



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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Drug Shortages Affect Patient Safety

Concerns about the frequency and duration of drug product shortages have increased in recent years and some of these shortages have led to adverse patient outcomes. Health care professionals have devised various methods to deal with drugs in short supply including purchasing products from another vendor, borrowing from another facility, compounding the product from raw materials, substituting with another product, and rationing existing quantities. Some of these methods, however, have led to product confusion and/or calculation errors resulting in the inadvertent administration of the wrong drug or wrong dose.

A recent survey of health-system pharmacists examined the impact of drug shortages.¹ Of those surveyed, 10% believed drug shortages resulted in a serious medication error, 4% reported a serious drug reaction, and 1% reported a sentinel event. The current shortage of flu vaccine in the U.S. further amplifies the potential negative consequences when patient care is either delayed

or simply not provided.

Data collected through USP's MEDMARXSM and Medication Errors Reporting (MER) programs provide additional information on the negative impact of drug shortages. From January 2003 to August 2004, 832 records were submitted to MEDMARX that identified *Drug shortage* as a **Cause of error**. There were 47 error reports involving drug shortages submitted to the MER program from October 1991 to October 15, 2004. For MEDMARX and MER Combined, approximately 2.6% of these reports resulted in some level of patient harm (Categories E-I). (Table 1).

Table 1. Level of Harm^a

Error Category Index ^b	n	Percent
A	192	22
B	307	35
C	319	36
D	37	4.2
E	16	1.8
F	3	0.3
G	2	0.2
H	1	0.1
I	2	0.2
Total	879	

a) Combined data from MEDMARX and MER.

b) See www.nccmerp.org for complete A-I Category definitions.

The top three most frequently reported **Types of Error** in MEDMARX were *Prescribing error*, *Improper dose/quantity*, and *Omission error*. (Table 2). The top three reported error types in the MER program were *Improper dose/quantity* (45%), *Unauthorized/wrong drug* (32%), and *Wrong drug preparation* (8.5%).

Table 2. Types of Error^a

Type of Error	n	Percent
Prescribing error	271	34.1
Improper dose/quantity	204	25.7
Omission error	176	22.2
Wrong time	84	10.6
Unauthorized/wrong drug	47	5.9
Wrong drug preparation	43	5.4
Wrong dosage form	21	2.6
Expired product	15	1.9
Extra dose	11	1.4
Wrong patient	9	1.1
Wrong route	5	0.6
Deteriorated product	3	0.4
Wrong administration technique	1	0.1

a) Findings from MEDMARX. Type of Error is a multi-select field. Not all records documented a specific *Type of Error*. Data is based on 794 records representing a total of 890 *Type of Error selections*.

There were 301 unique product groups identified in MEDMARX with medication errors involving

drug shortages. Methylprednisolone injection was the most frequently reported product. (Table 3).

Table 3. Top 15 Products Most Frequently Associated with Drug Shortage Errors

Drug Product/Group	n	Percent
Methylprednisolone Sodium Succinate	139	17.3
Methylprednisolone	18	2.2
Dexamethasone	17	2.1
Morphine*	17	2.1
Prochlorperazine	16	2.0
Insulin*	15	1.9
Pantoprazole*	14	1.7
Cefotetan	13	1.6
Ampicillin and Sulbactam	12	1.5
Cefoxitin	12	1.5
Piperacillin and Tazobactam	10	1.2
Sodium Bicarbonate	10	1.2
Heparin*	9	1.1
Ipratropium and Albuterol	9	1.1
Hydrocortisone	8	1.0
Hydrocortisone Sodium Succinate	7	0.9
Hydromorphone	7	0.9

* All dosage forms and formulations of the same generic name are combined to form a product grouping.

Selected Cases Reported to USP's MEDMARX and MER Programs:

Case #1: A patient who was admitted to the hospital with small bowel obstruction was ordered fentanyl injection 100 micrograms every 2 hours as needed for pain. The hospital pharmacy generally stocked and dispensed fentanyl 2mL ampoules (50 micrograms/mL), but because of a shortage, were forced to order the 5 mL (50 micrograms/mL) ampoules. These ampoules were then distributed as needed to the various patient care units and were also stocked in some automated dispensing devices. The nurse caring for the patient retrieved two 5 mL ampoules (total of 10mL or 500 micrograms) of fentanyl from an automated dispensing device. All 10 mL were administered to the patient representing a five-fold increase over the prescribed dose. The patient went into respiratory arrest and became cyanotic. A code blue was called, naloxone given, and the patient was soon stabilized and then transferred to the intensive care unit for observation prior to surgery. The patient did not experience any permanent adverse outcomes. Through a root cause analysis, it was determined that the total contents of the vial (i.e., total mg/total mL) was not clearly stated on the fentanyl label, and the purchase of the larger 5 mL ampoule size (total dose 250 mcg) instead of the standard 2 mL (total dose 100 mcg) created confusion for the nurse.

