**Indianapolis Coalition for Patient Safety, Inc. (ICPS) Patient-Controlled Analgesia (PCA) Safety Summit Consensus Recommendations**

**S:** ICPS consists of six health-systems, all of which use smart infusion pumps to deliver PCA medications.

**B:** Organizations operationalize the safe use of PCA [smart infusion pumps, order sets, staff assessment, electronic medical record (EMR) prompts, documentation, and policies]. Smart infusion pumps, containing dose error reduction systems (DERS), are an important safety tool for end users involved in administering PCA medications. Smart pumps alert staff to potentially incorrect medications orders, calculation errors, or programming mistakes that could result in incorrect delivery of medications used for PCA. Electronic medical records also contain a variety of tools to enhance safety surrounding the PCA medication use process.

**A:** ICPS brought together an interdisciplinary, diverse group of content experts (pharmacists, nurses, and respiratory therapists) representing the six local health-systems to review current state processes surrounding PCA. The group determined significant variation exists surrounding important processes related to PCA: ordering, patient assessment, administration, EMR design, documentation tools, smart pump drug library settings, policies, adverse event monitoring, and education.

**R:** Collectively, the group found an opportunity to standardize efforts and developed a series of consensus statements to address these important areas (highlighted in the table below).

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| **ORDERING** | Patient Screening | a. Consider patient-specific risk factors and opioid tolerance level when ordering and dosing PCAs. |
| | Naïve vs. Tolerant | a. Health system-specific definitions should exist for opioid "naïve" vs. "tolerant" (consider evidence-based recommendations for definition of opioid tolerance if needed) |
| **ADMINISTRATION** | Carrier Fluids (KVO) | a. KVO or carrier fluids are recommended to be included as part of the PCA order set.<br>b. Standard carrier fluid – normal saline or compatible fluid.<br>c. Standard KVO rate in adult or pediatric patients should be 10 mL/hr. |
| **DUAL SIGNATURES** | Process Requirements | Dual signatures are required and must be documented during any of the following process steps:<br>a. Set-up<br>b. Any new PCA order<br>c. Syringe replacement |
| | Forcing Function | Dual signatures, when required, should be a hard stop in the system to prevent further programming or administration until complete. |
| | Documentation | a. Dual signatures, when required, should always be documented.<br>b. Dual signatures shall be documented in the EMR (with the exception of waste, as described above). |
| | Waste | Second signature, when required for waste, may be documented on the proof of use form or at the ADC, depending on the original source of the product. |
| **ASSESSMENT** | Location of Documentation | a. All PCA documentation shall appear in the EMR under one PCA Flowsheet.<br>– If required elements are documented elsewhere within the EMR, these elements shall be linked so the data auto-populate into the PCA Flowsheet, to avoid double documentation.<br>b. Additional elements not documented elsewhere within the EMR shall be manually entered into |

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| **ASSESSMENT (continued)** | | the PCA Flowsheet. |
| | | c. Inclusion of a flowsheet row for name of person providing second signature may be considered. |
| | Required Assessments | The following assessments are required and shall appear within the PCA flowsheet (by a nurse or respiratory therapist):<br>a. Vital Signs<br>b. SPO2/O2 saturation<br>c. EtCO2<br>d. Respiratory Rate<br>e. Depth/Quality of Respirations<br>f. Comfort Function Goal<br>g. Pain Score<br>h. Sedation Score<br>i. POSS |
| | Required Documentation | The following parameters should be documented in discrete and retrievable fields by the nurse in the PCA Flowsheet during regular assessments:<br>a. Changes in basal rate<br>b. Bolus dose<br>c. PCA dose<br>d. Frequency<br>e. Concentration<br>f. Max dose<br>g. Lockout |
| | Frequency of Assessments | a. Assessments shall occur, at a minimum, every 2 hrs for the first 8 hrs upon initiation of PCA and then every 4 hrs following (or unit specific standards).<br>b. Required assessments targeting patient safety include:<br>– Pain score<br>– Sedation score<br>– Respiratory parameters<br>– O2<br>– EtCO2 [Routine EtCO2 monitoring is recommended for the first 24 hrs after PCA initiation or for 24 hrs following a change in any order settings (e.g., change in drug, increased dose, etc.). Patients may be monitored for a longer duration at the discretion of the nurse or provider.] |
| | | a. More frequent monitoring may be considered based on risk factors, patient areas, post-op, etc. |
| | | a. Information pertaining to the number of attempts, total dose delivered, and other PCA settings shall be documented on the PCA Flowsheet every 12 hrs or with any change in caregiver. |
| **POLICY** | Concomitant Pain Meds | PCA policies shall include information regarding review of other concomitant pain meds utilized with PCA therapy and shall not be documented in the PCA Flowsheet (and this should be outlined in the appropriate discipline-specific policy). IV push opioids shall not be used in conjunction with PCA therapy. |

