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**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.

## CAPSLink™

**March 2008**

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## Compounded Drug Preparation Errors in Hospitals

During the past several years, issues related to pharmaceutical compounding and compounded drugs have emerged as “hot topics” in the pharmacy profession. Additionally, national attention has been drawn to the subject of adverse events associated with compounded pharmaceutical preparations over concerns from the public and other medical and patient safety groups related to the lack of standardized federal and state laws and policies. There is also a perceived lack of public accountability for the safety and standardization of practices related to compounded pharmaceuticals. The FDA has been urged by numerous agencies and organizations to become more aggressive in regulating pharmacies involved in compounding.<sup>1</sup> Stories of preventable patient fatalities, such as the two deaths in Oregon and Washington in the spring of 2007 related to improperly prepared colchicine injections compounded by a compounding pharmacy in Texas, have brought these issues to the forefront as a patient safety concern.<sup>2</sup> In a past issue of the Compounding Today Newsletter, (Volume 4, Issue 30, August 3, 2007), Loyd V. Allen, Jr., PhD, RPh, the Editor-in-Chief also provided commentary on the issue of adverse events related to compounded drugs.<sup>3</sup> Albeit, pharmaceutical compounding is a safe and vital component of healthcare today. In an effort to determine the number and significance of medication errors associated with compounded drugs, a study of 277 records was conducted for medication errors reported to the USP MEDMARX<sup>®</sup> program between January 1, 2003, and August 31, 2007. Because MEDMARX is primarily a hospital/health-system based medication error reporting system, the errors associated with compounded drugs reported to this database will likely reflect more inpatient records than would most likely be seen if such errors were reported and compared for all compounded drug errors from community and compounding pharmacies.

Of 277 selected records, five (1.8%) were categorized as resulting in patient harm (NCC MERP *Error Category Index*, Categories E-H), with no fatality (Category I) documented. The majority of errors were reported as Categories C, errors that reached the patient but did not result in harm (n = 134, 48.4%) and B, errors intercepted before reaching the patient (n= 106, 38.3%). Table 1 summarizes the distribution of errors in the error categories.

**Table 1: Severity of Compounded Drug Preparation Errors<sup>a</sup>**

Error Category	n	% <sup>b</sup>
<b>Potential Errors</b>		
A	18	6.5
<b>Intercepted Errors</b>		
B	106	38.3
<b>Nonharmful Errors</b>		
C	134	48.4

D	14	5.0
<b>Harmful Errors</b>		
E-I	5	1.8
<b>Total</b>	<b>277</b>	

- a. For complete Index of Medication Error Categories, developed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), See: [www.nccmerp.org](http://www.nccmerp.org)
- b. Percentages have been rounded and may not total 100%.

### **Levels of Staff Associated with Compounded Preparation Errors**

Medication errors associated with compounded drugs were reported among all healthcare disciplines (as seen in Table 2). This correlates with the distribution of errors by node (phase) of the medication-use process. Dispensing represented 40.5% of all reported nodes, followed by prescribing at 22.4%, transcribing at 18.1%, and administration at 19.3%.

**Table 2. Staff Involved with Compounded Drug Preparation Errors<sup>a</sup>**

Staff	n	% <sup>b</sup>
Nurse (Registered)	83	32
Pharmacist	62	24
Physician	54	21
Pharmacy technician	44	17
Licensed vocational nurse	8	3.1
Unit Clerk/ Secretary	6	2.3
Nurse Anesthetist	1	0.39
Patient / family caregiver	1	0.39
<b>Total</b>	<b>259</b>	

- a. Based on 259 selections from 277 records reported during the period 01/03-08/07
- b. Percentages have been rounded and may not total 100%.

Furthermore, of the five (5) harmful errors as documented in Table 1 (categories E-F), two each were documented as occurring during the dispensing and monitoring nodes of the medication use process and one (1) harmful error (category F) reported to occur during the administration node.

