Preventing Opioid ADEs...
*The past, present and future*

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Conflict of Interest Disclosure

Kelly Besco declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.
Program Objectives

• Review the scope of the problem surrounding opioid safety and opioid induced respiratory depression.

• Describe criteria linking patients to risk for opioid induced adverse drug events (ADEs).

• Discuss strategies for risk stratified opioid prescribing to safely and effectively manage pain.
The Facts...

O-M-G! Did they really just prescribe 2 mg of HYDROMorphone IV?
The Facts... 1-4

• Each hospitalized patient is subjected to at least one medication error per day.

• Approximately one-third of cardiac arrests in US hospitals are from respiratory depression.

• 77% of opioid-related inpatient deaths occur in the first postoperative day.

• Very few providers complete training in pain management--- “It’s just part of the job!”

• The reporting of pain is highly subjective (i.e., Use of rating scales to dictate the opioid dose ignores patient’s risk for opiate depression.).


HYDROMorphone: A Cause for Alarm 5-6

- Lack of knowledge about potency and the difference as compared to morphine has led to serious errors.

  1 mg of HYDROMorphone = 6 mg of Morphine

- A study of adult ED patients observed that physicians & nurses were reluctant to give 6 to 10 mg of morphine due to risk.

- In contrast, same providers were not reluctant to give equianalgesic dose (i.e., 1 to 1.5 mg) of HYDROMorphone.

- In June 2011, FDA revised Prescribing Information to have new starting dose of 0.2 mg for intermittent IV therapy.
  - Previous Prescribing Information noted a starting dose of 1 mg.

Our Story...
Our Experience... 2009 (The Journey Begins)

• Two Serious Safety Events involving Patient Controlled Analgesia (PCA) HYDROmorphe therapy.

• This prompted further investigation into common causes of HYDROmorphe adverse events.
  – A Common Cause Analysis (CCA) was performed of reported HYDROmorphe medication events.
  – Most common reported HYDROmorphe events were related to PCA programming errors.
  – In response PCA therapy was standardized across the health-system.
### TOOL KIT

**Patient Controlled Analgesia (PCA) Guidelines of Care**
For the Opioid Naïve Patient

**PCA Project Improvements**

- Risk-Based Order Set
- One Concentration for Each Drug
- Initial and Change Orders
- Embedded Naloxone (Narcan®) Rescue Orders
- Orders for Treatment of Opioid-Induced Constipation
- Standardized PCA Policy

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**Patient Care and Monitoring**

<table>
<thead>
<tr>
<th>Initial Order</th>
<th>Change Order (Only Medication order section needs completed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do NOT administer supplemental opioids unless approved by the Prescribing physician.</td>
<td></td>
</tr>
<tr>
<td>2. Only the patient is permitted to push the PCA button.</td>
<td></td>
</tr>
<tr>
<td>3. If the patient does not have a mainline IV, start an IV of 0.9% Sodium Chloride at Keep Vein Open rate</td>
<td></td>
</tr>
<tr>
<td>4. Continuous pulse oximetry and/or capnography for duration of PCA therapy. May remove pulse oximetry during supervised therapy.</td>
<td></td>
</tr>
<tr>
<td>5. Assess and document the following 1) Prior to PCA initiation, then every 1 hour x 8 hours, then every 2 hours for 18 hours, then every 4 hours for duration of PCA, and 2) 30 minutes after a new administration bolus dose:</td>
<td></td>
</tr>
</tbody>
</table>

- **Respiratory Assessment:** Rate, Quality (depth, pattern, effort, sounds), and SpO2. Notify physician if respiratory < 10 (if ≤ 8, see “Treatment of Side Effects” on page 2) OR shallow and ineffective OR SpO2 < 90%.
- **Sedation Level:** Notify physician if POSS of 3 or 4; RASS of -3, -4, or -5 (only non-ventilated patients).
- **Pain Score:** Notify physician if pain level unacceptable to patient

**Medications:** Select regimen based on patient-specific parameters and/or risk factors for opioid-induced respiratory depression

- HYDROMorphone (Dilaudid) 15 mg/30ml
- **Opioid Naive**
- **High Risk (Any 1 of the following)**
- **Opioid Tolerant**

