If used, implement concentration limits
- Variable alerts/limits based on patient care areas and or drug concentrations
- Hard Stops
- Separating multiple concentrations of drugs
- Naming of drugs in dataset to match labels

# Monitoring

- Patient Assessment
  - Reassessment by nursing – workable frequency and defined actions
- Workable documentation/flow diagram for RN assessment and usage numbers
- Technology – implementation of ETCO<sub>2</sub>
  - Besides patient monitoring what does it mean
- Process assessment – requires active audit process
  - Change process assessment
  - Audit metrics



# Patient Safety Assessment

- Alert data from dataset
- Lack of Alarm data from ETCO2
- Process for determining ADE – Pyxis® removals

# SD Patient Safety Council

- Contact Erin Curtis –  
[erin.curtis@carefusion.com](mailto:erin.curtis@carefusion.com)
- Current project: Standardization and Best Practices of ETCO2 monitoring outside the ICU.



# **Recent Recommendations for Reducing Opioid Adverse Events**



# The Joint Commission Warning

**“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.”**

The Joint Commission  
Sentinel Event Alert “Safe use of opioids in hospitals”  
(Issue 49, August 8, 2012)

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# Opioid Use Most Related with Adverse Drug Events

*“Opioid analgesics rank among the drugs most frequently associated with adverse drug events”*

Two studies:

- most adverse drug events were due to drug-drug interactions, most commonly involving opioids, benzodiazepines, or cardiac medications
- 16% of inpatient adverse drug reactions attributable to opioids

# Causes of Opioid-Related Respiratory Depression

- Lack of knowledge about potency differences among opioids.
- Improper prescribing and administration of multiple opioids and modalities of opioid administration (i.e., oral, parenteral and transdermal patches).
- Inadequate monitoring of patients on opioids.

# Incidence of Opioid-Related Respiratory Depression

- Average about 0.5 percent
- Studies range from 0.16% to 5.2%

# Incidence of Opioid-Related Respiratory Depression: Patient-Controlled Analgesia (PCA)

- 13 million patients receive PCA annually
- Respiratory depression averages about 0.5% = 65,000 patients:
  - low 0.16% = 20,800 patients
  - high 5.2% = 676,000 patients
- Estimated 5,200 potentially preventable episodes of respiratory failure
- As many as 50% of PCA adverse events could be prevented with effective monitoring

Dr. Robert Stoelting

President

Anesthesia Patient Safety Foundation

(slides presented at Patient Safety, Science & Technology Summit (Jan 2013))

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# Incidence of Opioid-Related Respiratory Depression: Patient-Controlled Analgesia (PCA)



Dr. Richard Dutton  
(Executive Director, Anesthesia Quality  
Institute):

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

# Patient-Controlled Analgesia Safety Checklist

- **Dr. Christian Apfel (UCSF)**
- **Dr. James Berry (Vanderbilt)**
- **Dr. Art Boudreaux (Univ. 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 (Cogent Healthcare)**
- **Dr. Andrew Kofke (Univ. of Penn.)**
- **Dr. Elliot Krane (Stanford)**
- **Audrey Kuntz, RN (Vanderbilt)**
- **Karen Rago, RN (UCSF)**
- **Dr. Krish Ramachandran (Carilion Clinic)**
- **Dr. Adrienne Randolph (Harvard)**
- **Dr. Julius Pham (JHU)**
- **Dr. Peter Pronvost (JHU)**
- **Dr. Dan Sessler (Cleveland Clinic)**
- **Dr. John Williams (Society of Cardiovascular Anesthesiologists)**

# Patient-Controlled Analgesia Safety Checklist

## 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.**

# Patient-Controlled Analgesia Safety Checklist

- 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**



- Not a Recommendation for Risk Stratification:**
  - Note recent study published British Journal of Anesthesia by Singh et al “Proportion of surgical patients with undiagnosed obstructive sleep apnea”
  - found anesthesiologists and surgeons failed to identify significant number of patients with pre-existing OSA and symptomatic undiagnosed OSA
- A guide for identifying higher risk patients**

# Patient-Controlled Analgesia Safety Checklist

- Pre-procedural cognitive assessment has determined patient is capable of participating in pain management (note: pediatric patients may not be suitable for PCA)**
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The Joint Commission Sentinel Event Alert on Safe Use of Opioids in Hospitals

7. 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.
- 15
- 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.

When providing this information at discharge, also include phone numbers for a contact person call with questions.

