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USP Patient Safety
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.

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USP Medication Error Analysis

Errors Involving Drug Products Used to Treat Cardiovascular Diseases: Part 1

Drug products used to treat cardiovascular diseases (e.g., hypertension, congestive heart failure, ischemia, and arrhythmias) have been associated with a significant number of adverse drug events.¹ Cardiovascular drug products are among the most widely used in both the hospital and ambulatory care settings and previous studies that have examined cardiovascular patients suggest that a significant degree of morbidity and mortality may

be preventable.²

This issue of CAPSLink is the first segment of a three-part series examining errors involving medications used to treat cardiovascular disease. This issue will focus on therapeutic classes and selected drugs used to treat cardiovascular patients, locations where these errors occurred, and the staff associated with these events. The April issue (Part 2) will review the types and causes of cardiovascular medication errors as well as patient outcomes as the result of the error. The third and final segment of the series will examine more closely selected thrombolytic/anticoagulant agents used in the treatment of cardiovascular diseases.

The MEDMARX program uses the Veterans Administration Drug Classification System to categorize drug products into their respective therapeutic classes. Drugs categorized as cardiovascular agents fall into the following therapeutic classes: ACE Inhibitors, Antianginals, Antiarrhythmics, Antihypertensives, Antilipemics, Alpha-blockers/Related, Beta-blockers/Related, Calcium Channel Blockers, Cardiac Inotropic agents, Cardiovascular Agent/Other, Diuretics, Peripheral Vasodilators, and Sclerosing Agents.

Analyses of records submitted to USP's MEDMARX[®] program from January 2001 through August 2004 revealed over 80,000 errors involving a cardiovascular drug product. Approximately 46% (n=36,759) of these errors did reach the patient (Categories C and higher) and 1.8% (n=1,459) were harmful (Categories E-I). Among the harmful errors were 48 sentinel events (Categories G-I) including 16 fatalities (Table 1).

Table 1. Distribution by Error Category

Error Category ^a	n	%
Potential Error		
A	8,343	10.4
Intercepted Error		
B	35,280	44
Error Reaches Patient, No Harm		
C	28,606	36
D	6,694	8.3
Error, Harm		
E	1,158	1.4
F	253	0.3
G	16	0.02
H	16	0.02
Error, Death		
I	16	0.02

a) For complete error category definitions see www.nccmerp.org

Several cardiovascular drug categories were involved in more harmful errors than the historical 1.87% average harm occurrence seen for all errors reported to MEDMARX

from 2001-2004. The percentage of reported harm was the highest in five of the cardiovascular medication categories (Table 2).

Table 2. Top 5 Cardiovascular Medication Categories Involved in Harmful Errors

Cardiovascular Medication Category^a	Number of Errors	% Involved in Harmful Errors
Cardiovascular Agents, Other (e.g., misc. vasodilating agents, calcium salts, adrenergic agents, hemorrhheologic and platelet inhibitor agents)	1,370	4.4
Antiarrhythmics	3,749	3.1
Cardiac Inotropic Agents	4,824	2.8
Antihypertensives	6,924	2.6
Calcium Channel Blockers	10,067	2.5

a) Based on the Veterans Administration Classification System for medications.

There were 106 different cardiovascular drug products cited in the 1,459 harmful cardiovascular error events during the 1/1/2001 – 8/30/2004 time frame. The twenty most frequently reported drug products accounted for 73% of the total number of all cardiovascular drug selections (Table 3).

Table 3. Most Frequently Reported Cardiovascular Drug Products Involved in Harm^a

Generic Name	Therapeutic Class	Number of Times Cited	% of Total
Furosemide	Diuretics	208	12
Diltiazem	Calcium Channel Blockers	151	9
Nitroglycerin	Antianginals	115	7
Digoxin	Cardiac Inotropic Agents	105	6
Clonidine	Antihypertensives	90	5
Amiodarone	Antiarrhythmics	69	4
Metoprolol Tartrate	Beta-Blockers/Related	64	4

Lisinopril	ACE Inhibitors	62	4
Metoprolol	Beta-Blockers/Related	60	3
Atenolol	Beta-Blockers/Related	52	3
Verapamil	Calcium Channel Blockers	37	2
Amlodipine	Calcium Channel Blockers	36	2
Enalapril	ACE Inhibitors	31	2
Milrinone	Cardiac Inotropic Agents	29	2
Sotalol	Beta-Blockers	28	2
Hydralazine	Antihypertensives	27	2
Labetalol	Beta-Blockers/Related	26	1
Carvedilol	Beta-Blockers/Related	25	1
Isosorbide Mononitrate	Antianginals	22	1
Nifedipine	Calcium Channel Blockers	21	1

a) Based on 1,459 harmful error records listing 1,744 product selections. Product selections exceed the number of error records because some records listed more than one product involved in the error.