<table>
<thead>
<tr>
<th>PCA Dose</th>
<th>Lockout Interval</th>
<th>Continuous Dose</th>
<th>1-Hour Max Limit (Includes PCA Dose + Continuous Dose + all RN Bolus Doses in 1 hr)</th>
<th>1-Hour Max Limit (Includes PCA Dose + Continuous Dose + all RN Bolus Doses in 1 hr)</th>
<th>Maximum hourly limit = 2 mg</th>
<th>Loading Dose - Optional</th>
<th>RN Bolus Dose - Optional (Maximum of 4 doses in 8 hours)</th>
<th>Opioid Tolerant</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2 mg</td>
<td>10 minutes</td>
<td>Not Recommended</td>
<td>Maximum hourly limit = 2 mg</td>
<td>Maximum hourly limit = 15 mg</td>
<td>0.4 mg x 1 dose only</td>
<td>0.4 mg x 1 dose only</td>
<td>0.3 mg x 1 dose only</td>
<td>0.3 mg x 1 dose only</td>
</tr>
<tr>
<td>0.1 mg</td>
<td>10 minutes</td>
<td>Not Recommended</td>
<td></td>
<td></td>
<td>0.3 mg x 1 dose only</td>
<td>0.3 mg x 1 dose only</td>
<td>0.3 mg x 1 dose only</td>
<td>0.3 mg x 1 dose only</td>
</tr>
</tbody>
</table>

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Tool kit available at:
2010 (Journey Continues)

• A second CCA was performed to evaluate the impact of the PCA Standardization Project.

• Results: Majority of inappropriate dosing events involved intermittent IV opioid therapy.
  – Primarily linked to inappropriate dosing for opiate naive patients.

• Pilot conducted at member hospital to increase adherence with evidence based dosing regimens and decrease risk of respiratory depression.
  – Results linked to ~ 50 % decrease over 12 months in Preventable Adverse Events identified via Narcan Review.
Pain Management Intermittent Orders

- Appropriate dosing provided for naïve/high risk and tolerant categories
- Start low and go slow
- Utilizes one time dose escalation
- May only have orders for 1 Oral and 1 intravenous agent at a time

1. SPECIAL INSTRUCTIONS:

**PLEASE SELECT APPROPRIATE REGIMEN BASED ON RISK FACTORS FOR OPIATE DEPRESSION**

**HIGH RISK** for opiate depression: Age > 60 years old; Obesity (BMI > 30); Liver Impairment; Obstructive Sleep Apnea (OSA); COPD; Renal Impairment (CrCl < 40 mL/min); Multiple co-existing diseases, Concurrent CNS depressants.

Opiate Tolerant is defined as any patient regularly taking at least 30 mg of oxyCODONE/day (e.g., 6 tabs of PERCOET 5/325 mg) or equianalgesic opioid dose for approximately 7 days or more.

**Patient may only have orders for 1 oral and 1 intravenous agent at a time**

Opiate Naïve/High Risk ORAL Dosing Regimens:

- **oxyCODONE 5 mg PO every 4 hours PRN PAIN.**
  - For unrelieved pain, may repeat 5 mg PO dose within 60 minutes of initial dose.
  - If pain is relieved after repeat dose, change to 10 mg PO every 4 hours PRN PAIN.
  - If pain unreleased after repeat dose or patient requires dose reduction, call physician.

- **oxyCODONE/Acetaminophen 5 mg/325 mg (PERCOET), one tablet PO every 4 hours PRN PAIN.**
  - For unrelieved pain, may repeat one tablet PO within 60 minutes of initial dose.
  - If pain is relieved after repeat dose, change to 2 tablets of 5 mg/325 mg PO every 4 hours PRN PAIN.
  - If pain unreleased after repeat dose or patient requires dose reduction, call physician.

- **HYDROcodone/Acetaminophen 5 mg/325 mg (NORCO), one tablet PO every 4 hours PRN PAIN.**
  - For unrelieved pain, may repeat one tablet PO within 60 minutes of initial dose.
  - If pain is relieved after repeat dose, change to 2 tablets of 5/325 mg PO every 4 hours PRN PAIN.
  - If pain unreleased after repeat dose or patient requires dose reduction, call physician.

