Medication Error Prevention in the Home Setting: A Proactive Approach to Safety

Tuesday, April 5
7:00-8:45 a.m.
Hilton Orlando—Orange Ballroom FG

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A Symposium Held in Conjunction with the 2011 NHIA Annual Conference & Exposition
Medication Error Prevention in the Home Setting: A Proactive Approach to Safety

Education Overview:
Establishing and sustaining an environment of medication safety requires deliberate effort on the part of home care organizations. Error reporting is a retrospective, after-the-event process that only works to improve medication use processes after follow-up analysis and corrective action plans are implemented in response to reports. While there will always be a place for error reporting in a culture of medication safety, there is also a critical need for proactive assessments of risk that can lead to system change and error prevention.

The goal of this session is to stimulate home infusion organizations to take action and change how they approach medication safety, particularly in regards to high-risk medications administered in the home setting. The ISMP list of “High-Alert Medications” includes those categories of drugs that carry an increased potential for causing significant patient harm when they are used in error, many of which are commonly provided by home infusion pharmacies. Although mistakes may or may not be more common with these drugs, the consequences of an error can be more devastating to patients. Two high-alert drug categories that are commonly infused in the home setting include parenteral nutrition (PN) solutions and opioid/narcotics. After reviewing why these two classes of medications are included on the “high alert” list, this session will explore strategies to prevent and minimize medication error risks associated with prescribing, stocking, compounding, dispensing, administering and clinically monitoring response to these drugs.

Faculty: Matthew Grissinger, RPh, FISMP, FASCP, Director, Error Reporting Programs, Institute for Safe Medication Practices, Horsham, PA

Matthew Grissinger, RPh, FASCP is the Director of Error Reporting Programs at the Institute for Safe Medication Practices (ISMP). His responsibilities include working with health care practitioners and institutions to provide education about medication errors and their prevention, review medication errors that have been voluntarily submitted by practitioners to a national reporting program as well as serving as a clinical analyst for the Pennsylvania Patient Safety Reporting System (Pa-PSRS). He has extensive experience in long-term care, home care, and community pharmacy. Prior to joining ISMP, Matthew served as a home care and long-term care pharmacy surveyor for the Joint Commission. He is a frequent speaker on pharmacy topics and current issues in medication safety. He has published numerous articles in the pharmacy literature, including regular columns in P&T, U.S. Pharmacist, and the PSA Patient Safety Advisory. Matthew serves on the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), the National Quality Form (NQF) Common Formats Expert Panel, the Editorial Board for P&T, and the Publications Advisory Board for Davis’s Drug Guide for Nurses. He also served on the United States Pharmacopeia’s (USP) Safe Medication Use Expert Committee from 2005-2010, the FDA Proprietary Name Review Concept Paper workshop panel in 2008 and the Naming, Labeling, and Packaging Practices to Minimize Medication Errors workshop panel in 2010. He is also an adjunct assistant professor for Temple University School of Pharmacy and clinical assistant professor for the University of the Sciences in Philadelphia. Mr. Grissinger received a BS in Pharmacy from the Philadelphia College of Pharmacy and Science and is a fellow of the Institute for Safe Medication Practices as well as the American Society of Consultant Pharmacists.

Pharmacist and Nurse Education Objectives:
1. Describe a proactive process for identifying and resolving risk for medication errors in the home infusion setting.
2. List the medication errors most commonly associated with parenteral nutrition (PN) compounding and administration in the home.
3. Identify strategies to mitigate the risks of PN compounding and administration in home infusion.
4. List the medication errors most commonly associated with parenteral opioid administration in the home.
5. Identify strategies to mitigate the risks of opioid administration in home infusion.

Pharmacy Technician Education Objectives:
1. Examine the types of medication errors that have been reported in the home infusion setting.
2. Review the medication errors most commonly associated with parenteral nutrition (PN) compounding.
3. Identify strategies to mitigate the risks of error associated with PN compounding.
4. Review the medication errors most commonly associated with parenteral opioid preparation in the pharmacy.
5. Identify strategies to mitigate the risks of opioid preparation.
Learning Assessment Questions:

1. Information about a patient that is needed when processing prescriptions for opioids and TPNs include:
   a. Diagnoses and co-morbidities
   b. Allergies and reactions
   c. Lab values
   d. Current medication profile
   e. All of the above

2. All of the following may be considered “high alert” medications in home infusion pharmacy EXCEPT:
   a. TPN
   b. Gentamicin
   c. Opioids
   d. Chemotherapy
   e. All of the above

3. Which type of strategy would be most effective in preventing a medication error?
   a. Using a checklist and/or double check systems
   b. Adding a new rule and/or policy
   c. Using a forcing functions and/or constraints
   d. Providing education or information

4. All of the following methods to reduce medication errors associated with opioid drug packaging are true EXCEPT:
   a. Separate any problem products in your pharmacy
   b. Standardize the concentrations of your opioid infusions
   c. Apply Tallman lettering to dissimilar portions of name on product shelves or pharmacy labels.
   d. Consider ways to make things look similar to important information using items such as stickers, labels or highlighting.

5. Using error reports to quantitatively measure risk is an effective method to determine if you have any problems in your home infusion pharmacy.
   a. True
   b. False

Answers can be found on the last page of this booklet.
Medication Error Prevention in the Home Setting: A Proactive Approach to Safety

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Director, Error Reporting Programs
Institute for Safe Medication Practices

Disclosures

- Matthew Grissinger declares no conflicts of interest or financial interest in any service or product mentioned in this program.

- Clinical trials and off-label use will not be discussed.

Top 5 Things to Know for CE:

- Make sure your Badge is scanned each time you enter a session to record your attendance.
- Carry the Evaluation Packet you received on registration with you to every session. If you're not applying for CE, we still want to hear from you! Your opinions about our conference are very valuable.
- Pharmacists, Pharmacy Technicians, and Nurses need to track their hours on the Statement of Continuing Education Certificate form as they go.
- FOR CE: At your last session, total the hours and sign both pages of your Statement of Continuing Education Certificate form.
- Keep the pink copy for your records.
- Place the yellow and white copies in your Evaluation Packet.
- Make sure an evaluation form from each session you attended is completed and in your Evaluation Packet (forgot to pick up an evaluation form at a session? Extras are available in an accordion file near the registration desk.)
- Put your name and unique member ID number (six digit number on the bottom of your badge) on the outside of the packet, seal it, and drop it in the drop boxes in the NHIA registration area at the convention center.
High-Alert Medications

• Small number of medications that have a high risk of causing injury if misused

• Errors may or may not be more common with these than with other medications, but the consequences of errors may be devastating

High Alert Medications in Home Infusion Pharmacies

• opioids
• TPN
• cardioplegic solutions
• chemotherapeutic agents
  – Parenteral
• dextrose, hypertonic
  – 20% or greater
• peritoneal dialysis solution

• epidural & intrathecal
• glycoprotein IIb/IIIa inhibitors
• inotropes
• liposomes

High Alert Medications in Home Infusion Pharmacies

• heparin
  – low molecular weight
  – unfractionated
• insulin
  – subcutaneous
  – intravenous
• magnesium sulfate

• potassium concentrate IV
  – sodium & phosphate
• magnesium sulfate IV
• sodium chloride injection
  – more than 0.9% concentration
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Patient Information
- Guides prescribers in appropriate selection of medications, doses and routes of administration
- Guides clinical review by pharmacist of appropriateness of medication order
- Guides clinical review and appropriateness by nurses prior to administration and during patient monitoring

Patient Information Studies
- Leape et al. JAMA July 5, 1995
  - 18% of serious, preventable adverse drug events stem from practitioners having insufficient information about the patient before prescribing, dispensing and administering medications
  - More than 25% of prescribing errors alone were directly associated with inadequate patient information, particularly renal and hepatic function, allergies, and pregnancy status
2004 ISMP Medication Safety Self-Assessment

<table>
<thead>
<tr>
<th>Element</th>
<th>Max</th>
<th>Mean</th>
<th>% of Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Element I - (1) Patient Information</td>
<td>100</td>
<td>43</td>
<td>43%</td>
</tr>
<tr>
<td>Key Element III - (4) Communication</td>
<td>92</td>
<td>43</td>
<td>46%</td>
</tr>
<tr>
<td>Key Element IX - (16) Patient Education</td>
<td>52</td>
<td>25</td>
<td>48%</td>
</tr>
<tr>
<td>Key Element X - (17-20) Quality Processes and Risk Management</td>
<td>300</td>
<td>152</td>
<td>51%</td>
</tr>
<tr>
<td>Key Element II - (2,3) Drug Information</td>
<td>152</td>
<td>80</td>
<td>53%</td>
</tr>
</tbody>
</table>

Patient Information Data

- Age
- Height (cm,) and weight (kg, gm)
- BSA
- Allergies (updated), sensitivities and reactions
- Renal and hepatic function
- Co-morbid disease states

Patient Information Data

- Pregnancy or lactation status
- Results of laboratory tests
- Vital signs and monitoring parameters
  - baseline prior to high-risk procedures
  - e.g., PCA use, IV pain management and use of technology for monitoring
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**Preparation**

