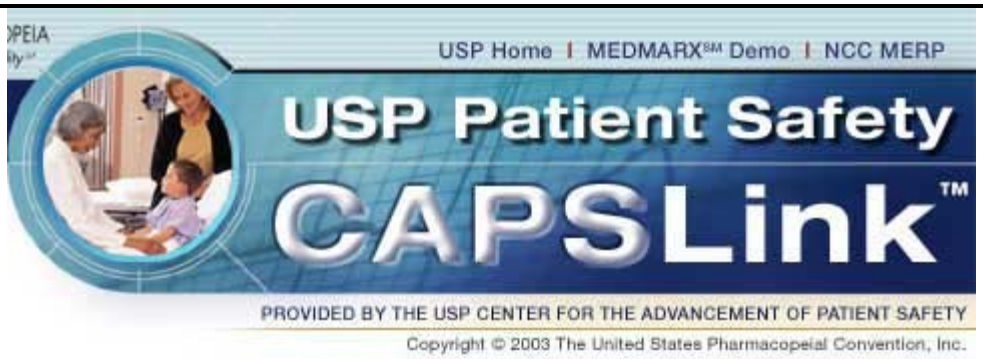
August, 2003



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USP Patient Safety CAPSLink™

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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

There are numerous drug products that require refrigeration and some (e.g., insulins and IV

piggyback antibiotics) are frequently prescribed. Refrigerators are a common appliance located throughout the hospital in both patient care and pharmacy-dispensing areas. During the past four years, USP's MEDMARX℠ medication error reporting program has received nearly 1,000 reports involving refrigerated medications with approximately 64% (n = 594) of these indicating that the error reached the patient. A small portion of these errors resulted in extra monitoring or required some type of intervention to preclude harm (7%, n = 63) or resulted in some level of harm ranging from temporary to permanent (2%, n = 17). (Table 1.)

Table 1. Errors Involving Refrigerated Medications[1]

Error Category[2]	Count
A (potential error)	152
B (intercepted error)	177
C (error reaches patient, no harm)	514
D (required monitoring and/or intervention to preclude harm)	63
E (temporary harm and required intervention)	15
F (temporary harm and required initial or prolonged hospitalization)	1
G (permanent harm)	1
H (required life-sustaining intervention)	0
I (may have resulted in death)	0

1. Data from USP□s MEDMARX program for years 1998-2002.
2. Categories E-I = harmful errors. For complete category definitions see www.nccmerp.org

Omission errors (sometimes leading to a surgical delay and prolonged hospitalization), *Unauthorized/wrong drug*, and *Wrong time* were the three most frequently reported **Types of error** associated with refrigerated medications. (Table 2)

Table 2.

Type of Error	Count	Percent
Omission Error	363	46%
Unauthorized/wrong drug	108	14%
Wrong time	86	11%
Improper dose/quantity	86	11%
Wrong drug preparation	66	8.4%
Wrong patient	28	3.6%
Extra dose	12	1.5%

Data from USP's MEDMARX program for years 1998-2002. Not all Types are depicted.

From these reports, USP has been able to identify several themes involving refrigerated medications:

- Accessibility and poor storage: Easy access to products that are poorly or improperly stored in a refrigerator can create the risk of drug mix-ups. Multiple types and strengths of vaccines, insulins, and antibiotics that are readily available in common storage bins or drawers within the refrigerator have led to numerous wrong-drug and wrong-dose errors. Also, drugs needing refrigeration are left un-refrigerated and vice versa.

- Products with similar packaging and labeling: Given the storage space limitations of refrigerators, there is an increased potential to confuse similar looking packages and labels.

- Nursing staff unaware of medications requiring refrigeration: The majority of medications nurses receive from pharmacy and eventually administer to patients are not stored inside a refrigerator. Therefore, they do not immediately think of looking in the medication refrigerator when tracking down a drug to administer at a scheduled time. In these instances, patients either get the drug much later than was originally scheduled or, even worse, not at all. Also, the lack of knowledge regarding which products require refrigeration leads to the disposal of drugs that have been left unrefrigerated or to the administration of drugs that have become unstable or less potent because of improper storage.

