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USP Patient Safety
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USP Patient Safety CAPSLink™

This message has been sent to you as a service of the U.S. Pharmacopeia, Center for the Advancement of Patient Safety (CAPS). USP is a not-for-profit, non-governmental organization that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies. CAPS is a component of USP's Patient Safety public health program. The USP Center for the Advancement of Patient Safety was created to encourage medication error reporting, conduct data analysis and research, develop educational programs, and propose standards, recommendations, and guidelines that ultimately improve the safety and quality of patient care.

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USP Medication Error Analysis

Drug Product Names Can Be Confusing

In a busy health care work environment, drug products are often mistaken for other products because of similar names. Many medication errors reported to the United States Pharmacopeia (USP) Medication Errors Reporting (MER) Program show that these errors can occur in prescribing, transcribing, or documenting the order or in dispensing and administering the medication and that they often result

in wrong-drug or wrong-dose errors.¹ Choosing a brand name can be critical to the success of a drug company's marketing efforts. The FDA does not evaluate all proprietary names for their potential to cause confusion and medication errors prior to product approval. However, of the proposed names it does evaluate, about one third are rejected.²

Proprietary Product Names

Confusion over the similarity of prescription and over-the-counter (OTC) drug names has accounted for as many as 25% of all reports to the USP MER Program.¹ Many of these reports involve the use of OTC brand names by a manufacturer for multiple products with different active ingredients--a practice called "brand name extension" by the pharmaceutical industry. To take advantage of name recognition among consumers and health care professionals, manufacturers like to give their new products names that are similar to the names of well-established, successful items in their product lines even though the active ingredients are not the same. This practice, however, can confuse users of the products and lead to medication errors.

Another potential problem arises when manufacturers include a portion of the company name in the proprietary name of drug products. For example, there are currently five prescription drug products on the market beginning with "rox." Errors resulting from confusion of the product names Roxicet®, Roxanol®, and Roxicodone® have been reported to USP. When Roxicet oral liquid (oxycodone 5 mg/5 mL and acetaminophen 325 mg/5 mL) 1–2 teaspoonfuls every 4 hours as needed for pain was ordered for a 24-year-old man with a fractured mandible, 10 mL of Roxanol 100 Concentrated Oral Solution (morphine sulfate 100 mg/5 mL) was given instead and the patient, subsequently, received 100 mg–200 mg of morphine sulfate instead of 5–10 mg of oxycodone). The patient experienced sedation, but his pulse and respiratory rate were unchanged. The error was discovered by a narcotics technician before additional doses were administered.

A pharmacy received a faxed prescription for Roxanol 10 mg/5 mL with instructions to give 1 mL every 2 hours as needed for distress to a 74-year-old female nursing home resident with breast cancer and numerous other health problems. A data entry technician at the pharmacy mistakenly selected a 20 mg/mL Roxanol product from a computer menu, and the error was not detected by the pharmacist who checked the order. A 1-mL dose of this product represents a ten-fold overdose. The patient received eight doses before a nurse detected the error. The patient later died.

Use of the term "concentrate" for oral morphine sulfate products is inconsistently applied to drug concentrations among manufacturers. For example, Roxanol Concentrated Oral Solution and Roxanol-T Concentrated Oral Solution (with tinting and flavoring) both contain morphine sulfate 20 mg/mL, but another marketed product, Morphine Sulfate Concentrate Oral Solution, contains 20 mg/5 mL. Errors related to the inconsistent use of product names when multiple concentrations or strengths are available might be avoided if prescribers would specify both the brand and the generic name, the concentration or strength, the

dose, and the volume per dose for liquids. A June 2003 letter from the U.S. Food and Drug Administration (FDA) urged prescribers of morphine sulfate oral solution to include the concentration, the intended dose of morphine in milligrams, and the corresponding volume in milliliters.³

Similar Brand Names for Products with Different Dosage Forms

Reports of errors involving the wrong dosage form (for example, the use of an immediate-release product when an extended-release form was intended) are not uncommon. Many of the errors involving confusion of immediate-release and extended-release products are attributed to the use of suffixes such as XR, SR, and XL in brand names of extended-release products. In one case, a 14-year-old boy was given a 30-mg dose of Procardia® (immediate-release nifedipine) instead of a 30-mg dose of Procardia XL (an extended-release dosage form).⁴ The boy was given intravenous fluids and kept in a supine position to manage the hypotension that resulted from the error.

In medical school, physicians often receive little formal education on adverse drug events and how to prevent them.⁵ After entering practice, they may find it difficult to stay fully informed about new drug products and dosage forms.

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) considered the contribution of brand name suffixes to medication errors at a recent invitational workshop. The Council plans to publish a summary of the meeting and consider recommendations to all stakeholders for addressing the suffixes problems.

