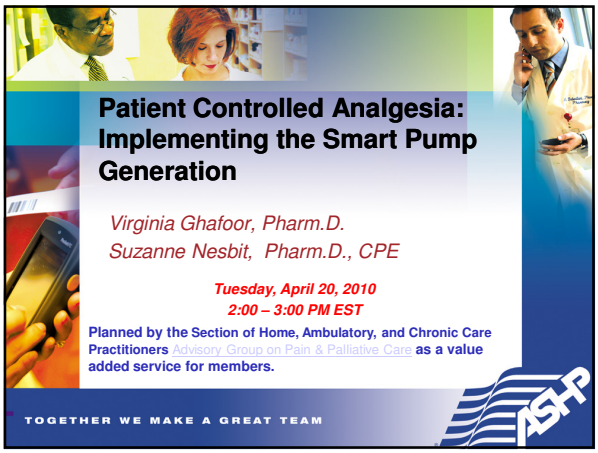


Objectives

- After participating in this webinar, the participant will be able to:
  - Incorporate patient safety recommendations regarding use of smart pump technology into patient care
  - Identify key stakeholders in the selection and implementation of PCA smart pumps
  - Define pump selection process
  - Convene an interdisciplinary team to design and build the PCA drug library
  - Develop and implement education and training for PCA smart pumps
  - Monitor continuous quality improvement parameters for PCA smart pumps

Recommendations for Change

- Institute of Medicine (IOM) recommendation for use of information technologies to reduce medication errors

  Preventing Medication Errors

  (http://www.iom.edu/Reports/2006/Preventing Medication Errors Quality Chasm Series.aspx)
- Institute for Safe Medication Practices (ISMP) recommendation for use of smart PCA pumps with dose error reduction software (DERS)

  Misprogramming PCA Concentration Leads to Dosing Errors

  (http:/www.ismp.org/Newsletters/acutecare/20080828.asp)

Diffusion of Innovation

Principle: innovations do not sell themselves

- **Must persuade others on the benefit of new technology**
- **Pearls**
  - **Find sound technology that can be implemented quickly**
  - **Identify individuals in your organization who support the change in technology**

Reference:
Berwick DM. Disseminating Innovations in Health Care. JAMA 2003; 289(15):1969-1975

Patient Controlled Analgesia (PCA) Pump Safety Hazards

- **Use of wrong analgesic medication**
- **Accidental pump misprogramming**
- **False triggering of PCA dose button**
- **Drug accumulation in IV deadspace**
- **Runaway fluid column due to "siphoning"**
- **Malfunction due to hardware failure**
- **Malfunction due to software design**
- **Retrograde flow of PCA medication into a secondary IV line due to catheter blockade**

Reference:
Schein JR, et al. Patient-Controlled Analgesia-Related Medication Errors in the Postoperative Period. Drug Safety 2009; 32(7):549-559

PCA Device Related Error Costs

	Nonharmful Mean Cost, Dollars (SD)	Harmful Mean Cost Dollars (SD)	Percentage Harmful	Weighted Average Cost Dollars
Overall	$28	$6,943	7.6	$552
Device safety	0	$3,483 (9,294)	0.5	$18
Indeterminate	$142 (1,804)	$6,120 (11,219)	21.7	$1,439
Operator error	$361 (2,910)	$5,756 (10,681)	48.1	$2,955
Patient-related	$11 (31)	$199 (NA)*	33.3	$74
Opioid ADE	0	$13,803 (15,707)	100	$13,803

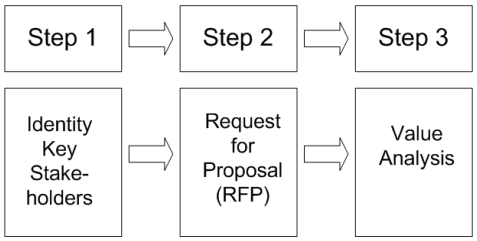
***NA = Not Applicable**

Reference:
Meissner B, et al. The Rate and Cost Attributable to Intravenous Patient-Controlled Analgesia Errors. Hospital Pharmacy 2009; 44:312-324

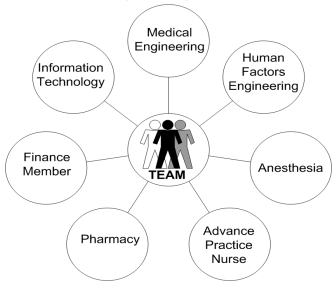
Smart Patient Controlled Analgesia (PCA) Desired Pump Features

