TOOL KIT

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

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About This Document
The purpose of this document is to provide San Diego County Acute Care settings with recommendations for the standardization of intravenous Patient Controlled Analgesia (PCA) medication administration in the care of the opioid naïve patient. These recommendations exclude the use of epidural PCA (PCEA), subcutaneous PCA use, the palliative care environment, and patients experiencing chronic pain.

Intended Audience
The document is intended for the Acute Care Clinical Leader.

Organization of This Document
The document is organized into two main sections: recommended clinical guidelines for Opioid PCA usage, and recommended plan for implementing the guidelines in your institution.

Acknowledgement
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Introduction

**Patient Controlled Analgesia (PCA)** is an interactive method of pain management that permits patients to manage their pain by self-administering doses of analgesics, usually opioids.\(^1\)

**Current State**

Patient Controlled Analgesia (PCA) can be an effective tool in reducing pain. However, IV medications in general are associated with the highest risk of harm to patients, and opioids are typically considered among the highest risk injectable medications.\(^1\)

PCA is a complicated, yet highly flexible means of providing opioids, consisting of several regimen elements addressed primarily in the Ordering and Administration stages of the medication process.\(^2\)

For the purpose of this document, PCA prescription elements will respect the nomenclature outlined in *Vendor Specific PCA Ordering/Programming Terms* (see Appendix A). A cross-walk also is provided for available PCA devices.

The use of PCA is a complex, high-risk treatment that is associated with harmful events and death.\(^3\)

Extensive variability exists within and between hospital environments. Variability in patient response, clinical staffing, equipment, physician orders, medication dosages, and concentrations all contribute to risk for error.

There is a shared need amongst hospitals to address PCA Guidelines of Care for the Opioid Naïve Patient. Every clinician and hospital environment has a PCA story\(^4\), such as evident in the national MedMARX database of voluntarily reported medication errors:

- **PCA errors represent a four-fold higher risk than other reported medication errors:**
  - PCA errors account for approximately one percent of all medication errors, but 6.5 percent were harmful.
  - PCA errors occur in every phase of the medication-use process.
  - PCA errors involve many disciplines including nurses, pharmacists, and physicians.


**PCA process is highly error prone and represents opportunities for improvement including the need to simplify, standardize, and clarify:**

- Equipment-related issues present challenges including pump misprogramming, complexity, and confusion of PCA screens and drug selection options.

Administration is especially vulnerable, with less opportunity to intercept an error as there is no inherent redundancy in this stage. Landmark medication safety research has found only a 0-2 percent medication error interception rate in the Administration stage.\(^5\)

In 1999, the Joint Commission recommended these practice changes to improve opioid safety:

- **Limit the opiates and narcotics available in floor stock.**
- **Educate staff about HYDROmorphine and morphine mix-ups.**
- **Implement PCA protocols that include double-checking of the drug, pump setting, and dosage.**

Other healthcare leaders also have strongly advocated for process simplification and standardization, including the Institute for Safe Medication Practice as published in their most recent safety improvement recommendations (summarized):\(^6\)

- **Assess vulnerability to serious errors.** Medication safety teams should review current practices around the use of custom concentrations.
- **Limit concentrations.** When possible, a single, standard concentration for each PCA drug should be used. If more than one concentration is deemed necessary by the organization, the number of standard concentrations should be limited to two at the most. Additionally, the use of custom concentrations should be minimized and, when possible, restricted to selected patient care areas.
- **Distinguish custom concentrations.** When a custom concentration is necessary, the container label should be very distinctive and should not look like the standard PCA syringe/bag label. Auxiliary labels (e.g., “High-Potency”) and a different color pharmacy label with specific instructions for programming the pump should be used for custom concentrations.
- **Clarify the label.** ISMP usually recommends presenting the total drug concentration in the bag/syringe first, followed by the amount of drug per mL below this within the same background or border on the product label.

Depending on the PCA pump vendor, the user may be prompted to enter the concentration in a mg/mL strength. In these cases, it would be safer

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to express the concentration with the amount of drug per mL listed first, and then the total amount of drug/total volume in the syringe/bag.

- **Match the MAR to the label.** The concentration on the Medication Administration Record (MAR) should be listed the same as the PCA label.
- **Employ an independent double-check.** The narcotics used for PCA are high-alert medications; thus, an independent double-check of the product and pump programming should be considered. When replacing an empty syringe/bag, the empty container should be compared to the new container to verify the concentration is the same.
- **Use barcoding technology.** Some infusion pumps incorporate barcoding technology. Scanning the barcode on the PCA bag would help ensure the correct concentration is entered during PCA programming.
- **Use smart pumps.** PCA pumps with Dose Error Reduction System (DERS) should be used whenever possible. Because the significance of a low concentration alert during pump programming is not fully appreciated, low concentration limits should always be set as hard limits. Additionally, clinical advisories should be in place to reinforce caution when using custom concentrations.

In 2000, the Institute of Medicine’s (IOM) original landmark patient safety report, “To Err Is Human: Building a Safer Health System” concluded:

> “Patient safety programs should... incorporate well-understood safety principles, such as, standardizing and simplifying equipment, supplies, and processes.”

The 2006 IOM report, “Preventing Medication Errors,” urges hospitals to take action to reduce the potential for errors. For all of these reasons and as part of continuing efforts to improve patient and medication safety, the San Diego Patient Safety Taskforce was formed for community-wide patient safety improvements. San Diego County hospitals identified PCA as a significant opportunity to reduce morbidity and mortality.

**Goal Charter**

The San Diego Patient Safety Taskforce members desired to develop county-wide, evidenced-based standards of care for safe and effective pain management using PCA in opioid naïve patients.

**Performance Improvement**

The taskforce consists of representatives from county acute facilities and disciplines. Taskforce members reviewed literature, applied process improvement tools, and obtained consensus to build a comprehensive set of recommendations to prevent potential PCA errors throughout the county. The tool kit includes tools and information to assist acute care organizations in implementing these recommendations.

