

U.S. PHARMACOPEIA
The Standard of Quality™

USP Home | MER | MEDMARX® Demo | NCC MERP

February 2006

USP Patient Safety
CAPSLink™

PROVIDED BY THE USP CENTER FOR THE ADVANCEMENT OF PATIENT SAFETY

Copyright © 2007 The United States Pharmacopeial Convention, Inc.

In this Issue

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.

Section I: *USP Medication Error Analysis*

- **Medication Errors in Intensive Care Units**

Section II: *In The News...*

1. FDA Updates
2. ISMP Issues Safety Action Priorities
3. Study Examines Physicians' Adherence to Black Box Warnings
4. Call for Eisenberg Safety Award Nominations
5. NQF Releases Patient Safety Classification System
6. HRSA Finds Link Between Accreditation and Medication Safety Measures



The below information represents a small portion of data and information contained in USP's most recent MEDMARX Data Report: **A Chartbook of 2000–2004 Findings from Intensive Care Units and Radiological Services**. For complete data findings related to medication errors in these clinical areas see:

<http://www.usp.org/products/medMarx/>

Medication Errors in Intensive Care Units

Intensive care units (ICUs) are one of the most expensive components of U.S. healthcare representing 10% of acute care beds, yet comprising approximately 30% of acute care costs.¹⁻³ More than 4 million people are admitted to ICUs annually and the number of ICU patients and their proportion of hospital admissions are expected to grow given the increasing number of elderly people and the increasing acuity of illness of hospitalized patients.

Patient care in ICU areas is complex, in part because of the broad scope of acute illnesses and pre-existing conditions present among ICU patients. On average, mortality rates for these patients range between 12 and 17%.⁴ Previous studies have shown that medical errors are common in ICU areas⁵ and one recent study estimates that there are approximately 1.5 serious medical errors per 10 critical care beds per day.⁹

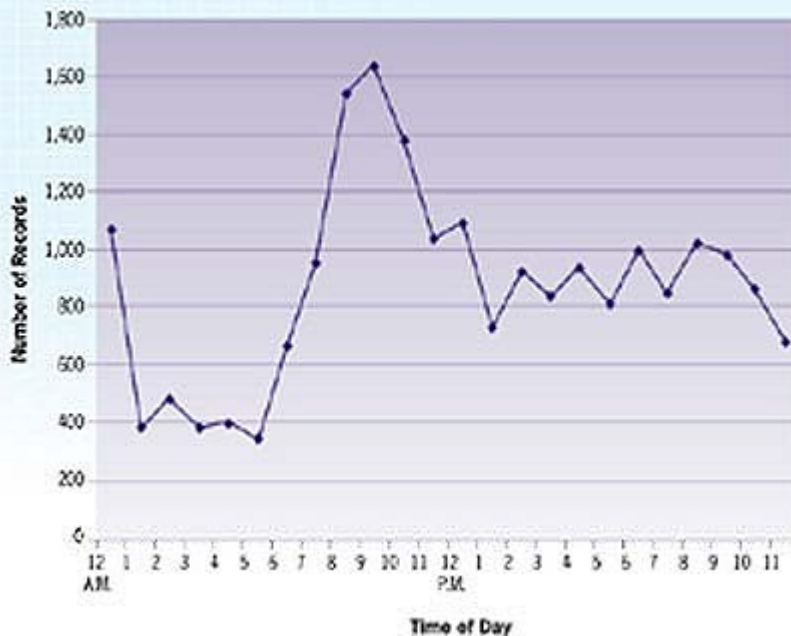
USP's Center for the Advancement of Patient Safety analyzed 38,371 records submitted to MEDMARX by 503 facilities during the 5-year period between January 1, 2000 and December 31, 2004 for error events that occurred in ICU areas. For purposes of this report, records specifically documenting the neonatal or pediatric ICU as the location of the medication error were excluded because of the special character of these units and their patient population.

The time of day when the largest number of medication errors were reported to have occurred was between the hours of 8 a.m. and 12 noon (n=6,744) with a peak around 9 a.m. (n=1,647) (Figure 1). Additional spikes in error occurrence were seen around 6 p.m., 8 p.m., and 12 a.m.

Physicians commonly conduct patient care rounds in the early morning hours, followed by preparing orders for lab tests, medications, and other treatments and/or procedures. Therefore, it is not surprising that the greatest number of ICU medication errors occurred between the hours of 8 a.m. and 12 noon. One of the implications for healthcare facilities is to recognize that there are variations in medication use volume throughout the entire day (and the corresponding opportunities for error) and perhaps better plan for and allocate the necessary resources to accommodate such fluctuations.

