Responding to The Joint Commission’s Sentinel Alert on Opioid Safety: The Role of Continuous Monitoring

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Hofstra North Shore-LIJ School of Medicine Director for Research
North American Partners in Anesthesia
Disclosures: Consulting fees and honoraria from Covidien and CareFusion
History

2004 - Joint Commission Sentinel Event Alert 33

2005 - CareFusion Pain Management and PCA Invited Conference

2006 - APSF Conference Recommendations

2011 – APSF Conference Recommendations

2012 - Joint Commission Sentinel Event Alert 49
October 2006 Conference
Recommendations

- No patient shall be harmed by respiratory depression in the postoperative period (zero tolerance)

- Continuous monitoring could prevent a significant number of cases of patient harm

- Urge health care professionals to consider continuous monitoring of oxygenation (pulse oximetry) and ventilation

- Supplemental oxygen decreases sensitivity of pulse oximetry as a monitor of hypoventilation

- Monitors must be linked to a process to summon help
“Perfect Storm” of Unrecognized Opioid Induced Respiratory Depression

Pain as the 5th VS (Villa et. al: >2 fold increase in opioid oversedation)¹

Opioids for mod-sev pain:
- 20-30X variability
- Pharmacogenetics/PK/PD

Med/surg monitoring deficiency
- Interval/spot checks q4hr
- High patient/nursing ratios
- Alarm fatigue
- RRT “threshold” triggers

Patient Demographic
^ elderly
^ obesity
^ chronic pain conditions
> ^occult sleep apnea
> ^chronic opiate use

Continuous Oximetry/Capnometry Monitoring Reveals Frequent Desaturation and Bradypnea During Patient-Controlled Analgesia

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Jarred Callura, BS§
Amy E. Herrin, MS†
Craig Henriques, PhD§

BACKGROUND: The most serious complication of patient-controlled analgesia (PCA) is respiratory depression (RD). The incidence of RD in the literature is derived from intermittent sampling of pulse oximetry (Spo2) and respiratory rate and defined as a deviation below an arbitrary threshold.

METHODS: We monitored postsurgical patients in a hospital ward receiving morphine or meperidine PCA with continuous oximetry and capnography. Nurses responding to audible monitor bedside alarms documented respiratory status and interventions.

RESULTS: A total of 178 patients were included in the analysis, 12% and 41% of whom had episodes of desaturation (Spo2 <90%) and bradypnea (respiratory rate <10) lasting 3 min or more. One patient required “rescue” with positive pressure ventilation, and none required naloxone. Patients over 65 years of age and the morbidly obese were at greater risk for desaturation. Patients over 65 years of age were also more likely to have bradypnea, whereas the morbidly obese and patients receiving continuous infusions were less likely to have bradypnea.

CONCLUSIONS: Our incidence of RD by bradypnea is significantly higher than the 1%-2% incidence in the literature, using the same threshold criteria but more stringent duration criteria, while our incidence of RD based on desaturation is consistent with previous estimates. We conclude that continuous respiratory monitoring is optimal for the safe administration of PCA, because any RD event can progress to respiratory arrest if undetected. Better alarm algorithms must be implemented to reduce the frequent alarms triggered by threshold criteria for RD.

Why not just continuous SpO2?
(pulse oximeter with RR)

<table>
<thead>
<tr>
<th>RR</th>
<th>EtCO₂ Average</th>
<th>SpO₂ Average</th>
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<tbody>
<tr>
<td>14</td>
<td>65</td>
<td>96</td>
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<tr>
<td>18</td>
<td>57</td>
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<tr>
<td>13</td>
<td>70</td>
<td>96</td>
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</table>

Threshold alarm MET/RRT
Bradypnea (RR<8)
Hypoxia (SpO₂ < 90%)

<table>
<thead>
<tr>
<th>Respiratory Depression cases</th>
<th>92 patients: 1697 hrs</th>
<th>Cashman(^1)</th>
<th>Walder(^2)</th>
<th>St Joe’s/Candler</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oximetry (\text{SpO}_2 &lt; 90%)</td>
<td>11.5%</td>
<td>15.2%</td>
<td>20 (24%) &gt; 2 min</td>
<td></td>
</tr>
<tr>
<td>Capnography (\text{RR} &lt; 10 \text{ bpm})</td>
<td>1.2%</td>
<td>1.6%</td>
<td>61 (74%) &gt; 2 min</td>
<td></td>
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Which patient do we monitor?
## DO’S

- REC: Serial assessments; *continuous* SpO2 and capnography when used. The APSF and ISMP recommend *continuous* monitoring of oxygenation and/or ventilation.