Generic Name Confusion

Since the introduction of several new insulin products (for example, insulin lispro, insulin aspart, insulin glargine) in recent years, concerns have been raised about the potential for wrong drug and improper dose/quantity errors because of confusion about human insulin product names. In the past, insulin concentrations were standardized (100 units/mL), and a single letter (for example, L for Lente, R for regular, N for NPH) was prominently displayed on labels and packages to reduce the risk for error. Now, reports have been received indicating that insulin glargine (Lantus) and insulin lispro may be mistaken for Lente insulin.

The potential for unauthorized drug errors involving conventional amphotericin B and lipid-based amphotericin was recognized years ago.⁶ However, four different amphotericin B products are now marketed, including conventional amphotericin B (Amphocin®, Fungizone®, and a generic product), amphotericin B cholesteryl sulfate complex (Amphotec®), amphotericin B lipid complex (Abelcet®), and amphotericin B liposomal (AmBisome®). To differentiate among these products and prevent errors, it is essential to use the brand name.

Thus, although hospitals often require drug orders to be written with the generic name to prevent confusion among similar-sounding/appearing brand names,

generic drug names also have this problem. For example, cancer agents cisplatin and carboplatin have been confused with serious results. Likewise, other generic names such as doxorubicin and daunorubicin carry the same type of risk.

Error Prevention Strategies

- Conduct prospective systematic reviews of new drugs and dosage forms from a safety perspective prior to acceptance on the facility's formulary.
- Exclude, when possible, a problematic drug from the formulary or select an alternate manufacturer's product or stock a therapeutic substitute.
- Use computer programs/software to help reduce errors associated with ordering and dispensing look-alike or confusingly-named medications.
- Use bar-coding technology. In 2004 FDA finalized a regulation that will require that most prescription and nonprescription drug products commonly used in hospitals have bar codes that include, at a minimum, the National Drug Code (NDC) number.⁷ The NDC number identifies the product manufacturer, brand name, strength, and package size. However, the NDC numbering system, for which FDA is responsible, is not as accurate and consistent as is necessary for uniquely identifying drug products. For example, Kaopectate® New & Improved has the same NDC number as Kaopectate Advanced, despite the substitution of bismuth subsalicylate for attapulgate. A USP recommendation to FDA in 2002 that the proposed bar coding regulation require the use of NDC numbers was contingent on revisions of the NDC system to provide greater accuracy and consistency.⁸
- Exercise vigilance in keeping abreast of product reformulations, or when a new product has a similar name but not the same ingredients as an existing product. Educate patients about such differences.

Many of the medication errors reported to USP that relate to naming have stemmed from a lack of familiarity with product names and uses. USP has constructed a list of commonly confused drug names as well as "Tips for Using USP's Similar Names List" to help practitioners assess and reduce the risk of problems associated with look-alike and sound-alike drug names.^{9,10}

Health care professionals have an obligation to stay informed about labeling changes reflecting contraindications, precautions, and adverse reactions that become evident only when the product is used by a large number of patients. About half of all the drug products that enter the U.S. market are subsequently shown to pose serious risks that lead to changes in the labeling or removal from the market.¹¹ In a typical month, the FDA Center for Drug Evaluation and Research approves safety-related changes in the professional labeling of 30 to 40 products.¹² More effort is needed to ensure that prescribers read the product labeling (the package insert) so that they are aware of these important changes.

The American Society of Health-System Pharmacists guidelines on preventing medication errors call on drug manufacturers and FDA to obtain the input of pharmacists, physicians, and nurses in making decisions about drug names, packages, and labels.¹³ The guidelines encourage manufacturers to avoid sound-

alike and look-alike names, as well as packages and labels with a similar appearance for multiple products. They discourage the use of prefixes and suffixes in brand names. They recommend that information that is vital for patient safety, such as the product name and strength or concentration, be displayed prominently on packages and labels, and that changes in product formulations or dosage forms be communicated to health care professionals.¹³

Patients and their caregivers can help reduce the risk of errors related to product name confusion by learning the names, strengths or concentrations, doses, and dosing schedules of their medications.¹⁴ Patients should be assertive in questioning health care professionals when medications seem incorrect (for example, when a medication looks different from what the patient is accustomed to using).¹³

A more detailed version of this story was published in the *Joint Commission Journal on Quality and Patient Safety*, November 2005.

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In the News...

1. Risk of Electromagnetic Interference with Medical Telemetry Systems

Tests conducted by the FDA indicate that medical telemetry systems operating in the 460-470 MHz frequency bands after December 31, 2005 face the risk of interference from mobile radio transmitters operating at the same frequency. The electromagnetic interference could lead to lapses in patient monitoring and missed alarms putting patients at risk. The anticipated interference will not be limited to urban areas and any medical facility in the vicinity of a mobile radio could be affected. In January 2006 the Federal Communications Commission will begin issuing new licenses for mobile radio transmitters to operate in the 460-470 MHz band. <http://www.fda.gov/medwatch/safety/2005/safety05.htm#EMI>

2. Communication and Teamwork Used to Reduce OR Errors

A recent article in the *Wall Street Journal* reported that many hospitals are launching programs to enhance communication and teamwork in the operating room (OR) to prevent medical errors. Patient safety organizations and experts recognize that many OR errors occur because OR staff (nurses, technicians, other staff) are afraid to raise questions or concerns with the surgeon. Data submitted to JCAHO shows that the number of reported wrong-site surgeries in U.S.hospitals has steadily risen during the last 10 years, from two in 1995 to 71 in 2004. Several hospital groups have begun implementing safety programs that mimic the preflight checklist used in the airline industry whereby surgeons and other OR staff participate in pre-operative briefings.

