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# USP Patient Safety CAPSLink™

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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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### Look-alike/Sound-alike Drug Products Affect Cognition

Human factors research has shed some light on the complexity of how individuals process information, make decisions, and acquire knowledge. Perceptual recognition has been described as an association between an incoming stimulus event (e.g., reading a medication order, label, or package) and a recognized "template" that is stored in long-term memory (e.g., recalling previous similar drug orders, labels, or packages)<sup>1</sup>. Perception can be significantly influenced by *expectancies* (i.e., what the person expects to see or hear). Memory can be negatively affected (i.e., loss of information)

when similarity exists between items in a group. Some research suggests that memory is best if each attribute (e.g., drug name or label) was distinct and dissimilar from others. Another approach to maximize differences between items is to eliminate the redundant elements that are identical across all items.

Reports submitted to USP's Medication Errors Reporting (MER) and MEDMARX<sup>SM</sup> programs underscore how similarity in a drug product's name, label, or packaging can lead to errors. Similarity of drug names involves confusion between look-alike and/or sound-alike brand names, generic names, and brand to generic names. This confusion is compounded by illegible handwriting, lack of knowledge of drug names, newly available products, similar packaging or labeling, and incorrect selection of a similar name from a computerized product list. From January 2000 to March 2004, there were 31,932 reports submitted to MEDMARX that listed one or more **Causes of Error** related to look-alike or sound-alike drug product names, packaging, and/or labeling. Approximately 2.6% of these reports were categorized as harmful to the patient (Categories E-I). (Table 1.)

Table 1. Selected Causes of Error and their Corresponding Severity of Harm

Cause of Error <sup>1</sup>	Error Category <sup>2</sup>								
	A	B	C	D	E	F	G	H	I
Brand names look alike	414	2,470	3,093	411	99	14	1	1	1
Brand names sound alike	290	1,996	2,392	326	72	16	-	-	-
Brand/generic names look alike	553	3,008	3,594	479	86	18	-	2	-
Brand/generic names sound alike	293	1,995	2,409	343	61	7	-	3	1
Generic names look alike	208	2,031	2,312	284	56	13	2	2	-
Generic names sound alike	168	1,416	1,772	227	48	9	1	3	-
Label (manufacturer's) design	245	715	1,158	255	36	14	1	-	1
Packaging/container design	633	1,552	2,208	469	106	20	-	2	1
Similar packaging/labeling	356	1,648	2,679	586	130	15	-	1	-

(1) Based on 31,932 records representing a total of 45,831 selections.

(2) See [www.nccmerp.org](http://www.nccmerp.org) for complete A-I Category definitions.

Cases submitted to the MER program between October—December 2003 also illustrate the confusion that may result from products that are packaged and/or labeled in a similar fashion. The following cases illustrate how such similarity can lead to errors or have a potential to cause errors. When reading these examples, it may be apparent to the reader that the products differ; but in a busy work environment where there can be many distractions, it is easy to mistake these products for one another.

**Case #1 (Actual error):** The pharmacy placed an Isuprel® (for ventricular arrhythmias) ampul in with the Lopressor® (for hypertension) ampuls in the cardiac support floor stock. Isuprel was removed from the stock and administered to a patient. Both products have the same blue stripe on the ampul and look very similar.



Front and back photos of similar labeling/packaging between Isuprel® and Lopressor®.

**Reporting pharmacist's recommendation/action taken:** As the stock of Lopressor ampuls is depleted, the facility will be switching to a generic metoprolol single-dose vial to avoid this confusion in the future.

**Case #2 (Potential error):** A healthcare professional recognized that the labeling of their heparin Carpujects® (for thromboembolic disorders) and digoxin Carpujects® (for congestive heart failure) were so similar that if the labels were faced away from the reader, the Carpujects® could easily be mistaken for one another.



Front and back photos of similar labeling/packaging between heparin and digoxin

**Reporting practitioner's recommendation/action taken:** An announcement identifying the similarity of these two products was created and distributed to the staff.

**Case #3 (Actual error):** The size and cap color of Abbott's naloxone (for the reversal of opioid depression) 0.4 mg/mL and tobramycin (for infection) 80 mg/2 mL vials are similar. Both vials have an orange colored cap and similar size. The medications were stocked near each other in the picking station using the brand names (Narcan® and Nebcin®, respectively). Some of the tobramycin vials were placed in the naloxone bin, which were subsequently placed on a medication tray for a crash cart. During a code, it was noticed that the crash cart tray contained one vial of tobramycin instead of naloxone. Naloxone was also on the tray, so the patient was not affected by this error.



Photo of similar size vials and colored caps between tobramycin and naloxone.

**Reporting pharmacist's recommendation/action taken:** The products were separated in the picking station and the facility is searching to find if one of the products can be purchased from a different vendor.

One of the Joint Commission's proposed 2005 National Patient Safety Goals explicitly requires accredited organizations to identify a list of look-alike/sound-alike drug pairs used in the organization and take appropriate preventative actions to minimize errors involving these same pairs. A recent USP *Quality Review* newsletter (#79) can serve as a resource for organizations in meeting this Joint Commission Goal. This newsletter includes reports submitted to both the MER and MEDMARX error reporting programs from their inception through December 31, 2002.