## DON’T’s

- Spot check monitoring of oxygenation (misses trends) and ‘manual’ assessment of ventilation (inaccurate).

## DO’s

- Continuous monitoring of oxygenation and ventilation for all patients receiving parenteral opioids.

## DON’T’s

- Continuous monitoring of oxygenation and ventilation for all patients receiving parenteral opioids.

### Risk Stratification: RF:

- Higher opioid doses
- Sleep apnea/ snoring (?)
- Morbid obese
- Extremes of age
- ASA 3/4
- Synergistic RD drugs
- Tolerance/abuse
- Opioid naïve
- Surgery type/duration
- Smoking (?)

- “Avoid rapid dose escalation of opioid analgesia above routine dose levels in opioid-tolerant patients”

- Continuous monitoring should be available for ALL patients.

### Risk stratification places patients at undue risk and is likely to miss OIRD in patients w/o RF

- Renal colic pain
- Strep throat
- % of patients who have ZERO JC
- STOP-BANG falsenegtvs (senst)

### When using supplemental O2.

- Staff should not rely on SpO2 alone

- Capnography and/or other airflow monitors MUST be used

- Suppl O2 reduces respiratory drive (RR and Ve)

### Educate and assess staff on:

- the potential effect of opioid on sedation and respiratory depression,
- the continuum of consciousness,
- the difference between ventilation and oxygenation,
- technological and clinical monitoring

- Education of providers (all levels) in:
  - pathophysiology
  - Pharmacology
  - clinical assessment for OIRD incl LOC.
  - supplemental O2

### Use patient-controlled analgesia (PCA) to reduce the risk of oversedation.

- Use smart infusion pump technology +dosage error reduction software

- Integration and trend analysis of > 1 physiologic parameter (ie SpO2 and RR) by smart alarm driven clinical decision support

- Reliance on single threshold alarms using point in time (or delayed) signal values

- PCA remains the most effective means to provide analgesia (high patient satisfaction)
The Respiratory Cycle has two separate physiologic processes: **Ventilation** & **Oxygenation**

**EtCO₂ Monitoring** (Measures **Ventilation**)
- Measures carbon dioxide
- Reflects breath-to-breath ventilation
- Detects hypoventilation / apnea immediately
- Should be used with pulse oximetry

**SpO₂ Monitoring** (Measures **Oxygenation**)
- Measures oxygen saturation (O₂ attached to hemoglobin)
- Reflects oxygenation
- Detects hypoxia
- Should be used with capnography

*Both assist in non-invasive monitoring of physiological status.*
Limitations of Pulse Oximetry

• Until recently, only practical method to assess respiratory function
• The pulse oximeter is a LATE detector of respiratory depression*
• Supplemental oxygen further delays detection*
  • $O_2$ no longer linearly correlates with $SpO_2$
• Frequently used for spot checks
• Historically, associated with frequent nuisance alarms
• Vital signs frequently stimulate patients prior to pulse oximetry assessment

Pulse Oximetry

The use of oxygen limits the ability to use the pulse oximetry to measure the patient’s state of breathing.

The higher the inspired oxygen concentration, the less the SpO₂ may move with even large decreases in PaO₂.

So the patient may be breathing, but the oximeter will not reveal quantitatively how well
Algorithm for use of EtCO₂ & SPO₂

All PCA patients are monitored with EtCO₂. Some patients are monitored with both.
Volume of Patients: PCA & Epidural
(n=5,515)
Events Related to PCA

- Time period prior to implementation (2001-2002) SJCHS experienced 3 events with serious outcomes associated with PCA therapy
- Implemented PCA w/respiratory monitoring in 2004
- **No events since 2004 (8+ years)**
- Significant reduction in liability self-insurance costs
Lessons Learned

- Undiagnosed Sleep Apnea more prevalent than expected
- Pain more effectively controlled in patients with both high and low opioid tolerance
- Post op respiratory depression unrelated to PCA detected
- Patients more compliant wearing nasal cannula when educated on the safety benefits
- Nurses and physicians outside of critical care need education to interpret and utilize EtCO₂ data
St. Joseph’s/Candler