- **Morphine Immediate Release 7.5 mg PO every 4 hours PRN PAIN.**
  - For unrelieved pain, may repeat 7.5 mg PO within 60 minutes of initial dose.
  - If pain is relieved after repeat dose, change to 15 mg PO every 4 hours PRN PAIN.
  - If pain unreleased after repeat dose or patient requires dose reduction, call physician.

Opiate Naïve/High Risk INTRAVENOUS Dosing Regimens:

- **Morphine Sulfate IV 2 mg every 3 hours PRN PAIN.**
  - For unrelieved pain, may repeat 2 mg dose within 30 minutes of initial dose.
  - If pain is relieved after repeat dose, change to 4 mg every 3 hours PRN PAIN.
  - If pain unreleased after repeat dose or patient requires dose reduction, call physician.

- **HYDROmorphine (Dilaudid) IV 0.25 mg every 3 hours PRN PAIN.**
  - For unrelieved pain, may repeat 0.25 mg within 30 minutes of initial dose.
  - If pain is relieved after repeat dose, change to 0.5 mg every 3 hours PRN PAIN.
  - If pain unreleased after repeat dose or patient requires dose reduction, call physician.
Pain Management
Intermittent Orders

- Embedded Naloxone (Narcan®) Rescue Orders
- Bowel Regimen

**Opiate Tolerant ORAL Dosing Regimens:**
- oxyCODONE 10 mg PO every 4 hours PRN PAIN. If pain unrelieved after dose call physician.
- oxyCODONE/Acetaminophen 5 mg/325 mg (PERCOCET), two tablets PO every 4 hours PRN PAIN. If pain unrelieved after dose call physician.
- HYDROcodone/Acetaminophen 5 mg/325 mg (NORCO), two tablets PO every 4 hours PRN PAIN. If pain unrelieved after dose call physician.
- Morphine Immediate Release 15 mg PO every 4 hours PRN PAIN. If pain unrelieved after dose call physician.

**Opiate Tolerant INTRAVENOUS Dosing Regimens:**
- Morphine Sulfate IV 6 mg every 3 hours PRN PAIN. If pain unrelieved after dose call physician.
- HYDROMorphine (Dilaudid) IV 1 mg every 3 hours PRN PAIN. If pain unrelieved after dose call physician.

2. **ADDITIONAL ORDERS:**
   - Naloxone (NARCAN)
     - For respiratory rate ≤ 8 per minute:
       - Mix Naloxone (NARCAN) 0.4 mg (1 mL) with 9 mL of Normal Saline to total 10 mL. Administer 0.1 mg (2.5 mL) IV Push every 2 minutes until respiratory rate is 10 or greater.
       - Notify the prescribing physician and/or appropriate staff for O2 and additional orders.
       - If patient is pulseless, breathless, AND unresponsive, call a Code and give undiluted Naloxone (NARCAN) 0.4 mg (1 mL) IV x 1 push over 30 seconds.

**BOWEL REGIMEN:**
- Senokot-S 1 tablet PO twice a day. Hold for loose stools. Not for abdominal surgery patients.
Pilot Results: Preventable ADEs

Opioid ADEs
(Identified Via Naloxone Administration)

- 2009: 31
- 2010: 20
- 2011 (Thru 9/11): 9

~ 50% Decrease in ADEs
2011 to early-2012 (Gaining Momentum)

• Health-System Opioid Safety Team chartered.
  – Multi-disciplinary Team
  – The risk stratified intermittent opioid orders were implemented in May 2012.
    – Direction provided by Leadership to integrate order set into new/updated health-system order sets.
  – Nursing & Pharmacists completed a mandatory Learning Module focused on Opioid Safety.
    – Equianalgesic Dosing “Badge Backers”
  – Pain Management Policy standardized

• Despite success demonstrated in pilot, Physician utilization was not overwhelming.
  – Increased utilization demonstrated at CPOE campuses due to ability to quickly integrate into order sets.
### Equianalgesic Dosing “Badge Backers”

