Responding to The Joint Commission Alert on Safe Use of Opioids in Hospitals

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Objectives and Disclosures

• Review the recommendations contained within the *Sentinel Event Alert Safe Use of Opioids in Hospitals*

• Report the gap analysis results

• Discuss potential actions to be taken in response to the document

• No relevant disclosures
Sentinel Event Alert (SEA)

- Identifies specific types of sentinel events
- Describes common underlying causes
- Suggests steps to prevent occurrences in the future
- Consider information when designing relevant processes
- Consider implementing relevant suggestions
Other Alert Topics

- Safe use of opioids in hospitals 8/2012
- Healthcare worker fatigue 12/2011
- Radiation risk with diagnostic imaging 9/2011
- Preventing errors with anticoagulants 9/2008
- PCA by proxy 12/2004
Definition of Sentinel Event

• an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response.

http://www.jointcommission.org/sentinel_event.aspx
SEA #49 Safe Use of Opioids in Hospitals: Background

- Respiratory depression, preceded by sedation
  - Incidence in postoperative patients 0.5%
- Excludes Emergency Department
- Causes of opioid adverse effects
  - Lack of knowledge about opioid potency
  - Improper prescribing and administration of multiple opioids or formulations
  - Inadequate monitoring

http://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf
Opioid-related adverse events

- TJC Sentinel Event database 2004-2011
- 47% wrong dose medication errors
- 29% improper monitoring of patient
- 11% other
  - Excessive dosing, medication interactions, adverse drug reactions
Opioid-induced respiratory depression

- Risk greater with higher opioid doses
- Occurrence may actually be higher than reported
- Higher incidence observed in clinical trials
- Patients at high risk: sleep apnea, morbidly obese, young, elderly, very ill, concurrent CNS depressants
Factors and activities to avoid accidental opioid overuse

- Screen patients for respiratory depression risk
- Assess history of analgesic use, abuse, tolerance
- Conduct a full body skin assessment
- Use multimodal analgesia
- Take extra precautions in patients new to opioids
- Consult a pharmacist or pain management expert for conversions
- Avoid rapid dose escalation
- Take extra care at care transitions
- Avoid using opioids to meet arbitrary pain rating

TJC recognizes that not all pain can be eliminated; our standards provide for goal-related therapy
Patient characteristics at risk for oversedation and respiratory depression

- Sleep apnea or sleep disorder
- Morbid obesity with high risk of sleep apnea
- Snoring
- Older age; risk is
  - 2.8 X higher age 61-70
  - 5.4 X higher age 71-80
  - 8.7 X higher > age 80
Patient characteristics at risk for oversedation and respiratory depression

• No recent opioid use
• Post-surgery, particularly upper abdominal or thoracic
• Increased opioid use requirement or habituation
• Longer length of time receiving general anesthesia
Patient characteristics at risk for oversedation and respiratory depression

- Receiving other sedating drugs, benzodiazepines, antihistamines, diphenhydramine, sedatives, other CNS depressants
- Preexisting pulmonary or cardiac disease or dysfunction or major organ failure
- Thoracic or other surgical incisions that may impair breathing
- Smoker
Actions suggested by The Joint Commission

• Effective processes
• Safe technology
• Appropriate education and training
• Effective tools
Effective processes

1. Policies and procedures for ongoing clinical monitoring of patients receiving opioid therapy
   - Often assessments should take place and define the period of time appropriate to adequately observe trends
   - Individualize monitoring according to patient response
   - Respiration
   - Sedation
   - Oxygenation using pulse oximetry
   - Ventilation using capnography
   - Pulse oximetry and capnography continuously rather than intermittently
2. Policies and procedures that allow for a 2nd level review of pain management plans by a pain management specialist or pharmacist, would include high risk opioids (e.g. meperidine, methadone, fentanyl, IV hydromorphone)

3. Policies and procedures for tracking and analyzing opioid-related incidents for QI purposes
Safe technology

- Red flags or alerts into e-prescribing systems for all opioids (dosing limits, verifications)
- Separate sound-alike look alike opioids
- Conversion support systems to calculate correct doses of opioids to help prevent problems with conversions from oral, IV, and transdermal routes
- PCA to reduce the risk of over sedation; use of smart infusion pump technology with dosage error reduction software can add another layer of safety
Appropriate education and training

