ISMP MEDICATION SAFETY ALERT!

Volume 7, Issue 10
May 15, 2002
Educating the healthcare community about safe medication practices

Safety Briefs

?"AD" is used sometimes as an abbreviation for right ear (aura dexter). One problem with this abbreviation is that a handwritten lower case "a" can easily look like an "o." Thus, a patient might risk getting an otic medication into the right eye (OD-oculus dexter) instead of the right ear, as occurred in a recently reported error. The physician had ordered **AURALGAN** (antipyrine, benzocaine, glycerin) two drops AD for an emergency room patient, but the nurse administered the drops into the patient's right eye. When the error was discovered, the eye was flushed and the patient suffered no permanent harm. Using AS for left ear or AU for each ear might cause similar problems. In addition, AD has been misread as QD (if the tail of a handwritten lower case "a" looks like a "q") and PO (when poorly handwritten). In fact, in 1975, in one of the earliest errors we ever published (Cohen MR. Medication error reports. *Hosp Pharm* 1975;10:167), a patient nearly received ear drops by mouth! Recently, yet another type of error has surfaced with the abbreviation AD. Tired of writing out "as directed" when transcribing prescriptions received by telephone, a pharmacist began to abbreviate that term as AD. Later, a pharmacy technician misinterpreted the directions for an oral liquid prescription transcribed as "5 mL TID AD" and typed the directions as "one teaspoonful three times a day in right ear." It seems like AD would be a good abbreviation for all of us to avoid!

?At a mail order pharmacy, prescription directions for **FOSAMAX** (alendronate) 70 mg tablets (indicated for once a week dosing only) were erroneously typed with directions to take the medication daily. A pharmacist recognized the error before the drug was dispensed because the 70 mg package was available in the pharmacy only in a unit-of-use blister package containing four doses. Hypocalcemia, hypophosphatemia, upset stomach, heartburn, esophagitis, gastritis, or ulcer may have resulted from the overdose. In our April 3, 2002 issue, we wrote about erroneous daily dosing of methotrexate when weekly dosing is indicated. As mentioned, errors are possible because relatively few medications are dosed on a once weekly basis. This latest incident should support the recommendation to prescribe and dispense unit-of-use dose packs when oral methotrexate or other medications are supposed to be taken on a weekly basis.

?In our April 17, 2002 issue, we mentioned possible confusion between **INVANZ** (ertapenem), a new antibiotic, with **AVINZA** (morphine sulfate extended release). This week, we heard that a physician wrote an order for Invanz 1 g IV q 24 h and the pharmacist misinterpreted this as "IV Vanc" 1 g q 24. The patient received one dose of vancomycin, but suffered no harm. Word stems used for drug names (like "Vanc") are prone to misinterpretation. In this case, the prescriber had not used a word stem when writing the order, but if the pharmacist had called to verify his interpretation of what he thought was a word stem, the error could have been

Atrocious labeling of plastic ampuls needs action now by FDA and manufacturers

PROBLEM: For nearly a decade, practitioners have been reporting concerns with the labels on respiratory therapy medications packaged in plastic (low density polyethylene - LDPE) ampuls, making this one of the more frequent product problems reported to the USP-ISMP Medication Errors Reporting Program. These concerns are well founded. Many products from various manufacturers (Alpharma, AstraZeneca, Dey Labs, Genentech, Nephron, Roxane, Sepracor, Zenith-Goldline, and others) are packaged in look-alike plastic ampuls with little difference in shape or color. Even worse, the ampuls have the drug name(s), strength, lot number and expiration date embossed into the plastic in transparent, raised letters, making it virtually impossible to read.

Practitioners have reported confusion between plastic ampuls of ipratropium (**ATROVENT**), albuterol (**PROVENTIL**), levalbuterol (**XOPENEX**), budesonide (**PULMICORT RESPULES**), dornase alfa (**PULMOZYME**), and cromolyn (**INTAL**). See our web site for pictures. Staff may not notice that a newer product, **DUONEB**, contains both ipratropium and albuterol because the label is so hard to read. Some products in plastic ampuls, like Pulmicort, Xopenex, and **ACCUNEB** (albuterol), also are available in multiple dosage strengths, but poorly visible labels make it hard to tell the difference. The risk of a mix-up is heightened if staff keep various respiratory medications in their lab coat pockets or mixed together in a "respiratory bin" in a refrigerator. To make matters worse, some manufacturers (AstraZeneca, Avitro, Vital Signs) have introduced *injectable* products, such as heparin for IV flush use and **NAROPIN** (ropivacaine), a local anesthetic, packaged in LDPE ampuls that carry the same risk of error due to the poorly visible labels.