<table>
<thead>
<tr>
<th>Opioids</th>
<th>Route</th>
<th>Onset (min)</th>
<th>Peak (min)</th>
<th>Duration (HOURS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine (immediate release)</td>
<td>PO</td>
<td>30-60 (PO)</td>
<td>60-90 (PO)</td>
<td>3-6 (PO)</td>
</tr>
<tr>
<td>Morphine</td>
<td>IV</td>
<td>5-10 (IV)</td>
<td>15-30 (IV)</td>
<td>3-4 (IV)</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>IV</td>
<td>1-5 (IV)</td>
<td>3-5 (IV)</td>
<td>0.5-4 (IV)</td>
</tr>
<tr>
<td>Fentanyl Patch Transdermal</td>
<td>TD</td>
<td>12-16 hrs (TD)</td>
<td>24 hrs (TD)</td>
<td>48-72 (TD)</td>
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<tr>
<td>Hydromorphone (Dilaudid®)</td>
<td>PO</td>
<td>15-30 (PO)</td>
<td>30-90 (PO)</td>
<td>3-4 (PO)</td>
</tr>
<tr>
<td>Hydromorphone (Dilaudid®)</td>
<td>IV</td>
<td>5 (IV)</td>
<td>10-20 (IV)</td>
<td>3-4 (IV)</td>
</tr>
</tbody>
</table>

**Please note equipotent dose:** IV Hydromorphone (Dilaudid®) 1 mg = IV Morphine 6 mg

<table>
<thead>
<tr>
<th>Opioids</th>
<th>Route</th>
<th>Onset (min)</th>
<th>Peak (min)</th>
<th>Duration (HOURS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone (Dolophine®)</td>
<td>PO</td>
<td>30-60 (PO)</td>
<td>60-120 (PO)</td>
<td>4-8 (PO)</td>
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<tr>
<td>Hydrocodone (as in Vicodin®, Lortab®)</td>
<td>PO</td>
<td>30-60 (PO)</td>
<td>60-90 (PO)</td>
<td>4-6 (PO)</td>
</tr>
<tr>
<td>Oxycodeine (as in Percocet®)</td>
<td>PO</td>
<td>30-60 (PO)</td>
<td>60-90 (PO)</td>
<td>3-4 (PO)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Agonist-antagonist</th>
<th>Route</th>
<th>Onset (min)</th>
<th>Peak (min)</th>
<th>Duration (HOURS)</th>
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<tbody>
<tr>
<td>Buprenorphine (Suboxone)</td>
<td>SL</td>
<td>5 (SL)</td>
<td>30-60 (SL)</td>
<td>unknown (SL)</td>
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</tbody>
</table>

(Modified from McCaffery, M, Pasero, C: Pain: Clinical manual, pp. 241-243, Copyright © 1999, Mosby, Inc.)
Late-2012 (Marathon—Mile 5)

• In August 2012, something wonderful happened...

2012 Joint Commission Sentinel Event Alert, recommendations include:

• Dosing based on individual need and condition and **not to meet an arbitrary pain rating** or discharge criteria.

• Screening patients for risk for respiratory depression

• Assessment of patient’s history of analgesic use, misuse, duration, side effects to identify opioid intolerance and tolerance
Late-2012 to 2013 (Marathon—Mile 5)

• Opioid Safety Team reinvigorated efforts to improve opioid safety.
  – Pain Management policy updated with SEA recommendations.
  – Patient Education developed for immediate release, sustained release opioids and methadone.
  – Methadone pre-printed order set developed.
  – Non-opioid Pain Management order set developed.
  – Began to build content for new EHR and embedded orders as appropriate.

• Preventable Opioid ADEs included on the FY’ 14 Pharmacy Services Clinical Scorecard.
Naloxone Trigger Project

• Use naloxone administration as a “trigger” to identify possible opioid-related medication errors.

