March 12, 2009  Volume 14 Issue 5

Safety Briefs

Purchase eye meds with care.
A pharmacy technician reported a look-
like packaging issue with Bausch and Lomb’s
polyoxym B and trimethoprim ophthalmic
solution, and the company’s neomycin, polyoxym
B, and gramicidin ophthalmic solution. The
technician had just read our February 26 article,
“Inattentional blindness: What captures your
attention?” and thought these
products were a great example of the lack of conspicuity—the degree
to which an object or piece of infor-
mation “jumps out” and captures
your attention? Wha t jumps out here
is the name of the company and
the highly stylized graphics, not the
names of the drugs in each
package (see photo). We agree with
the technician who noted that these
products are certain to be confused.

The problem of packaging similarities with
ophthalmic medications is related in part to FDA
approval of a color-coding system by pharmaco-
logic class, making all products within a class the
same color. All anti-infectives are tan; anti-inflam-
matories/steroids are pink; mydriatics and cyclo-
plegics are red; nonsteroidal anti-inflammatories
are gray; miotics are dark green; beta-blockers
are yellow; beta-blocker combinations are dark
blue; adrenergic agonists are purple; carbonic
anhdyrase inhibitors are orange; and prosta-
glandin analogs are turquoise. This is one of many
examples of dangerous, confusing ophthalmic
labeling mentioned in this newsletter. It remi-
nds us that group purchasing organizations, phar-
macies, and hospitals should purchase and use a
different manufacturer for individual ophthalmic
products within each class, whenever possible.

continued on page 2

Beware of basal opioid infusions with PCA therapy

Problem: A 63-year-old, 109 kg, opioid-
naive patient was admitted to a hospital
with fractures sustained in a fall. She was
given two doses of morphine 4 mg and one
dose of HYDROMORPHINE 1 mg in the
emergency department. Upon arrival to the
inpatient unit, she was started on HYDRO-
morphine PCA (patient controlled analgesia),
which included a basal infusion
of 0.5 mg per hour, a demand
dose of 0.2 mg with a lockout
interval of 10 minutes, and a 4
hour limit of 6 mg. Continuous
pulse oximetry was not in use.
Five hours later, the patient was
found unresponsive. Her respira-

tions were six per minute, and
her nail beds were beginning to
turn blue. Oxygen saturation
was checked with pulse oximetry and found to be 44%.

The rapid response team was called,
oxygen was started, and two doses of
naloxone were administered. In 15
minutes, the patient was alert and
talking. It was then that the patient
told a nurse she has sleep apnea and had
previously used a continuous positive airway
pressure (CPAP) machine at home. She
hadn’t been using the CPAP recently. So,
when the admitting nurse asked her if she
used any medical equipment at home, she
said “No.” The patient’s body mass index
(BMI) was 38.6 (BMI of 40 or more is
morbid obesity), placing her at risk for sleep
apnea and hypoxemia during PCA therapy.

Although no permanent harm ensued, the
hospital’s medication safety team used this
case as a learning opportunity. Three root
causes of the event were identified, as
described below.

Dosing guidance. The PCA standard order
form did not help guide prescribers to
appropriate doses; instead, it provided a
broad range of doses. For example, the range
for a HYDROMORPHINE basal infusion dose
was 0.1 to 0.5 mg/hour, and there was no
guidance for selecting appropriate candi-
dates for basal infusions. Many prescribers
routinely selected a 0.5 mg/hour basal
infusion, regardless of patient characteris-
tics. A basal opioid infusion was not ap-
propriate for this opioid-naive patient.

Studies have shown that patients with
basal opioid infusions are at least five times
more likely to experience respiratory
depression.1-4 The American Pain Society
cautions against using continuous
basal infusions because studies have
failed to demonstrate significant
differences in the quality of analgesia
with or without basal infusions.4 There may
also be an increased risk of programming
events when basal infusions are prescribed.5

Patient screening. The patient was not
sufficiently screened for obstructive sleep
apnea (OSA) and other risk factors for
PCA-induced respiratory depression. The
facility had an OSA screening process in
place for pre-operative patients, but
screening did not occur because this
patient was not a surgical candidate. The
incidence of respiratory depression in PCA
patients ranges from 0.19 to 5.2 percent,
depending on how it is measured.1-4 Figure
1 includes risk factors for respiratory
depression in PCA patients.