Our Investment in Infusion Technology

June 1998 – ISMP safety alert re PCA devices

Initiated evaluation of infusion technology

Implemented Smart Infusion

Implemented Smart Syringe

Implemented Smart PCA with monitoring

Implemented Wireless Network
## Table 2. Return on Investment of Intravenous Safety System

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<td>Capital purchases</td>
<td>($606,515)</td>
<td>($955,250)</td>
<td>($11,110)</td>
<td></td>
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<td>($1,572,875)</td>
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<td>Disposables saved</td>
<td>$28,193</td>
<td>$29,039</td>
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<td>Cost avoidance</td>
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<td>$721,985</td>
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<td>$848,750</td>
<td>$892,036</td>
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<tr>
<td>Totals</td>
<td>($606,515)</td>
<td>$723,464</td>
<td>($204,226)</td>
<td>$831,054</td>
<td>$879,557</td>
<td>$923,767</td>
<td>$2,547,101</td>
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<td>Cost per ADE assuming 6% inflation to 2006</td>
<td>$7,725</td>
<td>$8,022</td>
<td>$8,374</td>
<td>$8,750</td>
<td>$9,196</td>
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<td>Count of ADEs averted (increase of 7 per year in fiscal year 2005)</td>
<td>90</td>
<td>90</td>
<td>97</td>
<td>97</td>
<td>97</td>
<td>471</td>
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<tr>
<td>IRR</td>
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<td>NPV</td>
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<td>$1,866,973</td>
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</table>

*Assumed capital bought at start of each fiscal year regardless of actual month of purchase; "Disposables savings spread evenly over 5 years and inflated 3% per year; "Cost avoidance uses 2006 as base, deflated by Consumer Price Index Medical Care Component; "Net present value (NPV) discount rate used is 6%; ADE = adverse drug event; IRR = internal rate of return.

Addition of Epidural PCA to Requirement for Monitoring - 2006

- Request of medical staff leadership to assess & implement
- November 2006 implemented for post-partum patients
- Require EtCO₂ & SpO₂ during epidural & for a minimum of 6 hr after the last dose of epidural/intrathecal narcotic
Additional Requirements for Dilaudid

- Implemented in November 2007
- All patients receiving Dilaudid® PCA
- Patients receiving doses greater than 2mg IV
- Patients receiving doses more frequently than Q3H (i.e. 1mg IV Q2H)
- All should have end-tidal CO2 monitoring in place.
Additional Use of Capnographic Monitoring

- Epidural PCA – 2006
- Dilaudid IV doses – 2007
- Procedural Sedation in nontraditional locations (ED, EP lab, GI & bronch suite)
- Periodic monitoring of COPD & asthma patients in selected patient care areas
How do you successfully sustain change when implementing a monitoring program?

- Include nurses, respiratory therapy, physicians, leadership, risk management in all aspects of decision making prior to initiating the program
- Education plan and time line should be completed prior to go live
  - Utilize nurses, respiratory, physicians as trainers
  - Solicit outside educational resources from vendor
  - Include super user training
- Training of nurses, respiratory therapy, physicians and ancillary staff
  - Nurses should understand the role of the respiratory therapies in care of the patient receiving opioids and end tidal monitoring
- Policy procedure updates for nursing and respiratory
- Order set updates
- Individualized patient plans of care to reflect monitoring strategies to minimize adverse outcomes from opioid therapies
How do you successfully sustain change when implementing a monitoring program?

- Consider an awareness campaign for go live
  - Promoting the hospital’s key stakeholders who were included in decision making process
  - Posters with count down for go-live
  - Public/community promotion
- Patients should be educated about opioid monitoring strategies prior to hospital admission (surgical patients) when possible
  - During pre-op appointments, while going over surgery instructions
  - Provide patient brochure on essential monitoring strategies
  - Communicate patient expectations for compliance with monitoring
What are some essential elements for facilitate a culture change?

- Buy in from stakeholders
  - Including nurses, respiratory, physician in decision making process
- Allow opportunity for scripting for nursing, respiratory and physician about why this is important to the organization, reasons for implementation
  - Before go live: practice sessions for what the expectation is of the caregiver to communicate to patients and families
  - Verbalize patient expectations for compliance
- Campaigns
  - Brochures
  - Advertising to the community at large
What are some essential elements for facilitate a culture change?

