



USP Patient Safety CAPSLink™

October 2003

PROVIDED BY THE USP CENTER FOR THE ADVANCEMENT OF PATIENT SAFETY

Copyright © 2003 The United States Pharmacopeial Convention, Inc.

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*

- Errors Involving Vaccines

Section II: *In the News...*

1. JCAHO Updates
2. USP's Practitioners' Reporting News
3. FDA Updates
4. Medical Injuries Pose Significant Threat and Increase Costs
5. Pharmacists Help Reduce Preventable Adverse Drug Events
6. Cardinal Symposium Focuses on Medication Safety
7. CDC Committee Recommends Children Receive Flu Shots

USP Medication Error Analysis

The advent of Fall means it's flu season and millions of Americans will flock to their health care providers over the next two months for a flu vaccination shot. Vaccinations for other illnesses such as tetanus, diphtheria, and rubella are commonplace. When used correctly, vaccines provide a tremendous health benefit. However, the multiplicity of agents and formulations can create a scenario for error and may lead to serious consequences if improperly administered or given in the wrong dose.

Data reported to the USP's MEDMARXSM program revealed that most errors associated with vaccination products occurred in the administering phase. [see table 1] The data is based on 1,837 records that were submitted to USP between August, 1998 and December, 2002.

Table 1: Medication Use Process (MUP) Phase Where Errors Associated with Vaccines

Occur^a

MUP Phase	Count	Percent
Administering	910	49.5%
Documenting/Transcribing	371	20.2%
Dispensing	271	14.8%
Prescribing	128	7%
Monitoring	8	0.4%
Other*	149	8.1%

a. Data from USP's MEDMARXSM program for period 8/1998 - 12/2002.

*Represents Category A (i.e., potential error) records where MUP does not apply and data not provided.

The top five vaccine products associated with these reported errors are:

- 1st - Pneumococcal vaccine polyvalent**
- 2nd - Hepatitis B vaccine, recombinant**
- 3rd - Influenza virus vaccine**
- 4th - Tetanus and diphtheria toxoids absorbed for adult use**
- 5th - Rubella virus vaccine live.**

The most frequent types of error involving vaccine products include errors of *Omission* (leaving the patient unprotected from the targeted disease), *Unauthorized/wrong drug* (leaving the patient unprotected from the targeted disease and possibly incurring an adverse drug reaction from the unintended agent), and *Extra dose* (increasing the risk of an adverse drug reaction and incurring unnecessary medical costs).

Table 2: Types of Error Associated with Top 3 Vaccines ^a

TYPE of ERROR	Pneumococcal Vaccine		Hepatitis B, Recombinant Vaccine		Influenza Virus Vaccine	
	Rank	Count (%)	Rank	Count (%)	Rank	Count (%)
Omission error	1	507 (87%)	3	66 (17%)	1	50 (35%)
Unauthorized/ wrong drug	2	15 (2.6%)	2	77 (20%)	2	41 (28%)
Extra dose	3	12 (2.1%)	1	82 (21%)	3	15 (10%)
Wrong time	4	10 (1.7%)	4	48 (12%)	7	3 (2.1%)
Wrong drug preparation	5	9 (1.5%)	8	16 (4.2%)	6	9 (6.3%)
Wrong patient	6	7 (1.2%)	7	20 (5.2%)	8	2 (1.4%)
Improper dose/quantity	7	6 (1%)	5	35 (9.1%)	4	13 (9%)
Prescribing error	8	6 (1%)	6	27 (7%)	5	11 (7.6%)
Wrong route	9	4 (0.7%)	11	2 (0.5%)	-	0
Wrong administration technique	10	3 (0.5%)	13	1 (0.3%)	-	0
A type not determined	11	1 (0.2%)	9	6 (1.6%)	-	0
Expired product	12	1 (0.2%)	12	1 (0.3%)	-	0
Wrong Dosage Form	-	0	10	3 (0.8%)	-	0

a. Data from USP's MEDMARXSM program for period 8/1998 - 12/2002.

The most commonly reported causes for vaccine errors include *Procedure/protocol not*

followed (36%), Performance deficit (31%), and Knowledge deficit (19%). However **Transcription inaccurate/omitted**, and **Documentation** combined comprised approximately 23% of reported causes and **several causes related to the drug's name, packaging, and labeling** (e.g., brand/generic names look and/or sound alike) combined comprised approximately 13% of the total.

Selected Case Examples: Omission Errors

Case #1: Influenza and pneumococcal vaccines were ordered to be given to the patient upon discharge. Pharmacy recorded the order on the medication administration record (MAR) with a note for nursing to call the pharmacy for the dose prior to discharge. Nursing never called the pharmacy before the patient left the hospital and, therefore, the patient never received the vaccine.

Case #2: Consent forms were to be signed by the patient (or designee) prior to vaccine administration. An order was written for influenza and pneumococcal vaccines and sent to the pharmacy, but was not accompanied by the required consent form and the patient did not receive either vaccine.