### **Dosage Forms**

Injections (n = 70, 25.2%) were documented as the most common drug preparation formulation (dosage form) associated with compounded drug errors, (Table 3). Of interest, total parenteral nutrition (TPN) products accounted for 60% (n = 42) of all reported compounded drug errors involving injections. Additionally, drug specific preparations most reported for injection errors included bupivacaine and fentanyl at 21.4% (n = 15), which were identified for epidural administration. A variety of topicals (ointments, creams, gels) were reported as the dosage form in 9.7% (n = 27) of all compounded drug preparation errors, and solutions were documented in 22 reports (7.9%) with ophthalmic solutions as the specific drug products listed. Suspensions (primarily oral) were reported as the primary dosage form in 15 error reports (5.4%) with "Magic Mouthwash" (diphenhydramine, Mylanta<sup>®</sup>, lidocaine combination) listed as the specific drug preparation in 13 of the 15 reported suspensions. Numerous (n = 132/277, 47.7%) errors reported to

MEDMARX during this period did not document either a dosage form or specific preparation in those fields; however, the following additional injectable drug preparations were most mentioned in the error description field: heparin, nitroglycerin, albumin, furosemide, dopamine, potassium chloride, insulin, sodium bicarbonate, chemotherapy agents, and several injectable antibiotics.

**Table 3: Compounded Drug Preparation Dosage Form Errors**

Dosage Form	n <sup>a</sup>	% <sup>b</sup>
Injection	70	25.2
Topical (ointments, creams, gels, etc.)	27	9.7
Solution	22	7.9
Suspension	15	5.4
Inhalation	4	1.4
Tablet	4	1.4
Irrigation	3	1.1

a. Based on 145 reported selections and 277 records reported during the period 01/03-08/07. Each record may not have documented a specific dosage form or product

b. Percentages have been rounded and may not add up to 100%.

### Types of Errors

Types of medication errors that were reported with compounded drugs are documented in Table 4. Prescribing, omission, and improper dose/ quantity errors accounted for 64.7% of all error types reported, followed by unauthorized /wrong drug (n = 34, 12.3%) and drug prepared incorrectly (n = 24, 8.7%) rounding out the top five of all compounded drug error types. Therefore, almost 1/4 of all patients experienced an error due to the prescribing process or 1/5 did not receive their intended drug and 1/5 received either the wrong dose or quantity of the prescribed medication.

**Table 4: Types of Compounded Drug Preparation Errors**

Type of Error	n <sup>a</sup>	% <sup>b</sup>
Prescribing error	64	23.1
Omission	58	21.0
Improper dose/quantity	57	20.6
Unauthorized / wrong drug	34	12.3
Drug prepared incorrectly	24	8.7
Wrong time	16	5.8
Extra dose	9	3.2
Wrong patient	7	2.5
Wrong administration technique	6	2.2
Mislabeled	3	1.1
Deteriorated product	3	1.1
Wrong route	1	0.36

a. Based on 301 reported selections, and 277 records reported during the period 01/03-08/07. Each record may have one or more selections.

b. Percentages have been rounded and may not add up to 100%.

## Case Example<sup>a</sup>

The following case scenario illustrates how one error related to a compounded injectable preparation occurred and how implementation and adherence to standardized policies and procedures could have prevented or minimized such an error.

A 61-year-old patient was admitted to a hospital emergency department (diagnosis not specified) and found to have normal saline running with the drug Synercid<sup>®</sup> (quinupristin/dalfopristin) added to the base solution. The label on the Synercid IV bag was clearly labeled to only use D5W. Subsequently, the patient was observed to have a pink/red rash on the back of the legs and was transferred immediately to the facility's coronary intensive care unit (CICU) for further observation. The patient was also experiencing peritonitis and sepsis, which were undetermined if specifically related to this occurrence. Actions taken to prevent reoccurrence of this error included staff education on the incompatibility between normal saline and Synercid. Additionally, staff was reminded that neither normal saline nor heparin should be used to flush the line because of incompatibility concerns. Lastly, the staff was reminded to always visibly inspect the prepared solution for particulate matter prior to administration to the patient.