Patient monitoring. No process was in
place to trigger an evaluation of the need
for continuous pulse oximetry monitoring
(or capnography for appropriate patients)
during PCA.

continued on page 2

Figure 1. Risk factors for respiratory
depression in PCA patients

<table>
<thead>
<tr>
<th>Use of basal infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced age</td>
</tr>
<tr>
<td>Obesity</td>
</tr>
<tr>
<td>Upper abdominal surgery</td>
</tr>
<tr>
<td>Obstructive sleep apnea</td>
</tr>
<tr>
<td>Concurrent use of CNS depressants</td>
</tr>
<tr>
<td>Impaired renal, pulmonary, hepatic, or cardiac function</td>
</tr>
<tr>
<td>Pump programming errors</td>
</tr>
<tr>
<td>Families pushing PCA buttons (PCA by proxy)</td>
</tr>
<tr>
<td>Lack of opioid tolerance</td>
</tr>
</tbody>
</table>
**Basal Infusions continued from page 1**

**Safe Practice Recommendations:** The hospital’s medication safety team addressed these root causes by standardizing the PCA dosing process and revising the standard PCA order form as described below:

- Prescribers are guided to an appropriate dose based on age and opioid tolerance by providing default doses for three types of patients: most patients, patients over 64 years or with sleep apnea, and opioid-tolerant patients (see Figure 2).
- Basal infusions were eliminated except in opioid-tolerant patients.
- Basal infusions in patients with sleep apnea were prohibited.
- Opioid orders were rearranged to match the sequence in which the medications appear on the facility’s smart IV pumps.
- A registered nurse is required to screen the patient for OSA before PCA initiation, with further assessment by a respiratory therapist if the screening shows two or more risk factors (see Figure 3).
- Continuous pulse oximetry (or capnography if appropriate) is required while on PCA if the patient has a continuous opioid infusion or sleep apnea, or if the patient is morbidly obese or older than 64 years.
- Patient education is required and must include instructions to the patient’s family not to push the PCA button for the patient (PCA by proxy).

The hospital also uses smart pumps for PCA therapy, with one standardized concentration for each drug and dose limits set in the pump library. Before converting to smart pumps, two PCA programming errors had occurred in recent years, leading to serious respiratory depression. Vast improvements in programming accuracy have been reported since switching to the smart pumps.

In our February 22, 2007 newsletter (www.ismp.org/Newsletters/acuteCare/articles/20070222.asp), we recommended avoiding basal infusions unless the patient is opioid-tolerant. Unfortunately, the term “opioid-tolerant” is not well understood. It is defined as “those patients who have received opioids regularly for approximately 7 days or more.” Opioid-naïve patients who present with high opioid requirements may be an exception and require a basal infusion, but additional safety steps should be instituted under these conditions. Our July 24, 2003, newsletter includes many recommendations to improve PCA safety, including the following:

- Evaluate the patient’s level of pain, alertness, and vital signs, including rate and quality of respirations, every 2–4 hours.

**Figure 2. Recommended opioid doses on facility’s new PCA order form**

<table>
<thead>
<tr>
<th>HYDROMorphone</th>
<th>Most patients</th>
<th>Over 64 yrs or sleep apnea</th>
<th>Opioid-tolerant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PCA dose</strong></td>
<td>0.3 mg</td>
<td>0.2 mg</td>
<td>0.4 mg</td>
</tr>
<tr>
<td><strong>Lockout interval</strong></td>
<td>10 min</td>
<td>10 min</td>
<td>10 min</td>
</tr>
<tr>
<td><strong>Continuous dose</strong></td>
<td>none</td>
<td>none</td>
<td>0.3 mg/hr (with pulse ox)</td>
</tr>
<tr>
<td><strong>Maximum limit in 4 hrs</strong></td>
<td>4 mg</td>
<td>3 mg</td>
<td>6 mg</td>
</tr>
<tr>
<td><strong>Loading dose</strong></td>
<td>0.6 mg</td>
<td>0.4 mg</td>
<td>1 mg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MORPHINE</th>
<th>Most patients</th>
<th>Over 64 yrs or sleep apnea</th>
<th>Opioid-tolerant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PCA dose</strong></td>
<td>1 mg</td>
<td>0.7 mg</td>
<td>1.2 mg</td>
</tr>
<tr>
<td><strong>Lockout interval</strong></td>
<td>10 min</td>
<td>10 min</td>
<td>10 min</td>
</tr>
<tr>
<td><strong>Continuous dose</strong></td>
<td>None</td>
<td>None</td>
<td>2 mg/hr (with pulse ox)</td>
</tr>
<tr>
<td><strong>Maximum limit in 4 hrs</strong></td>
<td>20 mg</td>
<td>15 mg</td>
<td>30 mg</td>
</tr>
<tr>
<td><strong>Loading dose</strong></td>
<td>3 mg</td>
<td>2 mg</td>
<td>4 mg</td>
</tr>
</tbody>
</table>

Repeat loading dose IV every 4 hours if needed for breakthrough pain.