SAFE PRACTICE RECOMMENDATION: There's no doubt that better labeling of plastic ampuls is long overdue. So why has FDA allowed manufacturers to produce these products with unreadable, embossed labels? If a paper label is affixed to the ampul, or if the label information is embossed into the ampul using colored inks, there's concern that certain volatiles in the inks, adhesive and/or paper may ingress into the LDPE ampuls and potentially harm patients. While this concern is certainly valid, an unreadable embossed label is an unacceptable solution, even temporarily. If colored ink or paper labels *on the body* of a LDPE ampul is not safe at this time, then FDA should require such labeling *on the flashing portion* of the ampul that does not come into contact with drug solution. While this may require manufacturers to redesign the ampul's shape and retool the equipment used to produce it, the only safe alternative would be to disallow the use of LDPE ampuls.

Meanwhile, when other packaging alternatives exist (especially for injectables), practitioners and group purchasing organizations should avoid using products packaged in LDPE ampuls with embossed labels. For now, Dey Labs offers generic respiratory products (ipratropium, albuterol, cromolyn, and metaproterenol) in LDPE ampuls with readable, paper labels affixed. FDA is allowing Dey Labs to continue to produce these products in plastic ampuls with paper labels until more information is available (FDA will not allow Dey Labs to affix paper labels on newer products such as DuoNeb). Ensure that pharmacy staff order all respiratory medications and alert the manufacturers to ship the products separately (including different strengths) in well-marked boxes to promote accurate placement into storage. Keep the plastic ampuls in an outer package, which may be labeled more clearly, and avoid storing respiratory medications together in a single bin or lab coat pockets. If feasible, affix auxiliary labels to the products before

Safety Briefs *(cont'd)*

? A prescription for **ZOLOFT** (sertraline) Oral Concentrate 20 mg/mL, 60 mL, was taken to a pharmacy where a technician entered it into the computer. Not realizing that there are explicit directions on the bottle for use of this medication, he placed the computer-generated pharmacy label over the instructions on the bottle. The drug name, strength and NDC number remained visible. The pharmacist who checked the prescription was not familiar with the drug. With the manufacturer's directions covered up, he did not question the directions on the pharmacy label, which stated that the patient, an 11-year-old, should take 5 mL per day. Zoloft Oral Concentrate must be diluted before use. The packaging contains a dropper to remove the required amount of drug for mixing with 120 mL of water, ginger ale, lemon/lime soda, lemonade or orange juice ONLY. The dose must be taken immediately after mixing. When the patient's father picked up the prescription, he did not see the instructions to dilute the drug since the pharmacy label covered them. He later administered the undiluted drug to his child, who soon complained of a burning sensation in his throat. Concerned, the father called the pharmacy and discovered that he was supposed to dilute the medication before administration. Fortunately, the child suffered no permanent harm. Pharmacy labels, price labels, and other applied labels should never cover important manufacturer's label information. Pharmacists must be familiar with the proper use of products they dispense so they can provide important information to patients. Manufacturers need to know how their products are used in the field. Knowing that retail pharmacy labels often are applied directly to unit-of-use drug containers, it could be anticipated that the pharmacy label might hide the instructions and alternative methods might be needed to communicate the directions to a patient.

? There are currently two pneumococcal vaccines available in the US. Pneumococcal 7-valent vaccine (**PREVNAR**) is for routine immunization of infants and toddlers against pneumococcal bacteria that can cause life-threatening meningitis and blood infections. A pharmacist recently reported that this was confused with pneumococcal polyvalent vaccine (**PNEUMOVAX 23** or **PNU-IMUNE 23**), which is used for adults over 65 years of age, patients who are at increased risk of pneumococcal disease or its complications because of chronic illnesses, children over 2 years of age with chronic illnesses, and those with asymptomatic or symptomatic HIV infection. Three adult patients received Prevnar in error. The pharmacist read the top line of the Prevnar product, which reads Pneumococcal 7-valent, and thought it was the correct vaccine product. The brand name does not appear until the fourth line of the label and it is italicized, which makes it difficult to read. The first line of the Pneumovax product reads pneumococcal, and the brand name also does not appear until the fourth line. Both vaccines are stored under refrigeration, which may add to the risk of errors. In each of the above cases, the physicians and patients were notified of the error and an infectious disease consultant recommended revaccination with the adult product. The pharmacy now stores the vaccines in separate bins in different locations in the refrigerator. Also, they label the Prevnar bins, "For pediatric administration only." The vaccine manufacturers have been made aware of these errors. It should be noted that many vaccines are in short supply or are currently unavailable, including Prevnar.