Wireless technology that integrates with computerized prescriber order entry (CPOE), bar-code medication administration (BCMA), and electronic medical records
Functionality that prohibits practitioners from bypassing drug libraries for high-risk medications (e.g. opioids)
Libraries with the capacity to include all medications that will be administered
Administration modes for loading dose, PCA dose and continuous infusion
Alerts for medication dose soft limits (e.g. can override) and hard limits (e.g. hard stop) with clinician response records for override reports
Process for creation of reports on pump functionality, medication use, library content and alerts
Control substance medications secure from tampering and diversion

Smart PCA Pump Selection Process Overview



Step 1: Identify Key Stakeholders



Reference:
Ladak SS, et al. How Do We Select the Right Patient-Controlled Analgesia Device? Pain Management Nursing 2007; 8(4):140-45

Assigning Ownership and Responsibility

- **Corporate/Financial**
  - **Contract and purchase of the smart pump device**
  - **Budget for costs**
    - Staff training
    - Trouble shooting problems
    - Library upgrades (ongoing)
    - Risk management and quality improvement processes
- **Technology/Engineering**
  - **Software integration and maintenance of computer upgrades**
  - **PCA pump maintenance**
  - **Drug library protocol development and maintenance**

Assigning Ownership and Responsibility

- **Clinical Departments/Practitioners**
  - Medication policy and procedure
  - PCA order sets, guidelines for dispensing and administration
- **Quality Assurance/Performance Improvement**
  - Monitor PCA pump failure
  - Review manual overrides
  - Evaluate medication errors

Step 2: Request for Proposal (RFP)

Bidding Process Overview

- **Vendor invitation to bid**
- **Written response instructions**
- **Deadline for submission**

Bid Invitation

- Proposals on FDA-approved equipment and supplies
- Should consider multiple pumps that may be used for analgesic medication administration:
  - Large volume
  - PCA
  - Syringe pumps (pediatric patients)
  - Epidural pumps
  - Pump supplies (IV sets, etc)

Written RFP Should Include:

- History of company, regional office location, personnel assigned to pump
- Current financial statement of the company and parent corporation supporting the pump
- Experience and references of company staff providing services
- Contract commitment by the company for development of the organization's pump program, staff training and education

Written RFP Should Include:

- Warranty with extension provisions for pump device and support services by the company
- Trade-in and device upgrade options
- Delivery charges for pump and equipment
- Contract requirements
  - Term (time frame of agreement)
  - Pricing and alternative proposals
  - Future price increase
  - Contractual problems/cancellation of contract

Time Deadlines

- Submission questions
- RFP
- Vendor presentations
- Decision making

Step 3: Value Analysis

- Value of an item is determined by estimating how well it performs, divided by the cost
  - Customer focused
  - Process oriented
  - Data-driven
- Weighted-matrix recognizes PCA pump attributes that must be present
  - Weight of attribute indicates level of desire for a feature
  - Attribute score is the performance of the pump
  - Total weighted score for pump obtain by multiplying weight of attribute by the attribute score

    Pump with the highest total weighted score indicates it is the best performer

Example: Weighted Decision Matrix

Attribute	Weight of attribute (1-10 scale)	Attribute score for Pump #1 (1-4 scale)	Total weighted score for Pump #1	Attribute score for Pump #2 (1-4 scale)	Total weighted score for Pump #2
Vendor provides staff education materials	6	4	24	2	12
Vendor offers continuing education	1	2	2	4	4
TOTAL		8	26	6	16

Bid Award Criteria

- **Vendor ability to meet the organization's goals and objectives**
- **Total cost**
- **Vendor organization and experience**

Smart PCA Pump Limitations

Dose error reduction software does not replace "double checking" accuracy of information entered
Too many concentration options for each drug increases the potential for the wrong concentration to be selected
Soft stop alerts can be overridden
Hard stops that are not appropriately set can create a barrier to care and may result in nurses using "work arounds " to bypass safety features for operation of the pump
Incorrect medication selection or dose on physician orders will not be detected with the use of smart pumps

Failure Mode and Effects Analysis (FMEA)