Case #2: A patient was prescribed ticarcillin/clavulanate 3.1 grams every 4 hours. An existing market shortage of the individual 3.1 gram vials led the pharmacy to purchase 31 gram bulk bottles which would then be used to

prepare individual, 3.1 gram doses. The next two scheduled doses for the patient occurred during the night when the hospital pharmacy was closed. The evening nursing supervisor went into the pharmacy after hours and was only able to find the 31 gram bottles of ticarcillin/clavulanate. Two bottles were retrieved and brought to the patient's floor. The floor nurse assumed the prescribed dose was the content of the entire 31 gram bottle and proceeded to administer this amount for the next two scheduled doses representing a 20-fold overdosage. The patient developed seizures, acute renal failure, congestive heart failure, and eventually died of systemic candida and multi-organ failure.

Case #3: Prochlorperazine 5 mg IV was ordered to treat a patient's nausea. This product was unavailable to the hospital because of a market-wide shortage. The hospital's Pharmacy & Therapeutics Committee had approved an automatic substitution of droperidol 0.625 mg when prochlorperazine 5 mg was ordered. However, the nurse administering the product was not fully aware of the differences in dosing and inadvertently gave the patient 5 mg of droperidol. The patient became overly sedated requiring oxygen and increased observation.

Case #4: A patient was ordered a high dose of methylprednisolone IV but because of a drug shortage, dexamethasone was used as a substitute. However, the pharmacist miscalculated the dose conversion and the patient was sub-optimally treated causing a prolonged hospital stay.

Suggestions to Address the Adverse Effects of Drug Shortages ²

Drug shortages pose another set of challenges to healthcare providers and can lead to adverse patient outcomes. Proactive actions must be undertaken to identify, address, and prevent drug product shortages before patient care is compromised. The following suggestions can help practitioners minimize the negative impact of drug shortages:

- 1) Determine an appropriate medical-staff committee or governing body who will have the authority to mandate practice changes across medical disciplines including the approval of using alternative products, prioritizing patients, and product rationing.
- 2) Develop policies that outline the process for communicating and educating practitioners within the organization when shortages occur that pose a significant threat to patient care. The policies should identify a primary staff position whose purview includes coordinating and managing all the information surrounding the drug shortage.
- 3) Create ad-hoc committees that will aid in assessing the potential impact of a shortage. Such committees should investigate the anticipated length of the shortage, the degree to which the product is used within the facility, the location of the affected product throughout the facility, an estimate on how long the current inventory will last, and an estimate on which patients and services will be most affected.
- 4) Evaluate various options to address the product shortage including establishing a prioritization schema for selecting patients who will continue to receive the limited supply, compounding the product or contracting out the compounding, and selecting alternate therapies.
- 5) Seek out information from the product manufacturer, drug information centers, and in-house clinical staff when evaluating alternative therapies and changes to the facility's clinical pathways and protocols.

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1. Baumer AM., Clark AM, Witmer DR. National survey of the impact of drug shortages in acute care hospitals. Am J Health-Syst Pharm; Vol 61: Oct 1, 2004: 2015-2022.
 2. Based in part on proceedings of a breakfast symposium "Understanding & Managing Drug Shortages" held during the 37th ASHP Midyear Clinical Meeting on December 9, 2002.



In the News...

1. Flu Vaccine Shortage Leads to Price Inflation

A recent survey conducted by the American Society of Health-System Pharmacists (ASHP) revealed that opportunistic pharmaceutical distributors are offering the flu vaccine at highly inflated prices – in many cases more than four times the original market value.

<http://www.ashp.org/emplibrary/Flu%20Vaccine%20Survey%20Report.pdf>

HHS Secretary Tommy G. Thompson sent a letter to the Attorney General of each state today urging them to thoroughly investigate reports of price gouging involving the flu vaccine and to prosecute those found to be taking advantage of the vaccine shortage. The CDC is collecting reports on price gouging and sharing this information with the National Association of Attorneys General and state prosecutors. Information on who is recommended to get the flu vaccine is available from the Centers for Disease Control and Prevention (CDC) at www.cdc.gov/flu/protect/whoshouldget.htm

2. JCAHO Updates

Two Remaining Workshops on Medication Errors: There are only two remaining, one-day workshops titled - "Transforming Medication Error Data into Meaningful Information". This interactive program will be offered on the following dates in **2004**:

- **November 1 in Oakbrook Terrace, IL (at 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>

Corrections to 2005 Requirements for Hospitals: Joint Commission Resources recently published information regarding revisions to the 2005 Requirements for hospitals that pertain to medical staff. [Click here to read more.](#)

Alert Issued on Patient Awareness Under Anesthesia: According to a recent alert issued by the Joint Commission, the traumatic experience of patients who are partially awake while under anesthesia during a surgical procedure affects an estimated 20,000 to 40,000 patients each year representing one to two cases in every 1,000 general anesthetics administered. [Click here to read more.](#)

Collaboration on measures for deep vein thrombosis: JCAHO and NQF are working together to develop standardized performance measures for the prevention and care of deep vein thrombosis. The resulting measures will then be subjected to the NQF's Consensus Development Process, which will likely lead to formal endorsement of the measures as national consensus standards. http://www.jcaho.com/news+room/news+release+archives/jcaho_092704.htm

