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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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Errors Involving Drug Products Used to Treat Cardiovascular Diseases: Part 2

This is the second segment of a three-part series examining errors involving medications used to treat cardiovascular diseases. The first segment focused on therapeutic classes and selected drugs used to treat cardiovascular patients, locations where these errors occurred, and the staff associated with these events. This issue examines several other aspects of cardiovascular medication errors: (1) Their distribution across the medication use process; (2) Proportion of the **Types of Error**; (3) Proportion of the **Causes of Error**; and (3) The range

and level of patient care provided as a result of these errors. Data provided below are based on cardiovascular drug errors during the time period between January 1, 2001 through August 31, 2004.

According to records submitted to the MEDMARX[®] program, the administering and transcribing nodes (i.e., phases) of the medication use process (MUP) have historically comprised the largest proportion of where errors originate. This is the first USP analysis of MEDMARX data that shows a relatively equal distribution of an error's origin across four of the 5 MUP nodes (Figure 1). The **Dispensing Node** comprised a slight majority of where cardiovascular drug errors originate.

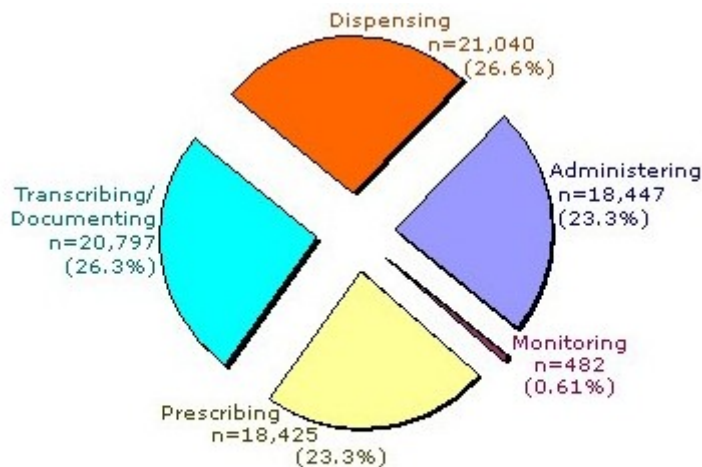


Figure 1: Distribution of Errors Across the Medication Use Process

The most frequently reported **Types of Error** involving cardiovascular drugs were *Improper dose/quantity*, *Omission error*, and *Prescribing error* (Table 1). A two-way cross tabulation analysis of **Types of Error** by **Error Category Index** revealed that several **Types** exceeded the historical overall percentage of harm of 1.87% for errors reported to MEDMARX from 1999-2003 (Figure 2). Similar to previous MEDMARX reports, the findings indicate that the most harmful errors disproportionately arise from *Wrong administration technique* errors (6.4%).

Table 1. Types of Error Involving Cardiovascular Drug Products ^a

Type of Error ^b	n	%
Improper dose/quantity	19,239	25.01
Omission error	18,429	23.96
Prescribing error	16,759	21.79
Unauthorized/wrong drug	11,009	14.31
Extra dose	5,543	7.21
Wrong patient	5,406	7.03

Wrong time	5,178	6.73
Drug prepared incorrectly	3,725	4.84
Wrong dosage form	2,209	2.87
Wrong route	915	1.19
Wrong administration technique	838	1.09
Expired product	102	0.13
Deteriorated product	74	0.10

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

b) Based on 76,918 unique error records documenting 89,426 Type of Error selections.