Success will be achieved when a safe, effective standard of care for PCA usage is implemented across San Diego County, as evidenced by a reduction in potential and actual harmful events.

**The Pain Management Process**

In order to develop a standard of care, the taskforce began by developing a high-level process map for pain management. This process is shown in Figure 1 and described as follows:

1. The patient is assessed by a registered nurse and a physician. The physician should determine whether the patient is opioid naïve and therefore, a candidate for standard PCA orders. A registered nurse assesses the patient’s cognitive function to determine if the patient is able to understand and participate in pain management. The nurse also reviews with the patient any education materials, including what is pain assessment and how to achieve pain relief with the PCA pump.

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**Figure 1: Pain Management Process**

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2. The surgical procedure is performed by the physician and the physician implements the standard PCA orders. The pharmacist validates that the appropriate PCA orders are used, based on whether the patient is opioid naïve, and dispenses the standard PCA syringe. The orders are executed, as well as obtaining the appropriate supplies, drug, IV access, monitoring devices, and equipment.

3. A registered nurse assesses the following: **vital signs, pain, sedation, and rate and quality of respirations**. Additional patient education should be provided prior to starting the PCA pump. The PCA pump is set up by the registered nurse with the pump programming independently verified by another registered nurse. The pump settings are documented in the patient’s Medication Administration Record.

4. A bolus of pain medication, if ordered, is administered by the registered nurse using the PCA pump. Subsequent doses of pain medication are self-administered by the patient using the PCA pump. The medication administration and follow-up assessments are documented in the patient’s record.

5. A registered nurse performs follow-up assessments and adjustments to the PCA settings based on standard orders. At consistent intervals, the nurse determines the patient’s response to the ordered pain management approach. Assessment results are documented in the patient’s chart.

6. The result of the process is safe and effective pain control.

### Guidelines for PCA Usage

#### Starting Standard Orders

It is strongly recommended as a best practice for healthcare professionals to use standard starting orders for PCA use to reduce the incidence of respiratory depression and improve patient safety.\(^8\)

#### Standard PCA Parameters for Opioid Naïve Adult Patients

The taskforce identified the starting parameters for PCA therapy for adults, as detailed in Table 1. This table provides parameters for the three most commonly used PCA drugs as a dosing conversion table. These orders are included in the complete standard order set in Appendix B.

| **Table 1: Standard PCA Parameters for Opioid Naïve Adult Patients** |
|-------------------------|-----------------|-----------------|-----------------|
| **Standard PCA Parameters** | morphine | HYDROMorphine | fentaNYL |
| Loading Bolus | 2 mg | 0.4 mg (400 mcg) | 20 mcg |
| Clinician Bolus | 2 mg | 0.4 mg (400 mcg) | 20 mcg |
| Number of Clinician Boluses Per Hour | 1 | 1 | 1 |
| PCA Dose | 1 mg | 0.2 mg (200 mcg) | 10 mcg |
| Lockout | 10 minutes | 10 minutes | 10 minutes |
| Total Drug Over Time | Optional | Optional | Optional |
| Max Number of Patient Demand Doses Per Hour | Optional | Optional | Optional |
| Basal | Not recommended for starting PCA |

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Standard PCA Starting Orders for Opioid Naïve Pediatric Patients

The taskforce identified the starting parameters for PCA therapy for children, as detailed in Table 2. The same drugs used for adults are used for children, but in doses adjusted by body weight. Children should be assessed for developmental age and cognitive ability prior to initiating PCA use.

Table 2: Standard PCA Parameters for Pediatric Patients

<table>
<thead>
<tr>
<th>Standard PCA Parameters for PEDIATRIC Patients</th>
<th>morphine</th>
<th>HYDROmorphine</th>
<th>fentaNYL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1x (single strength)</td>
<td>1 mg/ml</td>
<td>200 mcg/ml</td>
<td>10 mcg/ml</td>
</tr>
<tr>
<td>Loading Bolus</td>
<td>0.04 mg/kg (40 mcg/kg)</td>
<td>8 mcg/kg</td>
<td>0.5 mcg/kg</td>
</tr>
<tr>
<td>Clinician Bolus</td>
<td>0.04 mg/kg (40 mcg/kg)</td>
<td>8 mcg/kg</td>
<td>0.5 mcg/kg</td>
</tr>
<tr>
<td>Number of Clinician Boluses Per Hour</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>PCA Dose</td>
<td>0.01 mg/kg (10 mcg/kg)</td>
<td>2 mcg/kg</td>
<td>0.25 mcg/kg</td>
</tr>
<tr>
<td>Lockout</td>
<td>10 minutes</td>
<td>10 minutes</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Basal / Continuous Rate of Infusion</td>
<td>0.005 mg/kg/hr (5 mcg/kg/hr)</td>
<td>1 mcg/kg/hr Optional</td>
<td>0.25 mcg/kg/hr Optional</td>
</tr>
<tr>
<td>Total Drug Over Time</td>
<td>0.1 mg/kg/hr (100 mcg/kg/hr)</td>
<td>20 mcg/kg/hr</td>
<td>3 mcg/kg/hr Optional</td>
</tr>
<tr>
<td>Max Number of Patient Demand Doses Per Hour</td>
<td>Call if &gt;3 in 2 hours</td>
<td>Call if &gt;3 in 2 hours</td>
<td>Call if &gt;3 in 2 hours</td>
</tr>
</tbody>
</table>

Conversion Instruction/Table

Physicians and other healthcare professionals may be faced with switching to an alternative opioid during the course of a patient’s pain management. While PCA may be administered subcutaneously, it is most common for advanced disease or end-of-life care. Subcutaneous PCA and Epidural PCA are beyond the scope of this project.

The following conversion table is provided to assist healthcare professionals in determining dosing when changing from IV to PO.