3. Pay-for-Performance Bonuses

In October 2003, the Centers for Medicare and Medicaid (CMS) launched a pay-for-performance demonstration project. Hospitals participating in the project have show substantial improvement in the quality of care and an estimated \$8.85 million will be awarded those hospitals who demonstrated quantifiable improvement during their first year in the program. Composite quality scores rose in all five monitored clinical areas- patients with heart attacks, heart failure, pneumonia, coronary artery bypass graft, and hip and knee replacement. This is the first time CMS has awarded monetary bonuses to healthcare providers.

4. Oregon Considers Voluntary Error-Reporting System

In 2003, the state legislature of Oregon established the Oregon Patient Safety Commission to help reduce the risk of serious adverse events and encourage a culture of patient safety among healthcare providers within the state. According to a November 16 article in Portland's *Oregonian*, the Commission is proposing a state-wide, voluntary error-reporting system to enable hospitals, physicians, and nurses to disclose medical errors. According to the article, a draft of the proposed rules has been developed and will be made available for public comment in January with a goal that hospitals would begin reporting by June 2006. Hospitals that choose to participate must report all serious errors to the Commission "in detail" and inform the patient or family; error reports cannot be used against

providers in court, and the Commission is forbidden from sharing data with other state agencies.

5. Physicians and Patients Frequently Ignore Black-box Warnings

A recent study published in the journal *Pharmacoepidemiology and Drug Safety* finds that drugs with black-box warnings are widely prescribed but that patients and physicians frequently fail to follow the safety guidelines. Researchers found that 42% of patients were prescribed one or more drugs with a black-box warning and that nearly 50% of all drug therapy initiations that should have been followed by baseline laboratory monitoring were not. Given the large number of patients who take medications with black-box warnings, the researchers conclude that pharmacists and regulators should identify how the content of the warnings can be effectively communicated to clinicians and patients. [Click here for abstract.](#)

6. Joint Commission Resources-USP Workshop

Transforming Medication Error Data into Meaningful Information: Advanced Workshop Series: Back by Popular Demand - Joint Commission Resources and USP once again are offering day-long, interactive workshops that train patient safety practitioners to make sense of error data and assess the impact of risk-reduction strategies. This advanced workshop series will utilize demonstrations and case-study examples to provide attendees with specific “hands-on” experiences. There is only one date left to participate in this interactive program:

- December 3 in Las Vegas, NV (Preceding the ASHP meeting)

Participants will:

- Identify various error data collection methods and learn what minimum elements are needed to capture meaningful information on medication error events within the healthcare facility
- Learn to prioritize error-reduction strategies
- Learn various methods to analyze data collected through medication error reports
- Translate findings of medication error reports into meaningful information through interpretation of data findings and in their presentation to committees and staff
- Apply JCAHO Medication Management Standards and 2006 National Patient Safety Goals as they relate to the promotion of Medication Safety
- Evaluate the potential impact of proposed actions taken in response to error

For more information and to register call- JCR Customer Service toll free at 877-223-6866 or go on-line at [click here](#).

USP Medication Error Reporting Programs:



MEDMARX[®]—USP's comprehensive, Internet-accessible, anonymous medication errors reporting program, and quality improvement tool. The program facilitates productive and efficient documentation, tracking, trending, and prevention of medication errors.



Medication Errors Reporting (MER) Program—presented in cooperation with the Institute for Safe Medication Practices, this nationwide program makes it possible for health professionals to report medication errors confidentially and anonymously to USP.

Other USP patient safety resources:

- [MEDMARX Annual Data Summary reports](#)—provides readers with a wealth of information on reported error events including patterns in the types, causes, and level of harm associated with medication errors.
- [Understanding and Preventing Medication Errors: A Resource for Healthcare Practitioners](#)—a CD toolkit with practical guidelines, forms, and templates to help healthcare facilities improve error-reduction initiatives.
- [Advancing Patient Safety in U.S. Hospitals: Basic Strategies for Success](#)—a book in which hospitals share stories about how they reduced medication errors and promoted safer patient care.
- Medication Safety Pocket Reference—a pocket-sized reference booklet containing listings of similar drug names and dangerous abbreviations that could cause medication errors. Contact custsvc@usp.org and ask for item #3227702.
- Similar Drug Names Poster—a wall poster for easy reference listing look-alike and sound-alike drug names known to cause confusion and potential medication errors when handwritten or communicated verbally. Posters are packaged in quantities of 1 (item # 3728251) 10 (item # 3728252) and 50 (item # 3728253). Contact custsvc@usp.org and ask for the appropriate item number.

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