Selected Case Examples: Unauthorized/wrong drug Errors

Case #3: A physician ordered “H-flu” (intended to mean Haemophilus b Conjugate vaccine) but the order was interpreted by pharmacy as Influenza Virus vaccine. Pharmacy dispensed the wrong product and nursing administered the wrong drug to the patient.

Case #4: A physician wrote for HBV (intended to mean Hepatitis B vaccine) but the abbreviation was somewhat unclear and interpreted by pharmacy as Haemophilus b conjugate and the wrong drug was sent to the patient unit and administered.

Case #5: A clinic physician ordered the nurse to administer HIB vaccine (intended to mean Hepatitis B Immune Globulin) to a child but the nurse mistakenly retrieved and administered Hepatitis B Vaccine.

Case #6: Human Rabies Immune Globulin was ordered as HRIG. The physician's handwritten order was misinterpreted by pharmacy and entered into the pharmacy computer as Hepatitis B Immune Globulin (HBIG). The wrong drug was dispensed and administered.

Case #7: As part of a new employee orientation, Tuberculin purified protein derivative (PPD) 0.1 mL was to be administered intradermally. Influenza vaccine (FluShield) was stored in the employee health clinic refrigerator along with PPD and inadvertently retrieved. A total of 29 new employees were administered Influenza vaccine intradermally (instead of the PPD). Many of the new employees experienced redness/erythema and tenderness that resolved in 3 days.

Selected Case Example: Improper dose Error

Case #8: An immunization technician administered a 0.5 mL dose of flu vaccine to an 18 month-old rather than the appropriate 0.25 mL. In this case, the technician was providing 0.5 mL dose shots to older siblings of the patient at the same time and did not realize that the infant was to receive a lower dose.

Recommendations to Reduce Vaccination Errors

USP provides the following suggestions to health care practitioners to help minimize the opportunity for errors involving vaccinations:

- Conduct a Failure Mode & Effects Analysis (FMEA) on the names, packaging, and labeling of the vaccinations currently on your facility's formulary and assess the risk potential for confusion and drug mix-ups. Evaluate what actions should be taken regarding product selection, the storage and location of these products within pharmacy and patient care areas, and prescribing practices. Based on the FMEA, implement recommended changes for these particular products.
- Review the manner in which the various vaccinations are prescribed, including the use of unapproved abbreviations, particularly for formulations of pneumococcal, hepatitis, and influenza vaccines. (See CDC recommendations for uniform abbreviations – www.cdc.gov/nip/visi/prototypes/vaxabbrev.htm.)
- Establish clear protocols on the prescribing, documenting, dispensing, and administering of vaccinations. Widely disseminate these protocols to appropriate staff.
- Use an adequate number of clearly labeled storage bins in the refrigerator to separate different products and different strengths (e.g. pediatric versus adult dosage forms)
- Incorporate educational/training sessions into physician, pharmacy, and nursing staff meetings regarding the facility's protocols for vaccinations. At the end of such sessions, staff should be familiar with the types of vaccinations on the formulary, the basic differences between the various vaccinations, and the appropriate procedure for prescribing (including possible patient consent forms), transcribing/documenting, dispensing, and administering these products. Consider constructing a post-training test, tailored to the role of the staff (e.g. physician vs nurse vs pharmacist) to help solidify learning. Also consider making the passing test score a part of any required staff development program.

Note: This research was funded in part by the Agency for Healthcare Research and Quality as part of the UNC Center for Education and Research on Therapeutics (Alan D. Stiles, CERTs PI; award number U18 HS 010397).



1. JCAHO Updates

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

- November 11 (Oakbrook Terrace, IL)
- November 20 (New Orleans, LA)

The program will teach participants methods to categorize error events by severity, determine thresholds to signal performance problems, and evaluate the impact of actions taken. This workshop is offered in conjunction with JCR's - *Executive Briefings on JCAHO's New Medication Management Standards* to be conducted on November 10, and November 21. Significant savings in registration is offered when signing up for both programs. For more information and to register call JCR Customer Service Center toll free at 877-223-6866 or go on-line [Click here](#)

New FAQ Clarifies Goal on Infections and Hand Hygiene: To assist in implementation efforts for 2004, the Joint Commission has issued its long-awaited clarification of the newest National Patient Safety Goal (NPSG). The frequently asked questions (FAQ) document addresses questions related to both sentinel events involving infection and expected adherence to CDC guidelines for hand hygiene. [Click here to read more.](#)

Wrong Site Surgery Conference Slated for December 2: The Joint Commission's Wrong Site Surgery Conference on Tuesday, December 2, will examine the scope of this problem and share specific solutions to eliminate these tragic mistakes. The one-day conference will be held at the Chicago Hilton and Towers, Illinois and sessions will include a focus on the Commission's Universal Protocol for preventing wrong site, wrong procedure, and wrong person surgery, and on proven approaches to implementing the protocol in hospitals and ambulatory settings. To register, please call the Customer Service Center at 877-223-6866 or visit <http://www.jcrinc.com/>