Although not classified under the Veterans Association Drug Classification System as cardiovascular drugs, several blood coagulation modifiers (e.g., anticoagulants like enoxaparin, heparin, and warfarin) are commonly used to prevent and treat cardiovascular thromboembolic events. Combined, the number of errors involving these products was 31,488 with 2.2% - 3.9% resulting in some level of harm to the patient (Table 4).

Table 4. Percentage of Harmful Errors for Selected Blood Coagulation Modifiers

Drug Product ^a	Number of Errors	% Involved in Harmful Errors
Enoxaparin	7,809	2.2
Heparin	13,131	3.9
Warfarin	10,548	3.4

a) All dosages and formulations combined.

Locations of Where Errors Occurred

Depending on the therapeutic class/drug, there was some variation as to where errors were reported to have occurred (Table 5). The nursing/patient care unit was the location most often identified across all cardiovascular drug classes and other selected blood coagulation modifiers. The inpatient pharmacy setting was frequently the second most common place where the error occurred but, subsequent locations differed depending on the therapeutic class or product. Combined, four adult intensive care units accounted for 7% (n= 5,336) of where errors occurred.

Table 5. Twenty Most Frequently Reported Locations Where Errors Occurred Involving Cardiovascular Drugs and Selected Blood Coagulation Modifiers

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Location Where Error Occurred	Cardiovascular Drugs ^a		Enoxaparin ^b		Heparin ^c		Warfarin ^d	
	n	%	n	%	n	%	n	%
Nursing (Patient Care) Unit	40,241	50	4,603	65	7,864	64	6,317	64
Pharmacy, Inpatient	16,795	21	1,328	19	1,487	12	1,788	18
Pharmacy, Outpatient	8,481	11	41	0.6	19	0.2	356	4
Clinic, Outpatient	2,845	4	26	0.4	10	0.08	310	3
Emergency Department	2,090	3	255	4	827	7	83	1
Intensive Care Unit, Medical	1,908	2.4	220	3	531	4	85	1
Intensive Care Unit Coronary	1,727	2.2	188	3	383	3	84	1
Intensive Care Unit, Surgical	915	1	56	0.8	187	2	40	0.4
Intensive Care Unit, General	786	1	79	1	193	2	37	0.4
Long-term Care Facility	660	0.8	64	1	38	0.3	277	3
Psychiatric, Inpatient	520	0.6	13	0.2	6	0.05	47	0.5
Psychiatric	380	0.5	10	0.1	3	0.02	23	0.2
Hospital, another	325	0.4	37	0.5	48	0.4	41	0.4
Intensive Care Unit, Neonatal	284	0.3	4	0.05	121	1	-	-
Rehabilitation Care Unit	265	0.3	39	0.5	20	0.2	131	1
Pediatrics	209	0.3	12	0.2	43	0.3	10	0.1
Oncology Department	184	0.2	25	0.4	62	0.5	38	0.4
Intensive Care Unit, Pediatric	153	0.2	4	0.05	24	0.2	3	0.03
Cardiovascular/Pulmonary Services	152	0.2	19	0.3	20	0.2	12	0.1
Labor /Delivery	149	0.2	7	0.1	21	0.2	-	-

a) Based on 80,100 selections; b) Based on 7,123 selections; c) Based on 12,381 selections; d) Based on 9,822 selections.

Levels of Staff Involved in Error Events

Many different types of health care practitioners initiate, perpetuate, and discover medication errors. MEDMARX captures 34 different levels of staff who may be involved with an error event. When examining cardiovascular agents and other products used to treat cardiovascular disease, registered nurses, pharmacists, and physicians were the three staff levels most often reported making the initial error (Table 6). However, various support and ancillary staff were also involved in making the initial error.

Table 6. Staff Levels Most Frequently Reported Making Initial Error Involving Cardiovascular Drugs and Selected Blood Coagulation Modifiers

