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USP Patient Safety
CAPSLink™

May 2005

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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 III

This is the third 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. The second segment examined their distribution across the medication use process, proportion of the **Types** and **Causes of Error**, and the range and level of patient care provided as a result of these errors.

This issue will examine errors involving several blood coagulation modifiers (e.g., anticoagulants, thrombolytics, and antiplatelet agents) that are used to prevent and treat cardiovascular thromboembolic events. Data provided below are based on drug errors reported to USP's MEDMARX[®] program during the time period between January 1, 2001 through August 31, 2004.

Based on the Veterans Administration Drug Classification System, the following products are categorized as blood coagulation modifiers: Atelplase, Anistreplase, Anisindione, Bivalirudin, Cilostazol, Clopidogrel, Dalteparin, Enoxaparin, Eptifibatide, Heparin, Reteplase, Ticlopidine, Tirofiban, Urokinase, and Warfarin. No errors were reported with Atelplase or Anistreplase during the designated time frame of this analysis.

Combined, the number of errors involving the above blood coagulation modifiers was 35,511. Approximately 62% (n = 22,147) of these errors did reach the patient (Categories C and higher) and 3.2% (n=1,129) resulted in some level of patient harm (Categories E-I). Among the harmful errors, 71% (n=800) resulted in only temporary harm (Category E) whereas 47 were sentinel events (Categories G-I) including 13 fatalities (Table 1).

Table 1. Distribution of Errors Involving Blood Coagulation Modifiers by Error Category

Error Category ^a	n	%
Potential Error		
A	2,470	6.9
Intercepted Error		
B	10,894	30.7
Error Reaches Patient, No Harm		
C	14,995	42.2
D	6,023	16.9
Error, Harm		
E	800	2.3
F	282	0.8
G	23	0.06
H	11	0.03
Error, Death		
I	13	0.04

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

Several drug products within the blood coagulation modifiers (BCM) grouping were, as a percentage, disproportionately involved in harmful errors (i.e., the percentage of harmful events exceeded the 3.2% threshold of harm calculated for the entire BCM group as shown in Table 1). Heparin had the highest number of

harmful events (n=519) followed by Warfarin (n=358), Enoxaparin (n=175), and Clopidogrel (n=43).

Table 2. Number of Errors Overall and Number of Harmful Errors for Blood Coagulation Modifiers

Drug Product ^a	Number of Errors ^b	Number (%) Involved in Harmful Errors
Abciximab	166	7 (4.2%)
Anisindione	2	0 (0%)
Bivalirudin	37	4 (10.8%)
Cilostazol	189	2 (1.1%)
Clopidogrel	2,007	43 (2.14%)
Dalteparin	1,081	11 (1.0%)
Enoxaparin	7,809	175 (2.2%)
Eptifibatide	826	33 (4.0%)
Heparin [†]	13,131	519 (3.9%)
Retepase, Recombinant	59	3 (5.1%)
Ticlopidine	35	1 (2.8%)
Tirofiban	175	2 (1.1%)
Urokinase	23	1 (4.3%)
Warfarin	10,548	358 (3.4%)

a) All dosages and formulations combined.

b) Based on error records submitted from 1/1/01 – 8/31/04.

† Excludes heparin flushes.

When examining the different **Types of Error** for BCMs compared to all products involved in medication errors, there was a higher percentage of *Omission errors*, *Improper dose/quantity errors*, and *Extra dose errors* (Table 3). Conversely, there was a smaller percentage of errors involving BCMs related to *Prescribing*, *Wrong drug*, *Drug prepared incorrectly*, and *Wrong dosage form*.

Table 3. Types of Error Involving Blood Coagulation Modifiers Compared to All Products

Type of Error ^a	Blood Coagulation Modifiers ^b		Overall ^c
	n	%	%
Omission error	9,797	28.9	25.4
Improper dose/quantity	9,398	27.7	23.2
Prescribing error	5,390	15.9	19.4

Unauthorized/wrong drug	3,217	9.5	11.2
Extra dose	2,813	8.3	5.4
Wrong time	2,409	7.1	6.7
Wrong patient	1,497	4.4	4.9
Drug prepared incorrectly	666	2.0	4.5
Wrong administration technique	556	1.6	1.3
Wrong route	381	1.1	1.6
Wrong dosage form	296	<1	2.3
Expired product [†]	28	<1	<1
Deteriorated product [†]	17	<1	<1

a) Based on 33,942 unique error records involving blood coagulation modifiers documenting 36,465 Type of Error selections from 1/1/01 – 8/31/04.

b) The following products comprise blood coagulation modifiers: Anisindione, Bivalirudin, Cilostazol, Clopidogrel, Dalteparin, Eptifibatide, Enoxaparin, Heparin, Reteplase, Ticlopidine, Tirofiban, Urokinase, and Warfarin.

c) Based on 490,056 unique error records involving all products documenting 520,182 Type of Error selections from 1/1/01-12/31/03.