- Staging
- Mixing
- Checking

**Staging**
- Look-Alike/Sound-Alike
- Non-standardized concentration
- Non-standardized compounding worksheets
- Variation for special products (e.g. chemotherapy, TPN)
- Variation for special populations (e.g. pediatrics)
- Staffing & workflow issues
- Procurement during drug shortages

**Mixing**
- Source of diluents
- Storage of medication
- Lack of compounding recipe
- Unclear instructions
- Preparing more than one IV order
- Variation in determination of final volume
- Use of closed system transfer devices
- Staffing & workflow issues
Medication Error Prevention in the Home Setting: A Proactive Approach to Safety

Checking

• Use of technology
• Variation in checking method
  • “Pull Back” method
  • Drawn up syringes
  • Relying on label checks
• Attach tubing and prime line
• Variation in person checking
• Variation in documentation

Opioids

Leading Products in Harmful Medication Errors, CY 2006

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin*</td>
<td>385</td>
<td>11.3</td>
</tr>
<tr>
<td>Morphine*</td>
<td>164</td>
<td>4.8</td>
</tr>
<tr>
<td>Heparin*</td>
<td>120</td>
<td>3.6</td>
</tr>
<tr>
<td>Fentanyl*</td>
<td>98</td>
<td>2.9</td>
</tr>
<tr>
<td>HYDROMORPHONE*</td>
<td>91</td>
<td>2.7</td>
</tr>
<tr>
<td>Warfarin*</td>
<td>58</td>
<td>1.8</td>
</tr>
<tr>
<td>Potassium Chloride*</td>
<td>89</td>
<td>2</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>104</td>
<td>2</td>
</tr>
<tr>
<td>Enoxaparin*</td>
<td>53</td>
<td>1.6</td>
</tr>
<tr>
<td>Metoprolol Tartrate</td>
<td>42</td>
<td>1.2</td>
</tr>
<tr>
<td>Furosemide</td>
<td>41</td>
<td>1.2</td>
</tr>
<tr>
<td>Methyldiphenisalolane</td>
<td>35</td>
<td>1</td>
</tr>
<tr>
<td>Meperidine*</td>
<td>33</td>
<td>1</td>
</tr>
</tbody>
</table>

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Errors with opioids

- Approximately one out of four reports received in the Pennsylvania reporting program involve high-alert medications.
- Of those reports, 44% involved pain management medications including morphine, HYDROMORPHINE (DILAUDID®), meperidine (DEMEROL®) and fentanyl.

<table>
<thead>
<tr>
<th>Drug #1</th>
<th>Drug #2</th>
<th>Total Reports</th>
<th>Percent of Applicable Wrong Drug Errors (n=8400)</th>
</tr>
</thead>
<tbody>
<tr>
<td>morphine</td>
<td>HYDROMORPHINE</td>
<td>295</td>
<td>3.5%</td>
</tr>
<tr>
<td>HYDROMORPHINE w/ acetaminophen</td>
<td>OXYCODELONE w/ acetaminophen</td>
<td>192</td>
<td>2.3%</td>
</tr>
<tr>
<td>oxycodone</td>
<td>OXYCONTIN</td>
<td>188</td>
<td>2.2%</td>
</tr>
<tr>
<td>oxycodone</td>
<td>lorazepam</td>
<td>173</td>
<td>2.1%</td>
</tr>
<tr>
<td>oxycodone w/acetaminophen</td>
<td>OXYCODELONE w/acetaminophen</td>
<td>146</td>
<td>1.7%</td>
</tr>
<tr>
<td>OXYCODELONE</td>
<td>OXYCODELONE w/acetaminophen</td>
<td>108</td>
<td>1.3%</td>
</tr>
<tr>
<td>MS CONTIN</td>
<td>OXYCONTIN</td>
<td>79</td>
<td>0.9%</td>
</tr>
<tr>
<td>Novolog Mix 70/30</td>
<td>Novolin 70/30</td>
<td>75</td>
<td>0.9%</td>
</tr>
<tr>
<td>morphine</td>
<td>naproxen</td>
<td>70</td>
<td>0.8%</td>
</tr>
</tbody>
</table>

Predominant Medications Associated with Wrong Drug Errors with HYDROMORPHINE

<table>
<thead>
<tr>
<th>MEDICATION PRESCRIBED</th>
<th>MEDICATION ADMINISTERED</th>
<th>NUMBER</th>
<th>% OF TOTAL REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROMORPHINE</td>
<td>morphine</td>
<td>66</td>
<td>35.7%</td>
</tr>
<tr>
<td>Morphine</td>
<td>HYDROMORPHINE</td>
<td>63</td>
<td>34.1%</td>
</tr>
<tr>
<td>HYDROMORPHINE</td>
<td>Lorazepam</td>
<td>6</td>
<td>3.2%</td>
</tr>
<tr>
<td>HYDROMORPHINE</td>
<td>meperidine</td>
<td>6</td>
<td>3.2%</td>
</tr>
<tr>
<td>OXYCODELONE</td>
<td>HYDROMORPHINE</td>
<td>5</td>
<td>2.7%</td>
</tr>
</tbody>
</table>
**Dosing of HYDROMORPHONE**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Equi-analgesic Dose (mg)</th>
<th>Initial Oral Dose</th>
<th>Initial IV Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Oral</td>
<td>Parenteral^</td>
<td>Children (mg/kg)</td>
</tr>
<tr>
<td>HYDROMORPHONE</td>
<td>7.5</td>
<td>1.5</td>
<td>0.06</td>
</tr>
<tr>
<td>Meperidine</td>
<td>100</td>
<td>7.5</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Morphine</td>
<td>30</td>
<td>10</td>
<td>0.3</td>
</tr>
</tbody>
</table>

- Elderly: Starting dose should be lower for this population group.

- Morphine label states: i.V. Initial, Opiate-naive: 2.5-5 mg every 3-4 hours
- Based on chart, morphine 2.5 – 5 mg should be 0.375 – 0.75 mg of HYDROMORPHONE
- HYDROMORPHONE's label states: Initial IV dose for opioid-naive patients is 1 mg to 2 mg IV (slowly) every four to six hours as needed.
Adverse Drug Reaction (ADR) Reports Mentioning HYDROmorPHONE

- PSA analysts reviewed ADR reports submitted to the Authority to determine if there were cases that may have been preventable
- Greater than a 1 mg dose for the general adult population for an opioid-naïve patient
- 1 mg or greater for an elderly patient who was opioid-naïve
- Multiple opioids


Predominant Adverse Drug Reaction Categories Associated with the Use of HYDROmorPHONE

<table>
<thead>
<tr>
<th>EVENT TYPE</th>
<th>NUMBER</th>
<th>% OF TOTAL REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central nervous system and/or respiratory depression</td>
<td>449</td>
<td>47.9%</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>361</td>
<td>38.5%</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>39</td>
<td>4.2%</td>
</tr>
<tr>
<td>Unknown/reaction not specified</td>
<td>34</td>
<td>3.6%</td>
</tr>
</tbody>
</table>


Common “Preventable” ADR Categories Associated with the Use of HYDROmorPHONE

<table>
<thead>
<tr>
<th>EVENT TYPE</th>
<th>NUMBER</th>
<th>% OF TOTAL REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inappropriate dose</td>
<td>205</td>
<td>70.2%</td>
</tr>
<tr>
<td>Inappropriate doses and Multiple Drugs</td>
<td>44</td>
<td>15.1%</td>
</tr>
<tr>
<td>Multiple Drugs</td>
<td>26</td>
<td>8.9%</td>
</tr>
<tr>
<td>Inappropriate dose and contraindicated</td>
<td>9</td>
<td>3.1%</td>
</tr>
</tbody>
</table>
Examples of Preventable ADR Report
• An elderly patient was admitted with left leg edema and ulcerations with significant pain
• Within an eight-hour period, the patient received morphine 2 mg IV, HYDROmorPHONE 2 mg IV two times, and was started on a fentaNYL patch
• One hour later, the patient was found unresponsive. Naloxone was given and the patient responded immediately
• The HYDROmorPHONE pm order was discontinued, the fentaNYL patch remained on, and the patient had no further episodes of unresponsiveness

PCA Therapy

Medication errors involving PCA

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Note: All medications were involved patient safety and should be monitored closely. This chart was adapted from the NHIA March 1, 2008
PCA Example

- HYDROMorPHONE 0.2 mg/mL - 100 mL cassettes.
- Attached to labels was billing information which incorrectly listed 20 mL HYDROMorPHONE per cassette instead of 2 mL.
- RPh initiated worksheet and incorrectly wrote in total of 40 mL (of 10 mg/mL) as being needed.
- Tech followed sheet and used 20 mL each resulting in final 2 mg/mL concentration but labeled as 0.2 mg/mL.