# Patient-Controlled Analgesia Safety Checklist

- **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**



## **Leah's Four Essentials for Safety:**

1. Ensure patients/families are provided information on proper use of the PCA pump, so they understand:
  - Pump delivers a powerful narcotic
  - No PCA by proxy
2. Make sure patients/families understand why they must be monitored for safety reasons:
  - oximetry on finger
  - capnography cannula on nose
3. Save yourself some trouble and educate patients and families about monitor readouts.
4. Why alarms sound and what to do when they do sound.

# Patient-Controlled Analgesia Safety Checklist

- **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 Sentinel Event Alert on Safe Use of Opioids in Hospitals**

### **Adverse Events**

- 47% - wrong dose medication errors
- 11% - inc. excessive dosing, medication interactions and adverse drug reactions

# Patient-Controlled Analgesia Safety Checklist

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



## **The Joint Commission Sentinel Event Alert on Safe Use of Opioids in Hospitals**

➔ 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 Safety Checklist

**FREE Download off of [www.ppahs.org](http://www.ppahs.org)**

- **“checkable” word document**

<http://ppahs.files.wordpress.com/2012/07/pca-safety-checklist1.docx>

- **Pdf**

<http://ppahs.files.wordpress.com/2012/07/pca-safety-checklist3.pdf>



# **Impact of Continuous Monitoring**



# Case Study

Wesley Medical Center  