### Error Causes

Table 5 documents the significance of the human factors component (performance deficit, procedure/protocol not followed) related to causes of the compounded drug preparation errors. Although a total of 71 different causes were identified for compounded drug preparation errors, it is unusual to see abbreviations and documentation included among the top 6 causes as compared to historical MEDMARX data. Performance deficit (human) accounted for 35.4% (n = 98) of all compounded drug error causes reported to MEDMARX during the period January 1, 2003, through August 31, 2007. Procedure or protocol not followed documented 22% (n = 61) of all compounded drug related error causes reported during this same period and communications (n = 39) was documented at 14.1%.

**Table 5. Top Causes of Errors Related to Compounded Drugs<sup>a</sup>**

Cause	n	% <sup>b</sup>
Performance (Human Deficit)	98	35.4
Procedure / protocol not followed	61	22.0
Documentation	56	20.2
Communication	39	14.1
Knowledge deficit	20	7.2
Abbreviations	13	4.7

a. Based on 577 selections from 277 records reported during the period 01/03-08/07. Each record may document one or more selections.

b. Percentages are based on a denominator of 277 total records and have been rounded and may not total 100%.

## **Where the Errors Occurred**

Locations varied within hospitals and healthcare facilities where medication errors originated that were associated with compounded drug preparations. Based on the data reported to MEDMARX during the period January 1, 2003 –August 31, 2007, a preponderance (41.2%, n = 114) of all compounded drug errors were reported to have occurred on an inpatient nursing unit (ward) or other patient care areas. Of interest, the pharmacy where the majority of all drug products and preparations are formulated/prepared in a facility followed closely behind nursing units with 32.9% (n = 91). Outpatient clinic areas documented 27 compounded drug-related errors (9.7%) and intensive care units (medical, surgical and pediatrics) accounted for 20 errors (7.2%).

## **Case Example<sup>a</sup>**

The following case scenario illustrates how one error related to a compounded preparation occurred in a clinic as a result of inconsistent adherence to procurement and dispensing of bulk “clinic issue” medications.

A 52-year-old outpatient was seen in the dermatology clinic and received a concentrated topical camphor solution for dressing changes that needed to be diluted prior to use. The patient was then transferred (with the concentrated solution) for wound care to the general medicine clinic, where clinic nurses preparing the dressing changes failed to further dilute the concentrated solution. When the dressings were applied to the patient, the patient experienced burning pain. The area involved was flushed and pain medications (unknown) were given. The patient was observed and fully recovered. This error highlights the importance of ongoing communications among staff at every patient transfer (handoff) in addition to the significance of never dispensing a concentrated solution directly to a patient or clinic area.

a. Case reports reflect actual error reports but may have been modified for clarity.

## **Recommendations to Prevent Compounded Drug Preparation Errors**

Based on the reports studied, USP recommends:

- Implement training and competency assessment programs for all personnel (pharmacy, nursing, other) who are involved in any activities related to compounded sterile and nonsterile preparations.
- Develop and implement standardized operating procedures (SOPs) for the facility, personnel, equipment, ordering, preparation, dispensing, administration, packaging, stability, labeling, storage, quality control and records keeping of all compounded preparations (sterile and nonsterile).<sup>4</sup>
- Ensure all orders for compounded preparations are reviewed by a pharmacist.
- Ensure all compounded sterile and nonsterile preparations are checked by a pharmacist prior to dispensing or released to a patient care unit for administration to a patient.
- Standardize the prescribing (ordering) processes for total parenteral nutrition (TPN) and other routinely compounded intravenous solutions.<sup>5</sup>

- Implement independent “double-check” procedures for all compounded sterile and nonsterile preparations before and during the preparation, dispensing and administration of all compounded products.<sup>5</sup>
- Implement policies and procedures that ensure all patients who receive a compounded preparation are appropriately monitored for their response to the drug therapy.