3. USP Updates

Workshop to Preview Chapter '797' Changes: The workshop on November 12-13, 2004 entitled Practical Application of USP to Pharmaceutical Compounding, Packaging and Dispensing will focus on *USP-NF Chapter <797> Pharmaceutical Compounding- Sterile Preparations*, as well as other *USP-NF* general chapters and monographs as they relate to current pharmacy practice. Those in attendance of this workshop will have first access to proposed revisions to 797 and will have an opportunity to interact with the USP Expert Committee, which will be available to address comments and concerns regarding 797. A JCAHO representative will also be available to discuss the impact of the proposed changes on compliance requirements in your dispensing location. Current compounding and packaging issues, as well as official compendial standards will also be discussed. This workshop will be extremely beneficial to all persons responsible for compounding and packaging medications for patient administration, especially those engaging in sterile preparations. Participants completing the workshop will also receive a USP Certification of Completion, and 15 hours of Continuing Education Credit through the University of Wisconsin. Registration for this 2-day event is \$425. Registration information is available at: <http://www.usp.org/education/workshops/pharmacy.html>

USP Holds December Seminar on Low-density Polyethylene Containers: Healthcare practitioners, industry leaders, and regulators are invited to join in discussions and provide solutions for the labeling of Low-density Polyethylene (LDPE) Containers. USP is hosting a seminar that provides an opportunity to interact with USP experts and staff, as well as industry and government attendees in addressing the labeling concerns with LDPE containers and proposing possible solutions to present to the FDA for improved labeling and patient safety. The use of LDPE containers has been recognized as posing two particularly significant safety concerns:

- Permeability
- Legibility of the container label

In addition, there is potential for medication errors resulting from confusion between the inhalation products and injectable solutions (i.e., Heparin) also being packaged in the LDPE containers.

This *free* ½ day seminar is being held on Wednesday December 15, 2004, 1:00 PM to 5:00 PM EST, at USP Headquarters (Wood Room), 12601 Twinbrook Parkway, Rockville, Maryland. The seminar participants include:

- Mike Cohen (President, Institute for Safe Medication Practices)
- William Kelly (Chair- USP Safe Medication Use Expert Committee)
- Patty Kiang (Delivery Device & Package Support Schering Laboratories)
- Eugene Sullivan (Deputy Director, CDER, FDA)
- Vibhakar Shah (Chemist, CDER, FDA)

Please reserve a spot for this important seminar by completing the online registration form (www.usp.org/patientsafety) and submitting t E-mail— Conferences@USP.org Fax— 301-816-8236 Telephone—301-816-8510 (Kelly Coates)

4. FDA Updates

MedWatch Safety Information Postings: The August 2004 posting includes 36 drug products with safety labeling changes and includes sections/subsections changed and a description of new or modified safety information in the Contraindications, Boxed Warning, or Warnings sections. The Summary page: http://www.fda.gov/medwatch/SAFETY/2004/aug04_quickview.htm
Detailed list of the affected drug products and the specific sections that have changed:

<http://www.fda.gov/medwatch/SAFETY/2004/aug04.htm>

Lung Injury is Most Frequent Cause of Blood Transfusion Deaths: Acute lung injury was the most frequent cause of blood transfusion-related deaths in 2003. Transfusion-related acute lung injury (TRALI) is caused by an antigen-antibody reaction and some blood donors are more likely to carry these antibodies than others. The FDA has outlined ways to recognize and treat the condition in the October installment of its online video series, *FDA Patient Safety News*. Symptoms usually begin within one to two hours after the transfusion and are fully present within six hours. Depending on the severity of the symptoms, patients may require respiratory support.

Class I Recall of Ventilators: Healthcare professionals were recently notified by FDA and Pulmonetic Systems, Inc. of a recall of the LTV series of ventilators, models 1000, 950, 900 and 800. These ventilators are designed to automatically switch to an internal battery operation when an external power source is removed. However, the ventilators have malfunctioned when switching to the internal battery, causing failure of the ventilator to breathe for the patient. <http://www.fda.gov/medwatch/SAFETY/2004/safety04.htm#Pulmonetic>

5. Bar-Code 'Best Practices' are Identified

Based on the experience gained by the Veterans Health Administration, fifteen best practices for implementing a barcode medication administration system have been identified. <http://www.premierinc.com/all/safety/publications/09-04-downloads/04-vha-bcma.pdf>

6. AHRQ Releases Guide to Help Hospitals Use its Quality Indicators

AHRQ recently announced the availability of a new guide - *Guidance for Using the AHRQ Quality Indicators for Hospital-Level Public Reporting or Payment*. AHRQ's Quality Indicators are measurement tools that were originally developed to help hospitals use their own discharge data to better understand and improve the care they provide. The Guide was created to answer questions on how to productively use the Quality Indicators for public reporting and quality-based payment strategies. http://www.qualityindicators.ahrq.gov/downloads/technical/qi_guidance.doc

USP Medication Error Reporting Programs:



MEDMARXSM—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.

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