2. USP's Practitioners' Reporting News

Dangerous Mix Up With BP Monitor & IV Port: In a recent report submitted to the USP Medication Errors Reporting (MER) Program, a patient's blood pressure monitor tubing was attached to the Y-site of a needleless IV port. This occurred because the tubing on the blood pressure monitor's inflator had a male Luer connector that fit into a female connector on a disposable blood pressure cuff. Practitioners should check their tubing for the potential of this dangerous connection, apply warning labels to the monitor tubing, and inform staff of this possibility. [Click here to read more.](#)

Similar Drug Names Continue to be Reported: Some of the products and descriptions that were identified in MER reports received between March – August 2003 are displayed, where the brand names look alike/sound alike, brand and generic names look alike/sound alike, or generic names look alike/sound alike. Healthcare professional's submitting these reports make recommendations. Updated Use Caution Avoid Confusion similar names list to be released soon. [Click here to read more.](#)

3. FDA Updates

Toxicity and Death Associated with FD&C Blue No. 1: The FDA has alerted healthcare professionals of several reports of toxicity, including death, associated with the use of FD&C Blue No.1 (Blue 1). The coloring has been used to help in the detection and/or monitoring of pulmonary aspiration in patients being fed by an enteral feeding tube. Reported cases describe patients with blue discoloration of the skin, urine, feces, or serum and some were associated with serious complications such as refractory hypotension, metabolic acidosis and death. See MedWatch 2003 safety summary ([click here](#)).

Updated Safety-Related Drug Labeling Changes: The July 2003 FDA posting includes 15

drug products with safety labeling changes to the CONTRAINDICATIONS, BOXED WARNING, WARNINGS, PRECAUTIONS, or ADVERSE REACTIONS sections. The sections/subsections changed and a description of new or modified safety information can be found at ([click here](#)). The following drugs had modifications to the CONTRAINDICATIONS and/or WARNINGS/BOXED WARNINGS sections:

Zestril (lisinopril) Tablets
Retrovir (zidovudine) IV Infusion
Viramune (nevirapine) Tablets and Suspension
Lovenox (enoxaparin sodium injection)

Look-Alike/sound-alike Errors: FDA and USP continue to receive reports about errors associated with mix-ups between drugs that begin with the letter "Z". Zantac, Zyrtec, and Zyprexa, are especially problematic for pediatric patients. Some health care providers are mistakenly dispensing Zyrtec syrup, an antihistamine, when Zantac, an acid reducer, is prescribed. [Click here to read more.](#)

Dispensing errors have also been reported between Keppra (levetiracetam), an antiepileptic, and Kaletra (lopinavir/ritonavir), an antiretroviral. Patients with epilepsy, who do not receive their antiepileptic drug due to a dispensing error, would be inadequately treated and could experience serious consequences, including status epilepticus. [Click here to read more.](#)

4. Medical Injuries Pose Significant Threat and Increase Costs

An AHRQ study published October 8 in the *Journal of the American Medical Association* found that medical injuries during hospitalization resulted in longer hospital stays, higher costs, and a higher number of deaths. The study titled, "Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization" provides, for the first time, specific estimates for excess length of stay, charges, and the risk of death for 18 of the 20 AHRQ Patient Safety Indicators. [Click here to read more.](#)

5. Pharmacists Help Reduce Preventable Adverse Drug Events

A recent study published in *Archives of Internal Medicine* conclude that including a pharmacist on weekday rounds in a general medicine unit can reduce preventable medication errors by 75%. [Click here to read more.](#) (abstract)

6. Cardinal Symposium Focuses on Medication Safety

Cardinal Health is sponsoring a "Dimensions of Leadership Symposium" entitled "*Medication Safety Update 2003 -- New Standards, New Data, New Model for Improvement*". This symposium will be conducted on Sunday morning, December 7 at the Hilton New Orleans Riverside Hotel in New Orleans in conjunction with the ASHP Midyear Clinical Meeting. JCAHO's 2004 Medication Management Standards will be reviewed as well as the most recent error findings from USP's MEDMARXSM database. A complimentary copy of the nearly 60-page MEDMARX report entitled – *Summary of Information Submitted to MEDMARXSM in the Year 2002: The Quest for Quality*, will be provided to symposium attendees. For more information or to register go to <http://www.cardinal.com/leadership/> or call 614-757-7826.

7. CDC Committee Recommends Children Receive Flu Shots

The CDC Advisory Committee on Immunization Practices recently voted to recommend children ages six months to 23 months receive annual flu shots. The current inactivated influenza vaccine is not approved by FDA for use among children less than six months of age. The recommendation stipulates that previously unvaccinated children under the age of nine years should initially receive two doses of the flu vaccine a month apart, followed by annual shots in subsequent years. The new recommendation should pave the way for private insurers to cover the costs for the \$10-per-dose vaccine. [Click here to read more.](#)

You are currently subscribed to USP Patient Safety CAPSLink™. To refer colleagues or friends to subscribe to this newsletter click [here](#). To unsubscribe click on [this link](#).

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

USP does not sell or distribute e-mail addresses. Questions about USP CAPSLink™ should be sent to caps@usp.org.

Copyright 2003, U.S. Pharmacopeia. All rights reserved.