(See <http://www.usp.org/pdf/patientSafety/qr792004-04-01.pdf>).

When examining this extensive list, it is important to remember that some of

the product names may not sound alike as they are read or may not look alike when clearly and legibly printed, but when handwritten or communicated verbally, these names have caused or could cause confusion.

Errors reported to USP have led to changes in drug product packaging and labeling. Errors reported through the MER program are forwarded to the FDA's Division of Medication Errors and Technical Support (DMETS) in the Office of Drug Safety. The reports are evaluated and assessed if they contain an issue where FDA has regulatory oversight (e.g., drug product labeling, packaging, and nomenclature). DMETS performs a root cause analysis on the reported errors and provides a final analysis (including recommendations on how the names, labeling, and/or packaging should be revised in order to avert further error) to the appropriate review Division(s). The final decision regarding implementation of the recommendations is up to the review Division (s) and not the DMETS.

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1. Miller DP, Swain AD. Human error and human reliability. In: Salvendy G. ed. Handbook of human factors. New York: Wiley-Interscience Publication, 1987.



## **1. Joint Commission Resources and USP Offer Workshops on Medication Errors**

Back by Popular Demand - USP's Center for the Advancement of Patient Safety (CAPS) in conjunction with Joint Commission Resources (JCR) will conduct four, one-day workshops titled - "Transforming Medication Error Data into Meaningful Information". This interactive program will be offered on the following dates in **2004**:

- June 19 in Las Vegas, NV (Preceding the ASHP meeting)
- September 22 in Rockville, MD (at USP Headquarters)
- November 1 in Oakbrook Terrace, IL (JCAHO Headquarters)
- December 4 in Orlando, FL (Preceding the ASHP meeting)

The program is designed for nurses, pharmacists, risk managers, medication/patient safety officers, physicians, and quality improvement staff and will teach participants methods to categorize error events by severity, determine thresholds to signal performance problems, and evaluate the impact of actions taken. For more information and to register call - JCR Customer Service toll free at 877-223-6866 or go on-line at <http://www.jcrinc.com/education.asp?durki=7032&site=5&return=5933>

## **2. USP's Practitioners' Reporting News**

Cases submitted to USP's Medication Errors Reporting (MER) Program illustrate the confusion that may result from the similar labeling/packaging of products and the similarity of the drug products themselves. USP's Center for the Advancement of Patient Safety hopes that practitioners will become more and more aware of the safety issues surrounding product similarity—the informed practitioner is an empowered practitioner. Share your experiences with the MER Program. Other practitioners will benefit from your experiences and valuable insight. Actual and potential medication errors can be submitted

online at [www.usp.org/patientSafety/reporting/mer.html](http://www.usp.org/patientSafety/reporting/mer.html) or by requesting a reporting form at 1-800-23-ERROR (1-800-233-7767).

### **3. FDA Updates**

Proposed Rule for Providing Medication Information to the Public: A new rule is being proposed by FDA that would require all prescription medications dispensed to patients not in hospitals or institutions to bear the following instruction: "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088."

Pharmacies can choose several methods to convey this information including attaching a sticker to the container, using a preprinted prescription-vial cap, or by distributing a separate sheet of paper or the appropriate FDA-approved Medication Guide on which the instruction has already been printed. Comments on the proposal are due to FDA by July 21. [Click here to read more.](#)

Important Drug Interaction Announced: FDA's MedWatch Program recently informed healthcare professionals of an important drug interaction between Oxandrin, a synthetic derivative of testosterone, and the oral anticoagulant warfarin. Savient Pharmaceuticals, Inc. makers of Oxadrin, stated that concurrent dosing of the two products may result in unexpectedly large increases in the International Normalized Ratio (INR) or prothrombin time (PT) and doses of warfarin may need to be decreased significantly to maintain a desirable INR level and diminish the risk of potentially serious bleeding. [Click here to read more.](#)

### **4. Leapfrog Group Begins Safety Rankings**

Starting in late April, the Leapfrog Group (a coalition of major employers) began surveying hospitals on their progress toward implementing the 30 Leapfrog-recommended quality and safety practices (including the reporting of medication errors). The accuracy of the information collected from the surveys is not independently verified by the Leapfrog Group. Rankings can be found at [http://www.leapfroggroup.org/consumer\\_intro1.htm](http://www.leapfroggroup.org/consumer_intro1.htm)

### **5. Hospital Medication Safety Survey Underway**

The American Hospital Association and the Institutes for Safe Medication Practices have recently launched a nationwide survey to hospital pharmacy directors to assess the safety status of the medication use system. The results will be compared to a baseline set of findings obtained in 2000. USP is one of 24 organizations that have endorsed or supported this effort. The survey results, expected late this year, will help hospitals identify areas for improvement and enable them to compare their experiences with those of similar hospitals. The deadline for completing the survey is September 24, 2004. The survey can be completed on-line at <http://www.ismp.org/Survey/Hospital/Intro.htm>

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USP operates two complementary error reporting programs; the Medication Errors Reporting Program presented in cooperation with the Institute for Safe Medication Practices and MEDMARX. MEDMARX™ is an Internet-accessible, anonymous medication error reporting program and quality improvement tool used to track and trend medication errors.

For more information, visit [www.usp.org](http://www.usp.org)

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