Safety issues with patient-controlled analgesia (PCA)

- Improper patient selection
- Prescribing errors
- Drug product mix-ups
- Communication of Orders
- Inadequate staff training

Safety issues with patient-controlled analgesia (PCA)

- PCA pump programming
- Device design flaws
- Inadequate patient education
- PCA by proxy
- Patient monitoring problems
Improper patient selection

- Less than-ideal candidates
  - Infants
  - Young children
  - Confused elderly patients
- Candidates at risk for respiratory depression
  - Obesity
  - Asthma
  - Sleep apnea
- Concurrent drugs that potentiate opioids

Prescribing errors

- Patient allergies
- Inappropriate drug selection (i.e. meperidine)
- Opiate has been prescribed with dose for a different opiate (i.e. morphine/HYDROMORPHONE)
- Verbal orders
- Concurrent orders for other opioids
Prescribing Errors

Factors that Contribute to Errors with PCA Therapy

- Drug product mix-ups
  - Multiple concentrations
  - With or without preservatives
  - Look-alike pharmacy labeling
  - Opioids are typically in unit stock/ADC
  - Mix-ups between morphine and HYDROMORPHONE

Misprogramming of Pump

- Misprogramming of the PCA pump is a frequently reported practice-related issue.
  - Wrong concentrations
  - Wrong basal rate
  - Programming basal rate that isn't ordered (bolus dose only order)
  - Wrong bolus dose
  - Wrong lock-out times
  - Patient changes settings
PCA by Proxy

- 72-year-old woman, following cancer surgery, was prescribed PCA with a 2 mg morphine loading dose and 1 mg every 10 minutes as needed (6 mg maximum per hour).
- Despite the patient’s inability to verbalize pain, nurses pushed the PCA button and delivered frequent doses of morphine over the next 48 hours.
- Subsequently, the patient suffered a cardio-respiratory arrest and seizure, leading to hypoxic encephalopathy.
- She died several months later without ever regaining consciousness.

Total Parenteral Nutrition (TPN)

- TPN was prescribed for a preterm infant born at 26 weeks gestation.
- On the day of the event, the physician’s TPN order included directions to add zinc in a concentration of 330 mg/100 mL.
- Zinc dose entered in the pharmacy computer in mg, not mcg.
- Resulted in a final concentration of 330 mg/100 mL—a 1,000-fold overdose.

mg or mcg of Zinc?

- TPN was prescribed for a preterm infant born at 26 weeks gestation.
- On the day of the event, the physician’s TPN order included directions to add zinc in a concentration of 330 mg/100 mL.
- Zinc dose entered in the pharmacy computer in mg, not mcg.
- Resulted in a final concentration of 330 mg/100 mL—a 1,000-fold overdose.
System Based Causes

- Method used to prescribe zinc was different than entering order into automated compounding software program
- Dosing alerts did not occur in pharmacy computer or when directions were scanned into the automated compounding system
- Limited education and experience, along with ineffective competency validation

System Based Causes

- TPN order was processed during the evening when staffing was limited
- Tech felt intimidated to express concern
- Ineffective or nonexistent systems for independent double-checks
TABLE IV

<table>
<thead>
<tr>
<th>Method by which IV electrolyte quantities are ordered</th>
<th>Quantity Expression</th>
<th>Process Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>mEqL or 100 mL for normal saline</td>
<td>62</td>
<td></td>
</tr>
<tr>
<td>mEqL or 100 mL for normal saline</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>mEq/kg or 100 mL for normal saline</td>
<td>94</td>
<td></td>
</tr>
<tr>
<td>mEq/L or 100 mL for normal saline</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Volume (mL) of multieutelectrolyte concentrate</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Volume (mL) of electrolyte concentrate (eg. 25 mL of 10% NaCl)</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>mg/L (eg. sodium phosphate)</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>mg/L (eg. sodium chloride)</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

*These methods were not included as a selection in the survey but were provided by respondents when asked whether other methods were used.

Potassium Phosphate

- 50 mL Single PDL
- Only
- 150 mg/50 mL Phosphate
- 100 mg/50 mL Potassium

Potassium Phosphate

- 5 mL Single PDL
- Only
- 100 mg/50 mL Phosphate
- 25 mL of 4% sodium chloride

Example

- Sodium acetate vials for injection were ordered that looked like sterile water vials
- The technician grabbed a sodium acetate vial and used it to reconstitute ampicillin syringes
- The technician discovered her error, brought it to the pharmacist’s attention
Insulin or TB Syringes?

• ISMP and PA-PSRS have received several reports of errors in which TB syringes were used in place of insulin syringes.
  – The nurse selected a TB syringe instead of an insulin syringe and administered 0.9 mL (90 units) of insulin, resulting in a 10-fold overdose.
  – In other cases, a patient received 60 units of insulin instead of 6 units, and another patient received 40 units instead of 4 units.
  – Also occurred when compounding TPNs
    • Order for 10 units becomes 100 units in the TPN.
Modifying TPNs at Home

- In response to lab results showing hypokalemia, the child’s physician wanted potassium chloride added to the TPN
- Instead of making new solutions, the home care pharmacy sent several syringes containing potassium chloride concentrate
- Mother placed these syringes with a supply of sodium chloride syringes

Strategies to Mitigate Risks with Opioids and TPN Therapy
How do you Identify Risk?

Incident reports 0.01-0.05%
Prescription order review 0.3%
Observation 15-20%

Incident reports are ... “the tip of the iceberg”

Voluntary Reporting

“We found that less than 4% of all adverse drug events involving use of rescue drugs were reported.”
Studies of medical services suggest that only 1.5% of all adverse events result in an incident report.

Methods of Data Collection

• Proactive Risk Assessment
  – Self Assessments
  – Failure Mode and Effects Analysis (FMEA)
  – External Sources of Data
• Concurrent Risk Assessment
  – Trigger and Markers
  – Pharmacy Interventions
• Retrospective Risk Assessment
  – Observational methodology
  – Data from Technology
  – Chart reviews
  – Internal voluntary reporting
FMEA

- New Products
- Devices
- Current subprocesses
  - Communication of orders to pharmacy
  - Delivery of medications to patient units
- New subprocesses
  - New pathway/order set
  - Use of automated dispensing cabinet in the PACU
Medication Error Prevention in the Home Setting: A Proactive Approach to Safety

Pharmacy-Nursing Interventions

- Order interventions
  - Corrections in orders for opioids
- Computer screening
  - Patient information
  - Lab information
  - Drug database
- Independent double-check process
  - Wrong drugs/concentrations

Retrospective Risk Assessment

- Observation Methodology
- Data from Technology
- Chart Reviews
- Internal, voluntary reporting

Observation

- Processes
  - Verbal orders
  - IV Compounding
  - Workflow
- Storage conditions
- Communication dynamics
Data from Technology

- Pharmacy Information systems
- Bar code point of care systems
- Infusion pumps (Smart pumps)

Constraints That Limit Access

- Prohibit pharmacy access by non-pharmacists
- Reduce access to dangerous items by careful selection of medications and quantities in storage
- Move problem products out of reach
  - Potassium chloride,
  - Neuromuscular blockers
  - Chemicals

Constraints

- Limit choices
  - Limit the variety of medications used for PCA
  - Limit concentrated oral liquid opioids to opioid tolerant patients ONLY
Medication Error Prevention in the Home Setting: A Proactive Approach to Safety

**Standardization**
- Standard concentrations
  - Infusions
  - Vials
- Standardized units of measure for electrolytes
- Standardized protocols and preprinted orders

**PCA Standardized Order Sets**
- Redesign standard order sets to guide
  - Drug selection
  - Doses
  - Lockout periods
  - Patient monitoring
  - Precautions, such as avoiding concomitant analgesics
  - Breakthrough pain
  - How and when to administer oxygen and naloxone

**Fail Safes**
- Use products that design error out of the system
  - Dangerous order can’t be processed in computer system
  - Automatic fail-safe clamping mechanism on intravenous infusion pumps

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Separate Problem Products

- Look-alike packaging
  - Store vials of heparin and insulin apart, including under the hood
- Look-alike drug names
  - Computer mnemonics designed so similar names do not appear on same screen

Differentiate items that are similar

- Purchase one of the products from another source
- Apply upper case lettering to dissimilar portions of name
  - morphine vs. HYDROmorPHONE
- Use other means to “make things look different” or call attention to important information
  - Stickers, labels, enhancement with pen or marker

Differentiate

- Stock morphine and HYDROmorPHONE in different strengths or forms
- Tall-man lettering; “HYDROmorPHONE”
  - Pharmacy labels
  - Auxiliary labels
  - MARs
  - Drug listings in order entry systems and ADC screens
- Affix an auxiliary label to concentrated solutions to avoid confusion with standard concentrations
Independent Double Checks

- Probability that two individuals will make the same error is small
  - PCA pump rate and concentration set by one person with independent confirmation by another
  - Calculations for TPN, concentration changes for opioids

Use Reminders

- Place auxiliary labels on containers for clinical warnings and error prevention messages
- Incorporate warnings into computer order processing and selection of medications from dispensing equipment
- Place labels on IV lines to prevent mix-ups between IV lines and enteral feeding lines
- Protocols, checklists, visual and audible alarms
Medication Error Prevention in the Home Setting: A Proactive Approach to Safety

**Improve Access to Information**
- Use computerized drug information resources
- Computer order entry systems that merge patient and drug information, provide warnings, screen orders for safety, etc.
- Readily available texts in current publication
- Pharmacists availability to prescribers, nurses and patients