†These selections were added during calendar year 2003.

When examining the **Causes of Error** for BCMs compared to all products, the BCMs had a relatively higher percentage of *Procedure/protocol not followed* (23.1% vs 17.4%), *Transcription inaccurate/omitted* (15.8% vs 13.4%), and *Communication* (14% vs 8.8%), Table 4.

Table 4. Top Ten Causes of Error Involving Blood Coagulation Modifiers Compared to All Products

Cause of Error ^a	Blood Coagulation Modifiers ^b		Overall Products ^c	
	n	%	n	%
Performance deficit	13,500	39.5	180,848	37.6
Procedure/protocol not followed	7,870	23.1	83,775	17.4
Transcription inaccurate/omitted	5,408	15.8	64,461	13.4
Communication	4,764	14.0	42,292	8.8
Documentation	4,522	13.2	54,900	11.4
Computer entry	3,604	10.6	56,062	11.6
Knowledge deficit	3,502	10.3	50,653	10.5
Written order	2,045	6.0	26,108	5.4

Calculation error	1,516	4.4	12,177	2.5
Monitoring inadequate/lacking	1,505	4.4	12,125	2.5

a) Based on 34,137 unique error records involving blood coagulation modifiers documenting 61,874 Cause of Error selections from 1/1/01 – 8/31/04.

b) The following products comprise blood coagulation modifiers: Anisindione, Bivalirudin, Cilostazol, Clopidogrel, Dalteparin, Eptifibatide, Enoxaparin, Heparin, Reteplase, Ticlopidine, Tirofiban, Urokinase, and Warfarin.

c) Based on 481,305 unique error records documenting 808,869 Cause of Error selections submitted to the overall MEDMARX database from 1/1/01-12/31/03.

Observations

1. The percentage of harm associated with BCMs (3.2%) was nearly twice the overall percentage of harm (1.7%) for all MEDMARX error records submitted for years 2001- 2003. This may indicate a greater potential for patient harm when a BCM product is part of the patient's drug regimen.

2. When a patient is prescribed a BCM agent, it appears there is a greater potential for the wrong dose or quantity to be given, an extra dose to be given, or a failure to administer the drug at all.

3. Because BCMs are considered "high-risk" (i.e., have a higher potential for patient harm if misused), structured procedures and protocols surrounding their use are often developed. However, the findings indicate that such procedures and protocols are not sufficiently followed. Healthcare facilities should further examine their existing procedures and protocols for BCMs and identify areas where improvements in clarity, feasibility, and training/implementation can be made. The widespread use of several BCMs (e.g., heparin and warfarin) within hospitals and health systems may account for the higher percentage of breakdowns in communication and transcription of the order.

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

The Institute for Safe Medication Practices (ISMP) recently made available a safety self assessment tool specifically for antithrombotic therapy that is designed to help hospitals assess medication safety practices surrounding the use of antithrombotic agents. This tool can be found at:

<http://www.ismp.org/PDF/ASAISMPAssessment.pdf>

In the News...

1. JCAHO Updates

Transforming Medication Error Data into Meaningful Information: Advanced Workshop Series: Back by Popular Demand - Joint Commission Resources and USP once again are offering day-long, interactive workshops that train patient safety practitioners to make sense of error data and assess the impact of risk-reduction strategies. This advanced workshop series will utilize demonstrations and case-study examples to provide attendees with specific “hands-on” experiences. This interactive program will be offered on the following dates in **2005**:

- **September 2 in Rosemont, IL** (at JCAHO Headquarters) *
- **September 16 in Dallas, TX** (at Wyndham Arlington DFW Airport South) *
- **November 2 in Rockville, MD** (at USP Headquarters)
- **December 3 in Las Vegas, NV** (Preceding the ASHP meeting)

*JCR's *Hospital Executive Briefings* will be held in the same location one day following the workshop. A discount is available for joint registration.