![ISMP Smart Pump Guidelines](image)

**In The News**

Patch advisory. FDA issued a public health advisory last week regarding transdermal patches worn during an MRI. In our April 8, 2004 newsletter, an FDA Advis-ERR noted that some patches are formulated with an aluminumized backing that could cause injury to the patient if worn during an MRI. Patches may also contain metal in a layer that is not visible or in contact with the skin. An MRI requires the use of radiofrequency (RF) pulses to create the magnetic resonance signal. Although the metallic component of patches is nonferromagnetic, a concentration of electrical currents sufficient to cause excessive heating or tissue damage is possible when the patch is within the RF field. Patients have reported skin burns at the patch site when wearing a patch during an MRI. Most, but not all, patches that contain metal have a label warning about the risk of burns during an MRI. According to the advisory, FDA was alerted in January to the missing warning on Teva Pharmaceuticals’ fentanyl transdermal system. An investigation found that the warning was also missing on other transdermal patches. As experienced recently by an ISMP staff member, MRI centers may not ask about medication patches. Therefore, hospitalized patients being discharged on a transdermal medication should be educated to remove the patch temporarily when undergoing an MRI. Also teach them how to reapply the patch after the procedure. Facilities should follow published recommendations concerning patients who wear patches (Kanal E, et al. ACR guidance document for safe MR practices: 2007. AJR 2007;188:1–27, and Guidelines for Screening Patients for MR Procedures and Individuals for the MR Environment, Institute for Magnetic Resonance Safety, Education, and Research: 2009; Available at: www.imrser.org).

**Figure 3. RN screening for sleep apnea**

- Is the patient’s body mass index greater than 25?
- Does the patient have a history of excessive daytime sedation?
- Does the patient have a history of snoring?
- Does the patient have a history of hypertension?

If two of the factors are positive, consult respiratory therapy for a modified Berlin sleepiness screening.

Please encourage your patients and staff to visit www.consumermedsafety.org often. It may save a life!
Basal infusions continued from page 2

- Evaluate 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 hypoventilation and nocturnal hypoaxia may occur.
- Employ early warning devices such as apnea alarms at night and pulse oximetry or capnography, which can alert practitioners to respiratory insufficiency.

Additional recommendations related to safe PCA use can be found in our July 24, 2003 newsletter (www.ismp.org/Newletters/acutecare/articles/20030724.asp).

Topical lidocaine gel and mammography

FDA issued an advisory last month (www.fda.gov/cder/drug/advisor/topical_anesthetics.htm) to remind patients, healthcare professionals, and caregivers about potentially serious hazards associated with overuse of topical anesthetics. The FDA report specifically mentioned a study that used topical lidocaine to reduce discomfort during breast mammography (Lambertz CK, et al. Premedication to reduce discomfort during screening mammography. Radiology 2008;248(3):765-72). Breast tenderness, anxiety, and anticipation of discomfort during the procedure often discourage women from getting screened. In the study of 418 women, some received a placebo gel, some received a pre-mammogram over-the-counter (OTC) analgesic such as acetaminophen, and some received the pre-mammogram OTC analgesic along with lidocaine gel. The OTC analgesics alone did not reduce breast discomfort, but women who also received lidocaine gel experienced about 20% less pain and discomfort.

In the alert, FDA expressed concern that, as more and more women learn about this study via the Internet, other media sources and word of mouth, improper use of topical anesthetics prior to mammography will rise. Excessive absorption of the drug may cause life-threatening side effects such as cardiac arrhythmia, seizures, breathing difficulties, coma, and even death. There are several topical anesthetics available by prescription or OTC, including lidocaine in up to a 5% concentration.

Topical lidocaine gel and mammography

Our February 10, 2005, newsletter (www.ismp.org/Newletters/acutecare/articles/20050210.asp) highlighted two fatal events involving young women who died after receiving pharmacy-compounded topical lidocaine and tetracaine creams prior to laser hair removal. Improper use of these products may result from:

- Applying too much topical anesthetic
- Using highly concentrated topical anesthetics
- Applying to a large area of skin
- Applying to irritated or broken skin
- Covering the skin with a wrap or using a heating pad after applying the topical anesthetic (skin temperature can also increase during exercise).