**Staff Education**
- Monitoring Checklist for PCA therapy
  - Signs and symptoms of opioid toxicity and withdrawal
  - Need to assess patients with minimal verbal or tactile stimulation
  - Distinction between over sedation and other pulmonary, neurologic, or cardiovascular complications

**Suspect a problem**
- If the patient is not responding to the PCA doses, suspect an error, especially before administering bolus dose, and re-verify;
  - Drug
  - Concentration
  - Pump settings
  - Line attachment
- If patient’s electrolytes results unexpectedly change
Questions?
### Example of a Health Care Failure Mode and Effects Analysis for IV Patient Controlled Analgesia (PCA)

<table>
<thead>
<tr>
<th>Processes &amp; Subprocesses Prescribing</th>
<th>Failure Modes (what might happen)</th>
<th>Causes (why it happens)</th>
<th>Effects</th>
<th>Severity</th>
<th>Probability</th>
<th>Hazard Score</th>
<th>Actions to Reduce Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess patient</td>
<td>Inaccurate pain assessment</td>
<td>Cultural influences; patient unable to articulate</td>
<td>Poor pain control</td>
<td>2</td>
<td>4</td>
<td>8</td>
<td>Standard scale to help assess pain; training on cultural influences</td>
</tr>
<tr>
<td>Choose analgesic/mode of delivery</td>
<td>Wrong analgesic selected</td>
<td>Clinical situation not considered (age, renal function, allergies, etc.); tolerance to opiates not considered; standard PCA protocols not followed (or not available); concomitant use of other analgesics not considered; drug shortage; knowledge deficit; improper selection of patients appropriate for PCA</td>
<td>Improper dosing; improper drug; allergic response; improper use of substitute drug</td>
<td>4</td>
<td>3</td>
<td>12</td>
<td>CPOE with decision support, clinical pharmacy program; standard PCA protocol with education on use; point-of-use access to drug information; feedback mechanism on drug shortages with information on substitute drugs available; selection criteria for PCA patients</td>
</tr>
<tr>
<td>Prescribe analgesic</td>
<td>Wrong dose (loading, PCA, constant, lock-out), route, frequency</td>
<td>Knowledge deficit; mental slip; wrong selection from list; information about drug not available</td>
<td>Overdose; under-dose; ADR</td>
<td>4</td>
<td>3</td>
<td>12</td>
<td>CPOE with decision support; clinical pharmacy program; standard PCA protocols</td>
</tr>
<tr>
<td></td>
<td>Proper patient monitoring not ordered</td>
<td>Knowledge deficit; mental slip</td>
<td>Failure to detect problems early to prevent harm</td>
<td>4</td>
<td>3</td>
<td>12</td>
<td>Standard PCA order sets with monitoring guidelines</td>
</tr>
<tr>
<td></td>
<td>Prescribed on wrong patient</td>
<td>Similar patient names; patient identifier not clear; name does not appear on screen when ordering medications</td>
<td>Wrong patient receives inappropriate drug and dose; ADR; allergic response</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>Match therapy to patient condition; alerts for look-alike patient names; visible demographic information on order form or screen</td>
</tr>
<tr>
<td></td>
<td>No order received</td>
<td>Unable to reach covering physician</td>
<td>Poor pain control</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Proper physician coverage and communication channels</td>
</tr>
</tbody>
</table>
Safety issues with patient-controlled analgesia

Part II – How to prevent errors

Patient-controlled analgesia (PCA) has considerable potential to improve pain management. However, errors happen frequently, sometimes with tragic consequences. In Part I, published in our July 10, 2003 newsletter, we described how PCA errors happen. Part II presents a checklist of efforts related to practice, systems, products, pumps, and regulations that can reduce the risks associated with this patient-centered technology.

When purchasing a PCA pump

- Perform a failure mode and effects analysis using the actual PCA pump under evaluation. Examples of questions to explore:
  1. Can the pump be programmed easily to deliver the desired concentrations?
  2. Could unsafe administration sets that allow free-flow be used accidentally?
  3. Is the pump operation intuitive for the clinician and patient?
  4. What are the default settings for the opiate concentrations in use?
  5. Do the drugs, units of delivery, and strengths appear in a logical sequence?
- Limit PCA pumps to a single model to promote proficiency with programming.
- Before distributing the new pumps, verify that all pump default settings are set up as expected, and place a warning label on the activation button that states “FOR PATIENT USE ONLY.”

Before prescribing, dispensing, or initiating PCA

- Require PCA prescribers to undergo a privileging process to verify proficiency with this form of pain management. Limit the prescribing of fentanyl for epidural PCA to anesthesia staff, pain management teams, or critical care prescribers.
- Design standard order sets to guide drug selection, doses, and lockout periods; patient monitoring; and precautions such as avoiding concomitant analgesics, and how and when to administer oxygen and naloxone. Test the order sets using the pump's programming sequence to reduce the risk of errors.
- Provide nurses with relevant information about opiates used for PCA. Alert them to the dangers of administering a dose for the patient (PCA by proxy) and the differences between hydromorphone and morphine.
- Teach nurses and pharmacists how to program PCA pumps, and verify their ability to enter a PCA prescription accurately. Ensure that training occurs close to the introduction of new pumps, not months before use, and offer practice sessions as needed to maintain proficiency.
- Run simulations in which staff purposely write incomplete orders; select an inappropriate drug or dose; misprogram a pump; ignore double checks; forget critical monitoring points; and miss obvious signs of toxicity so that clinicians can identify these at-risk behaviors.
- Ensure that nurses recognize the signs and symptoms of opiate toxicity and withdrawal, the need to assess patients with minimal verbal or tactile stimulation, and the ability to distinguish between oversedation and other pulmonary, neurologic, or cardiovascular complications.
- Provide ongoing education to clinicians about PCA errors to build awareness, and encourage internal and external (FDA, ISMP, USP) reporting of PCA errors.
- Require annual competency assessments for all professionals who prescribe, dispense, and administer PCA.
- Establish patient selection criteria for PCA. Candidates should have an appropriate level of consciousness and cognitive ability to self-manage pain. Infants, young children, and confused patients are unsuitable candidates.

SafetyBriefs

An example of how color-coding can contribute to medication errors. In 1996, the American Academy of Ophthalmology (AAO) urged manufacturers to convert to a uniform color-coding system based on therapeutic class for eye solutions and ointments. For example, antinfectives are tan, steroids are pink, mydriatics and cycloplegics are red, beta-blockers are yellow. See a complete list at www.aao.org/aao/member/policy/color.cfm. The color-coding system reportedly helps ophthalmologists and patients quickly differentiate medications. FDA and manufacturers have supported the initiative. However, they may not have considered how color-coding might actually contribute to errors made by nurses and pharmacists who must contend with a growing number of products in the same class, all similar in appearance. Color-coding may work well in an office setting or in the patient’s home, but when similar corporate logos, fonts, and package sizes are also factored in, it may not be safe in pharmacies or on nursing units. The ophthalmics in the photo above were found together in the same storage location, even though they should have been stored alphabetically by generic name. A pharmacy technician confused these while putting away an order from the wholesaler. We’ve also received reports of mix-ups between cyclopentolate hydrochloride 1% solution and tropicamide 1% solution, both packaged in almost identical red and white cartons. The containers inside these cartons are equally similar. It takes four times longer to recover from the effects of cyclopentolate than tropicamide, so a mix-up could be significant. All of these ophthalmics are marketed by Falcon Pharmaceuticals, an affiliate of Alcon Laboratories.
Safety Briefs continued
We’ve contacted FDA, AAO, and various manufacturers about ophthalmic mix-ups within the same class, but we’re not optimistic that the situation will change. Purchasing ophthalmics within the same class from different vendors may help prevent errors by minimizing the similarities.

Your reports prompt a label change. Bedford Laboratories, a division of Ben Venue Laboratories, has redesigned their acetazolamide injection 500 mg labels based on reports that they looked dangerously close to the company’s acyclovir 500 mg vials (see photo of old labels from our July 24, 2002, newsletter). The new labels are green and the drug name is printed using “tall man” lettering as required by FDA. This helps differentiate acetazolamide from acyclovir. Thank you for reporting the problem, and thanks to Bedford for fixing it!

Unit-dose capsules for inhalation. If you are planning to add FORADIL (formoterol fumerate) to the formulary, you might benefit from knowing about a problem that surfaced nearly 30 years ago. When cromolyn sodium was first marketed, it was available in a capsule formulation in unit-dose packages. But the capsule was not for oral use; it was for administration by inhalation for prophylaxis against allergy-induced asthma. To administer the medication, the capsule was placed into a special inhaler that accompanied the drug. When activated, the capsule was punctured and fine powdered cromolyn was dispersed into the lungs as the patient inhaled. This helps differentiate bronchial asthma from hay fever. When prescribed for prophylaxis against hay fever, the patient was given the inhaler, the capsule, and an instruction sheet. But in many hospitals, the unit-dose capsules were dispensed as individual doses along with oral unit-dose medications. Since the manufacturer’s label did not alert staff to inhalation use only, it did not alert the patient to use only the inhaler.