- **FMEA process identifies key failure modes in the medication process**
- **FMEA should be conducted prior to implementation of the new pump to evaluate:**
  - **Potential barriers to programming the pump**
  - **Accessing and using the drug library**
  - **Presence of conditions that could result in bypassing safety features**

Reference:
Wetterneck TB, et al. Using failure mode and effects analysis to plan implementation of smart IV pump technology
Am J Health-Syst Pharm 2006; 63:1528-38

Example: FMEA Rating System University of Minnesota Medical Center

FMEA Score

- Score is obtained by multiplying the severity by the probability
- Detectable is "yes" or "no" depending on whether or not the failure mode would be detected before reaching the patient

Rating	Severity	Probability
1-3	Minor	Doubtful
4-6	Moderate	Possible
7-9	Major	Likely
10	Catastrophic	Absolute

Failure Mode	Severity Score	Probability Score	Total Score	Detectable
Multiple concentrations available-wrong selection	8	8	64	Yes
Calculation error when determining drug dose	7	7	49	No

Error Prevention

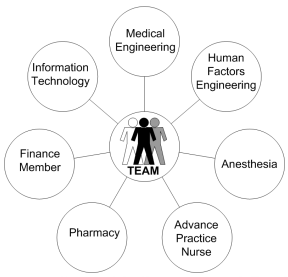
Error Type	Examples	Plan
NURSE PRACTICE	**Failure to adhere to the policy:** •Expired cassettes hanging •Not discontinuing PCAs •Wrong concentration hung •Missing order to change settings	Staff Education
PROGRAMMING	**Incorrect settings:** rate, bolus dose, volume, calculation errors	Smart Pumps Smart Order sets Staff Education
PRESCRIBER	Improper patient selection, conversion of P.O. to I.V., concurrent orders for other opiates	Smart Pumps Smart Order sets Staff Education
Other	IV infiltrations, missing PCA keys, falls and one episode where the patient used the prime function to self-bolus	Staff Education
CONTINUITY OF CARE	Poor communication surrounding transfers of care from one unit to another	Staff Education
TRANSCRIPTION	Incorrect orders result in over or under dosing of patients	Smart Pumps Smart Order sets
PUMP AVAILABILITY	Hoarding by units; possible loss	Staff Education
MEDICATION AVAILABILITY	Lack of medications in stock	Smart Pumps will allow tracking of medication usage through future QI features
PUMP MALFUNCTION	Rare	Smart Pumps with new technology Policy updates
PCA BY PROXY	Family or staff administering doses resulting in over sedation, respiratory depression and potential for sentinel event	Policy updates Staff Education

Drug Library Development & Implementation

- Form an interdisciplinary committee
- Establish development and implementation timeline
- Policy revisions or development
- Create drug library
- Committee approvals
- Technology readiness
- Staff education
- Maintenance schedule

Proceedings from the ISMP Summit on the Use of Smart Infusions Pumps: Guidelines for Safe Implementation and Use

Interdisciplinary Drug Library Team



Establishing a Timeline

- Identify clinical uses of PCA smart pumps
- Adult and/or pediatric libraries
- Identify new clinical practices
- Policy development and approval
- Standardization of PCA medication formulary
- Validation and testing
- Education and training

Policy Development

- Define responsibilities of prescribers, nursing and pharmacy
- Ordering of PCA pumps and medications
- Assessment and monitoring of patients receiving analgesia via PCA pumps
- Reportable conditions
- Documentation
- Process for library requests and updates

Drug Library Development

- Medications
- Concentrations
- Routes of administration
- Protocols
- Continuous rate
- PCA dose
- Lockout
- Soft and hard limits
- Volumes
- Alarms
- Settings
- Codes
- Color
- Therapy/Qualifier
- Capnography

Standardization

- Medications, i.e., opioids, local anesthetics, clonidine
- Concentrations
- Syringe, cassette or infusion bag
- Volumes
- Nomenclature
- Dosing : defaults, weight based
- Order sets
- Consistency and compatibility with CPOE, pharmacy systems, MARs and labels