1. Advise to use both pharmacologic and non-pharmacologic alternatives

   – Multi-modal adjuvant therapies such as physical therapy, acupuncture, manipulation or massage, ice, music therapy
   – Non-narcotic analgesics, such as APAP, NSAIDS, antidepressants, anticonvulsants (gabapentin and pregabalin), muscle relaxants (baclofen, tizanidine), can be used before prescribing opioids
   – When used in combination with opioids, these non-narcotics may reduce the dose of opioids required to effectively manage pain
Appropriate education and training

2. Educate and assess the understanding of staff that care for patients receiving opioids about potential effect of opioid therapy
   - Sedation and respiratory depression
   - Continuum of consciousness
   - Ventilation vs oxygenation
   - Technological and clinical monitoring
   - How to assess patients for ADR
   - Recognize advancing sedation
   - Importance of timely adjustments to the plan of care based on patient risk
Appropriate education and training

3. Educate and provide written instructions to patients/care-giver who are on opioids
   - Brand/generic names, route of administration of opioids (help prevent confusion and accidental duplication)
   - Risk/SE (constipation, falls, N/V)
   - Cognitive and psychomotor impact
   - Interactions
   - Tolerance, addiction, physical dependency, and withdrawal symptoms
   - Dangers associated with opioid combination such as transdermal and oral (fentanyl patches)
   - Storage
   - Include phone numbers for a contact person to call with questions
Appropriate education and training

- Assess organizations need for training based on ADE, near misses, and staff observations
Effective tools

- Provide standardized tools that can be used to screen patients for risk factors associated with oversedation and respiratory depression (POSS, RASS)
- Tools for opioid misuse (SOAPP, ORT, SISAP)

POSS – Pasero Opioid-Induced Sedation Scale
RASS – Richmond Agitation-Sedation Scale
SOAPP – Screener and Opioid Assessment for patients with Pain
ORT – Opioid Risk Tool
SISAP – Screening Instrument for Substance Abuse Potential
<table>
<thead>
<tr>
<th>JC Sentinel Event #49</th>
<th>APSF 2011 Recommendations</th>
<th>Clinical vignettes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DO'S</strong></td>
<td><strong>DON'T's</strong></td>
<td><strong>DO's</strong></td>
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<tr>
<td>REC: Serial assessments: <em>continuous</em> SpO2 And capnography when used. The APSF and ISMP recommend <em>continuous</em> monitoring of oxygenation and/or ventilation</td>
<td>Continuous monitoring of oxygenation and ventilation for all patients receiving parenteral opioids</td>
<td>Spot check monitoring of oxygenation (misses trends) and 'manual' assessment of ventilation (inaccurate)</td>
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<tr>
<td><strong>Risk Stratification;RF:</strong></td>
<td></td>
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<tr>
<td>• Higher opioid doses</td>
<td>“Avoid rapid dose escalation of opioid analgesia above routine dose levels in opioid-tolerant patients”</td>
<td>Continuous monitoring should be available for ALL patients.</td>
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<tr>
<td>• Sleep apnea/ snoring (?)</td>
<td></td>
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<tr>
<td>• Morbid obese</td>
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<tr>
<td>• Extremes of age</td>
<td></td>
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<tr>
<td>• ASA 3/4</td>
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<tr>
<td>• Synergistic RD drugs</td>
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<tr>
<td>• Tolerance/abuse</td>
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<tr>
<td>• Opioid naïve</td>
<td></td>
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<tr>
<td>• Surgery type/duration</td>
<td></td>
<td></td>
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<tr>
<td>• Smoking (?)</td>
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<tr>
<td><strong>When using supplemental O2.</strong></td>
<td>Staff should not rely on SpO2 alone</td>
<td>Capnography and/or other airflow monitors MUST be used</td>
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<tr>
<td><strong>Educate and assess staff on:</strong></td>
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<tr>
<td>• the potential effect of opioid on sedation and respiratory depression, the continuum of consciousness, the difference between ventilation and oxygenation, technological and clinical monitoring</td>
<td>Education of providers (all levels) in:</td>
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<tr>
<td></td>
<td>• pathophysiology</td>
<td></td>
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<tr>
<td></td>
<td>• Pharmacology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• clinical assessment for OIRD incl LOC.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• supplemental O2</td>
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<tr>
<td><strong>Use patient-controlled analgesia (PCA) to reduce the risk of oversedation. Use smart infusion pump technology +dosage error reduction software</strong></td>
<td>Integration and trend analysis of &gt; 1 physiologic parameter (ie SpO2 and RR) by smart alarm driven clinical decision support</td>
<td>Reliance on single threshold alarms using point in time (or delayed) signal values</td>
</tr>
</tbody>
</table>
Ventilation and Oxygenation

