



USP Patient Safety CAPSLink™

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In this Issue

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.

Section I: *USP Medication Error Analysis*

- Examining Medication Errors That Occur in the Patient's Home

Section II: *In the News...*

1. FDA Updates
2. USP Quality Review: Too Much Similarity
3. USP Case Study Book Stresses Error Prevention
4. JCAHO Updates
5. Workshop on Compliance with USP Compounding Chapter 797
6. Bar Code Product Review



Examining Medication Errors That Occur in the Patient's Home

The majority of medication safety research and published healthcare literature has focused on hospital or ambulatory settings where the patient's care is provided at a site away from their home. Errors that occur within the home need to be examined to help develop strategies that will improve the safety of medication use throughout the continuum of care.

USP's Safe Medication Use Expert Committee created a work group to examine reports submitted to USP's medication error reporting programs when the error occurred in the patient's home. The findings from this study will be utilized by the Committee to develop practice recommendations for healthcare professionals and/or safe medication use recommendations for consumers.

Reports where the location of the error was identified as the patient's home were analyzed

from MEDMARXSM and the USP Medication Errors Reporting (MER) Program.* MEDMARX data include records submitted from September 1, 1998 through August 31, 2003. MER program data include reports received from 1991 through August, 2003. The actions taken and recommendations in response to the errors were also reviewed for recurring medication use problems and solutions.

*The USP MER Program is presented in cooperation with the Institute for Safe Medication Practices.

Results

Medication errors occurring in the patient's home resulted in some form of harm (Categories E-I) to the patient 11% of the time (Table 1). Of the harmful errors, 12% (11/87) resulted in permanent harm (3 cases), a life-threatening situation (4 cases), or death (4 cases).

Table 1^a Severity of Error

Error Category	Count	Percent
A	6	0.75%
B	59	7.35%
C	515	64.2%
D	135	16.8%
E	47	5.83%
F	29	3.61%
G	3	0.37%
H	4	0.49%
I	4	0.49%
Total	802	

a) Represents combined MEDMARX and MER data

Improper dose/quantity and *Omission error* were the top two reported **Types of Error** (Table 2). When compared to prior USP studies, this study found that Extra dose (12%) was more frequently reported as a **Type of Error**.

Table 2^a Type of Error

Error Type	Count	Percent
Improper dose/quantity	253	36%
Omission error	197	28%
Extra dose	81	12%
Unauthorized drug	54	8%
Wrong time	50	7%
Prescribing error	43	6%
Wrong drug preparation	27	4%
Wrong patient	16	2%
Wrong administration technique	15	2%
A type not determined	11	2%
Wrong dosage form	7	1%
Wrong route	4	0.6%
Deteriorated product	1	0.1%

a) There were 704 records associated with

759 selections in this multi-select field

Communication (21%), *Knowledge deficit* (19%), and *Monitoring inadequate/lacking*

(4%) were recurring **Causes of Error**. *No access to patient information* (10%) was reported more frequently as a **Contributing Factor** and warfarin (9%) was the product most frequently associated with medication errors at home (Table 3).

Table 3^a. Products^b Most Frequently Involved in Home Errors

Generic Name	Count	Percent
Warfarin†	60	9%
Insulin†	46	7%
Morphine†	30	4%
Vancomycin	29	4%
Enoxaparin	18	3%
Furosemide	18	3%
Heparin†	16	2%
Cyanocobalamin	14	2%
Epoetin	13	2%
Total Parenteral Nutrition	12	2%
Potassium Chloride†	11	2%
Oxycodone	10	1%
Palivizumab	10	1%
Cefazolin	9	1%
Digoxin†	9	1%
Metoprolol	9	1%

a) There were 676 records associated with 763 selections

b) * Includes all dosage forms and formulations

† High-alert medication

The type of individual involved with the error is outlined in Table 4.

Table 4^a Level of Individual Initiating the Error

Most Frequent, Initiated	Count	Percent
Patient/family member/caregiver	306	39%
Registered nurse	286	36%
Physician	53	7%
Pharmacist	35	4%

a) There were 793 records that made a selection from the pick list

Observations/Conclusions

In many of the cases, patients did not understand how to take their medication, misunderstood the abbreviations used for dosing, or did not ask questions when the appearance of the product (i.e., tablet or capsule) or instructions on their refilled medications were different. Practitioners and patients did not have adequate training in the use of programmable pumps. Pumps were described as hard to use and the processes surrounding the programming of the pumps was complicated. Warnings and auxiliary labels on containers were either lacking information or not prominent enough, especially on containers that looked like eyedrop bottles. Errors were also reported due to the lack of patient-specific labeling on medication samples provided by physician offices - often times such samples were not accompanied by a product information sheet outlining its

use, side effects, and warnings.