PCA Issues continued
When prescribing PCA
- Require the use of PCA standard order sets (all sections completed) and limit verbal orders to dose changes.
- Always dose PCA opiates in mg or mcg, not by volume (mL).
- Check patient allergies before selecting the opiate used with PCA.
- Use morphine as the opiate of choice. Use hydromorphone for patients who need very high doses of opiates. Reserve meperidine for patients who are allergic to both morphine and hydromorphone.
- Consider other medications that the patient has received (e.g., analgesics taken at home, intraoperative medications) or currently has prescribed (e.g., antihistamines, nighttime sedatives) when determining the loading and maintenance doses.
- Reassess the appropriateness of PCA therapy at regular intervals.

When dispensing PCA
- Establish one standard concentration for each opiate used for PCA.
- Stock only the standard concentrations of morphine and hydromorphone in patient care units (meperidine for PCA should be dispensed from the pharmacy).
- Separate the storage of hydromorphone from morphine in the pharmacy and patient care units to avoid mix-ups.
- Check patient allergies and ensure that they are listed in the interactive allergy field on the patient profile before entering PCA orders into the computer.
- Set maximum dose limits for PCA opiates in the pharmacy computer so an alert appears if safe doses are exceeded during order entry.
- Affix prominent warnings if dispensing an opiate in a nonstandard concentration.
- Use prefilled syringes/bags/cassette whenever available commercially. Have pharmacy prepare all PCA products that are not commercially available.
- Require a pharmacist to review all PCA orders before initiation (exception: when a pharmacist is not on site) and suggest renal dose adjustments or an alternative opiate when appropriate. If meperidine PCA is used, have pharmacy set dose limits and reassess the patient every 24 hours.
- Use “tall man” lettering on pharmacy-applied labels for HYDROMORPHONE to help avoid confusion with morphine.
- Alert clinicians to potential drug shortages with PCA opiates and, if encountered, recommend an alternative drug with clear dosing instructions.

When initiating PCA
- Check patient allergies, which should be visible on the medication administration record (MAR), before initiating PCA.
- Connect PCA to a port close to the patient (to avoid dead space) and prominently label the infusion line at this connection to avoid mix-ups with other lines.
- Provide laminated instructions for programming PCA pumps for reference by nurses who may infrequently initiate PCA.
- Require two clinicians to independently double-check the patient’s identification, drug and concentration, PCA pump settings, and the line attachment before use (and before pump refill or programming change). Bedside bar-coding can be used to verify the patient and drug/concentration; however, pump settings may still require an independent double check.
- Avoid nurse-controlled PCA unless special monitoring in place (see page 3).
- Verify PCA settings each shift, immediately after receiving report.
- Avoid administering concomitant opiates (an alert should appear on the MAR).
- Have oxygen andnaloxone readily available.
- Educate patients about the proper use of PCA before initiation. Start during the preoperative testing visit so patients are not too groggy to understand. Warn family members and visitors about the danger of PCA by proxy.
**Safety Briefs continued**

not take long for reports to reach us about oral administration. Although the problem does not exist today (the drug is now available as an inhalation solution or aerosol), a similar risk exists with Foradil. As with the original cromolyn product, Foradil is available in a capsule formulation that requires a special inhaler (the AEROLIZER inhaler), and the capsules are in unit-dose packages without cautions against oral use (see photo below). Staff used to administering oral medications from unit-dose packages could eventually administer Foradil orally. Patients might make the same mistake. In fact, we’ve already heard that a patient in France was given the capsules to swallow. To prevent errors, staff and patient education is critical. Also keep the box and inhaler together and don’t dispense the capsules separately. If the product is dispensed as loose unit-dose capsules, each package should have a cautionary label affixed stating “for inhalation, using special dose capsules, each package should have a caution-
inhaler together and don’t dispense the capsules
patient education is critical. Also keep the box and
inhaler only.” We’ve asked Schering-Plough, which
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PCA Issues continued

**When monitoring the effects of PCA**

- Establish a standard measurement scale to assess the patient’s level of pain.
- Develop monitoring requirements for patients who are receiving PCA and be alert for signs of oversedation. At a minimum, evaluate the patient’s level of pain, alertness, and vital signs, including rate and quality of respirations, every 4 hours.
- Evaluate all patients with minimal verbal and tactile stimulation to obtain an accurate assessment of their level of sedation.
- Monitor patients more frequently during the first 24 hours and at night, when hypventilation and nocturnal hypoxia may occur.
- Establish risk factors that could increase respiratory depression (e.g., obesity or low body weight, concomitant medications that potentiate opiates, preexisting conditions such as asthma and sleep apnea) and determine the level of enhanced monitoring that would be required if these patients use PCA (e.g., capnography, apnea alarms at night).
- Identify the infrequent situations where critical care patients may be suitable for nurse-controlled analgesia, and the level of enhanced monitoring that would be required for these patients.
- Do not rely on pulse oximetry readings alone to detect opiate toxicity. Since capnography is currently not available for all PCA patients, reserve its use for those with a heightened risk of toxicity, and with nurse-controlled analgesia.
- Keep flowsheets at the bedside to document PCA doses and patient monitoring.
- Monitor the use of naloxone to identify adverse events related to PCA.

**Recommendations for pharmaceutical companies**

- Improve the visibility of label information about preservatives in opiates.
- Distinguish the packaging of opiates and the varying strengths used for PCA. Use “tall man” letters for HYDROMorphone to help avoid confusion with morphine.
- Seek FDA approval of hydromorphone for PCA so the product can be packaged in prefilled syringes or bags for PCA use.
- Provide wholesalers and healthcare providers with early warnings about potential drug shortages to allow providers time to prepare for short-term alternatives.

**Recommendations for PCA pump manufacturers**

- Ensure free-flow protection for all administration sets and extension tubing.
- Provide visual and auditory feedback to patients about doses that are administered when the activation button is pressed.
- Require pumps to be programmed in mg/mL or mcg/mL, not just mL.
- Establish default settings of zero for all opiate concentrations.
- Change the appearance of the activation button to avoid looking like a call bell.
- Develop technology to alert users and stop PCA if a syringe or bag is empty.
- Explore design standards to prevent connecting an IV PCA to an epidural line.
- Develop technology for PCA to alert clinicians to unsafe dose settings, programming errors, and respiratory depression.
- Contact healthcare providers immediately when pump problems are recognized.

**Recommendations for regulatory bodies**

- Require PCA pump manufacturers to provide a patient guide for use.
- Enhance FDA communication to providers about PCA problems, and issue hazard alerts or recalls on unsafe devices currently on the market.
- Require pump manufacturers to perform premarket testing of the device using clinicians and potential patients.
- Require pump manufacturers to apply existing human factors design guidelines for medical devices (see [www.cssinfo.com/info/aami.html](http://www.cssinfo.com/info/aami.html)).
Patient-controlled analgesia (PCA) has considerable potential to improve pain management for patients, allowing them to self-administer more frequent but smaller doses of analgesia. When used as intended, PCA actually reduces the risk of oversedation, which is an unintended consequence of the more traditional method of nurse-administered analgesia in larger, less frequent doses. In fact, with PCA, patients often develop a synergism with the device and can quickly learn how to manage their pain while avoiding undue mental clouding. However, through the USP-ISMP Medication Errors Reporting Program, the USP MEDMARX program, and a sizeable response we received from readers answering our call for information about PCA problems, it’s clear that errors happen frequently, sometimes with tragic consequences.

Just last week, we met with staff at FDA’s Center for Devices and Radiological Health (CDRH) to discuss medication errors associated with PCA. At the meeting, we presented in-depth information about the following factors that have frequently contributed to the problem.

**PCA by proxy.** Several safety features exist with PCA to make sure patients do not receive too much analgesia. These include a lockout interval that specifies the minimum amount of time between each dose, and a maximum allowable amount during 1- or 4-hour intervals. Another “built-in” safety feature that’s often overlooked is that the device is intended for patient use. A sedated patient will not press the button to deliver more opiate, thus avoiding toxicity. However, family members and health professionals have administered doses for the patient, by proxy, hoping to keep them comfortable. This well-intentioned effort has resulted in oversedation, respiratory depression, and even death.

**Improper patient selection.** Since an important safety feature with PCA is that the patient delivers each dose, candidates for PCA should have the mental alertness and cognitive, physical, and psychological ability to manage their own pain. However, the benefits of PCA have led providers to extend its use to less-than-ideal candidates such as infants, young children, and confused elderly patients. This has facilitated the dangerous practice of PCA by proxy. PCA use in these types of patients has also spurred ethical debates about the potential for undertreatment caused by the poorly coordinated efforts of family members (who are not at the bedside continuously) and clinicians, and the inability of these patients to clearly communicate their pain level. In addition, oversedation has occurred in less than ideal candidates at risk for respiratory depression due to comorbid conditions such as obesity, asthma, or sleep apnea, or use of concurrent drugs that potentiate opiates.