Staff Making Initial Error	Cardiovascular Drugs ^a		Enoxaparin ^b		Heparin ^c		Warfarin ^d	
	n	%	n	%	n	%	n	%
Nurse, Registered	23,961	31	2,705	38	7,446	60	3,841	39
Pharmacist	15,991	20	1,379	19	1,412	11	1,898	19
Physician	15,410	20	1,546	22	1,395	11	1,468	15
Pharmacy Technician	9,957	13	177	3	401	3	568	6
Unit Secretary/Clerk	4,027	5	439	6	503	4	825	8
Nurse, Licensed Practical/Vocational	2,732	4	308	4	348	3	561	6
Physician, Resident	1,655	2	209	3	136	1	128	1
Pharmacy Personnel, non-specific	1,470	2	51	1	104	1	86	1
Nursing Personnel, non-specific	1,121	1	125	2	212	2	165	2
Student	367	0.5	17	0.2	23	0.2	26	0.3
Physician Assistant	336	0.4	20	0.3	27	0.2	24	0.2
Nurse Practitioner/Advanced Practice Nurse	304	0.4	25	0.4	23	0.2	27	0.3
Patient/Family Member/Caregiver	225	0.3	8	0.1	27	0.2	70	1
Nurse, Graduate	133	0.2	8	0.1	25	0.2	15	0.2
Unlicensed Assistive Personnel	129	0.2	8	0.1	19	0.15	13	0.1
Nurse, Travel	122	0.2	19	0.3	48	0.4	27	0.3
Nursing Assistant/Aide	119	0.2	10	0.1	13	0.1	26	0.3
Physician, Intern	105	0.1	16	0.2	8	0.06	7	0.07
Radiology Technician	29	0.04						
Emergency Medical Services	2	0.1	1	0.01	4	0.03	-	-

a) Based on 78,293 selections; b) Based on 7,079 selections; c) Based on 12,315 selections; d) Based on 9,794 selections.

Observations

Based on the above findings, several general observations can be made:

- 1) Five out of 15 cardiovascular drug classes are reportedly involved more often in harmful events and, therefore, should stimulate special attention as to how they are used throughout the medication use process.
- 2) Certain antiplatelet and anticoagulation agents are more often associated with harmful events than what is seen in the general MEDMARX database suggesting a need for additional safety measures in the use of these agents.
- 3) Cardiovascular drug errors occur in a variety of patient care areas, including diagnostic areas (e.g., cardiac catheterization lab) and ambulatory settings (e.g., outpatient clinic).
- 4) Pharmacists and physicians reportedly made approximately the same number of errors regardless of drug class.
- 5) Nursing, pharmacy, and medicine supportive personnel (e.g., technicians, unit clerks, aides, unlicensed personnel, students) combined made 22% of the errors involving cardiovascular drugs compared to 17% with warfarin, 12% with enoxaparin, 11% with heparin, and 5% with abciximab. This may suggest that additional training and oversight of supportive personnel is warranted.

Recommendations to Improve Safety with Cardiovascular Medications

The various clinical conditions comprising cardiovascular disease (e.g., coronary artery disease, heart failure, and hypertension) combined with the number of drug products used to treat these conditions has led to a broad spectrum of guidelines, recommendations, and suggestions for improving medication safety. Numerous organizations have developed recommendations targeting specific diseases (e.g., hypertension) and specific drug products (e.g., warfarin). The National Guideline Clearinghouse™ (NGC) is a public resource for evidence-based clinical practice guidelines. NGC is an initiative of the [Agency for Healthcare Research and Quality \(AHRQ\)](#).

The following are a few of the NGC guidelines pertaining to the treatment of cardiovascular disease with some relevance to medication safety:

- [Expert consensus document on angiotensin converting enzyme inhibitors in cardiovascular disease](#)
- [Improving medication management for older adult clients](#)
- [American Heart Association/American College of Cardiology Foundation guide to warfarin therapy](#)
- [Guide to anticoagulant therapy: heparin: a statement for healthcare professionals from the American Heart Association](#)
- [Expert consensus document on the use of antiplatelet agents. The task force on the use of antiplatelet agents in patients with atherosclerotic cardiovascular disease of the European Society of Cardiology](#)

General approaches to improving medication safety also apply to improving the safety of medications used in treating cardiovascular diseases including:

- 1) Use standardized medication order forms for high-risk medications and avoid the use of abbreviations for the generic or brand name of any drug product.

- 2) Review drug protocols to ensure they require that an appropriate assessment is made of all recent drug therapy.
- 3) Provide alerts or prompts on order forms to record the patient's weight for weight-based therapy.
- 4) Limit the number of products in a given therapeutic class to avoid confusion and look-alike/sound-alike errors.

Another general approach to reducing medication errors that was advocated in the Institute of Medicine's report *To Err Is Human: Building a Safer Health System* is to include a pharmacist's participation in patient rounds. A study on the use of a clinical pharmacist on the cardiology wards at Duke University Hospital showed improvement in the identification and correction of medication errors.³

Watch for Part II in April

1. Bates DW, Miller EB, Cullen DJ, et al. for the ADE Prevention Study Group. Patient risk factors for adverse drug events in hospitalized patients. *Arch Intern med.* 1999;159:2553-2560.
2. Bedell SE, Deitz DC, Leeman D, et al. Incidence and characteristics of preventable iatrogenic cardiac arrests. *JAMA.* 1991;265:2815-2820.
3. Lapointe NM, Jollis JG. Medication errors in hospitalized cardiovascular patients. *Arch Intern Med.* 2003;163:1461-1466.