Table 3: Equianalgesic Table Conversion IV to PO

<table>
<thead>
<tr>
<th>Equianalgesic Table Conversion IV to PO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid</td>
</tr>
<tr>
<td>--------</td>
</tr>
<tr>
<td>codeine</td>
</tr>
<tr>
<td>fentaNYL*</td>
</tr>
<tr>
<td>HYDROcodone</td>
</tr>
<tr>
<td>HYDROmorphine</td>
</tr>
<tr>
<td>morphine</td>
</tr>
<tr>
<td>oxymorphone</td>
</tr>
<tr>
<td>oxyCODONE</td>
</tr>
</tbody>
</table>

Assessment for PCA Appropriateness

Recommendations by the taskforce for assessments prior to and throughout the administration of opioids using PCA are as follows:

- Pre-Procedure Cognitive Assessment
- Opioid Tolerant or Opioid Naive?
- Pain Assessment
- Sedation Assessment
- Respiratory Assessment.

Further description of each assessment is described in the following sections.

Pre-Procedure Cognitive Assessment

PCA requires patients are active participants in their pain relief. The purpose of the cognitive assessment is to determine if a patient is capable of participating in his/her pain management.

For this reason, it is necessary to evaluate the patient’s mental status, level of consciousness, and developmental status to be sure that PCA is an appropriate method to manage pain. This can be accomplished with a standard nursing assessment.10

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Furthermore, it is recommended that PCA is initiated only when a patient is able to and has indicated the following:

- A willingness to use PCA for pain management,
- An understanding of the relationship between pain, pressing the PCA button, and pain relief,
- An understanding of the dosing interval, and
- A return demonstration of self-administering a PCA dose by pushing the PCA button, or simulating this action if a PCA pump is not available.

**PCA Patient Education**

Patient and family education is critical for safe, effective use of PCA. Education must be provided to patients prior to initiation of PCA and must address their role in managing their pain, specific information on pump operation, safety measures, and when to alert a nurse. Education must include family members to clearly emphasize the hazards of anyone other than the patient administering a PCA dose. Serious adverse events can result when family members administer “PCA by proxy.”

Written and verbal patient education must include the following elements:

- Definition of what PCA is and the patient’s responsibility in managing pain.
- Clarification of the goal of pain management: not to completely eliminate pain, but to effectively control pain so the patient can engage in therapeutic activities.
- General pump operation and function of the PCA button.
- Safety features of the pump to prevent overdose, such as pump delay or lockout interval, limit on total dosage in a set time interval, and patient administered dosing.
- Prominent warning on dangers of PCA by proxy.
- Elements, purpose, and frequency of ongoing monitoring, so the patient understands and expects to be awakened/to be monitored frequently to assess level of sedation.
- Description of when to alert the nurse: inadequate pain control; side effects such as nausea, sleepiness, itching, and constipation; help with getting out of bed; and any safety concerns, such as pump operation.

Verbal instruction is essential to verify patient understanding, preferably pre-operatively for the patient undergoing surgery. A written resource or handout also is necessary to reinforce PCA information. Offering written resources in a language the patient understands should be considered.

**Opioid Tolerant or Opioid Naïve?**

Critical to the pain management process is determining if the patient is opioid naïve or opioid tolerant. The following definitions should be used as guidelines when determining a patient’s opioid status:

**Definition of Opioid Tolerant**

“Patients who are considered opioid-tolerant are those who have been taking, for a week or longer, at least 60 mg of morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral HYDROMorphone daily, or an equianalgesic dose of another opioid.” (Food and Drug Administration)

This history must immediately precede the intended course of PCA therapy. If a wash-out period of a week or longer has occurred since the above dosages were taken, reconsider whether the patient truly meets this definition of tolerance.

**Definition of Opioid Naïve**

Patients who do not meet the definition of opioid tolerant, who have not had narcotics doses at least as much as those listed above for a week or more, are considered to be opioid naïve.

If the patient is opioid tolerant and in need of chronic pain management, it is recommended that experts for pain management are consulted. If the patient is opioid naïve and needs postoperative pain management, the orders contained within this tool kit are suggested.

**Pain Assessment**

Consistent pain assessment is essential to support appropriate continued monitoring and evaluation of a treatment’s effectiveness. Standard pain assessment is useful for eliciting a patient’s response or description of discomfort, as well as ensuring clear communication. It is useful to show the patient each of these scales to see which they feel best helps them describe the pain.

The taskforce’s recommended tool for pain assessment is the 0-10 Pain Faces Scale (Wong-Baker Faces Scale) (Figure 3). This scale combines facial expressions, textual description, and numeric values ascribed to pain level. This scale was originally developed in the pediatric environment, and then extended to adults as the cartoon faces proved to avoid gender, age, and racial bias. This scale is recommended for patients three years to adult.

**Figure 3: Standard PCA Parameters for Pediatric Patients**

![Figure 3](image-url)

Sedation Assessment

Sedation precedes respiratory depression as less opioid is required to produce it. Therefore, the most effective monitoring of the patient receiving opioids is the systematic ongoing assessment for sedation. For patient’s using PCA, sedation assessment is critical.

The taskforce conducted a thorough literature review of Pasero, Ramsey, and RASS sedation scales.\(^{11,12}\) Taskforce members also discussed thoroughly which sedation scale to select. RASS is the top choice because it is concise, simple to use, and combines sedation and agitation into one scale.

Some members of the taskforce have elected to use the Paseo-McCaffery scale in their organization specifically for opioid-induced sedation. While there was not a consensus on a specific scale, the taskforce recommends using a consistent scale across the organization for sedation assessment. It also is recommended that sedation assessment scales use patient behavioral descriptors as scale reference points. RASS and Paseo-McCaffery scales have been included in this tool kit for reference (Tables 4 and 5).