Participants will:

- Identify various error data collection methods and learn what minimum elements are needed to capture meaningful information on medication error events within the healthcare facility
- Learn to prioritize error-reduction strategies
- Learn various methods to analyze data collected through medication error reports
- Translate findings of medication error reports into meaningful information through interpretation of data findings and in their presentation to committees and staff
- Apply JCAHO Medication Management Standards and 2005 National Patient Safety Goals as they relate to the promotion of Medication Safety
- Evaluate the potential impact of proposed actions taken in response to error

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=9241&site=5&return=8386>

Documenting the Patients' Primary Language: Beginning January 1, 2006, the medical record of each hospital patient must note that person's race, ethnicity, and primary language spoken. [Click here to read more.](#)

2. AHRQ Updates

Compendium of Patient Safety Studies: AHRQ and the Department of Defense recently released *Advances in Patient Safety: From Research to Implementation* - a compilation of 140 peer-reviewed articles examining the successes and challenges to improve patient safety and reduce medical errors. Contact the AHRQ Publications Clearinghouse at (800) 358-9295, or send an e-mail to

ahrqpubs@ahrq.gov.

Hospitals and Othes Sought to Test Survey Tool: In an effort to develop a standard methodology for collecting and reporting consumer satisfaction data, AHRQ is seeking hospitals, vendors and other interested parties to pilot a revised tool called HCAHPS. This tool is a hospital version of the payer-focused Consumer Assessment of Health Plans. Once the tool is finalized, collected information will be posted on the AHRQ and CMS Web sites so consumers can compare hospital data, hospitals can compare each other and state regulatory agencies can have access to useful data. [Click here to read more.](#)

3. FDA Updates

FDA Launches New Drug Safety Initiative: FDA recently announced it is launching a new program to make drug safety information easily available to consumes, patients, and healthcare professionals. The Drug Safety Initiative has the following components:

- [Drug safety information located together in a new web location](#)
- [Drug specific information for healthcare professionals, patients, and other consumers](#)
- [Other consumer education](#)
- Draft Guidance: FDA 's "Drug Watch" for Emerging Drug Safety Information [[PDF](#)] [[Word](#)] [[HTML](#)]
- [Manual of Policies and Procedures \(MaPP\): Drug Safety Oversight Board \(DSB\)](#)
- Questions and Answers on FDA's New Drug Safety Initiative [[PDF](#)] [[Word](#)] [[HTML](#)]

According to the FDA's proposed guidelines, the Drug Watch site would provide a forum in which emerging safety information could be easily communicated to the public. Drug companies would be alerted before a drug is placed on the Web site. <http://www.fda.gov/cder/drugSafety.htm>

Implanted Neurological Stimulators are Source of Concern:Healthcare professionals were recently notified by the FDA that serious injury or death can occur when patients with implanted neurological stimulators undergo MRI procedures. Serious injury, including coma and permanent neurological impairment has been reported. The mechanism for these adverse events is likely to involve heating of the electrodes at the end of the lead wires, resulting in injury to the surrounding tissue. The public health notification also offered recommendations for preventive actions.

<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#MRI>

Safety of Albumin in Critically ILL Patients: The FDA notified healthcare professionals of an update and revision to a 1998 notice with advice regarding the safety of albumin administration in critically ill patients. This action has been taken following FDA's review of recent studies on the safety of albumin, and is consistent with recommendations made on March 17, 2005 by members of the

Blood Products Advisory Committee (BPAC).
<http://www.fda.gov/cber/infosheets/albsaf051605.htm>

4. CMS Web Site for Consumers

A new Web site allows consumers to compare hospitals' performance on 17 key quality measures for myocardial infarction, heart failure, and pneumonia, including the rationale for those measures. The site, called "Hospital Compare," is sponsored by the Centers for Medicare and Medicaid Services and represents data collected under the Hospital Quality Alliance initiative.
<http://www.hospitalcompare.hhs.gov/>

5. ISMP Self-Assessment Survey for Antithrombotic Therapy

A new tool has been developed by the Institute for Safe Medication Practices (ISMP) to assist hospitals in evaluating antithrombotic therapy. The self-assessment survey tool (which has been mailed to hospitals with a submission deadline of September 1, 2005) will help organizations examine medication safety practices associated with the use of antithrombotic drugs. Hospitals may submit data through a secure Web-based form, which will allow them to compare their weighted scores with aggregate data from similar hospitals.
<http://www.ismp.org/Survey/Asa/Intro.htm>

6. Physicians Not Engaged in Quality Improvement Efforts

A recent study in *Health Affairs* indicates that many physicians are not pursuing significant quality improvement efforts and many do not believe quality data should be shared with the general public. The study was conducted by the Commonwealth Fund and found that only 33% of the surveyed practicing physicians were engaged in significant efforts to improve care quality. While 75% of those surveyed "definitely or probably" would share information about their clinical performance with the medical leadership of their employing institutions, more than 66% said the general public should "probably or definitely" not be permitted to see such information. Subscription is required to view the complete article. <http://content.healthaffairs.org/cgi/content/abstract/24/3/843>

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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