Announcement

The Institute for Healthcare Improvement (IHI) is holding an international summit, *Innovations in Patient Safety*, June 12-14, 2002 in Salt Lake City. IHI has been collaborating with change-minded organizations in the comprehensive redesign of care systems to achieve dramatically improved levels of patient safety. You can learn about the summit on IHI's website at http://ihi.org.

Lidocaine absorption after topical application during bronchoscopy can lead to problems

PROBLEM: For topical anesthesia, a patient undergoing intranasal bronchoscopy was initially given 10 mL of 2% lidocaine jelly and was sprayed with **CETACAINE** (benzocaine and tetracaine) to anesthetize the upper airway prior to introduction of the bronchoscope. Subsequently, lidocaine 4% was administered to the tracheobronchial tree via the bronchoscope to achieve local anesthesia. In all, as much as 80 mL of lidocaine 4% was used. During the procedure, the patient had a seizure and lidocaine toxicity soon was suspected. The patient was intubated, given midazolam, and he recovered. Later, it was calculated that the patient received more than 3 g of topical lidocaine. Lidocaine is extensively absorbed, up to 35%, after topical administration to mucous membranes, which can lead to therapeutic and even toxic plasma levels.

We've written before about this subject. In our April 10, 1996 issue, we told the story of a 19-year-old student volunteer in a research protocol at a New York hospital. As part of the research, a pulmonologist performed a bronchoscopy using topical lidocaine for local anesthesia. Either the patient's size and weight were not taken into account, or there was a lack of recognition of the amount and extent of absorption of the topical lidocaine. The student was later discharged. At home, she had a seizure and arrested. She was resuscitated by paramedics and brought to the hospital, but she died two days later. The medical examiner confirmed that the cause of death was lidocaine toxicity. In other reported cases of toxicity, topical lidocaine solution had been prepared incorrectly from a more concentrated form or the wrong concentration had been used.

SAFE PRACTICE RECOMMENDATION: In the New York case, the State Department of Health ruled that the hospital had violated its own policy, which stated that lidocaine doses should not exceed 300 mg (http://www.health.state.ny.us/nysdoh/consumer/pressrel/96/wan.htm). The Merck Manual guidelines for bronchoscopy (17th edition, chapter 65) also recommend "trying to limit total lidocaine use to 300 mg" and guidelines from the Thoracic Society of Australia and New Zealand state that "the total recommended dose is 4 to 5 mg/kg" (http://www.thoracic.org.au/fibreopticbronchoscopypospaper.pdf). Doses as large as 600 mg have proven safe in asthmatics undergoing research bronchoscopy (Langmeck EL et al. Serum lidocaine concentrations in asthmatics undergoing research bronchoscopy. *Chest* 2000;117:1055-60). Extra care is needed in infants, the elderly, and those with liver or cardiac impairment. Many institutions lack adequate safeguards, including a specified maximum dosage of topical lidocaine. It is worth noting that, in teaching hospitals, first year pulmonary fellows often perform bronchoscopies. They may not be familiar with topical lidocaine's significant absorption and potential for neurotoxicity or cardiac toxicity, and they may not be working with experienced technicians. With new residents and fellows soon to arrive, it would be a good idea to let this article serve as a reminder to new house staff.

 Editors: Judy Smetzer, RN, BSN, Michael R. Cohen, RPh, MS, DSc; **Reviewers**: ISMP staff and Thomas Burnakis, PharmD, George Di Domizio, JD, Steve Meisel, PharmD, Thomas Paparella, DO, John Senders, PhD, Daniel J. Sheridan, MS, RPh, Joel Shuster, PharmD, BCPP. **Institute for Safe Medication Practices, 1800 Byberry Road, Suite 810, Huntingdon Valley, PA 19006. Tel. 215 947 7797; Fax 215 914 1492**; **E-MAIL: ismpinfo@ismp.org.**