**Best Practice Recommendation:**
It is recommended that a healthcare organization use one sedation assessment scale for PCA opioid use.

### Table 4: Richmond Agitation Sedation Scale (RASS)\(^ {11}\)

<table>
<thead>
<tr>
<th>Score - Term – Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>+4 Combative</td>
</tr>
<tr>
<td>Overtly combative, violent, immediate danger to staff</td>
</tr>
<tr>
<td>+3 Very Agitated</td>
</tr>
<tr>
<td>Pulls or removes tube(s) or catheter(s); aggressive</td>
</tr>
<tr>
<td>+2 Agitated</td>
</tr>
<tr>
<td>Frequent non-purposeful movement, fights ventilator</td>
</tr>
<tr>
<td>+1 Restless</td>
</tr>
<tr>
<td>Anxious but movements not aggressive vigorous</td>
</tr>
<tr>
<td>0 Alert and Calm</td>
</tr>
<tr>
<td>-1 Drowsy</td>
</tr>
<tr>
<td>Not fully alert, but has sustained awakening (&gt;10 seconds)</td>
</tr>
<tr>
<td>(eye-opening/eye contact) to voice</td>
</tr>
<tr>
<td>-2 Light Sedation</td>
</tr>
<tr>
<td>Briefly awakens with eye contact to voice (&lt;10 seconds)</td>
</tr>
<tr>
<td>-3 Moderate Sedation</td>
</tr>
<tr>
<td>Movement or eye opening to voice (but no eye contact)</td>
</tr>
<tr>
<td>-4 Deep Sedation</td>
</tr>
<tr>
<td>No response to voice, but movement or eye opening to</td>
</tr>
<tr>
<td>physical stimulation</td>
</tr>
<tr>
<td>-5 Unarousable</td>
</tr>
<tr>
<td>No response to voice or physical stimulation</td>
</tr>
</tbody>
</table>

### Table 5: Opioid-induced Sedation Scale\(^ {12}\)

<table>
<thead>
<tr>
<th>Pasero-McCaffery Opioid-induced Sedation Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>S = Sleep, easy to arouse</td>
</tr>
<tr>
<td>1 = Awake and alert</td>
</tr>
<tr>
<td>2 = Slightly drowsy, easily aroused</td>
</tr>
<tr>
<td>3 = Frequently drowsy, arousable, drifts off to sleep during conversation</td>
</tr>
<tr>
<td>4 = Somnolent, minimal of no response to physical stimulation</td>
</tr>
</tbody>
</table>

### Procedure for RASS Assessment

The basis of the RASS assessment is to see what amount of stimulation is necessary to evoke a response and evaluate sedation.

It is recommended to conduct the RASS assessment prior to PCA use, perform the assessment at regular intervals with other assessments, and use the assessment to drive clinical decisions (e.g., continue PCA use, escalate treatment, or reduce or reverse opioid treatment).

The recommended procedure for conducting a RASS assessment and target are:

1) **Observe patient.**
   a) Patient is alert, restless, or agitated. (Score 0 to +4)
   b) Patient awakens with sustained eye opening and eye contact. (Score –1)
   c) Patient awakens with eye opening and eye contact, but not sustained. (Score –2)
   d) Patient has any movement in response to voice but no eye contact. (Score –3)

2) **If not alert, state patient’s name and say “open eyes and look at (speaker).”**
   a) Patient has any movement to physical stimulation. (Score –4)
   b) Patient has no response to any stimulation. (Score –5)

### Target:
- (or 2 on Pasero)
  - RASS Level 1
  - With adequate spontaneous respiration.
  - Monitoring should be increased and PCA doses adjusted downward.

If RASS Level 2:
- (or 3 on Pasero)
  - The narcotic should be stopped, physician notified, and continuous monitoring conducted. Airway, breathing, and oxygen support should be provided as needed, as well as Naloxone if indicated.

- (or 4 on Pasero)
  - The narcotic should be stopped, physician notified, and continuous monitoring conducted. Airway, breathing, and oxygen support should be provided as needed, as well as Naloxone if indicated.

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Respiratory Assessment

Monitoring of a patient’s respiratory status with ongoing sedation assessment is critical to detecting respiratory depression in opioid-sedated patients on PCA.\textsuperscript{13, 14} The taskforce recommends respiratory rate and quality of respirations should be included in a respiratory assessment, as follows:

**Respiratory Rate:** Should be counted for 30 seconds and if respiratory rate is less than 12/minute, then it should be counted for a full minute. Respiratory rates vary a great deal, and normal has quite a wide range. Regarding PCA use, a respiratory rate below 8/minute should concern anyone. A rate below 9/minute is probably where most clinicians would draw the line, but many policies use 10/minute as a cut-off where opioids would be discontinued. The rate of respiration assessment should be made in context with sedation and pain assessments.

**Quality of Respirations:** The quality of respirations is usually determined by the depth and pattern of respirations, the level of effort, and adventitious sounds. The following terms can be used to describe the quality of respirations (normal in italics):

- **Depth:**
  - **Normal:** Chest or abdomen moves average depth with each breath not using accessory muscles
  - **Shallow:** Slight movement of chest or abdomen
  - **Deep:** Increased movement of chest or abdomen

- **Ventilatory Effort:**
  - **Effortless/Comfortable:** Appears relaxed, very little work to breathe
  - **Labored:** Patient has to work hard to move air in and out; use of accessory muscles; nasal flaring; retraction (especially in infants and children)

- **Sound:**
  - **Clear:** Breathy sound when breathing in or out
  - **Blocked:** Obstructed, stuffed sound when attempting to breathe in or out
  - **Noisy:** Partially blocked sounds when breathing in or out
  - **Snoring:** Partially blocked sounds when breathing in or out
  - **Gurgling:** Fluids in the airway sounds when breathing in or out
  - **Stridor:** Noisy harsh sound when breathing in or out


Monitoring

Complete Respiratory Assessment

As opioids depress respiratory effort through central nervous system depression, evaluation of ventilatory status is essential. Using a method that would provide earlier warnings for respiratory problems could improve patient outcomes especially in those patients with known and/or unrecognized respiratory disease. The taskforce examined the limits and benefits of available monitoring devices.\textsuperscript{15}

**Best Practice Recommendation:** Respiratory assessment should be performed by a registered nurse, and not be a delegated task.