• Opioid Safety Team serves as inter-rater reliability team to assess preventability of the events and identifies opportunities for improvement.
## Monthly Naloxone Report

Standardized monthly generated naloxone usage report includes:

- **Patient name, age, gender, admitting diagnoses**
- **Medical record number,**
- **Admission and discharge dates**
- **Date/time of naloxone (Narcan®) administration(s), dose, quantity, location, order entry - automated dispensing cabinet (ADC)**
- **Opioids and benzodiazepines administered in past 24 hours, date/time, medication, dose, quantity, location, order entry - ADC**

### Table of Naloxone Administration

<table>
<thead>
<tr>
<th>Rx #</th>
<th>Date</th>
<th>Medication</th>
<th>Dose</th>
<th>Qty</th>
<th>Stock Area</th>
<th>Type</th>
</tr>
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<tbody>
<tr>
<td>80608203</td>
<td>7/22/14 15:50</td>
<td>NALOXONE</td>
<td>0.4 MG</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Opioids Previous 24 Hrs**

<table>
<thead>
<tr>
<th>Rx #</th>
<th>Date</th>
<th>Medication</th>
<th>Dose</th>
<th>Qty</th>
<th>Stock Area</th>
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</thead>
<tbody>
<tr>
<td>80434062</td>
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<tr>
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<td>1</td>
<td>ADMIN</td>
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<tr>
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<td>ADMIN</td>
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<td>ADMIN</td>
<td></td>
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<td>80434313</td>
<td>7/21/14 23:22</td>
<td>OXYCODONE</td>
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<td>ADMIN</td>
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<td>80585756</td>
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<td></td>
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<tr>
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<td>7/22/14 13:07</td>
<td>FENTANYL</td>
<td>200 MCG</td>
<td>1</td>
<td>RMH1GENDO</td>
<td>PYXIS</td>
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<tr>
<td>80601597</td>
<td>7/22/14 13:07</td>
<td>FENTANYL</td>
<td>200 MCG</td>
<td>-1</td>
<td>RMH1GENDO2</td>
<td>QUICK CHAR</td>
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<tr>
<td>80601599</td>
<td>7/22/14 13:07</td>
<td>MIDAZOLAM</td>
<td>2 MG</td>
<td>1</td>
<td>RMH1GENDO</td>
<td>PYXIS</td>
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<tr>
<td>80601599</td>
<td>7/22/14 13:07</td>
<td>MIDAZOLAM</td>
<td>2 MG</td>
<td>-1</td>
<td>RMH1GENDO2</td>
<td>QUICK CHAR</td>
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<tr>
<td>80608201</td>
<td>7/22/14 15:50</td>
<td>FLUMazenil</td>
<td>0.5 MG</td>
<td>1</td>
<td>RMH1GENDO2</td>
<td>PYXIS</td>
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</tbody>
</table>
Opioid ADE Collection Worksheet

Demographics

Patient History:
- Comorbidities
- Risk stratification: naïve, high risk, tolerant, combination

Brief event summary

Opioid Dosing Information

Preventability Matrix
- Auto-Exclude
- ADE Team Review Required
- Preventable vs. Non-Preventable
### PREVENTABILITY MATRIX

**NON-ADEs: Non-Preventable**

- Naloxone drip ordered for pruritus
- Naloxone administered for reversal after a procedure
- No opioids administered before naloxone given (e.g., treatment of overdose in ED)
- No documentation/evidence that naloxone administered (i.e., charged for but no evidence in chart administered)
- No patient response to naloxone administration (e.g., no change in respiratory rate or sedation level)
- Undetermined response to naloxone (e.g., D50 administered for hypoglycemia at the same time naloxone given and patient condition improves).
- Respiratory failure due to clinical condition unrelated to opioids (e.g., brain herniation, septic or cardiogenic shock)
- Opioid dosing is appropriate and no other sedating medications administered to the patient
- Patient leaves clinical inpatient unit and returns lethargic (e.g., outdoor smoking, family visit)
- OTHER:

### ADEs: Preventable

- More than recommended amount of opioid administered to patient (also includes dose stacking in PACU)
- ADE was preventable due to dose, administration time and/or documented sedation at the time of administration
- Concurrent administration of sedating medications in addition to opioids
- Failure to reassess patient following opioid administration
- Inappropriate dosing regimen based on patient risk factors for opiate depression/exposure history
- Pump programming error
- Medication administered to the wrong patient
- OTHER:
Preventable Opioid ADEs