Wichita, KS



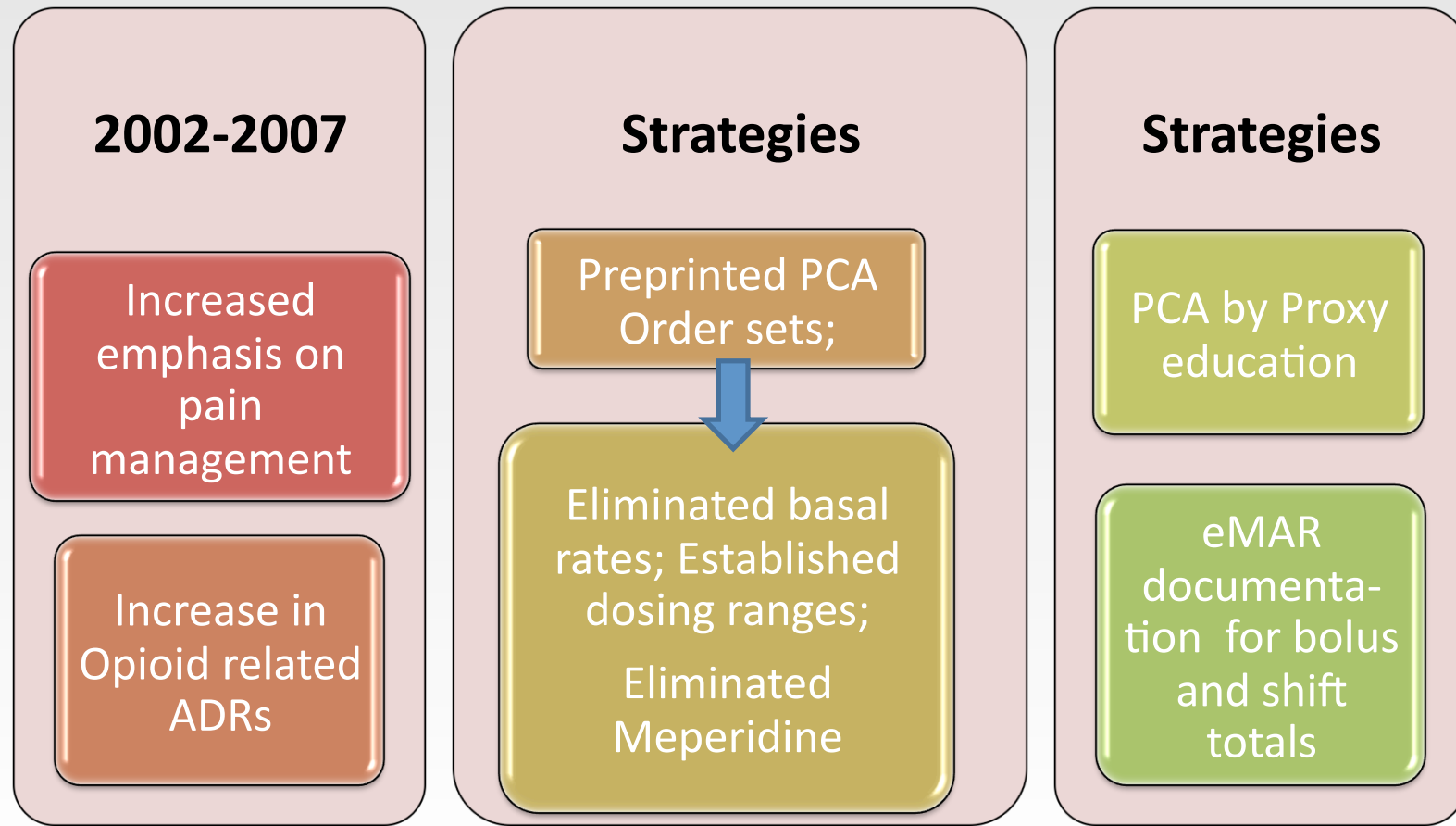
Licensed for 760 Beds  
HCA Facility

700 physicians  
3,000 employees

28,000 Inpatient Admissions  
18,000 Surgeries  
150-225 pts/mo PCA therapy

# Wesley's Experience:

## Previous Strategies Implemented



# Wesley's Results

Opioid ADRs by Severity	2007	2008
%Mild	47.80%	36.4%
%Mod	32.60%	49%
%Severe	19.60%	14.60%
% Code Mod/Severe (All Opioids)	37.50%	31.40%
% Code Mod/Severe (PCA Only)	16.70%	11.4%

# Wesley's Experience

## Implementation of Smart Pump Technology

**2009**

- Expanded Multidisciplinary Implementation Team
- Identification of High Risk Patients
  - All patients screened on admission
  - Modified STOP BANG score

**May  
2009**

- Conversion to "Smart" Pump system
- Included Capnography
- Policy/Procedures to monitor all PCA pts and all High Risk patients receiving IV opioids for first 48 hours

**Goal**

- Effective pain management
- Reduce Severe Adverse Drug Events
- Improve Patient Safety

# Wesley's Experience

## PCA Volumes and Risk Scoring

		2010	2011	2012
<b>PCA Stats</b>				
	Total PCA Orders	4122	3531	2268
	Total PCA Patients	3580	3114	2037
	Orders Using Order Set	4037	3472	2267
	% PCA Ord Using OS	97.94%	98.33%	99.96%
<b>Patient Risk Scoring</b>				
	Total PCA Pat w/ RS	3118	2961	1923
	High Risk	178	156	170
	Low Risk	2645	2428	1551
	Missing	488	265	114
	Diagnosed	274	251	202
	Not Eval	0	14	0
	% Pats w/PCA Ord w/RS	87.09%	95.09%	94.40%