**Inadequate monitoring.** Even at therapeutic doses, opiates can suppress respiration, heart rate, and blood pressure. Thus, nurses or other caregivers typically monitor patients at frequent intervals while they are using PCA. However, these monitoring activities may not alert caregivers to opiate toxicity. First, patients may not be monitored frequently enough, especially during the first 24 hours and at night when nocturnal hypoxia can occur. But more often, the way that caregivers assess patients may be at the root of the problem. Patients who are experiencing opiate-induced respiratory depression or toxicity are often overlooked because they are not at the bedside continuously.
have a system that coordinates the activities of the doctor and office staff. But this doctor surely would not have initiated the prescription if he had seen that there was no patient name, incorrect spelling of the product, and an incorrect strength. What probably happened is that he wanted to prescribe Fosamax weekly for his patient, but he relied on the office system to get the prescription to the patient. However, without a proper check system in place, he could not ensure that an appropriate prescription was delivered. In fact, it’s not uncommon for office staff to have pre-signed prescriptions to fill in the blanks, based on the day’s notes, medical record, or some other signaling system such as a verbal order. A new law in Florida, although certainly well intentioned, might actually encourage scenarios like this. As of July 1, 2003, written prescriptions issued by Florida healthcare practitioners must be legibly printed or typed, the quantity of the drug prescribed must appear in both textual and numerical formats [e.g., “ten (10)”], and the prescription must be dated with the month written out in textual letters (e.g., “October 5, 2003”; not “10/5/03”). Ostensibly, the law would encourage clear communication and perhaps even computerized prescribing, either of which would reduce the risk of dispensing errors. However, it could also encourage some physicians to delegate more of the actual prescription-writing responsibility to office staff who may not have requisite training and supervision. And, as in the case above, the physician may fail to review the prescription before it’s given to a patient. Also, pharmacists could be forced to reject all cursive prescriptions, in which case, the law could lead to treatment delays for sick patients and stress doctor-pharmacist-patient relationships. Interestingly, there’s no requirement in the law for prescribers to include the drug’s purpose on the prescription, which invariably helps pharmacists identify the medication.

The cost of safety. Much evidence has been published about the substantial costs associated with malpractice claims that stem from medical error. However, two physicians recently published rather compelling reasons why this information may “fall on deaf administrative ears” when used to garner resources to minimize error (Weeks et al. 2003). Misprogramming of the PCA pump is, by far, the most frequently reported practice-related issue. Pump design issues that have led to programming errors are described in the section that follows. Other practice-related issues that have contributed to PCA errors include incorrect transcription of prescriptions into pharmacy computers or medication administration records (often related to look-alike product names), calculation errors when determining the patient’s dose or rate of infusion, and IV admixture errors. Unavailability of hydromorphone in prefilled syringes or premixed bags necessitates IV admixture of this opiate. Drug shortages, most notably with fentanyl, also have required the use of less familiar products, such as sufentanil, which has led to serious dosing errors.

Device design flaws. Programming a PCA pump requires multiple steps, but the pump’s design is often far from intuitive. In fact, two device models (Abbott Lifecare PCA II and APM Infusers) have been under close scrutiny for years because of the frequency of programming errors, many of which have resulted in patient deaths. Most of these programming errors have resulted because concentration settings for opiates such as morphine default to 0.1 mg/mL or 1 mg/mL, but a higher concentration is available and used. Other design flaws that have facilitated programming errors include pumps that do not require users to review all settings before the infusion starts, and pumps that require users to program the dose in mL, not mg, leading operators to overlook the amount of drug the patient is actually receiving. Siphoning (free flow) also has been reported after entrainment of air into the system due to

oversedation can easily be stimulated to a higher level of consciousness and an increased respiratory rate. Thus, if patients are disturbed in order to make the assessment, the level of consciousness and respiratory rate observed is not helpful in detecting toxicity. Once the stimulus is removed, patients quickly fall back into an oversedated state. There’s also too much reliance on pulse oximetry readings, which can offer a false sense of security since oxygen saturation is usually maintained even at low respiratory rates, especially if supplemental oxygen is in place.

Inadequate patient education. Most patients who are suitable candidates for PCA can be taught how to use the device successfully. However, patients who have been taught to use the device during the immediate postoperative period have often been too groggy to fully understand its use, and they often report poor pain control during the first 12 hours after surgery. Alert, intelligent patients also have misunderstood the directions for use, most often believing that they must press the button every 6 minutes or so, even when they are sleepy and comfortable. At times, family members have awakened patients so that they can press the button frequently, or they may press the button for the patient if they have not been alerted to avoid PCA by proxy.

Drug product mix-ups. Some of the opiates used for PCA have similar names and packaging, which has led to drug selection errors. Prefilled syringes of meperidine and morphine have been packaged in similar-looking boxes. Morphine is available in prefilled syringes in two concentrations, but the packaging may not help to quickly differentiate the strengths. Differentiation between opiates with and without preservatives is not prominent on labels. All pharmacy-applied labels may look similar on extemporaneously prepared syringes or bags. Name similarities have also led to inadvertent mix-ups between morphine and hydromorphone, or the mistaken belief that hydromorphone is the generic name for morphine. Since opiates are typically in unit stock, these errors are rarely detected and, most often, they have led to significant overdoses; less often, they have led to undertreatment of pain or to an allergic response to the medication.

Practice-related problems. Misprogramming of the PCA pump is, by far, the most frequently reported practice-related issue. Pump design issues that have led to programming errors are described in the section that follows. Other practice-related issues that have contributed to PCA errors include incorrect transcription of prescriptions into pharmacy computers or medication administration records (often related to look-alike product names), calculation errors when determining the patient’s dose or rate of infusion, and IV admixture errors. Unavailability of hydromorphone in prefilled syringes or premixed bags necessitates IV admixture of this opiate. Drug shortages, most notably with fentanyl, also have required the use of less familiar products, such as sufentanil, which has led to serious dosing errors.

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Device design flaws. Programming a PCA pump requires multiple steps, but the pump’s design is often far from intuitive. In fact, two device models (Abbott Lifecare PCA II and APM Infusers) have been under close scrutiny for years because of the frequency of programming errors, many of which have resulted in patient deaths. Most of these programming errors have resulted because concentration settings for opiates such as morphine default to 0.1 mg/mL or 1 mg/mL, but a higher concentration is available and used. Other design flaws that have facilitated programming errors include pumps that do not require users to review all settings before the infusion starts, and pumps that require users to program the dose in mL, not mg, leading operators to overlook the amount of drug the patient is actually receiving. Siphoning (free flow) also has been reported after entrainment of air into the system due to
SafetyBriefs continued

PB, Wallace AE. Broadening the business case for patient safety. Arch Intern Med 2003;163:1112. First, although costs from malpractice claims are high—$27 million for adverse drug event claims alone in the Department of Veteran Affairs over 10 years—they are trivial in context of the overall health system budget (well less than 1% of total budget). Next, significant time delays between an incident, a claim, and legal settlement of the case often result in discounting the possibility of future malpractice costs; they may or may not materialize as a result of harmful errors. But the most disheartening reason that malpractice costs may not drive change is that the cost of medical errors is not borne fully by the organizations in which they occur. Patients and employers bear much of the burden through increased out-of-pocket expenses, sick time costs, and disability payments; malpractice insurers bear much of the legal costs; insurers (or employers, if self insured) bear the brunt of higher charges associated with care delivery, charges that may ironically result in higher revenues for the healthcare system. The physicians note that enumerating the indirect costs associated with medical errors, things like bad press, loss of contracts, and poor staff retention, are likely to be more motivating to decision makers in a competitive environment.

Successful meeting...

FDA, ISMP, and the Pharmaceutical Research and Manufacturers of America (PhRMA) conducted a public meeting, "Evaluating Drug Names for Similarities: Methods and Approaches," on June 26, 2003, in Washington, DC. Nearly 300 attended the full-day meeting, which focused on the design of premarket studies to detect drug name confusion, the need for validation, the use of technology such as handwriting and voice recognition, and the role of expert panels and computer-assisted decision analysis. One idea discussed was to have FDA establish "good naming practices (GNPs)" to guide manufacturers in conducting premarket name confusion studies. FDA plans to incorporate what was learned in a guidance document for the industry. Visit www.fda.gov/cder/meeting/drugnametran-script.doc for a transcript of the meeting.

PCA errors continued

A fractured glass syringe. It also may happen when a cassette breaks and detaches from a CADD pump that lacks attached anti-siphon tubing. Mechanical problems, such as short circuits, are possible but quite rare.

Other design flaws are related to the patient's use of the pump and are common to many PCA pumps currently on the market. First, the activation button looks just like a nurse call bell, so patients have inadvertently given themselves a dose of analgesic while believing they were pressing the button to call a nurse. Another problem is that, with lockout intervals set, unless the pump provides some visual or auditory feedback, patients cannot tell whether the press of the button has resulted in the actual delivery of medication. As a result, some patients press the button more frequently than they would with proper feedback, and others become frustrated and give up, resulting in undertreatment of pain. While pump manufacturers are required to perform human factors testing, this regulation is loosely enforced and these types of design problems may not be identified up front because practitioners and patients are not closely involved in the testing procedures.