It is apparent from these data that adequate education and training, as well as proper communication, are integral parts in improving patient outcomes in the home. In many cases, patients did not understand how to take their medication, or did not ask questions when something about the medication was different or did not seem right. If healthcare professionals expect to have an impact on improved outcomes in the patient's home, patient counseling processes need to improve.

Some of the recommendations reported by healthcare professionals include:

- evaluate the need for education and training for staff and/or patient and family members/caregivers
- establish better communication and patient counseling processes
- provide better warning and auxiliary labels on containers
- create easier programming features for IV pumps
- encourage patients to inquire if something is different or doesn't seem right when taking or being administered a medication

Understanding the characteristics of these errors can contribute to the development of strategies to improve the safe use of medications both in the home and other health care settings.



1. FDA Updates

Publishes Final Bar Code Rule: A final rule titled, *Bar Code Label Requirements for Human Drug Products and Biological Products* was published this month by the FDA. At a minimum, the bar code must contain the drug's NDC number while bar codes for blood and blood components will require the facility identifier, the lot number relating to the donor, the product code, and the donor's ABO and Rh. The final rule requires linear bar codes on most prescription drugs and on over-the-counter drugs commonly used in hospitals and dispensed pursuant to an order. The final rule is posted on the Internet at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/04-4249.htm>

Topamax Carries New Warning: The prescribing information for the antiepileptic drug Topamax (topiramate) has been revised by its manufacturer, Ortho-McNeil Pharmaceuticals, to include a warning that the drug causes hyperchloremic metabolic acidosis. This condition is not readily apparent and in many patients, the only sign of the acidosis is decreased serum bicarbonate. Metabolic acidosis can cause patients to experience hyperventilation or non-specific symptoms such as fatigue and anorexia, but can also lead to more severe symptoms such as cardiac arrhythmias or stupor. <http://www.accessdata.fda.gov/psn/transcript.cfm?show=25#3>

New web site launched: FDA has launched a new, easy-to-use web site to help consumers and health professionals find information about FDA-approved drug products. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

2. USP Quality Review : Too Much Similarity

Cases submitted through USP's Medication Errors Reporting (MER) Program illustrate how the similarity in product labeling and packaging and the drug product itself can lead to errors or have a potential to cause errors. While facilities may not have direct control over the design and appearance of packaging and labeling and the physical product itself, healthcare professionals can take action to avoid these and similar errors from occurring. <http://www.usp.org/patientSafety/briefsArticlesReports/qualityReview/qr782004-02-01.html> A PDF of the newsletter is also available at <http://www.usp.org/pdf/patientSafety/qr782004-02-01.pdf>

3. USP Case Study Book Stresses Error Prevention

This month, the United States Pharmacopeia (USP) released *Advancing Patient Safety in U.S. Hospitals: Basic Strategies for Success*, a case study book that offers personal error accounts, prevention strategies, and ways to foster a culture change that embraces error reporting systems. More than two dozen health care administrators and practitioners were interviewed for this book, representing large and small U.S. hospitals. Their telling accounts describe the steps they have taken to change their hospitals' cultures of blame; how they convinced staff members to report more medication errors; how error reports are analyzed to identify trends; and how their hospitals have instituted process changes to reduce medication errors. Please also note that all hospital representatives interviewed for this book are available for comment. To order a copy of the book go to <http://store.usp.org>

4. JCAHO Updates

Frequently Asked Questions (FAQs) Re: 2004 National Patient Safety Goals Updated: Several FAQ's have been updated including information about the abbreviations requirement, use of the Rule of 6, and the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery. http://www.jcaho.org/accredited+organizations/patient+safety/04+npsg/04_faqs.htm

5. Workshop on Compliance with USP Compounding Chapter 797

A two-day workshop will be conducted May 14-15 at USP headquarters in Rockville, MD that will provide attendees with an in-depth analysis of current compounding and packaging issues and discusses new, official compendial standards and their applicability to pharmacy practice. JCAHO has indicated that it will begin surveying compliance with these standards as part of its accreditation process. Larry Trissel, R.Ph., director of Clinical Pharmaceutics Research at the University of Texas M. D. Anderson Cancer Center and Lawson G. Kloesel, R.Ph., chairperson of the Board of Professional Compounding Centers of America and several other faculty and USP staff will provide expert guidance and interpretation on the official *USP-NF* General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, and <1146> Packaging Practice—Repackaging a Single Solid Oral Product into a Unit-Dose Container. The program is targeted toward pharmacists, pharmacy technicians, and any others responsible for compounding and packaging medications for patient administration. To register see: <http://www.usp.org/education/workshops/pharmacy.html>

6. Bar Code Product Review

The Neuenschawander Company has recently announced the availability of a new publication that reviews point of administration barcode scanning systems. The book covers several salient issues to consider including electronic medication administration records, point of administration hardware, and radio frequency identifiers. For more information on this publication titled, *To The Bedside: A review of point of administration barcode scanning systems—with commentary* see www.hospitalrx.com or call 425-644-6797.

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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. MEDMARXSM 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

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