1. CAPSLink Readership Survey (Final Phase)

This is the final phase of a survey we are conducting of this newsletter's readership in an effort to continuously improve its quality. The intent of the survey is to gauge the perceived value and usefulness of the information, recommendations, and news items. As a token of appreciation for your time to complete this survey, USP will send each respondent a Similar Drug Names Poster--a wall poster for easy reference that lists look-alike and sound-alike drug names known to cause confusion and potential medication errors when handwritten or communicated verbally. We look forward to hearing from you! <http://www.usp.org/survey/CAPS/Reader05E.html>

2. FDA Updates

Fatal Gas Mix-Ups: Patient deaths have been previously reported where patients were accidentally given the wrong gas, such as nitrogen or CO₂, instead of oxygen. A recent report to the Institute for Safe Medication Practices indicates that gas mix-ups are still involved in fatal errors.

<http://www.accessdata.fda.gov/psn/transcript.cfm?show=37#7>

Brethine-Methergine Mix-ups: Both USP and ISMP have previously reported on dangerous mix-ups between Brethine® (terbutaline sulfate) and Methergine (methylergonovine maleate). The packaging of both products looks similar with each available as 1mL ampuls packaged in amber plastic tubes covered by a foil label with the product name in small print. Both products are frequently used in labor and delivery settings, but are used for very different clinical reasons.

<http://www.accessdata.fda.gov/psn/transcript.cfm?show=37#8>

Read USP report: [Click here.](#)

3. Proper Reconciliation Helps Avoid Medication Errors

According to the Institute for Healthcare Improvement (IHI), forty-six percent of all medication errors occur at transition points (patient admission, transfer to different level of care or discharge). Many of these errors are the result of either wrong or incomplete information about the medications the patient is taking. Wrong or incomplete information is a system failure that health care providers need to address. IHI offers various tools to help health care facilities improve their medication reconciliation activities.

<http://www.ihl.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/#Medication%20Reconciliation>

4. NQF and AHRQ Identify Safe Practices

Member organizations of the National Quality Forum (NQF) have endorsed "30 Safe Practices for Better Health Care," and believe that these 30 safe practices should be universally adopted in all applicable health care settings to reduce the risk of harm to patients. AHRQ, which supported NQF's work, released a new fact sheet on these safe practices. Read the [fact sheet](#) and select to read the [executive summary](#) of the full report. A print copy of the fact sheet is available by sending an e-mail to ahrqpubs@ahrq.gov

5. CPOE Systems Can Contribute to Medication Errors

Earlier this month, a study published in *JAMA* identified 22 types of medication errors that may have resulted from the computerized physician order entry (CPOE) system used at the Hospital of the University of Pennsylvania. USP's 5th Anniversary MEDMARX report released in January also identified areas where CPOE systems may themselves be a "source of errors." [Comments on JAMA study](#)
[USP MEDMARX Report:](#)

6. JCAHO Updates

Improving Communication: Joint Commission's Patient Safety Goal #2: Recognizing that improving communication among caregivers requires additional attention when giving or receiving verbal orders, using abbreviations, preparing labels, and reporting lab values, the Joint Commission offers suggestions for compliance with this National Patient Safety Goal. <http://www.jcinc.com/publications.asp?durki=9101>

Turning Data into Information Five Tips for Transforming Data: Once your organization has succeeded in collecting sufficient data, the next step is to analyze the data to identify areas needing improvement and implement appropriate strategies. Joint Commission offers tips for transforming your data into knowledge.

<http://www.jcinc.com/publications.asp?durki=9259>

Campaign to Prevent Medication Mistakes: A new national campaign is urging Americans to "Speak Up" to help avoid medication errors. The objective of this

campaign is to encourage individuals to share all the medications they are currently taking with their pharmacists, doctors and other caregivers as part of any routine or emergency treatment. To obtain free Campaign and other related educational materials, go to the Joint Commission Web site or call the Joint Commission Resources Customer Service at 877.223.6866, 8 a.m. to 8 p.m. CT, Monday through Friday.

http://www.jcaho.org/news+room/press+kits/medication_mistakes/index1.htm

7. John M. Eisenberg Patient Safety and Quality Awards

The Joint Commission and National Quality Forum are now accepting nominations for the 2005 John M. Eisenberg Patient Safety and Quality Awards, which recognize individuals and healthcare organizations that are making significant contributions to improving healthcare quality and patient safety. The deadline for submissions is May 27, 2005.

Nomination forms are available at www.qualityforum.org. Questions about the awards may be directed to EisenbergAward@jcaho.org or info@qualityforum.org

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 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 and ask for the appropriate item number.

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12601 • Twinbrook Parkway • Rockville • Maryland • 20852