# Wesley's Experience

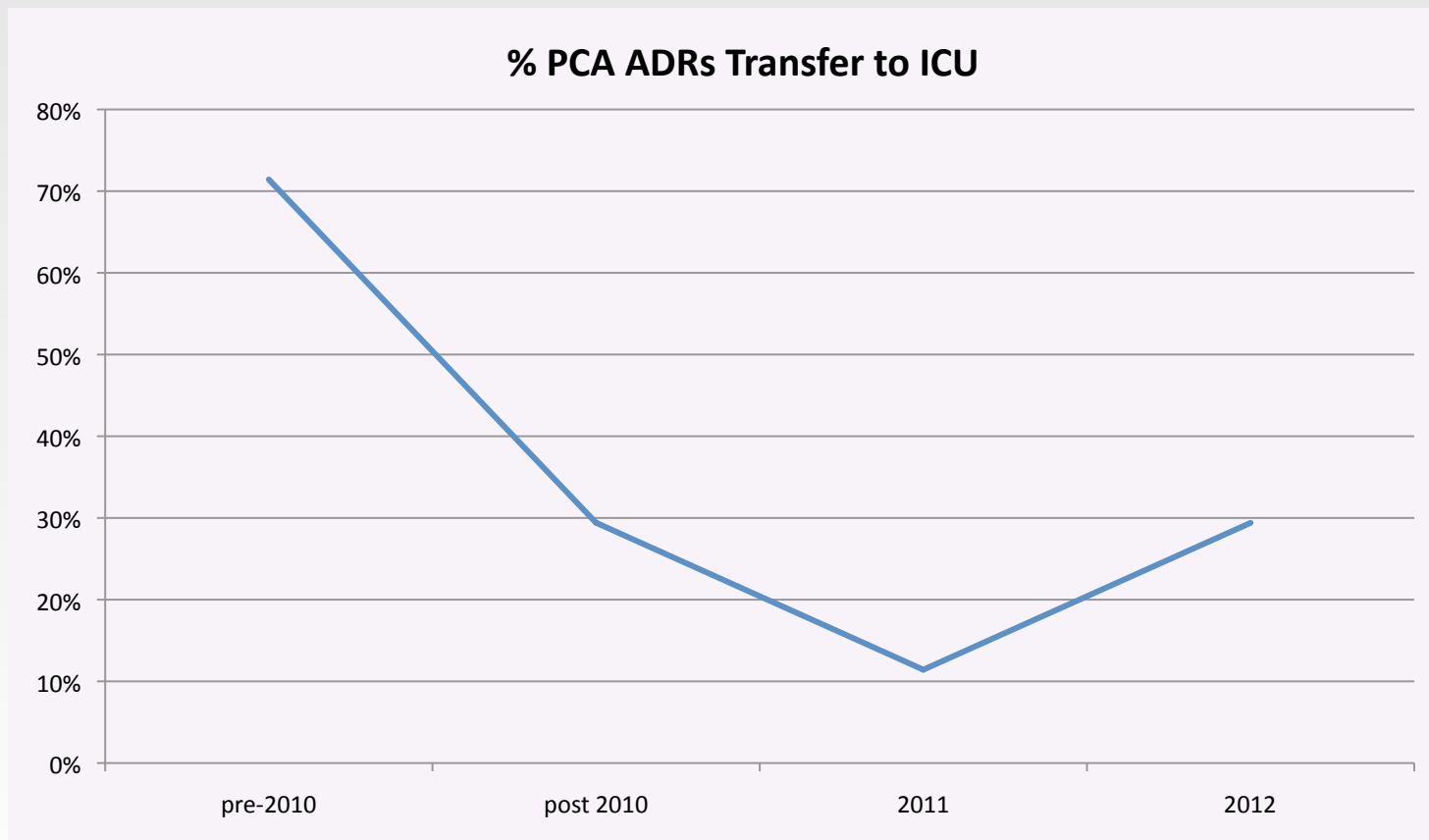
## Results:

Opioid ADRs by Severity	2007	2008	2009	2010 pre-ETCO2	2010 post-ETCO2	2011	2012
%Mild	47.80%	36.4%	35.1%	27.6%	54.2%	45.9%	60.2%
%Mod	32.60%	49%	51.4%	41.4%	39.0%	50.5%	35.6%
%Severe	19.60%	14.60%	13.50%	31.0%	6.80%	3.6%	1.4%
%Code Mod/Severe (All Opioids)	37.50%	31.40%	20.80%	42.8%	11.1%	10.0%	10.3%
% Code Mod/Severe (PCA Only)	16.70%	11.4%	12.5%	14.3%	3.70%	1.7%	3.4%