- Facilitate education about hospital policy and procedure for preventing over-sedation related to opioid therapy for new hires
  - Core orientation for nursing, respiratory therapy, physicians
- Mechanism for competency for existing clinicians
Monitoring and Metrics

- Consider what your hospital goals should be for monitoring effectiveness
- Over-sedation
  - Who will monitor
  - How will the events be monitored
  - What venue will they be reported
    - Medication Safety Team/Committee
    - PCA Committee
- Narcan use for over-sedation
Monitoring and Metrics

- Develop a systematic approach to monitor compliance with
  - Documentation
  - Order set use
  - Policy
  - Interventions for over-sedation
  - Patients who refuse monitoring
  - Rapid response calls related to over-sedation
  - Transfer’s to different level of care
Consider clinical expert(s) at your hospital to:

- Review literature, clinical guidelines, recommendations on regular basis (Sentinel Event Alerts)
- Provide opportunities for education
- Serve as a resource for clinicians
ECRI Technology Assessment

Alarm Analysis Overview

• An analysis of ETCO2 alarms was completed
  • Monitoring data from 03/05/2012 to 04/08/2012 was analyzed and compared to data from 04/09/2012 to 05/14/2012

• Total of 49,385 ETCO2 Alarms received
  • 25,781 ETCO2 Alarms were received from 03/05/2012 to 04/08/2012
  • 23,604 ETCO2 Alarms were received from 04/09/2012 to 05/14/2012
ETCO2 High Alarms - Top 20 ETCO2 high values causing alarm
Respiratory Rate Low (BPM) Alarms

- 14,949 Respiratory Rate Low (BPM) Alarms were received from 03/05 to 04/08

- 7,633 Respiratory Rate Low (BPM) Alarms were received from 04/09 to 05/14

  - No PCA Pause alarms were received from 03/05 to 04/08 or from 04/09 to 05/14
Respiratory Rate Low (BPM) Alarms – 04/09 to 05/14
BPM low < 8  7504
EtCO2 high > 60  71
Both  9

Aggregated
50 patients SJC January 2006

low BPM versus high EtCO2
in same minute

Intensity Graph

BPM minute-minimum (per minute)

EtCO2 minute-maximum (%)

Occurrence Frequency

- 1000
- 100
- 10

BPM low Alarm if below
EtCO2 high Alarm if above
Current Alarm Settings - Adults

Breaths Per Minute
- Low 6 BPM
- High 35 BPM

End-tidal Carbon Dioxide
- Low 6
- High 60

Pulse Oximetry
- Pulse: Low 50
- High 120
  - Oxygen Saturation: <90%

PCA Pause Values:
- Oxygen Saturation: 88%
- Respiratory Rate: 4
Conclusion

- “Nuisance alarms” significantly reduced by settings in the system
- Most alarms self-corrected by the patient
- Alarms stimulate patients to take a breath
- Nurses infrequently have to intervene
- No alarms at SJH have been associated with negative patient outcomes in 8 years at SJ/C
Wesley Medical Center
Wichita, KS

- Licensed for 760 beds
- 700 physicians; 3,000 employees
- Inpatient admissions 28,000; ED Visits 70,000; 18,000 surgeries
- HCA facility
END TIDAL CO2 MONITORING: Role of the Respiratory Therapist

- Integral role – RTs have expertise in ventilation
- Development of policies/procedures,
- Establishing alarm limits
- Identification of high risk patients
- Staff Education
  - Nurses, ARNPs, PAs, physicians
  - Initial and on-going education
  - Pulse oximetry vs. ETCO2 monitoring
- Bedside support for problem solving and patient assessment
Improving Compliance with ETCO2 Monitoring

- **EDUCATION**
  - Patient
  - Family
  - Staff

- **Alarm management**
  - Reduce nuisance alarms
  - Alarm fatigue

- **Monitoring Compliance**
  - PCA therapy
  - High-risk patients receiving intermittent IV opioids
Wesley Protocol for Responding to Alarm Situations