FDA notes that if a topical anesthetic is recommended, patients should:

- Apply the topical anesthetic sparingly
- Use a topical anesthetic that contains the lowest amount possible of medication that will relieve the pain
- Apply the topical anesthetic only to the area where pain exists or is expected
- Do not apply the topical anesthetic to broken or irritated skin
- Be aware that if wrapping or covering the skin with any type of material or dressing is recommended or considered, this can increase the chance of serious side effects, as can applying heat to the treated area while the medication is still present
- Ask the doctor what side effects are possible and how to lower the chance of life-threatening effects from anesthetic drugs.
10-Minute ISMP Survey on Look-Alike and Sound-Alike (LASA) Drug Names

Please take a few minutes to complete our short survey on look-alike and sound-alike (LASA) drug names, and submit your responses by April 17, 2009, via our website at: www.ismp.org/survey/Survey200902.asp (or fax to 215-914-1492 if Internet access is unavailable). We are very interested in the opinions of all staff involved in the medication use process, including unit secretaries who transcribe medication orders and pharmacy technicians who help dispense medications. Even if you know little about the topic, ISMP would sincerely appreciate your response to the survey. The survey is longer than usual only because the table for question 10 is detailed to make it easy for you to pick your responses. Completing the survey should take about 10 minutes or less. Thank you for participating in our survey!

1) Does your organization maintain a targeted list of look-alike and sound-alike (LASA) drug name pairs that could be confused with each other?
   □ Yes □ No □ Don’t know (If you answered “No” or “Don’t Know,” skip to question 13)

2) Without looking at your organization’s LASA drug name pairs list, how many of the name pairs can you cite from memory?
   □ None □ A few □ Half □ Most □ All

3) After checking your organization’s LASA drug name pairs list, how many drug name pairs are on it?
   □ 1-5 □ 6-9 □ 10 □ 11-15 □ Greater than 15

4) How did your organization select the LASA drug name pairs on the list? (Check all that apply)
   □ The Joint Commission LASA list □ FDA list of drug name pairs with recommended tall man letters
   □ ISMP LASA list □ ISMP list of drug name pairs with recommended tall man letters
   □ USP LASA list □ Staff reports of mix-ups or potential mix-ups between drugs with LASA names
   □ Professional or trade literature □ Don’t know
   □ Other: __________________________________________________________

5) Have you added any new drug name pairs to the LASA drug name pairs list since compiling the initial list in your organization?
   □ Yes □ No □ Don’t know

6) Has your organization identified risk-reduction steps to reduce confusion between the drug name pairs on the list?
   □ Yes □ No □ Don’t know (If you answered “No” or “Don’t Know,” skip to question 13)

7) Has your organization implemented all or some of the risk-reduction steps identified for your organization?
   □ Implemented all □ Implemented some □ Implemented none □ Don’t know

8) How did your organization establish the risk-reduction steps for the list of LASA drug name pairs? (Check all that apply)
   □ Analysis of your medication use system □ ISMP website/resources □ Don’t know
   □ Best practices/recommendations in the literature □ Staff suggestions
   □ The Joint Commission website/resources □ Safety-focused committee deliberations
   □ Other: __________________________________________________________

9) Do the risk-reduction steps taken in your organization address the following phases of the medication use process?
   Procurement: □ Yes □ No □ Don’t know □ Drug Storage: □ Yes □ No □ Don’t know
   Prescribing: □ Yes □ No □ Don’t know □ Transcribing: □ Yes □ No □ Don’t know
   Dispensing: □ Yes □ No □ Don’t know □ Administration: □ Yes □ No □ Don’t know

continued on page 5
10) Please tell us whether your organization has employed the risk-reduction steps listed in column A.