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| **POLICY (continued)** | Required Policy Elements | Recommend a PCA specific policy<br>Required elements should include at least the following (outlined in the appropriate discipline-specific policy):<br>-PCA<br>-EtCO2<br>-Monitoring<br>-Assessments<br>-Education<br>-Review of alerts and reporting |
| | Tracking & Reporting Adverse Events | Recommend tracking adverse events related to PCAs and over-sedation and reporting these findings to the appropriate committee for follow-up, as needed. |
| | Auditing Documentation | Recommend to develop a mechanism for auditing nursing adherence to documentation for PCAs per policy. |
| | Pain Committee | Recommend to develop an interdisciplinary Pain Committee (which will include overseeing activities related to PCA compliance and reporting, among other aims). |
| | EtCO2 Considerations | a. EtCO2 is recommended to be monitored using a smart pump module for adult PCA patients, and therefore, other devices are not required for EtCO2 monitoring when a smart pump module is in place.<br>b. EtCO2 monitoring in pediatric patients is not required but may be performed if part of institutional practice.<br>c. Any additional exclusions from EtCO2 monitoring that are allowed shall be outlined in hospital policy. |
| | Education | In adults, only the patient can push the button. In pediatric patients, a proxy may push the button as outlined per policy. |
| **EDUCATION** | Nursing Staff Education | a. At a minimum, education shall be provided during orientation and with any major process/policy changes.<br>b. Unit-specific education or competencies may be utilized where applicable.<br>c. Sites may also consider required Annual Education regarding PCAs.<br>d. Didactic required elements:<br>– Drug information, use, side effects, waste, etc.<br>– Policies and procedures for PCA and EtCO2<br>– Patient education elements required below<br>– Include additional pertinent screen shots (e.g., patient education module, PCA flowsheet, etc.)<br>e. Skill-based required elements:<br>– Competency checkoff for setup, spike, prime<br>– Critical elements checkoff sheet specific to PCA skills to take back to the unit to do with their preceptors (with detailed directions for the preceptors as to what the process should be and required steps to achieve/complete each item) |

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| **EDUCATION (continued)** | Pharmacist and RT Staff Education | a. Recommend some required education during orientation for pharmacists and RTs regarding PCAs and EtCO2 consistent with usual system-specific education practices.<br>b. Education should be tailored for each discipline based on its own responsibilities and scope of practice. |
| | Patient/Family Education | a. Patient and/or family education shall be completed by the nurse.<br>b. Key elements (e.g., age-appropriate instructions for use, side effects, family restrictions, EtCO2, appropriate patients, monitoring, safety, etc.) should be shared with the patient and/or family in writing when possible and reinforced verbally with the patient and/or. If written is not possible, verbal education can be provided with scripting in the EMR for the nurse to use when educating. The education provided should also reference who can push the button.<br>c. Education should be documented in the usual Education section of the EMR. This is more than just a note – this would be whatever the key elements are normally required in the Education section (written vs. verbal, handout, etc.). |
| **SMART PUMPS** | Drug Libraries | a. Have at least 2 profiles - one for lower dose and one for higher dose (e.g. ICU/palliative/Hem Onc vs. Standard, naïve vs. tolerant, etc.)<br>b. Pick one concentration for each drug to be used consistently across all profiles/therapies. Larger syringe sizes are allowed for higher dose profiles.<br>c. Recommend soft min, soft max, and hard max be programmed into guardrails (can be organization-specific).<br>d. Recommend a hard max for loading doses (this can be organization specific).<br>e. Recommend a soft max for lockout interval of no more than 30 minutes. |
| | Documentation | a. When documenting and/or reporting your cumulative dose, indicate if this does or does not include bolus doses.<br>b. When documenting and/or reporting your cumulative dose, indicate if this is a 1 hour or 4 hour interval. |

**REFERENCES:**


1. Hospital Coalition Group Endorses APSF Recommendations for PCA Monitoring. http://www.apsf.org/newsletters/html/2010/spring/12_coalition.htm. Accessed: July 3, 2018.
2. Walroth TA, Smallwood S, Arthur K, Vance B, Washington A, Staublin T, Haslar T, Reddan JG, Fuller J. Development of a standardized, city-wide process for managing smart pump drug libraries. *Am J Health Syst Pharm* 2018 Jun 15;75(12):893-900.
3. ECRI: In Depth – Dose Error Reduction Systems. https://1technation.com/ecri-depth-dose-error-reduction-systems/. Accessed: July 3, 2018.


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