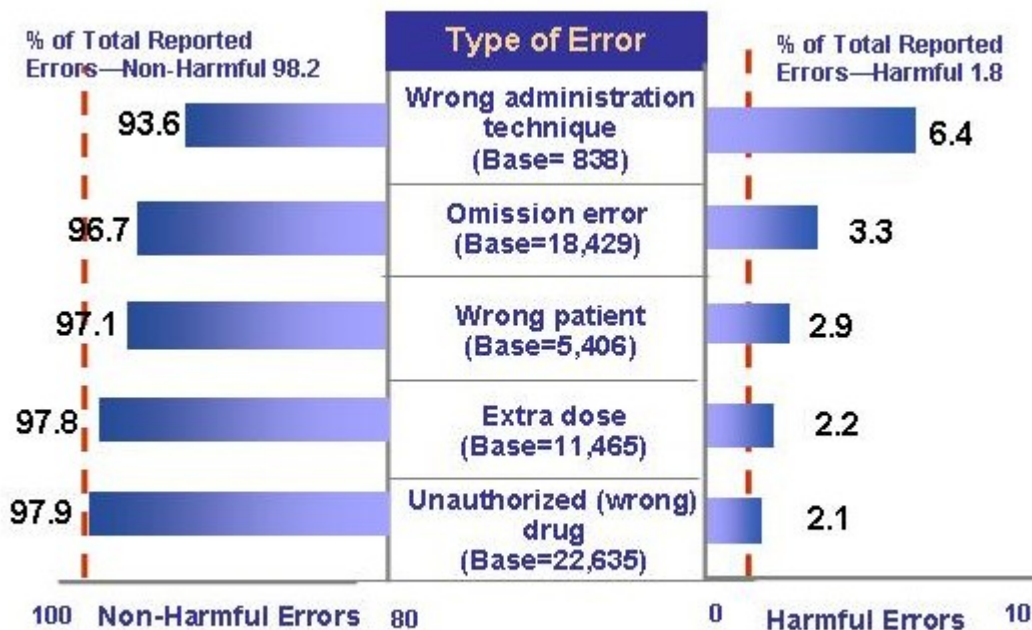


Figure 2. Percentage of Harm by Type of Error

MEDMARX captures over 60 different **Causes of Error** - the top 30 causes involving cardiovascular drug products are shown in Table 2.

Table 2. Top 30 Causes of Error Involving Cardiovascular Drugs ^a

Cause of Error ^b	n	%
Performance deficit	30,997	40.6
Procedure/protocol not followed	13,604	17.8
Transcription inaccurate/omitted	12,800	16.8
Documentation	10,492	13.8

Computer entry	9,815	12.8
Knowledge deficit	8,218	10.8
Communication	7,324	9.6
Written order	5,180	6.8
Drug distribution system	5,129	6.7
Look-alike names (Brand-Brand, Brand- Generic, and Generic-Generic)	4,062	5.3
Dispensing device involved	3,805	4.9
Handwriting illegible/unclear	3,003	3.9
Sound-alike names (Brand-Brand, Brand- Generic, and Generic-Generic)	2,890	3.8
System safeguard(s)	2,528	3.3
Abbreviations	2,013	2.6
Dosage form confusion	2,006	2.6
Monitoring inadequate/lacking	1,869	2.4
Fax/scanner involved	1,753	2.3
Verbal order	1,413	1.8
Calculation error	1,320	1.7
Contraindicated, drug/drug	1,221	1.6
Labeling (your facility's)	794	1.0
Computer software	774	1.0
Computerized prescriber order entry	750	0.9
Similar packaging/labeling	736	0.9
Non-formulary drug	687	0.9
Packaging/container design	676	0.9
Preprinted medication order form	668	0.9
Workflow disruption	599	0.8
Patient identification failure	598	0.8

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

b) Based on 76,268 unique error records documenting 142,522 Cause of Error selections.

Depending on their severity, medication errors can result in the provision of additional care and resources. MEDMARX captures over 20 different levels of care that may be rendered in response to an error event. For records documenting a level of care post error event, nearly three-quarters (72.5%) cited that no additional care was provided (Table 3). However, increases in both patient observation and patient monitoring and changes in drug therapy were provided in

response to approximately 46% of the errors.

Table 3. Level of Patient Care Provided as a Result of Cardiovascular Drug Errors

Level of Patient Care Rendered	n	%
None	17,972	72.5
Drug therapy initiated/changed	4,162	16.8
Observation initiated/increased	3,768	15.2
Vital signs monitoring initiated/increased	3,525	14.2
Laboratory tests performed	752	3.0
Transferred to a higher level of care	289	1.2
Hospitalization, prolonged 1-5 days	261	1.0
Delay in diagnosis/treatment/surgery	237	1.0
Oxygen administered	122	0.5
X-ray, CAP, MRI, or other diagnostic test(s) performed	121	0.5
Antidote administered	97	0.4
Hospitalization, initial	70	0.3
Airway established/patient ventilated	22	0.1
CPR administered	19	0.08
Cardiac defibrillation performed	13	0.05
Narcotic antagonist administered	13	0.05
Hospitalization, prolonged 6-10 days	12	0.05
Hospitalization, prolonged more than 10 days	12	0.05
Surgery performed	6	0.02
Dialysis	2	0.01

Selected Cases

Case #1: Omission Error

All oral medications were placed on hold the day a male patient was scheduled for surgery. Prior to the surgery, the patient had a dialysis treatment. The patient did not return to the patient care unit until the early evening. The following morning, the patient developed atrial fibrillation and rapid ventricular response. The medication nurse discovered that none of the patient's oral medications (including several cardiovascular drugs) had been administered upon his return to the floor.

Case #2: Omission Error

An i.v. diltiazem drip was discontinued when the patient converted to a normal sinus rhythm and an order for oral diltiazem 60mg was made. However, 24 hours later, the patient returned to atrial fibrillation and necessitated an extra day in the hospital. It was discovered that the order for oral diltiazem 60 mg was never administered.

Case #3: Wrong Administration Technique

A calcium chloride infusion was ordered per protocol, but the patient did not have a central i.v. access line. The nurse began the infusion peripherally in the patient's hand. A few hours later, cyanosis of the hand was noted and the calcium chloride infusion was stopped. Central venous access was obtained, but the patient's hand remained cyanotic for at least 24 hours.