Inadequate staff training. Entering a PCA prescription into a pump requires a number of steps. However, nurses may not always receive adequate training in pump programming, or they may not retain their proficiency once trained if multiple pumps are in use or if PCA is encountered infrequently. Additionally, prescribers may not undergo a credentialing process designed to verify proficiency with this form of pain management. Prescription errors, including improper drugs or doses, have resulted.

Prescription errors. The PCA order itself can be a source of error. Physicians have made mistakes in converting an oral opiate dose to the IV route (most problematic is hydromorphone, which has an oral to IV conversion range of 3:1 to 5:1). They have prescribed a drug to which the patient is allergic, and have selected an opiate that is not appropriate for the patient (meperidine in patients with renal impairment). Occasionally, one opiate has been prescribed but the accompanying dose has been appropriate for a different opiate. Even with correct PCA orders, clinicians have been known to mishear or misread verbal or written orders, sometimes leading to serious errors. Concurrent orders for other opiates (oral or parenteral) while PCA is in use has also resulted in opiate toxicity. As of yet, none of the PCA pumps have the safety features available in new general purpose "smart pumps," which alert when maximum doses or flow rates are exceeded.

Again, we thank our readers for giving us feedback about PCA errors. The information provided allowed us to share insightful examples describing just how PCA errors have happened. Part II in our next newsletter will cover the error-reduction strategies that were shared with FDA, which include a balanced approach of practice-related, system-related, product-related, device-related, and regulatory-related efforts. It's time we work together to reduce the risks associated with this wonderful technology.
In October 2006, an infant received a lethal dose of zinc stemming from an error that occurred during the order entry and compounding of a TPN solution. While not privy to a full root cause analysis, ISMP has learned details about the event\(^1\)\(^-\)\(^3\) which are offered below in the sincere hope that the lessons learned from this tragic event will be applied in hospitals across the nation to prevent similar tragedies.

**SUMMARY OF THE EVENT**

TPN was prescribed for a preterm infant born at 26 weeks gestation. On the day of the event, the physician’s TPN order included directions to add zinc in a concentration of 330 mcg/100 mL. Because the automated compounder used for TPN required entry of zinc in a mcg/kg dose, the pharmacist converted the mcg/mL dose to a mcg/kg dose. She performed this calculation correctly, but accidentally entered the concentration of zinc in the pharmacy computer in mg, not mcg. This resulted in a final concentration of 330 mg/100 mL—a 1,000-fold overdose. Another pharmacist checked the work and product labels that were printed for preparation of the TPN, but she did not notice the mg to mcg error. A pharmacy technician prepared the TPN using a 500 mL bag. The technician had to replenish the compounder syringe that contained zinc 11 times while preparing the solution, which required dozens of vials of zinc sulfate. Several TPN additives had to be added manually, which the technician prepared and brought to a third pharmacist to check before adding them to the solution. The final TPN bag was then dispensed to the neonatal intensive care unit (NICU).

Around 3 a.m., a nurse hung the bag of TPN. Around 6 a.m., the technician who prepared the TPN discussed the previous evening’s work with the oncoming lead technician, noting the unusual preparation of the TPN that required numerous replenishments of the zinc syringe. The oncoming technician checked the order, discovered the error, and alerted a pharmacist, who immediately called the unit to stop the infusion. The pharmacist quickly called Poison Control and searched the Internet for treatment guidelines. The infant received edetate calcium disodium (CALCIUM DISODIUM VERSENATE, also referred to as calcium EDTA), which had been compounded by an external pharmacy, but the chelation therapy was unsuccessful, and the infant died. The coroner listed cardiac failure caused by zinc intoxication as the cause of death.

**SYSTEM-BASED CAUSES OF THE EVENT**

The automated compounder required entry of the zinc additive in mcg/kg. A preprinted order form was used to prescribe neonatal TPN. The usual TPN ingredients listed on the order form prompted the physician to prescribe their doses by weight (e.g., mEq/kg, mg/kg). However, zinc was not listed on the form, so the physician wrote a free-text order for zinc, 330 mcg/100 mL. The pharmacist had to convert the dose to mcg/kg, after which she mistakenly chose “mg” instead of “mcg” from a pull-down list when entering the dose of zinc. The units of measure were next to each other on the pull-down list.

The method used to prescribe the zinc additive was different than the method required to enter the order into the automated compounder software program, which contributed to an order entry error.

Fatal 1,000-fold overdoses can occur, particularly to neonates, by transposing mcg and mg
Your Reports at Work continued

With the original packaging, these products were frequently confused, resulting in immunization of adults with the pediatric vaccine and vice versa. Similar brand names, generic designations, and vaccine abbreviations (Tdap, DTaP) also contribute to confusion; thus, mix-ups are still possible even with the new package design. Some drug references, drug information databases, and wholesalers reference Adacel’s component antigens as diphtheria, tetanus, and acellular pertussis rather than the way they are listed on the label, with tetanus toxoid first. Another factor that adds to the confusion is a federal regulation that requires labeling of nonproprietary names on labels of biologics above the brand name. This is inconsistent with the labeling of other drugs. Also, the font size and typeface of the nonproprietary name must be at least as prominent as that used for the brand name. To prevent mix-ups between these products, separate their storage and build alerts in computer software to warn practitioners about the differences between the adult and pediatric formulations. If possible, configure the order entry system to disallow selection of the wrong product based on the patient’s age. Also verify the patient’s age prior to dispensing or administering vaccines.

New design. In our October 19, 2006 newsletter, we mentioned a problem with PharMEDium’s use of a universal male-female cap to seal the port on IV minibags containing admixtures compounded for the Baxter APII pain management pump. The solid plastic cap had reversible fittings (female on one end, male on the other end), so it was possible to connect it to the Luer end of the pump’s tubing if the clinician forgot to remove the cap. Although the cap’s design looked like it would allow fluid to flow through it, the cap occluded the fluid pathway, which led to cases in which patients did not receive the intended drug. PharMEDium has now introduced a new cap for use with all pain management admixtures compounded in the Baxter APII containers. The new design features a proximal female Luer for connection to the minibag tubing, and circumferential fins inside the distal end of the cap to prevent connection to the pump’s tubing (see photo). We appreciate PharMEDium’s efforts to create a safe, sterile product designed to minimize the risk of errors.

Overdoses continued from page 1

The pharmacy computer order entry system and the automated compounding used to mix the TPN did not alert the pharmacist that a 1,000-fold overdose had been entered into the systems for the zinc additive.

The TPN order was processed during the evening when staffing was limited despite a hospital policy to receive TPN orders and prepare TPN solutions before 5 p.m.

On the day of the error, the physician prescribed the TPN at 4:30 p.m., but the order was not scanned and transmitted to the pharmacy until after 5 p.m. The pharmacist entered the order after 7 p.m. and the TPN solution was compounded later in the evening when less pharmacy staff were available to process complex orders such as TPN. Staffing was further reduced on the evening of the event due to the absence of a technician who typically compounded products.

Limited education and experience, along with ineffective competency validation regarding compounding products, particularly for infants, contributed to the technician’s failure to notice the TPN order entry error.

The technician who prepared the TPN did not have sufficient orientation or experience to immediately appreciate the significance of the large volume of zinc required by the automated compounder to prepare the TPN. Her prior training consisted of a week of shadowing another technician, during which she compounded fewer than 20 products using the automated compounder. In that time, she had never replenished a syringe on the compounder. Although she thought it unusual to replenish the zinc syringe 11 times during the course of making the TPN, she did not mention this to a pharmacist. (Zinc was typically added to TPN manually due to the small volume needed, but the compounder was used in this case because the error resulted in directions to add a large volume of the zinc to the bag.) The inexperienced technician also did not think to question the need to use a 500 mL bag to make the TPN, rather than a 250 mL bag which was typically used for neonatal TPN. Concerns about the technician’s level of training had been raised by staff previously, but on the day of the event, the technician had been asked to compound a few products because the usual compounding technician was not available.

The technician reported the unusual circumstance of replenishing the zinc syringe 11 times while compounding the TPN to the lead technician the following morning, but she did not mention her concern to the on-duty pharmacist on the evening of the event.

The inexperienced technician reported feeling intimidated talking to the pharmacist about a condition she found potentially unusual, when she was uncertain whether it signaled an actual error. She believed the pharmacist who entered the order must be correct, and that she should not question the pharmacist.

Ineffective or nonexistent systems for independent double-checks allowed the error to bypass at least six staff members without notice.

At several points during the dispensing and administration process, pharmacists or nurses checked the TPN orders and/or labels, but the error was not recognized. The first check failed, primarily due to human error, when the pharmacist who compared the work and product labels to the original order did not notice that the zinc dose was expressed in mg, not mcg. The next faulty check involved verifying only the additives that had been added manually to the TPN. Hospital policy only required pharmacists to check the vials and syringes of the additives against the label; they were not required to compare the TPN product label to the original order. To verify the additives, the pharmacist in this case looked at the identifying information on the top of the label, and then skipped down to the bottom of the label to identify the additives to be added manually, thus failing to read the middle of the label which noted that 481.8 mL of zinc had been added to a bag that contained 560 mL. Another ineffective check occurred in the
Worth Repeating...