Pulse Oximetry (SpO2) Monitoring Recommendations

Oxygen saturation is a prudent supplemental assessment measure in patients on PCA therapy, especially those with:

- History of sleep apnea
- Obesity
- Conditions that decrease ventilatory capacity
- Over 65 years.

Pulse oximetry is primarily useful for assessing changes in oxygenation; it is a late indicator of ventilatory depression.\textsuperscript{16} SpO2 readings may remain normal or near normal for minutes after a patient stops breathing. While it is not an early indicator of ventilatory failure, it eventually falls as the patient stops breathing. Its ubiquitous presence in hospitals, simple measurement, and relatively low expense make it the monitor of choice.

It is recommended that at a minimum the healthcare professional monitor with pulse oximetry, yet be mindful of the limits to this useful device.

Supplemental Oxygen Therapy

Supplemental Oxygen Therapy obscures the effectiveness of using SpO2 for a respiratory assessment. SpO2 assessment should be done on room air. For patients on PCA with supplemental oxygen therapy, there is no evidence that routine monitoring of oxygen saturation provides an additional measure of safety. It may provide a false sense of security, since decreased oxygen saturation is a very late sign of respiratory depression in these patients.

Capnography (ETCO2) Monitoring Recommendations

ETCO2 should be considered for assessing ventilation. Capnography measures ventilation continuously and is a more sensitive indicator of hypercapnia. Early studies indicate that capnography is more effective than pulse oximetry in providing early warning of respiratory depression in patients receiving supplemental oxygen. While there needs to be more research, early research shows that patients with the highest risk need additional monitoring, specifically ETCO2 monitoring for opioid-induced sedation.17

Capnography is capable of significantly clarifying the respiratory picture with regard to over-sedation, and when used in conjunction with oxygen saturation can dramatically enhance the overall picture of the patient’s respiratory status. Adding capnography to monitoring efforts can optimize patient safety. Although it is expensive and requires training, it is especially useful in patients on supplemental oxygen.

Frequency and Elements of Monitoring

Appropriate assessment drives clinical decision-making. The essential elements of a good assessment are evaluating the right indicators at the right intervals. Table 6 presents the taskforce’s recommendations for PCA monitoring by registered nurses.

Minimal recommended times for a nurse to evaluate pain, sedation, and respiratory assessment also are provided in Table 6. These critical times for evaluation are summarized as follows:

- **Baseline** – prior to initiating the opioid
- **Initiation** of the opioid – especially just after surgery as the patient likely still has opioids circulating from anesthesia
- **Any Change in Drug Supply**:
  - Change of syringe
  - Change of settings
  - Dose change or bolus
- **Event or Deterioration** – such as over-sedation (i.e., RASS scale of -2)
- At any time there is a “Hand-off” of care:
  - **Transfer of care** – recommend whenever there is a change in the patient’s care provider.
  - **At Shift change** – recommend that the person assuming care of the patient does an independent check of the pump settings, and the off-going care provider and the on-coming care provider conduct the assessment together.

- Document total amount of opioid used at the end of each shift. For those patients who have uncontrolled pain, knowing the amount of opioids used each shift will help facilitate an easier transition to other routes of administration.

<table>
<thead>
<tr>
<th>Cognitive</th>
<th>Opoid Tolerance</th>
<th>Respiratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Sedation</td>
<td>Rate</td>
</tr>
<tr>
<td>Baseline</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Initiation OR Change in Drug*</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Q15 min x 1 hr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 hr x 4 hrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Then Q2hrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose Change OR Bolus</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Q1 hr x 4 hrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Then Q2hrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event OR Deterioration</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Q15 min x 1 hr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 hr x 4 hrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Then Q2hrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand-offs/Shift change*</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

* independent check

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Adjuvant Therapies

Nausea, vomiting, constipation, and itching are common opioid-induced side effects experienced by patients. Evidenced-based recommendations for treatments to relieve or treat these side effects are discussed in this section. The taskforce strongly recommends that any order set for opioid-naïve PCA use includes treatment for these conditions.

Constipation Prevention and Treatment

Individuals are considered constipated if bowel movement frequency is less than three times per week. Determining the baseline bowel habits for a patient is recommended as part of the nursing assessment.

The use of opioids for sedation puts each patient at risk for constipation. To address this side effect, the taskforce conducted a review of literature to recommend a treatment. In addition to this treatment, it is important to adjust the patient’s diet, activity, and fluid intake as appropriate to promote normal bowel habits. Recommendations for therapy dosage for opioid-induced constipation in adults and children are provided in Table 7.

Table 7: Recommended Therapy for Opioid-Induced Constipation

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Adult</th>
<th>Pediatric</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.) Start treatment with following therapy:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senna-S or Senna Plus Docusate</td>
<td>2 tablets PO every morning</td>
<td>50 mg/ tablet PO BID 2-5 yrs = ½ tablet 6-12 yrs = 1 tablet Over 12 yrs = 2 tablets</td>
</tr>
<tr>
<td>2.) If the above therapy is ineffective, try the following therapies:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MOM</td>
<td>30 ml PO q6hrs PRN</td>
<td>-</td>
</tr>
<tr>
<td>Miralax</td>
<td>-</td>
<td>17 gm/packet ½-1 packet per age/weight</td>
</tr>
<tr>
<td>Bisacodyl suppository</td>
<td>1 suppository PR q6hrs PRN</td>
<td>Less than 2 yrs – 5 mg/day single dose PRN 2-11 yrs – 5-10 mg/day single dose PRN</td>
</tr>
<tr>
<td>3.) If none of the above therapies are effective, try the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fleets Enema, PRN</td>
<td>Pediatric Fleets, PRN</td>
<td></td>
</tr>
</tbody>
</table>

Nausea/Vomiting

Recommendations for therapy dosage for opioid-induced nausea and vomiting in adults and children are provided in Table 8 and 9.