- **EtCO2 monitoring**
  - Measures carbon dioxide
  - Reflects breath to breath ventilation
  - Detects hypoventilation or apnea
  - Should be used with pulse oximetry

- **Measures oxygen saturation**
  - Reflects oxygenation
  - Detects hypoxia
  - Should be used with capnography
APSF 2006 recommendations

• No patient harmed by respiratory depression in postoperative period
• Continuous monitoring could prevent significant number of cases of patient harm
• Consider continuous monitoring of oxygenation and ventilation
• Supplemental oxygen decreases sensitivity of pulse oximetry
• Monitors linked to process for assistance

Figure 1. Continuous capnography tracing of patient receiving morphine via patient controlled analgesia (PCA). (A) Gradual decrease in RR after bolus doses of morphine. Pharmacokinetic model shows concentration of morphine at effect site (brain) increasing. ETCO2 increases as RR falls (B). After opioid level peaks, RR increases gradually (C) while ETCO2 levels fall (D).
Gap analysis – meeting recommendations

• 2\textsuperscript{nd} level review of opioids - meperidine restrictions
• Tracking and analyzing opioid-related incidents – MERIT, PSNs, P&T Committee
• Restrictions in systems – meperidine, methadone
• Conversion support systems – Lexicomp, HOP
Gap analysis – meeting recommendations

• Red flags or alerts into e-prescribing systems for all opioids (dosing limits, verifications)
• Separate sound-alike look alike opioids
• PCA smart pump technology – CADD Solis PCA, Alaris
• Provide standardized tools to screen patients for risk factors – RASS
Gap analysis-
recommendations not met

- Screen for risk factors
- Assess patients previous opioid history
- Full body skin assessment for patches or implanted pumps
- Multimodal analgesia
- Patients new to or restarting opioids
- Consult pharmacist or pain management expert when converting opioids
Gap analysis—recommendations not met

• Avoid rapid dose escalation of opioid analgesia in opioid-tolerant patients

• Take extra precautions when transferring patients between units, facilities, and discharging patients

• Avoid using opioids to meet an arbitrary pain rating or a planned discharge date—base dosing on individual patient need
Gap analysis: recommendations not met

- Individualize monitoring according to patient response
  - Respiration, sedation
  - Oxygenation using pulse oximetry
  - Ventilation using capnography
  - Continuously rather than intermittently
Gap analysis—recommendations not met

- Policies and procedures that allow for a 2\textsuperscript{nd} level review of pain management plans by a pain management specialist or pharmacist, would include high risk opioids
  - methadone
  - Fentanyl (IV and patches)
  - IV hydromorphone
Gap analysis - recommendations not met

- Conversion support systems with conversions – integrate into order sets
- Advise to use both pharmacologic and non-pharmacologic alternatives
- Educate and assess the understanding of staff that care for patients receiving opioids about potential effect of opioid therapy
- Educate and provide written instructions to patients/care-giver who are on opioids
- Tools for opioid misuse
Action items

• Create POE item for implanted pumps
• Developing methadone order set
• Need fentanyl and hydromorphone order sets
• Review peds PCA by Proxy policy

• Opioid infusions in locked device
• Knowledge & attitudes survey of pharmacists
How to we assess education and training effectiveness?

• Knowledge and Attitudes Survey Regarding Pain; initially designed in the 1980s
• Extensively studied and validated
  – Construct validity, retest reliability and internal consistency have been established
• 38 question tool
  – True/False, Multiple Choice, Case Scenarios
  – Topics include addiction, cultural issues, pharmacokinetics, equianalgesia and patient assessment

Ferrell B, McCaffery M. Knowledge and Attitudes Survey Regarding Pain. http://prc.coh.org
# Demographics

<table>
<thead>
<tr>
<th></th>
<th>Nurses</th>
<th>Pharmacists</th>
<th>Mid-Level Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N=111</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Respondents</td>
<td>99</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Percent of Staff Responding</td>
<td>58%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Age in years, mean (range)</td>
<td>31 (22-56)</td>
<td>32 (27-41)</td>
<td>50 (33-57)</td>
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<tr>
<td>Years of Experience, mean (range)</td>
<td>6 (1-31)</td>
<td>6 (2-12)</td>
<td>17 (7-27)</td>
</tr>
<tr>
<td>Previous Education in Pain Management, mean</td>
<td>16.2%</td>
<td>42.9%</td>
<td>0%</td>
</tr>
</tbody>
</table>
## Percent Correct