Preventing mix-ups between various formulations of amphotericin B

The National Patient Safety Agency in the United Kingdom (UK) issued a medication alert on Monday warning healthcare providers of the risk of confusion between different formulations of intravenous amphotericin used to treat serious fungal infections. Alerts issued by ISMP since 1997 and by ISMP Canada since 2002 have called attention to mix-ups between the lipid-based and conventional formulations of this drug. Mix-ups have led to overdoses—sometimes fatal—or underdoses resulting in subtherapeutic treatment. Two recent deaths in the UK prompted a call for the country’s hospitals to take action, such as the suggestions noted below, which are based on prior ISMP recommendations.

1. Conventional amphotericin B deoxycholate doses should not exceed 1.5 mg/kg daily.
2. Encourage prescribers to communicate orders using both the proprietary name and the complete generic name: FUNGIZONE (amphotericin B deoxycholate), AMBISOME (amphotericin B liposomal), ABELCET (amphotericin B lipid complex), and AMPHOTEC (amphotericin B cholesteryl sulfate complex). List both the generic and brand names on protocols, preprinted orders, pharmacy labels, and medication administration records (MARs).
3. Include the patient’s weight in kg and dose calculations as part of the prescription.
4. Verify the dose if you are unfamiliar with the drug and/or usual dose prior to prescribing, dispensing, and/or administering the drug.
5. Ensure that detailed, technical drug information is easily and readily accessible in clinical areas that use amphotericin products.
6. Add a warning statement to all IV administration guidelines or drug charts produced by the hospital specifically describing the risks associated with these products.
7. Restrict the preparation and dispensing of amphotericin products to the pharmacy.
8. Differentiate or separate the storage of different formulations of amphotericin within the pharmacy (and in other areas where the drugs might be stored). Use cautionary labels to remind staff about the differences between the products. Add these statements to MARs.
9. Require an independent double-check before administering amphotericin products.

Overdoses continued from page 2

NICU unit. One nurse read the “numbers” associated with the dose for each ingredient from the TPN label, but not the units of measure (e.g., mg/kg, mg/dL), to another nurse who was reading the original order. While the “numbers” (including “330” for the zinc additive) matched, the accidental entry of mg instead of mcg was, again, not noticed. Sadly, many clues that pointed to the error were overlooked during the verification processes, including the fact that the TPN bag was unusually large—bigger than the infant herself. One final note about check systems: The pharmacist’s initial calculation to change the mcg/mL dose to a mcg/kg dose was never verified by another pharmacist. Although the calculation in this case was correct, and the check would have averted the error, an independent double-check of calculations should always occur.

Safe Practice Recommendations

- Standardize the prescribing methods.
  Standardize the method of ordering TPN solutions (and other routinely compounded solutions) for neonates, pediatric patients, and adults, so that each prescribed ingredient matches the dosing templates used for entering the orders into the computer system and automated compounding. Use preprinted forms or standard order sets that list typical ingredients and prompt the correct dosing method. On the rare occasions that calculations are necessary, require two clinicians to calculate the dose independently and compare their answers for verification.

- Prescribe and transmit TPN orders during the day.
  Policies that require prescribers to order TPN daily during the day shift should be established and enforced to maximize the safety with which these solutions are prepared and dispensed. Pharmacy staff should be aware of patients who are receiving TPN and check if orders have not been received by the established time.

- Allow manual-only additions of low volume ingredients.
  For TPN ingredients that typically require very small volumes, require staff to prepare, check, and inject those ingredients manually. Do not allow a trace element such as zinc to be loaded on a compounding for automated preparation.

- Build, test, and heed automated warnings.
  Install, test, and maximize automated dose-limit warnings in the pharmacy computer system and automated compounders, particularly for high-alert medications such as TPN and its ingredients. Baxa, an automated compounding vendor with a large share of the hospital market, allows users to add soft warnings and hard stops if a dose limit is breached when entering an order. The company’s more recent compounding software has “catastrophic” limits that stop the process completely when 100-fold or 1,000-fold overdoses caused by decimal point errors or mcg to mg selection errors occur. Consider printing all alerts encountered during the order entry process so the person checking the order entry can also view and respond to the alerts. Reinforce the importance of reading and reacting to the alerts with all staff.

- Heighten the suspicion of an error.
  Continually emphasize that the following should trigger a full review of the patient’s medications and treatment plan to ensure an error has not occurred:

  - The need to use more than a few dosage containers (whether it be tablets, capsules, vials, ampuls, etc.) to prepare or administer a single dose of any medication
  - Unexpected differences in the appearance of medications or solutions
  - Other unusual circumstances regarding a medication or solution
  - Unexpected patient response to a medication.

Technicians who compound products should be required to stop the process if they encounter situations in which they need to add an electrolyte or mineral in large doses or in large volumes in order to complete a single preparation. A full review of the work label and order by a pharmacist should be required before proceeding. Nurses who work in pediatric and neonatal units should question products...
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Worth Repeating... continued

10. Include liposomal forms of drugs on your organization’s list of high-alert medications; such products are included on ISMP’s list (www.ismp.org/Tools/highalertmedications.pdf).


Look What’s New!

Special Announcement…

ISMP-USP workshops. ISMP and USP are offering workshops on collecting, analyzing, and prioritizing adverse drug event data. The full-day programs, Using Data Effectively to Manage the Risks to Medication Safety, will be held in Tampa, Chicago, Rockville, and Las Vegas, between September and December 2007. Participants will learn how to select effective risk-reduction strategies and the best way to report findings to demonstrate improvement. Breakout sessions will offer participants an opportunity for hands-on practice working with safety data. For details, visit: www.ismp.org.

Overdoses continued from page 3 that are dispensed in larger quantities than typically supplied for children or neonates. Create a culture that encourages all staff, despite their level of experience or education, to speak up about unusual conditions. (See our March 11 and March 25, 2004, issues for suggestions to reduce staff intimidation.)

 Carry out effective redundancies. Conduct independent double-checks during the dispensing and administration processes associated with TPN. At least three verification processes should occur in the pharmacy: after initial order entry of TPN; before manually injecting additives into the TPN; and once the TPN has been compounded. Each verification should require a pharmacist to compare the actual prescriber’s order to the printed labels, and the printed labels to the additives and final product, as appropriate. Verification of manual additives should include inspection of the actual vials and syringes that contain the additives. The final verification of the compounded TPN should include a comprehensive review of the TPN order, the label on the product, and the work label. As appropriate, quality control checks and verification of replacement solutions on the compounding either manually or via bar-coding should also be required, as should an independent double-check of any calculations. Before administering TPN, two nurses should also independently compare the label on the solution with the physician’s order.

 Provide education and validate competency. Establish a formal training process for pharmacy staff who are required to enter TPN orders into the pharmacy computer, compound the solutions, or check the products after preparation. Designate and train specific staff members to function as preceptors and provide one-on-one supervision until trainees are comfortable providing the service and have demonstrated the skills and knowledge necessary to function independently. Training should focus on dose and dose concentration, not just the volume of additives, when preparing the solutions. If compounding services are provided for neonatal and pediatric patients, include age-specific training emphasizing weight-based dosing, and validate the competency of all staff who serve the pediatric population. Develop learning modules and competency validation tools to expose trainees to a broad spectrum of responsibilities that they might not encounter during their on-the-job orientation. Plan adequate staffing with trained practitioners to cover vacations, illnesses, and other causes of planned and unplanned absences. Establish guidelines for closer supervision of work if emergency coverage with an inexperienced staff member is necessary.


ISMP thanks the Nevada State Board of Pharmacy for its contribution to the above article by sharing many of the details of its investigation of the event with ISMP.

September: Caution on No-Name Drug Patches; Preventing Patient Deaths from Fentanyl Patches
July: Avoiding Dangerous Mix-ups between Insulin and Heparin
June: Preventing Drug Mix-Ups: Bumetanide and Norpinephrine
March: Possible Dose-Counter Errors with the Asmanex Twisthaler

PDUFA IV. The Pharmaceutical Research and Manufacturers of America (PhRMA) issued a news release last month that acknowledged creation of a “good naming practices” (GNPs) document as noted in our August 9, 2007, newsletter article, Progress with preventing name confusion errors. PhRMA noted that the PDUFA IV (Prescription Drug User Fee Act IV) legislation before Congress addresses GNPs but goes even further because it allows FDA to implement other measures to reduce medication errors. For example, it would fund development, in consultation with industry, academia, and others, of guidance statements on proprietary name evaluation and on naming, labeling, and packaging of drugs and biologics. FDA would also initiate a pilot program for industry to submit data in support of drug names. We expect that approval would be based on testing protocols that use healthcare practitioners and safety experts to evaluate names for look-alike and sound-alike similarity, something that ISMP and others have previously suggested.

Free FDA patient safety videos. The latest medication safety-related videos, developed by FDA in cooperation with ISMP, are now available free for viewing or downloading on the ISMP website (www.ismp.org/Tools/fdavideos.asp). See below for the latest 2007 offerings.

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Medication Error Prevention in the Home Setting: A Proactive Approach to Safety

Answers:
1. E
2. B
3. C
4. D
5. B
SHAPING OUR HORIZON

Maximizing 20 Years of Achievement to Craft a Future of Possibilities