Selected Case Reports:

<u>Accessibility and Poor Storage</u>

Case #1: Patient "A" had been receiving an IV piggyback of ampicillin/sulbactam but the order was discontinued. However, the piggyback IV bags for that patient were not removed from the refrigerator during the course of one 8-hour shift. Patient "B" was in the same room as Patient "A" and was receiving cefazolin IV piggyback. A nurse who intended to retrieve cefazolin from the refrigerator mistakenly retrieved one of the ampicillin/sulbactam piggybacks instead (both piggybacks were placed in the same drawer within the refrigerator) and administered the wrong drug to Patient "B".

Case #2: The pharmacy dispenses Epogen vials with patient-specific labeling including a "keep refrigerated" label on the zip-lock bag. However, once the initial dose is administered to the patient, the vials are generally not returned to the zip lock bag containing the reminder label. Consequently, many vials are found left in the patient's medication drawer instead of being returned to their appropriate storage environment. In these situations, the length of time that the vial has been outside the refrigerator is difficult to determine and, therefore, the product must be discarded because the medication's potency is in question.

Products with Similar Packaging and Labeling

Case #3: Various types of Insulin were stored in the same section of the refrigerator. Patient-specific vials were not dispensed from pharmacy, rather individual insulin doses were withdrawn from floor stock vials. A patient was ordered Humalog Mix 75/25 but instead received Humulin 70/30. Both insulin vials were stored in close proximity in the refrigerator.

Nursing Staff Unaware of Medications Requiring Refrigeration

Case #4: Four liters of Golytely were ordered to be given to a patient over a two-hour period. The first 2 liters were given to the patient by the day-shift nursing staff. However, the day-shift nurses failed to inform the evening shift that the remaining two liters of Golytely were being stored in the refrigerator. Approximately three hours past the scheduled administration time, the remaining two liters were found in the refrigerator. The physician was informed of the complications related to the administration of the Golytely and made a decision to delay the patient's surgery.

Case #5: An IV bag of total parenteral nutrition (TPN) solution that was being infused into a patient was nearly empty and the next bag needed to be hung. However, the floor nurse could not locate the next scheduled dose in the unit's medication room and she could not request another bag to be compounded since the pharmacy was already closed for the evening. The nurse temporarily stopped the TPN and started the patient on D10W until a dose could be compounded and dispensed by the pharmacy. Upon delivery of the replacement TPN the following morning, the pharmacy technician discovered that the "missing" TPN was actually in the unit's medication refrigerator, but the evening shift was unaware that the TPN's were stored in the refrigerator. Because of the interruption in the TPN regimen, extra lab tests were ordered to ascertain the patient's electrolyte levels.

Case #6: Zithromax was ordered on Day #1 at 07:00, but nursing staff could not locate the item and circled 11:00 am on the MAR as drug not available and therefore, not given. The patient did not receive the antibiotic for 24 hours. On Day #2, the nursing staff discovered two bags of Zithromax for this patient in the refrigerator that were marked with the date for Day #1. The patient was very discouraged upon learning that administration of his antibiotic had been delayed for so long given his history of a heart transplant and battle with osteomyelitis of the mandibular bone. The patient had to be re-evaluated and upon a review of the chest x-ray, it was found that there was infiltrate in the left lower lung

Recommendations for Minimizing Errors Involving Refrigerated Medications

1. Use an adequate number of clearly labeled storage bins to separate different products and different strengths. Consider obtaining a larger refrigerator that will accommodate the unique needs of a particular patient care area. Also, post a chart within the pharmacy and on each nursing unit medication room/area that identifies products that both *should* and *should not* be refrigerated.

2. Devise a system that eliminates or minimizes all look-alike products in a refrigerator.

Because most insulins are stable for 28-30 days at room temperature (consult package and drug information literature for product-specific storage recommendations), consider keeping all patient-specific insulin vials in the patient's medication drawer rather than storing the vials in the refrigerator. Conduct an inventory of the types of products stored in the facility's refrigerators. Request that the Pharmacy and Therapeutics Committee, or other appropriate safety committee, review this inventory of commonly stored products to identify look-alike pairs and evaluate where and how to eliminate these potential mix-ups.

3. Develop systems that alert and remind nursing staff of medications stored in refrigerators (e.g., display chart/ table on outside of refrigerator door listing most common refrigerated items for that particular unit). Incorporate information regarding typical medications requiring refrigeration into periodic unit-staff meetings and/or inservices.