47 % Decrease in preventable events!
Preventable Opioid ADE—Trend Analysis

- FY’14 Patient Trends
  - Majority of preventable events occurred in females with co-morbidities (e.g., advanced age, obesity) that placed them at higher risk for respiratory depression.
    - Age greater than 60, most common
    - Risk of respiratory depression increases with age. Patients over the age of 80 are 8.7 time more likely to experience respiratory depression.
Improvements

• FY’ 2014 - 2015
  – Shared data/performance “ad nauseam” (e.g., Nursing Shared Governance, P&T, Patient Safety Committee)
  – Prescriber/nursing/pharmacy education regarding risk-based dosing
  – Education and adjustment of scheduled administration times to avoid stacking of sedating medications
  – Adopted Pasero Opioid-Induced Sedation Scale (POSS) scale in PACU units to assess opioid-related sedation
  – Adopted Richmond Agitation and Sedation Scale (RASS) scale in Procedural areas giving intentional sedation
  – Standardized Epidural order set and policy
**Topic:** Concurrent administration of opioids and medications that can cause sedation.

*February, 2014*

Learning from experience is foundational to improving patient safety. The scenario reported in this document is fictional. This document is published for educational purposes to promote patient safety and process improvement.

Please distribute to: Nursing  Physicians  Pharmacy  Other

**Preventable ADE Event:** At 18:57 an opioid naive patient received the following medications: Oral Diazepam (VALIUM®) 5 mg, Pregabalin (LYRICA®) 225 mg and Oxycodone/acetaminophen (PERCOCET®) 10mg/325mg. At 21:03, the patient had a respiratory rate of 10 breaths per minute, accessory muscle use, and sedation described as falling back to sleep after opening eyes to stimuli (i.e., POSS score of 3) and was given 0.1 mg of naloxone (NARCAN®).

**Lessons Learned:** Simultaneous administration of medications that can cause sedation places the patient at higher risk for dangerous sedation and opioid-induced respiratory depression. When administering medications that can cause sedation, it is safer to stagger the administration times to prevent the sedation from reaching peak effect at the same time. Staggering administration times can prevent these adverse events from occurring. Examples of medications to avoid administering together include:

<table>
<thead>
<tr>
<th>Examples of medications to avoid administering at the same time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids (e.g., long and short acting)</td>
</tr>
<tr>
<td>Medications for sleep (e.g., Ambien®)</td>
</tr>
<tr>
<td>Sedatives (e.g., Haldol®)</td>
</tr>
<tr>
<td>Anti-anxiety medications (e.g., benzodiazepines)</td>
</tr>
<tr>
<td>Muscle relaxants (e.g., Flexeril®)</td>
</tr>
<tr>
<td>Some anti-emetics (e.g., Compazine®, Phenergan®)</td>
</tr>
<tr>
<td>Some anti-histamines (e.g., Benadryl®)</td>
</tr>
<tr>
<td>Some anti-psychotics (e.g., Seroquel®)</td>
</tr>
</tbody>
</table>

**Preventable Actions:** Use caution when administering more than one medication that can cause sedation. Consider staggering the administration of the sedating medications by 30 to 60 minutes to avoid more than one medication from reaching peak effect at the same time. Partner with Pharmacy to adjust administration times if necessary.

**Additional Safety Pearls:** Remember to monitor the patient’s sedation level before and after opioid administration. Micromedex is available under “Resources” in Care Manager for addition information on medication peak times.


Please contact ______________________ @ _____________________ for questions or concerns.
Evaluation of a Standardized Sedation Assessment for Opioid Administration in the Post Anesthesia Care Unit

- Measured efficacy of POSS in assessing sedation and administering opioids for pain in the PACU.

- Impetus for the study came from PACU nurses who requested help to standardize sedation and opioid management.
Conclusions

• Opioid dosing is risky business.
  – Prevention of adverse events requires the layering of multiple mitigation strategies.
  – We have made significant strides, but our work is not complete!
    – Capnography
    – Smart Pump-EHR Interoperability
    – Real-time “trigger” interventions
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