### References:

1. WebMD Health News. Closer Scrutiny Urged for Compounded Drugs. [Available from:](#) accessed 9/6/2007, 02/12/2008).
2. FDA MedWatch, 2007 Safety Alerts for Drugs, Biologics, Medical Devices, and Dietary Supplements. Information on colchicine Injectable Products. April 30, 2007 [available at:](#) (accessed 9/14/2007, 02/12/2008)
3. Allen L. Adverse Event Reporting in Compounding. Compounding This Week Newsletter Volume 4, Issue 30. August 3, 2007. Available at: <http://www.compoundingtoday.com/>
4. Chapter <1075> Good Compounding Practices, USP30/NF25, U.S. Pharmacopeia (USP), Rockville, MD.
5. Fatal 1,000-Fold Overdoses can occur, particularly in neonates, by transposing MCG and MG. Institute of Safe Medications Practices (ISMP) Acute Care Newsletter, September 6, 2007. [Click here](#)



### 1. USP Offers Educational Programs on Revised Chapter <797>

USP will conduct educational Webinars and Workshops on General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. The sessions will provide practitioners with a variety of tools to facilitate implementation of the revised standard by June 2008. Learning exercises will include developing a gap analysis, creating implementation time lines, and establishing standard operating procedures. Webinar participants will receive a free copy of the new *Guidebook to Pharmaceutical Compounds*. Pharmacy continuing education credits (ACPE) will be provided for all Workshop sessions.

#### <797> Webinar Series 2008 (90 minutes each)

**Remaining Dates-** Apr. 3, May 1, May 15, Jun. 5

**Topics-** Chapter <797> revisions, microbial contamination, sterilization methods, disinfectant cleaning, garbing, media fill testing, hazardous drugs, environmental monitoring controls, facility design, radiopharmaceuticals, and specialty CSPs.

**To Register for the Webinars**

Visit [www.intellor.com/usp/797webinars](http://www.intellor.com/usp/797webinars)

**<797> Workshops 2008 (2-day program)**

**Remaining Dates-** Apr.1, Apr.17–18, May 22–23

**Topics-** Facility design, media fill testing, isolator types, clean rooms, implementation timelines, septic gap analysis, CSP microbial contamination, sterilization methods, developing SOPs, training employees and more.

**To Register for the Workshops**

Call (301) 230-6304, or email [www.usp.org/goto/797resources](http://www.usp.org/goto/797resources)

**2. FIP Global Conference on the Future of Hospital Pharmacy**

The International Pharmaceutical Federation (FIP), which is the international organization representing 2 million pharmacists worldwide, will hold a conference August 30-31, 2008 as part of the 68<sup>th</sup> FIP Congress in Basel, Switzerland, to address issues that will shape the future of hospital pharmacy practice. Hosted by the FIP Hospital Pharmacy Section, the conference is open to any hospital pharmacist or other individuals interested in hospital pharmacy practice. A primary goal of the conference is to identify opportunities for improving all aspects of the medication-use process, including the procurement, preparation, distribution, prescribing and administration of medicines in hospitals. An outcome expected from the conference is the development of consensus statements that offer guidance on the development of tools, time-lines and strategies for achieving advancements to the practice of hospital pharmacy.

For additional information about this conference, please visit the conference website at [www.fip.org/globalhosp](http://www.fip.org/globalhosp)

**3. NCC MERP Issues Recommendations Promoting Safe Use of Suffixes**

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) recently issued its latest recommendations, which are intended to promote the safe use of drug suffixes and prevent errors and adverse drug events associated with their use. Council recommendations on suffixes available at: <http://www.nccmerp.org/council/council2008-08-01.html>

**4. ISMP Advises on Preventing Methadone Errors and Adverse Events**

The February 14, 2008 issue of the Institute of safe Medication Practices (ISMP) Medication Safety Alert included information on safe practice recommendations in an effort to prevent life-threatening errors with methadone. The communication provided healthcare professionals with risk-reduction actions related to the prescribing, dispensing and administration of the drug. Additionally, important patient information (what to tell the patient) was provided. For more detailed information from the FDA on this subject, see:

<http://www.fda.gov/cder/drug/advisory/methadone.htm>

**5. Heparin Flush and Injection Public Health Update from the FDA**

The Food and Drug Administration recently issued an update related to heparin to inform the public that Baxter Healthcare Corporation has extended its recall of multi-dose vials of heparin sodium for injection to also include single-dose vials of heparin sodium for injection. As a precautionary measure Baxter is also recalling its heparin lock flush products. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the US market. FDA has also confirmed that there are multiple U.S. suppliers of heparin lock flush products with substantial inventory, making a shortage of these products unlikely. FDA investigators and scientists are working independently and in collaboration with the Centers for Disease Control and Prevention, and Baxter to discover the underlying cause of the adverse events. To access the FDA Press Release, [click here](#)

## **6. FDA Advisory on Correctly Using Spiriva<sup>®</sup> and Foradil<sup>®</sup> Capsules**

A public health advisory was recently announced by the FDA to highlight the correct use of Spiriva (tiotropium bromide inhalation powder) and Foradil (formoterol fumarate inhalation powder) capsules. The active drug component is inhaled through an inhalation device to improve breathing in patients with asthma and in individuals affected by chronic obstructive lung disease (COPD) and bronchitis. Both Spiriva and Foradil will not treat a patient's breathing condition if the contents of a capsule are swallowed rather than inhaled. Doctors, nurses, and pharmacists are encouraged to discuss with patients how to correctly use the Spiriva HandiHaler or Foradil Aerolizer. FDA Advisory available at: [http://www.fda.gov/cder/drug/advisory/tiopropium\\_formoterol.htm](http://www.fda.gov/cder/drug/advisory/tiopropium_formoterol.htm)

## **7. Consumer Toll Free Number for ADE Reporting now Required**

The FDA has issued an interim final rule that is posted in the *Federal Register*, requiring pharmacies to provide patients with a toll free number to report adverse drug events. The toll free number is 1-800-FDA-1088 and although the new law went into effect January 1, 2008, enforcement actions will not begin until January 2009 to allow pharmacies and the pharmaceutical industry adequate time to implement procedures to ensure compliance. To review the FDA Final Rule, [click here](#)

## **8. Proposed Rule Issued for Implementation of Patient Safety Act**

The Department of Health and Human Services (HHS) has issued the proposed rules that will implement the 2005 Patient safety and Quality Improvement Act, which will allow for the formation of Patient Safety Organizations (PSOs). The proposed rule is posted to the Federal Register and is open to public comment until April 14, 2008. To access the Federal Register Notice, [click here](#)

## **9. Look-Alike Sound-Alike Drug Names Lead to Errors**

The 8<sup>th</sup> annual national MEDMARX<sup>®</sup> Data Report released in February by the U.S. Pharmacopeia (USP) revealed that more than 1,400 commonly used drugs are involved in errors linked to drug names that look alike or sound alike.

According to findings in the MEDMARX report, 1.4% of the errors resulted in patient harm, including seven errors that may have caused or contributed to patient deaths. The study's authors further point out their belief that due to the under-reporting of errors, the actual number of adverse events resulting from look-alike/sound-alike errors is most likely understated. USP Press Release available

at: <http://www.usp.org/aboutUSP/media/newsCenter.html?article=105435>

## 10. MA Study Documents 10% of Patients Experience a Drug Error

According to a report released in mid February 2008 documenting the study of six Massachusetts community hospitals, one in ten (10%) of all patients experienced a serious and preventable medication error. To view the Boston Globe article, [click here](#)

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### USP Medication Error Reporting Programs:



**MEDMARX**®—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.
- Medication Safety Pocket Reference—a pocket-sized reference booklet containing listings of

similar drug names and dangerous abbreviations that could cause medication errors. Contact [custsvc@usp.org](mailto:custsvc@usp.org) and ask for item #3227702.

Similar Drug Names Poster—a wall poster for easy reference listing look-alike and sound-alike drug names known to cause confusion and potential medication errors when handwritten or communicated verbally. Posters are packaged in quantities of 1 (item # 3728251) 10 (item # 3728252) and 50 (item # 3728253). Contact [custsvc@usp.org](mailto:custsvc@usp.org) and ask for the appropriate item number.

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