Table 8: Recommended Therapy Dosage for Opioid-Induced Nausea/Vomiting (Adults)

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoclopramide (Reglan)</td>
<td>10 mg IV q6hrs PRN nausea/vomiting</td>
</tr>
<tr>
<td></td>
<td>(this agent is possibly advantageous over others if poor GI motility is considered the cause of Nausea/Vomiting)</td>
</tr>
<tr>
<td>Promethazine (Phenergan)</td>
<td>6.25 mg IV q6hrs PRN nausea/vomiting Safety precautions: Dilute in 10 ml NS – assure IV patency before giving; give slowly; if patient complains of pain, stop; use a large vein or preferably a central line if available; may repeat x1 if ineffective in 15 minutes</td>
</tr>
<tr>
<td>Ondansetron (Zofran)</td>
<td>4 mg IV q12hrs PRN nausea/vomiting if no relief in 30-60 minutes following administration of metoclopramide</td>
</tr>
</tbody>
</table>

Table 9: Recommended Therapy Dosage for Opioid-Induced Nausea/Vomiting (Pediatrics)

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Pediatrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoclopride (Reglan)</td>
<td>0.15-0.25 mg/kg/dose IV q6hrs PRN (max 10 mg/dose) May be alternated with (Ondansetron (Zofran) for severe nausea and vomiting</td>
</tr>
<tr>
<td>Promethazine (Phenergan)</td>
<td>NO (Not to be used for children in general; FDA prohibits use in &lt; 2 year olds)</td>
</tr>
<tr>
<td>Ondansetron (Zofran)</td>
<td>0.15 mg/kg/dose IV q6hrs PRN (max of 4 mg/dose) If the above is ineffective, then Metoclopramide (Reglan)</td>
</tr>
</tbody>
</table>

18 University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core. Management of Constipation Evidenced-Based Guideline. Written 1996, Revised 6/98, Reviewed 03/01.
Itching
Itching is a common opioid-induced side effect experienced by patients, and it can be severe. For this reason, the taskforce strongly recommends careful attention to itching and modify treatment as needed.

Recommendations for therapy for opioid-induced itching in adults and children are:

1.) Start treatment with the following therapy:
   - Benadryl (diphenhydramine)

2.) If the above therapy is ineffective, try the following agents:
   - Atarax (hydR0XYzine)
   - Nubain (nalbuphine)
   - Zantac (ranitidine)
   - Claritin (loratadine)
   - Zofran (ondansetron)

3.) If none of the above therapies are effective, try the following:
   - Switch opioid usage for PCA to fentaNYL

Complementary Therapies
There are other treatments that may be used to help manage pain in addition to opioid therapy. Complementary therapies and multimodal pain management provide an approach to managing pain at different pain pathways. These therapies should target reducing pain by 25 percent, which may reduce the amount of opioid needed. The net result may be fewer side effects of opioid therapy.

Consider around the-clock use of agents, such as:
1. Acetaminophen
2. Neurontin (gabapentin)
3. Non-steroidal anti-inflammatory drugs:
   - Ketorolac (toradol)
   - Celebrex (celecoxib)

Guidelines for Implementing PCA Care
This section provides a description of the methodology used by the taskforce to develop the guidelines in this tool kit. It is recommended that this same methodology is used to implement PCA guidelines at a healthcare facility.

Mobilize Commitment
To start, form a taskforce and manage resistance by identifying the organization stakeholders:
- Critical Care Nurses
- Acute Care Nurses
- Clinical Pharmacists
- Pharmacy Leadership
- Pharmacy Buyers/Wholesaler Supplier
- Process Improvement Department
- IS/IT Pharm-IT Department
- CNO/Nursing Leadership
- Pain Service
- Pharmacy and Therapeutics Committee
- Policy and Procedure Committee
- Those responsible for standard order sets
- CNS/Educators
- Others, as needed

Define and Evaluate the Current State
The current state must be identified to effectively target change. The taskforce needs to gather the data in preparation for implementing these recommendations. It is important to work with all stakeholders to obtain agreement on suggested standards for the organization. Recommended information would include:
- Summarize PCA incidents or other quality indicators in the organization(s).
- Identify the PCA equipment used.
- Perform an area-wide inventory of opioid medication concentrations and dosage units.
- Perform an area-wide inventory of assessment tools, practices, policies, and procedures.
- Determine where variations exist in current practice.

Create a Shared Need
The case for standardization must be based on research, literature reviews, etc. Additionally, facilitation should be encouraged to allow for discussion and clarification on the front end to be sure that the group is in full alignment on what is included and excluded in the project. The outcome should be a concise description of the case for standardization.
Elevator Speech
An “Elevator Speech” can be used to quickly convey key elements of the campaign to staff, such as:

- **What:** The goal of this project is to implement an evidence-based standard of care for safe and effective pain management using PCA within ___ months. (identify time span)
- **Why:** This is important because PCA use is a complex, high-risk treatment associated with harmful events and death.
- **Success:** We will have achieved success with this project when we have implemented a safe, effective standard of care in PCA usage across our organization, as evidenced by a reduction in harmful events. (Identify the frequency of evaluation after implementation.)
- **Need:** We need your support and commitment in developing and adopting these standards in your organization and infusing this change to all applicable areas and individuals.

Standardize, Simplify, and Clarify
A standard approach to PCA administration across healthcare facilities within a region should extend beyond assessments, drug concentrations, and dosing units. It is recommended policies and procedures, documentation, standard orders, product, supply and storage, packaging, and equipment are standardized to simply and clarify PCA administration for improved patient safety.