Observations

1) Cardiovascular drug errors appear to originate with equal frequency across most nodes or phases of the medication use process. Pharmacies face a unique safety challenge in dispensing activities given the large number of products used to treat the various cardiovascular diseases. Look-alike/sound-alike names, labeling and packaging similarities, storage space limitations both in central and decentralized pharmacies as well as within automated dispensing devices, can all contribute to the risk of an error event.

2) Although *Improper dose/quantity errors* and *Prescribing errors* were the 1st and 3rd most frequently reported **Types of Error**, neither fell into the top 5 most harmful error types (i.e., neither resulted in a percentage of harm that exceeded the overall 1.8% of harm for all cardiovascular agents). *Omission errors*, sometimes thought to be a relatively "benign" type of error, resulted in a harmful outcome nearly twice as often as other types of error overall. This finding provides further evidence that *Omission errors* can and do negatively impact patient care.

3) **Causes of Error** that involve some aspect of communication (e.g. verbal orders, illegible handwriting, abbreviations, look-alike or sound-alike names) comprise 37% of all causes thereby approaching the top error cause - *Performance deficit*. Combined causal factors associated with transcription and documentation followed in frequency with 30%, computer entry-related activities 15%, and knowledge deficit 11%. These broad areas appear to comprise a large majority of the causes associated with cardiovascular drug errors and are worthy of further focus by healthcare facilities.

Recommendations to Improve Safety with Cardiovascular Medications

Suggested recommendations along with links to other resources for improving medication safety were provided in the March, 2005 CAPSLink issue. See:

http://www.magnetmail.net/actions/email_web_version.cfm?recipient_id=6787258&message_id=85786&user_id=USP

Watch for Part III in May



In the News...

1. FDA Updates

Risk-Management Guidelines are Finalized: Earlier this month the FDA issued three final guidance documents whose aim is to identify and address potential safety concerns about drug products at all stages of clinical testing and during the postmarketing period. <http://www.fda.gov/bbs/topics/news/2005/NEW01169.html>

Confusion Over Extended-release Formulations: Drugs that are available in various extended-release formulations (e.g. Wellbutrin XL and Wellbutrin SR or Ritalin LA and Ritalin SR) have a real potential for causing confusion and subsequently lead to medication errors. FDA cites a recent ISMP alert warning about the dangers of confusing various extended-release forms of the same drug.

Question of Sterility Prompts Recall: All strengths of 50 ml admixtures of Magnesium Sulfate in 5% Dextrose solution have been recalled by PharMEDium Services because of a potential lack of sterility assurance for these products. The company is also voluntarily ceasing production and distribution of this product until it can determine and correct the source of this problem. www.fda.gov/medwatch/SAFETY/2005/safety05.htm#PharMEDium

2. AHRQ Updates

New National Patient Safety Web Site Launched: This month AHRQ launched a new national Web site called the Patient Safety Network, or [PSNet](http://psnet.ahrq.gov). PSNet is intended to be a one-stop portal of resources for improving patient safety and preventing medical errors. This web site represents a comprehensive effort to help both health care providers and consumers learn about all aspects of patient safety. <http://psnet.ahrq.gov/help.aspx>

Report Show States Improving: Between 2002 and 2003, a 3% improvement was seen in 14 categories of healthcare quality across the states, according to a new government report released April 4. AHRQ examined data from nearly 100 measures from records at hospitals, health plans, nursing homes, home health agencies, and other organizations. No one state performed well in every category, according to the report. The first report was published in December 2003.

3. JCAHO Sentinel Event Advisory Group Meets

The 2006 Sentinel Event Advisory Group selected sixteen 2006 National Patient Safety Goals (NPSGs) and associated requirements that it determined to be

achievable. A field review conducted from January 27 to February 25, 2005 yielded more than 1,500 responses. The Advisory Group's final recommendations for the 2006 NPSGs was recently considered by the Standards and Survey Procedures (SSP) Committee at its April 27 meeting, and will go to the Joint Commission's Board of Commissioners for final action in May. Contact: Rick Croteau, rcroteau@jcaho.org

4. Executive Walkarounds

A recent study examined the impact of “Executive Walkarounds” on the safety culture within a healthcare organization. This study specifically examined how walkarounds affected nurses, as measured with safety climate surveys.

www.biomedcentral.com/content/pdf/1472-6963-5-28.pdf

5. Medication Reconciliation

Reconciling medications across the continuum of care and even within an individual healthcare facility can be a daunting challenge. The Massachusetts Coalition website describes how a group of hospitals in Massachusetts implemented a medication reconciliation strategy and provides various tools and forms for others to adopt or adapt. <http://www.macoalition.org>

6. Opinions Differ on Impact of Law Requiring Notification of Medical Error

Three years ago, Pennsylvania enacted a law requiring hospitals to notify patients of medical errors. However, according to a report in *The Patriot-News* of Harrisburg, PA., it's unclear whether or not hospitals are in full compliance. Hospitals claim they are compliant and that the law has helped reduce the number of medical malpractice suits filed. The law also requires written notification to patients. In contrast, personal injury lawyers claim the state's hospitals still underreport medical errors. [Click here to read more.](#)

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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