- RN notifies RT of Alarm situation
- Bedside collaboration w/pt assessment
  - Sedation Scale
  - Respiratory Rate / tidal volume
- Confirm correct placement of sampling cannula
- Collaborate to review pain medication orders
  - Contact physician
  - Naloxone reversal if indicated
- RT may initiate non-invasive ventilation (NIV)
  - BiPAP (IPAP 15, EPAP 5, Rate 12)
  - Continue ETCO2 monitoring with NIV
- Follow-up call to physician after 1 hr if ventilator assistance is still needed. Consider transfer to ICU.
Wesley’s Experience

- Conversion to “Smart” Pump system including capnography in May 2010
- Multidisciplinary team
- Identification of high risk patients
- All PCA patients and high-risk patient receiving intermittent IV opioids
- Goal of improving patient safety – reducing severe adverse drug events
INTEGRAL ROLE OF RESPIRATORY THERAPISTS IN A COMPREHENSIVE PAIN MANAGEMENT PROGRAM USING END TIDAL CO2 MONITORING.

BACKGROUND: A hospital-wide conversion to a new ‘smart’ infusion pump system including capnography provided an opportunity to develop a comprehensive program to safely and effectively manage pain. Effective pain management is vital to patient satisfaction. Patient monitoring with end-tidal CO2 (ETCO2) is essential in reducing adverse events and preventing respiratory depression from pain medication overdose.

METHOD: A multidisciplinary team of Respiratory Therapists (RTs), Nursing, Pharmacists, and Physicians developed policies and procedures for the new system. The components of the program included utilizing the “smart” pump technology to prevent medication administration errors, identifying high risk patients using a modified STOP/BANG scoring, and providing ETCO2 monitoring for all patients receiving patient controlled analgesia (PCA) therapy and all high risk patients receiving intermittent intravenous opioids. Staff education for nursing and RTs regarding patient monitoring focused on ETCO2 technology and patient assessment. Nursing response to alarm situations is to notify RT and work together to follow established protocols for clinical interventions. The importance of collaboration between the bedside nurse and RT is emphasized with shared responsibilities for the initiation of monitoring, frequency of checks, and its use with oxygen and CPAP/BiPAP devices. Educating the patient about the reasons for monitoring is critical in acceptance of the ETCO2 device. The impact of ETCO2 monitoring in preventing respiratory depression was measured by the number of adverse drug events related to PCA and opioid pain medications and the use of opioid reversal agent Naloxone.

RESULTS: Comparison of the reported adverse drug events from different time periods are displayed in the table below. The data show a shift from severe (life-threatening) events to the mild (nonspecific respiratory) and moderate (multiple naloxone reversals or other intervention required) categories. This shift may be attributed to earlier recognition of respiratory depression and intervening before the patient progresses to a life-threatening event.

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<tbody>
<tr>
<td></td>
<td>#</td>
<td>%</td>
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<tr>
<td>Mild</td>
<td>46</td>
<td>83%</td>
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<tr>
<td>Moderate</td>
<td>20</td>
<td>34%</td>
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<tr>
<td>Severe</td>
<td>11</td>
<td>19%</td>
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<tr>
<td>Total</td>
<td>77</td>
<td>93%</td>
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CONCLUSIONS: Respiratory therapists play a central role in the implementation and success of a comprehensive, hospital-wide program of pain management. The use of end-tidal CO2 monitoring is an effective method for early detection of respiratory depression in patients receiving PCA and intermittent IV opioid pain medication.

American Asso. for Respiratory Care International Congress, Poster presentation, November 2011 in Tampa FL

## Wesley’s Experience

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<th>Sep 10</th>
<th>Oct 10</th>
<th>Nov 10</th>
<th>Dec 10</th>
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<th>May 11</th>
<th>Jun 11</th>
<th>July 11</th>
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<tbody>
<tr>
<td># Pts w/ PCA</td>
<td>280</td>
<td>299</td>
<td>312</td>
<td>262</td>
<td>350</td>
<td>303</td>
<td>254</td>
<td>286</td>
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<table>
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<th>% PCA Pts using order set</th>
<th>% PCA Pts w/ ETCO2 used</th>
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<tr>
<td>Aug 10</td>
<td>95.7</td>
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## Wesley’s Experience

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<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>19.6%</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>
Wesley’s Experience

% Severe

% Mod/Severe Progress to Code
CE Link

Please email Steve Glass at Educational Review Systems

sglass@edu-review.org