Adult/Ped PCA Drug Library Example

Therapy	Qualifier	Drug
Adult IV PCA	Standard High Extreme/Chronic pain/Oncology	Morphine 5mg/ml Hydromorphone 0.2 mg/ml Fentanyl 20 mcg/ml
	Neuro/Palliative Care	Morphine 5 mg/ml Midazolam 1 mg/ml
Adult Epidural	OB Laboring Patient Standard	Fentanyl w/ Bupivacaine Bupivacaine
Adult Peripheral Nerve Catheter	Region/Acute Pain Service	Ropivacaine 0.2%
Adult Subcutaneous	Standard High	Morphine 20 mg/ml Hydromorphone 5 mg/ml
Adult Intrathecal	Interventional Pain Service	Morphine Hydromorphone Fentanyl Clonidine Bupivacaine Ziconotide Baclofen

Therapy	Qualifier	Drug
Ped Intravenous	<5kg 5-9kg 10-19kg 20-39kg 40-59kg >60kg	Morphine Hydromorphone Fentanyl
Ped Epidural/Bupiv 500mg	5-9kg 10-19kg 20-39kg 40-59kg >60kg	Hydromorphone/Clonidine Hydromorphine Fentanyl Fentanyl/Clonidine Clonidine
Ped Epidural/Lidoc 1500mg	5-9kg 10-19kg 20-39kg 40-59kg >60kg	Lidocaine Clonidine Fentanyl/Clonidine Fentanyl
Ped Epidural/Lidoc 2500mg	5-9kg 10-19kg 20-39kg 40-59kg >60kg	Lidocaine Clonidine Fentanyl/Clonidine Fentanyl
Ped Peripheral Nerve Cath	5-9kg 10-19kg 20-39kg 40-59kg >60kg	Ropivacaine Bupivacaine
Pediatric Neonatal Epidural	Neonatal	Lidocaine
Pediatric Intrathecal	Ped Neurosurgery	

Drug Limits

- Soft limits can usually be overridden
- Hard limits cannot
- Consider patient populations and clinical areas
- Procedure for when a hard stop is reached
- For opioids, consider naïve vs. tolerant patients
- Maximum doses/hour or delivery limit
- High risk, high alert agents
- Limits should help minimize catastrophic events

Alarms and Settings

- May be customizable per protocol
- Standardize if possible
- Employ human factors engineer
- Beware of alarm fatigue!
- Explore with vendor nuances of different setting and alarms
- High vs low priority alarms
- Color matching

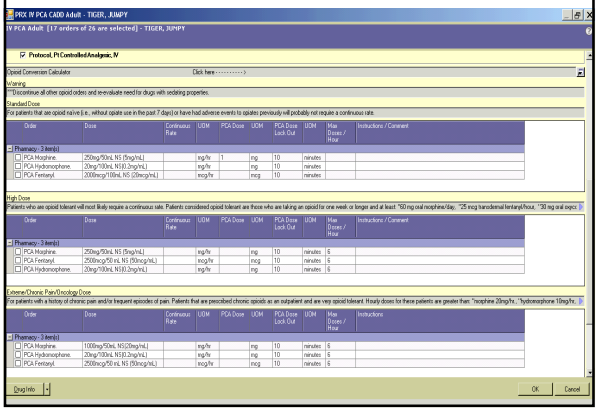
Capnography

- End tidal CO2 monitoring
- Separate module
- Patient assessment and monitoring
- Specific patient populations

Technology Interface

- PCA order set development
- Computerized physician order entry (CPOE)
- Pharmacy systems
- Bar code medication administration
- Medication administration records
- Clinical biomedical engineering
- Materials management

POE Adult Intravenous PCA Order Set



Education and Training

- Utilize vendor resources
- Prescribers, nursing and pharmacy
- Provide training within 4-6 weeks of rollout
- Verbal and written training
- Simulation of patient care scenarios
- Competency
- Resources available again after rollout

Rollout!

- Query all patient care areas affected
- Prioritize sequence of deployment
- Utilize teams of nursing, pharmacy and IT
- Vendor and super user support

QI Monitoring

- Updates to the drug library
- Soft limit overrides
- Use of Manual or Open protocols
- Incidence of reprogramming the pump due to alerts, soft limits and hard limits
- Nuisance alerts or alarms
- New medications or clinical use
- Wireless communication
- Drug library administrator and steering committee

Conclusions

- Incorporate patient safety recommendations regarding use of smart pump technology into patient care
- Essential to identify key stakeholders in the selection, library design, and implementation of PCA smart pumps
- Define what features of smart pump technology is desirable for your institution and patient populations
- Integrate PCA smart technology into other institutional technology where possible
- Define the process for updating the PCA drug library
- Monitor continuous quality improvement parameters for PCA smart pumps