Policies, Procedures, and Process
Standard policies, procedures, and work processes are effective methods that provide a margin of safety in minimizing variance in PCA practice.

Documentation
It is recommended that a comprehensive and careful analysis of documentation should be conducted to identify documentation forms, both paper and computerized, that need to be changed and standardized. For example, Nursing Assessment, MAR, and Input and Output documentation need to be updated with new assessment guidelines, adjunctive therapies, and dosage units.

A sample standard Initial Pain Screening and Assessment Tool is available online at Cardinal Health, Sharp HealthCare, and many taskforce members’ web sites.

Establish Standard Order Sets
Standard order sets ensure consistent and accurate product ordering, delivery, and use, thereby reducing potential medication errors. The taskforce recommends that each hospital establishes standard order sets for PCA drug orders.

Appendix B provides the key elements the taskforce recommends for a standard order set for PCA drug orders.

- Assure there is physician participation in changes needed for a standard approach.
- Pharmacy and Therapeutics Committees should be kept apprised of planned changes in medication use.

Standardized Product
Errors in initiating PCA infusions can occur at any point in the programming process. By using a limited number of standard concentrations, standardizing order forms, implementing smart PCA pumps with DERS, and requiring an independent double-check of the PCA programming, hospitals have put in place effective tools to help reduce PCA dosing errors.21

- Identify drugs that need to be changed and consolidate the data to eliminate unnecessary variability.
- Develop an agreed-upon list of standardized orders, drugs, and concentrations for common PCA infused opioid medications.

PCA Safety Software Limits
If you have smart pump or alert setting on the PCA pump, the taskforce **strongly recommends** enabling a hard stop for the low concentration alarm setting. This alarm identifies data entry errors where the concentration has been incorrectly entered.

For example, a 60 mL syringe with a standard concentration of 1 mg/mL was inadvertantly programmed as containing a 1 mg/60 mL concentration. This resulted in a programmed concentration that was 1/60th of the actual concentration, and a single patient request for a 1 mg dose delivered all 60 mgs (60 mL) of narcotic in the syringe.

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Labeling Guidelines Recommendations
To clarify PCA syringe product labeling, the taskforce recommends the following to reduce potential patient safety mistakes:

- Use Tall Man lettering on all PCA syringe product labels (e.g., HYDROMorphone)
- Use Dose per ml in large font and Total dose per syringe in small font to communicate dosage information (e.g., 1 mg/mL, 50 mg/50 ml)
- Ensure PCA syringe/bag label is consistent with programming settings on the PCA pump.
- If custom concentrations must be used, change the container label to a different color to distinguish the concentration from the standard PCA syringe/bag label.
- Implement technology such as barcoding to program the PCA pump. This would eliminate concentration keystroke errors during programming of the PCA.

Other suggestions to make the process safer can be found in the August 25, 2008 ISMP Alert. Some of these recommendations are summarized below, along with recommendations from the San Diego Patient Safety Taskforce:

- Try to consistently use standard concentration and products.
- Make the information on the label match how the nurse will program the pump.
- Make the formatting of the order set match the programming elements, nomenclature (e.g., “PCA Dose”, etc.), and their sequence within the pump.
- Distinguish custom concentrations using a different label and/or use auxiliary labels so the labels are distinctly different.

Product Supply and Storage
It is recommended that standard doses of medications reside in unit medication dispensing cabinets. Any concentrated doses other than the single, standard concentration for PCA drugs should be sequestered in the pharmacy and dispensed on a per case basis.

Equipment
It is recommended that one type/one model of PCA pump is used throughout the organization to reduce PCA medication errors.
Appendices

Appendix A. Vendor Specific PCA Ordering/Programming Terms

There is a high rate of turnover in nursing staff within San Diego County, with many nurses working in multiple settings and transferring between area hospitals. Some staff are more successful than others in translating the different terms between equipment and clinical practice from one environment to another. Aligning the terminology across area hospitals will help clarify and translate this information, as well as reduce the variability.

The following table provides a cross-walk of terms between PCA pumps.

<table>
<thead>
<tr>
<th>Vendor Specific PCA Ordering/Programming Terms</th>
<th>Alaris</th>
<th>Baxter</th>
<th>Braun Curillin Pain Pump</th>
<th>Hospira Lifecare</th>
<th>Hospira Genstar</th>
<th>Sigma (2008)</th>
<th>CAUD Legacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Dose At Initiation Of Tx</td>
<td>Loading Dose</td>
<td>Loading Dose</td>
<td>Loading Dose</td>
<td>Loading Dose</td>
<td>Loading Dose</td>
<td>Loading Dose</td>
<td>Loading Dose</td>
</tr>
<tr>
<td>Clinician Boluses PRN During Tx</td>
<td>Bolus Dose</td>
<td>Clinician Bolus</td>
<td>Clinician Activated Loading Dose</td>
<td>Clinician Activated Loading Dose</td>
<td>Clinician Activated Loading Dose</td>
<td>Clinician Activated Loading Dose</td>
<td>Clinician Bolus</td>
</tr>
<tr>
<td>Number of such Clinician Boluses allowed per hour</td>
<td>N/A (defined in orders)</td>
<td>N/A (defined in orders)</td>
<td>N/A (defined in orders)</td>
<td>N/A (defined in orders)</td>
<td>N/A (defined in orders)</td>
<td>N/A (defined in orders)</td>
<td>N/A (defined in orders)</td>
</tr>
<tr>
<td>Amount Delivered When Patient Presses DOSE Key or Remote Dose Button</td>
<td>PCA Dose</td>
<td>PCA Dose</td>
<td>Bolus</td>
<td>PCA</td>
<td>Bolus Dose</td>
<td>Patient Dose</td>
<td>Demand Dose</td>
</tr>
<tr>
<td>Amount Of Time That Must Elapse Between such Demand Doses (Appears If Demand Dose is Programmed)</td>
<td>Lockout Interval</td>
<td>Lockout Interval</td>
<td>Bolus Int</td>
<td>Lockout Interval</td>
<td>Bolus Lockout Interval</td>
<td>Drug Lockout</td>
<td>Demand Dose Lockout</td>
</tr>
<tr>
<td>Continuous Rate Of Infusion (Ml/HR, Mg/HR, Mcg/HR)</td>
<td>Cont. Dose</td>
<td>Basal</td>
<td>Basal</td>
<td>Continuous</td>
<td>Continuous</td>
<td>Basal Rate</td>
<td>Continuous Rate</td>
</tr>
<tr>
<td>Total Drug Over Time</td>
<td>Max Limit</td>
<td>Cumulative Dose</td>
<td>(use log)</td>
<td>(use log)</td>
<td>(use log)</td>
<td>Drug Given (use log)</td>
<td></td>
</tr>
<tr>
<td>Maximum Number Of (Patient) Demand Doses Allowed In Any One Hour Period (Appears If Demand Dose is Programmed And Demand Dose Lockout Is Less Than One Hour)</td>
<td>Maximum Patient Dose</td>
<td>Doses Per Hour</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix B. Sample Standard IV PCA Order Set for Opioid Naïve ADULT Patients