<table>
<thead>
<tr>
<th></th>
<th>Nurses (n=99)</th>
<th>Pharmacists (n=7)</th>
<th>Mid-Level Providers (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Percent Correct, mean</td>
<td>69.2%</td>
<td>78.9%</td>
<td>71%</td>
</tr>
<tr>
<td>Previous Education in Pain Management, mean</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>71.7%</td>
<td>83.3%</td>
<td>N/A</td>
</tr>
<tr>
<td>No</td>
<td>68.7%</td>
<td>75.6%</td>
<td>71%</td>
</tr>
<tr>
<td>Years of Experience, mean</td>
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<td></td>
<td></td>
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<tr>
<td>Greater than 10 years</td>
<td>67.2%</td>
<td>80%</td>
<td>70.8%</td>
</tr>
<tr>
<td>Less than 10 years</td>
<td>69.7%</td>
<td>78.5%</td>
<td>71.3%</td>
</tr>
</tbody>
</table>
Survey Items > 80% of Nurses Answered Correctly

- Vitals are not reliable indicators of pain
- Patients may sleep despite severe pain
- Usefulness of multimodal analgesia
- Opioids can be used in patients with substance abuse
- Placebo dosing should not be used
- Elderly patients can tolerate opioids
- Effect of spiritual and cultural beliefs on pain
- Children are reliable in reporting their own pain
- Doses of opioids are adjusted based on patient response
- Gabapentin does not produce optimal results after 1 dose
- Recommended route of administration for severe, acute pain
Survey Items < 50% of Nurses Answered Correctly

- Promethazine and hydroxyzine are not reliable potentiators of opioid analgesics
- Morphine does not have a dose ceiling
- Equianalgesic dose conversions
- Risk of respiratory depression
- Optimal analgesic dosing for postoperative pain
- Difference between physical dependence and addiction
- Time to peak effect of oral morphine
## Risk of Respiratory Depression

<table>
<thead>
<tr>
<th>Survey Item Results</th>
<th>Nurses</th>
<th>Pharmacists</th>
<th>Mid-Level Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1%*</td>
<td>12.1%</td>
<td>42.9%</td>
<td>40%</td>
</tr>
<tr>
<td>1-10%</td>
<td>37.3%</td>
<td>42.9%</td>
<td>20%</td>
</tr>
<tr>
<td>11-20%</td>
<td>18.2%</td>
<td>0%</td>
<td>40%</td>
</tr>
<tr>
<td>21-40%</td>
<td>13.1%</td>
<td>14.3%</td>
<td>0%</td>
</tr>
<tr>
<td>Greater than 41%</td>
<td>10.1%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Correct Answer
<table>
<thead>
<tr>
<th>Survey Item Results</th>
<th>Nurses</th>
<th>Pharmacists</th>
<th>Mid-Level Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine 5mg IV</td>
<td>27.3%</td>
<td>28.6%</td>
<td>40%</td>
</tr>
<tr>
<td>Morphine 10mg IV*</td>
<td>46.5%</td>
<td>42.9%</td>
<td>20%</td>
</tr>
<tr>
<td>Morphine 30mg IV</td>
<td>13.1%</td>
<td>0%</td>
<td>40%</td>
</tr>
<tr>
<td>Morphine 60mg IV</td>
<td>4%</td>
<td>14.3%</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Correct Answer*
Summary of Survey Results

• Pharmacists scored highest overall
• Exaggerated fear in 1/4 of nurses regarding respiratory depression in an opioid tolerant patient
• The majority of respondents (75%) could not distinguish between physical tolerance, addiction and tolerance
• Case Scenarios
  – Nurses and pharmacists demonstrated good compliance with documenting patient reported pain rating
  – Less than half of respondents correctly increased morphine dose
  – Significant portion of respondents would undertreat a patient based on whether a patient demonstrated physical signs
Questions

• How to we assess education and training effectiveness?
• How to operationalize screening for risk factors for respiratory depression?
• How to integrate ventilation monitoring via capnography?
• How do we ensure patients receive multimodal analgesia?
• What is required by TJC?