1. 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 three, 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 at Click here for registration information.

2. Annual Patient Safety Training Program Launched

On September 15, 2003 the Agency for Healthcare Research and Quality and the Veterans Administration will begin offering free patient safety training to state patient safety officers and their selected hospital guests through a new partnership program called the Patient Safety Improvement Corps. The program will entail one-week sessions in September, January and May. Forty participants will be accepted in the 2003-2004 year representing approximately 10-20 state patient safety teams with plans for expansion in subsequent years. Only states may

submit applications, but the state applications may include up to two hospital partners selected by the state. http://www.ahrq.gov/qual/psimpcorps.htm.

3. FDA Posts Products with Safety Labeling Changes

On their web page, the FDA regularly posts any changes that have occurred in drug product labeling over a given time period. The latest posting (April 2003) includes 40 drug products with safety labeling changes to the CONTRAINDICATIONS, BOXED WARNING, WARNINGS, PRECAUTIONS, or ADVERSE REACTIONS sections. The Summary page -- http://www.fda.gov/medwatch/SAFETY/2003/apr03_quickview.htm ...provides drug names and a listing of the sections changed. The Detailed view -- http://www.fda.gov/medwatch/SAFETY/2003/apr03.htm includes sections/subsections changed and a description of new or modified safety information in the Contraindications or Warnings sections.

4. Air Force Automates Pharmacy System

The Air Force is in the first phase of developing a $25 million pharmacy automation system that includes medication bar coding, automatic dispensers and a robotic system. The program aims to improve patient safety, standardize medication error reporting and increase efficiency. Air Force bases are currently bar coding all medications. Once the system is complete, dispensers will only administer medications when a bar code is scanned to verify an order. The system will display a picture of each drug on a computer screen and will be able to identify drug interactions. The system should be completed by late 2004, and could save an estimated $54 million by FY 2005. http://www.federaltelemedicine.com/n081903.htm

5. ASHP Provides Information on Bar-Codes

A compilation of resources dealing with bar code technology has been assembled by the American Society of Health-System Pharmacists to help practitioners enhance medication safety. Information on this web page includes a practical guide on bar coding, experience of the Department of Veterans Affairs using a bar-code scanning system, and FDA□s proposed rule. http://www.ashp.org/practicemanager/InfoTechRes.cfm

6. HHS, AHA, and AMA to Distribute *5 Steps to Safer Health Care*

A campaign to distribute information about improving patient safety to both practitioners and patients across the country was recently announced by the Department of Health and Human Services (HHS). HHS, in partnership with the American Hospital Association and the American Medical Association, will promote new posters and fact sheets called 5 Steps to Safer Health Care. The posters and fact sheets offer evidence-based, practical tips to help patients avoid errors related to prescription medicines, laboratory tests and procedures and surgery. These materials are available in English and Spanish. To access the 5 Steps to Safer

Health Care. A print copy also is available by sending an e-mail to ahrqpubs@ahrq.gov.

7. Pennsylvania Plans Mandatory Online Error Reporting System

Pennsylvania□s Patient Safety Authority is preparing to launch an online reporting system for medical errors and near-errors beginning in late September. Officials hope the reporting program will help reduce the number of lawsuits against physicians and lower malpractice premiums by identifying and correcting practice patterns that lead to medical errors. The authority also will issue an annual report to the public, which will include the number of errors and near-errors reported and recommendations for improving patient safety.
Click here to read more.

8. Practitioners' Reporting News --Barr Recalls Nortrel® 7/7/7

Barr Laboratories, Inc. initiated a voluntary recall of Nortrel® 7/7/7. The recall was initiated from two reports - - one of those reports was submitted to the USP Medication Errors Reporting (MER) Program. (To be posted on Practitioner's Reporting News [PRN] after August 31, 2003). Summaries and case studies of medication error reports from healthcare professionals are available by visiting the Practitioners' Reporting News http://www.usp.org/patientSafety/briefsArticlesReports/practitionerReportingNews/index.html and Quality Review http://www.usp.org/patientSafety/briefsArticlesReports/qualityReview/archive.html

Practitioners are encouraged to report similar medication errors to the USP MER Program at www.usp.org/patientSafety/reporting/mer.html.

USP operates two complementary error reporting programs; the ***Medication Errors Reporting Program*** which operates 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