1. D/C All previous opioid pain medications, including removal of FentaNYL patches.
2. Start PCA: ASAP or at ____________
3. Educate family: PCA by proxy is NOT allowed

4. PCA settings
   (Single strength standards)
   - Morphine (1 mg/ml)
   - HYDROmorphone (DILAUDID®) 0.2 mg/ml
   - FentaNYL (SUB-LIMAZE®) 10 mcg/ml
   - Other: ____________

   Loading Bolus
   - 2 mg __ mg
   - 0.4 mg __ mg
   - 20 mcg __ mcg

   PCA Dose
   - 1 mg __ mg
   - 0.2 mg __ mg
   - 10 mcg __ mcg

   Lockout Interval
   - 10 min __ min

   Optional Basal/Continuous Dose
   (Hold if RR < 12, O₂ saturation <90% or not easily aroused)
   - _______ mg/hr
   - _______ mg/hr
   - _______ mcg/hr

   Optional Max limit (1 hr)
   (PCA & Basal combined)
   - _______ mg/hr
   - _______ mcg/hr
   - _______ mg/hr

   Bolus by RN PRN Breakthrough Pain
   (Hold if: RR < 12, O₂ saturation < 90% or not easily aroused)
   - 2 mg
   - _____ mg
   - IV q _____ hrs prn

5. PCA DOSE (ONLY) ADJUSTMENTS:
   - Nurse may increase or decrease PCA DOSE (ONLY) if acceptable level of pain not met with next assessment.
   - Increase by:
     - morphine 0.2 mg
     - HYDROmorphone 0.04 mg
     - fentaNYL 2 mcg
   - The maximum total number of PCA DOSE INCREASES allowed before calling the prescriber are _______
   - Call prescriber for any dosage adjustment

6. RESPIRATORY DEPRESSION:
   - If RR < 10/min, very shallow and ineffective, or if patient is unarousable or difficult to arouse (RASS -3):
     - Stop PCA, maintain IV and NOTIFY MD STAT
     - Naloxone (Narcan®) 0.1 mg STAT IV (SC if IV not possible; do not give IM) & q 2 min until RR > 10/min and arouses easily.
     - Apply O2 PRN, maintain airway

7. TREATMENT AND PREVENTION OF OTHER SIDE EFFECTS:
   - Constipation:
     - Senna-S or Senna Plus Docusate - 2 tabs PO every morning
     - MOM - 30 ml PO q6hrs PRN, or if NPO, Bisacodyl (DULCOLAX®) - 1 suppository PR q6hr PRN
     - If above therapies not effective: Fleets - Enema, PRN
   - Nausea/Vomiting:
     - Administer in the sequence below unless ordered otherwise:
       - Promethazine (Phenergan) - 6.25 mg IV q6hrs PRN for nausea/vomiting
         (Safety precautions: Dilute in 10 ml NS – assure IV patency before giving; give slowly; if patient complains of pain, stop! Use a large vein or preferably a central line if available; may repeat x1 if ineffective in 15 min.)
       - Ondansetron (Zofran) - 4 mg IV q12hrs PRN nausea/vomiting if no relief in 30-60 minutes following administration of promethazine
       - Metoclopramide (Reglan) - 10 mg IV q6hrs PRN nausea/vomiting (possibly advantageous over others if poor GI motility is considered the cause of N/V)
   - Itching:
     - Diphenhydramine (Benadryl) 25 mg IV q6hr PRN; MR x1 at 15 minutes if ineffective.
     - If Diphenhydramine 50 mg is ineffective, contact prescriber to consider alternative therapies or opioids (e.g., change morphine to HYDROMorphone or to fentanyl).

8. MONITORING:
   Before initiation of PCA: Baseline vital signs and assess PAIN, SEDATION, RESPIRATORY RATE and QUALITY.
   Initiation of PCA or Change in Drug: Monitor PAIN, SEDATION, RESPIRATORY RATE and QUALITY – q15 min x 1 hr, q1 hr x 4 hrs, then q2 hrs; Nursing to start PCA flow sheet, document total dose and number of attempts at end of shift
   Dose Change (Bolus): Monitor PAIN, SEDATION, RESPIRATORY RATE and QUALITY – q1 hr x 4 hrs, then q2 hrs
   Event or Deterioration: Monitor PAIN, SEDATION, RESPIRATORY RATE and QUALITY – q15 min x 1 hr, q1 hr x 4 hrs, then q2 hrs
   IV required to maintain access; Call prescriber if IV cannot be maintained