<table>
<thead>
<tr>
<th>A. Risk-reduction Steps</th>
<th>B. Are the steps taken in your organization?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes Fully</td>
</tr>
<tr>
<td>1 Limit Access</td>
<td></td>
</tr>
<tr>
<td>a. Avoid unit stock of certain concentrations, strengths, forms</td>
<td></td>
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<tr>
<td>b. Dispense the targeted drugs in unit doses</td>
<td></td>
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<tr>
<td>c. Limit use to a single product/strength</td>
<td></td>
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<tr>
<td>d. Limit variety of stock in patient units</td>
<td></td>
</tr>
<tr>
<td>2 Separate Storage</td>
<td></td>
</tr>
<tr>
<td>a. Separate LASA drugs in pharmacy</td>
<td></td>
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<tr>
<td>b. Separate LASA drugs in patient units</td>
<td></td>
</tr>
<tr>
<td>c. Separate storage of different strengths, forms, and releases (e.g., immediate/sustained)</td>
<td></td>
</tr>
<tr>
<td>3 Differentiate</td>
<td></td>
</tr>
<tr>
<td>a. Stock potentially confused drugs in different strengths (e.g., morphine/HYDROMorphone)</td>
<td></td>
</tr>
<tr>
<td>b. Change appearance of LASA names on computer screens (e.g., bold font/color/tall man letters)</td>
<td></td>
</tr>
<tr>
<td>c. Change appearance of LASA names on shelves/bins (e.g., bold font/color/tall man letters)</td>
<td></td>
</tr>
<tr>
<td>d. Change appearance of LASA names on pharmacy labels (e.g., bold font/color/tall man letters)</td>
<td></td>
</tr>
<tr>
<td>e. Use auxiliary labels</td>
<td></td>
</tr>
<tr>
<td>f. Affix “name alert” stickers to areas where look- or sound-alike products are stored</td>
<td></td>
</tr>
<tr>
<td>4 Add Redundancy</td>
<td></td>
</tr>
<tr>
<td>a. Prescribe by brand and generic names</td>
<td></td>
</tr>
<tr>
<td>b. Include brand and generic names on MARs</td>
<td></td>
</tr>
<tr>
<td>c. Employ double-checks (manual)</td>
<td></td>
</tr>
<tr>
<td>d. Employ double-checks (technology—bar coding, electronic prescribing)</td>
<td></td>
</tr>
<tr>
<td>e. Print daily medications from the pharmacy computer system for physician review</td>
<td></td>
</tr>
<tr>
<td>5 Improve Access to Information</td>
<td></td>
</tr>
<tr>
<td>a. Specify the drugs’ indication when prescribing medications</td>
<td></td>
</tr>
<tr>
<td>b. Display entire drug names on screen when stems are used as a mnemonic (e.g., “Met”)</td>
<td></td>
</tr>
<tr>
<td>c. Specify the dosage form, drug strength, and complete directions on prescriptions</td>
<td></td>
</tr>
<tr>
<td>d. Consider the possibility of name confusion when adding a drug to the formulary</td>
<td></td>
</tr>
<tr>
<td>e. Utilize computer alerts to remind providers about potential problems</td>
<td></td>
</tr>
<tr>
<td>6 Include the Patient</td>
<td></td>
</tr>
<tr>
<td>a. Advise patients taking LASA drugs about the risk of mix-ups and how to avoid them</td>
<td></td>
</tr>
<tr>
<td>b. Encourage patients to question medications that look different than expected</td>
<td></td>
</tr>
<tr>
<td>c. Investigate patient concerns about drug appearance</td>
<td></td>
</tr>
<tr>
<td>7 Ensure Staff Awareness</td>
<td></td>
</tr>
<tr>
<td>a. Periodically educate staff involved in handling LASA drugs about risks and risk-reduction strategies</td>
<td></td>
</tr>
<tr>
<td>b. Ensure knowledge of differences among LASA drug name pairs (e.g., lipid vs. conventional products, morphine vs. HYDROMorphone)</td>
<td></td>
</tr>
<tr>
<td>8 Others</td>
<td></td>
</tr>
<tr>
<td>Please list:</td>
<td></td>
</tr>
</tbody>
</table>

11) Do you believe the risk-reduction strategies taken in your organization to guard against confusion with LASA drug name pairs have been effective?
☐ Yes ☐ No ☐ Don’t know

12) Do you believe the risk-reduction strategies taken in your organization to guard against confusion have prevented you from making a mistake?
☐ Yes ☐ No ☐ Don’t know

13) Please check the category that best describes you.
☐ Staff Pharmacist ☐ Clinical Pharmacist ☐ Pharmacy Director/Manager ☐ Pharmacy Technician ☐ Unit Secretary
☐ Staff RN ☐ Staff LPN/VPN ☐ Nurse Clinical Specialist ☐ Nurse Manager
☐ Nurse Educator ☐ Quality/Risk ☐ Physician ☐ Other: _____________________________