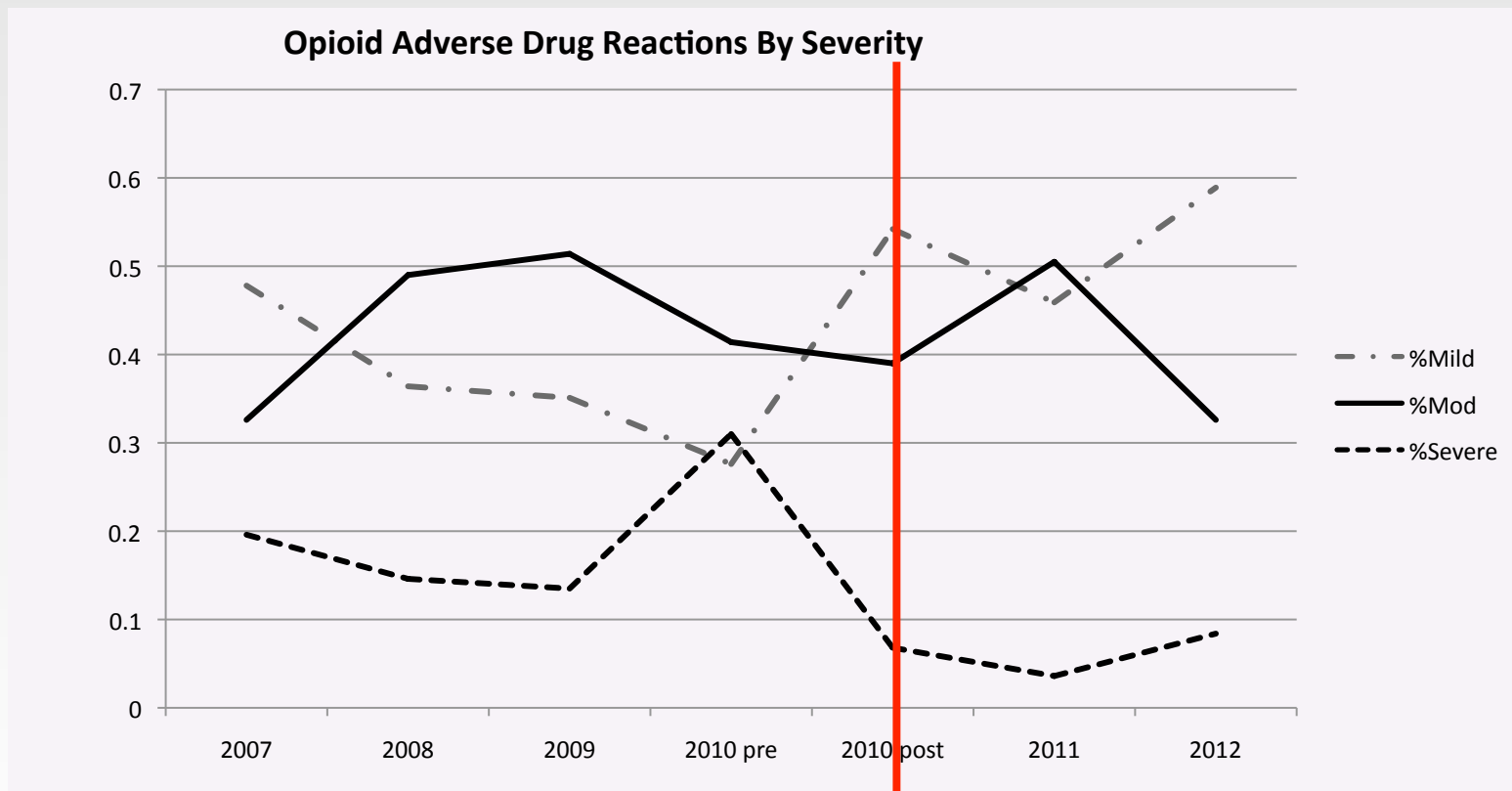
# Wesley's Experience

## Transfer to ICU



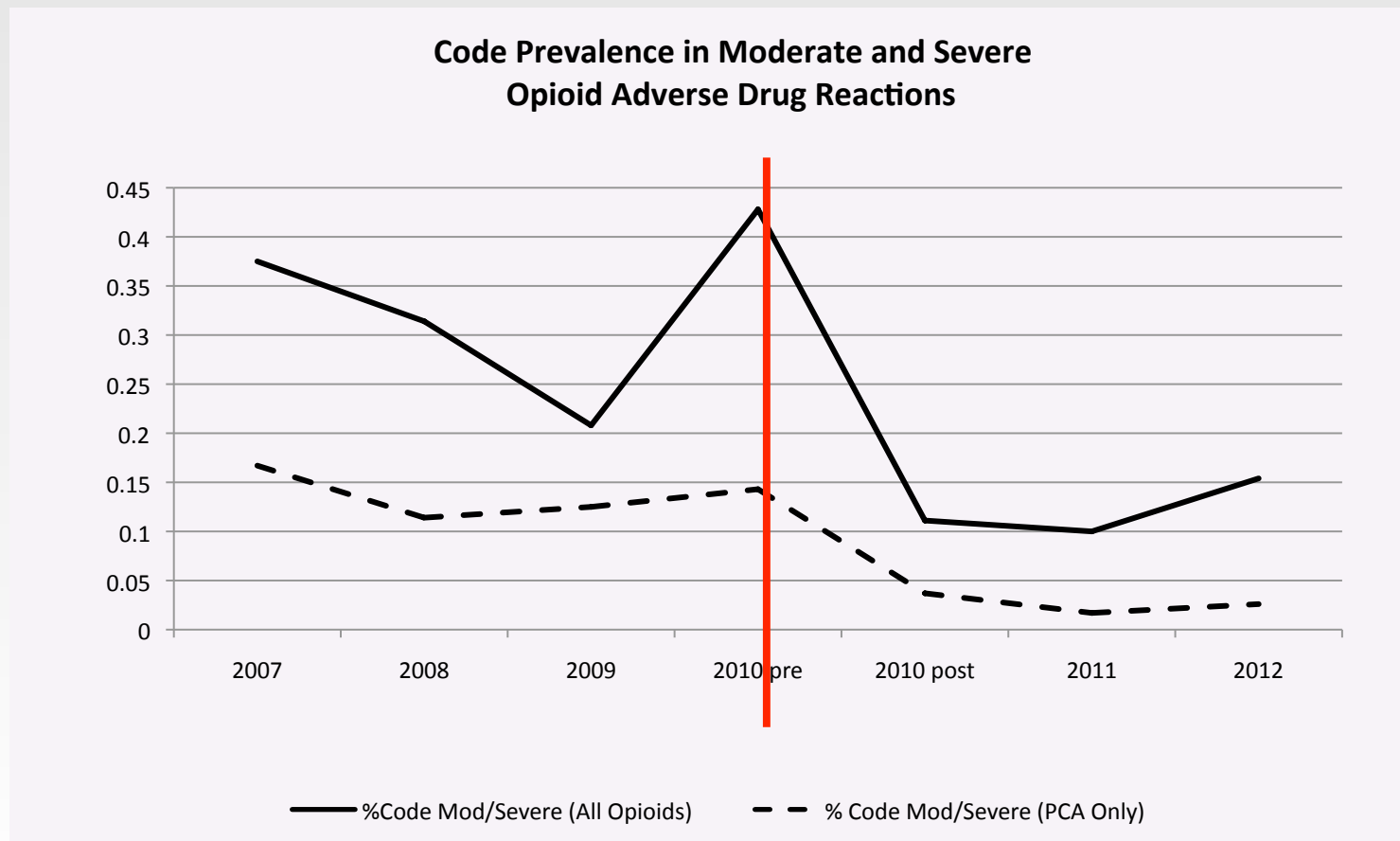
# Wesley's Experience

## ADRs by Severity



# Wesley's Experience

## Code Prevalence



# Wesley's Experience

## Ongoing Performance Improvement

Reduce Severity in Non-PCA ADRs

Dec. '12:  
Monitor all Post-  
op pts receiving  
IV opioids for 1<sup>st</sup>  
24 hrs

Methodology to  
identify other  
risk factors for  
respiratory  
depression?

Medical  
patients  
receiving IV  
opioids?

# Wesley's Experience

## Lessons Learned

**Staff Education: ETCO<sub>2</sub> Pulse Oximetry**

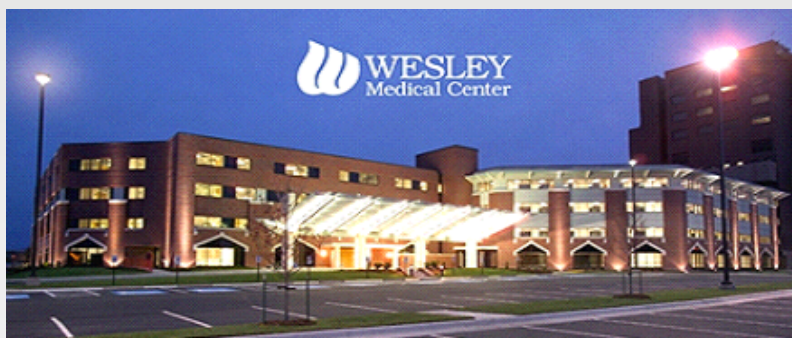
**Patient Education**

**Management of Alarms**

**Team Collaboration**

**ETCO<sub>2</sub> an effective tool for early detection of Respiratory Depression**

# Recognition



In recognition for our efforts to improve patient-controlled analgesia (PCA) outcomes, Wesley Medical Center was honored by the Institute of Safe Medication Practice with the

**Cheers Award in 2012.**

# Resources

- PCA Safety Checklist
- Leah's Story Video
- PCA Tool Kit
- PCA High-Risk IV Medication Tool Kit
- Continuous Respiratory AHRQ Article
- ICU Sedation Order Set
- ICU Sedation Tool Kit
- ISMP FMEA of PCA
- ISMP – Hydromorphone
- Safe Administration of High Risk Medication Tool Kit
- Erin Curtis – CareFusion:Med Safety Group - [erin.curtis@carefusion.com](mailto:erin.curtis@carefusion.com)