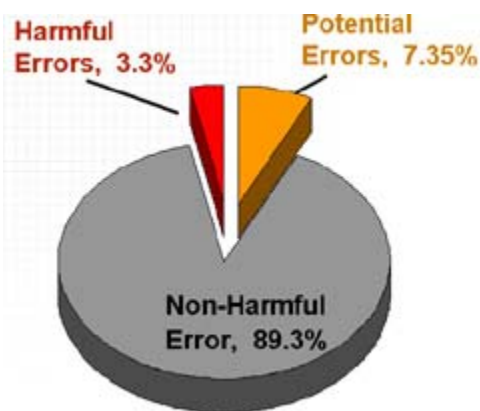
Figure 1. ICU Medication Errors by Time of Day When Error

Occurred



A little over 7% (n=2,819) of the ICU medication errors were categorized as potential errors whereas 89.3% (n=34,282) were non-harmful and 3.3% (n=1,270) resulted in some level of patient harm (Figure 2). Among the harmful errors, 83.7% (n=1,063) resulted in temporary harm whereas 68 were sentinel events including 14 fatalities. The percentage of harmful ICU errors (3.3%) is nearly twice the overall harm threshold of 1.7% for all MEDMARX records for the same 5-year period.

Figure 2. Severity of Medication Errors in ICUs



Nearly half of the medication errors originated in the *Prescribing* and *Transcribing/Documenting* nodes (i.e., phases) of the medication use process (Table 1). Errors originating in the *Administering* node represented the largest percentage of actual errors (42.5%), the largest

percentage of harmful errors (61.1%), and the largest percentage of sentinel events (57.4%). Errors originating in the *Prescribing* node resulted in the second highest percentage of sentinel events (29.4%), a result that is disproportionately high considering the small number (n=168) of harmful errors in the *Prescribing* node.

Table 1. Errors in ICUs by Node: Actual Compared to Harmful and Sentinel Events

Node ^a	Actual Errors (Categories B–I)		Harmful Errors (Categories E–I)		Sentinel Events (Categories G–I)	
	n	%	n	%	n	%
Prescribing	8,665	24.4	168	13.2	20	29.4
Transcribing/Documenting	8,550	24.0	186	14.6	3	4.4
Dispensing	2,661	7.5	79	6.2	3	4.4
Administering	15,106	42.5	776	61.1	39	57.4
Monitoring	570	1.6	61	4.8	3	4.4
Total ^b	35,552	100.0	1,270	100.0	68	100.0

a. Node is not applicable for Category A error records.

b. Percents may not add to 100% as a result of rounding.

Five types of error exceeded the overall ICU harm threshold of 3.3%. As a percentage, *Wrong administration technique* errors ranked first with nearly 11% resulting in patient harm (Table 2). This percentage is substantially higher when compared to the 6.3% incidence of *Wrong administration technique* errors seen in the general MEDMARX data set. Examples of *Wrong administration technique* include administering an IV drug too rapidly, mixing a drug in an incompatible solution so that a precipitate forms, not activating the drug product chamber into the main IV solution chamber, not flushing an IV line, and crushing sustained-released tablets.

Table 2. Leading Types of Error for ICUs by Non harmful and Harmful Outcomes^a

Types of Error	Non harmful ^b		Harmful ^b	
	n	%	n	%
Wrong administration technique	845	89.3	101	10.7 ^c
Improper dose/quantity	8,586	95.1	438	4.9 ^c
Unauthorized/wrong drug	3,527	95.8	156	4.2 ^c
Extra dose	1,922	96.2	76	3.8 ^c

Drug prepared incorrectly	1,181	96.5	43	3.5 ^c
Omission error	9,427	96.8	309	3.2
Wrong route	686	97.6	17	2.4
Wrong patient	1,538	98.0	31	2.0
Wrong time	2,422	98.4	39	1.6
Prescribing error	7,621	98.6	108	1.4

a. Represents a cross-tabulation of Types of Error by Error Category for the 5-year period 2000-2004.

b. Data based on 36,790 records with 39,894 selections.

c. Exceeds the 3.3% of harm calculated for all ICU error records combined.

Combining related, but somewhat infrequent causes of error identified several common problems. IV pumps and other equipment were cited a total of 1,237 times of which 10.8% were harmful (Table 3). Causes related to drug product packaging/labeling were cited a combined total of 949 times, of which 7.4% were harmful. Six communication-related causes totaled 5,021 selections, of which 5.4% were associated with harm. The use of IV pumps and other medical equipment is more extensive within ICUs than in most other patient care areas. The percentage of harm associated with errors involving pumps/equipment, drug packaging/labeling, and communication point to problem areas that warrant further attention.

Table 3. Selected Causes of Error Related to Equipment, Product Packaging/Labeling, and Communication in ICUs

Causes of Error	n (Non harm + Harm)	% Harmful
Equipment-Related Causes: <ul style="list-style-type: none"> • Pump, failure/malfunction • Pump, improper use • Equipment design • Equipment (not pumps) 	1,237	10.8
Drug Product Packaging/Labeling-Related Causes: <ul style="list-style-type: none"> • Label (the facility's) design • Similar packaging/labeling • Packaging/container design • Label (manufacturer's) 	1,236	6.9

design <ul style="list-style-type: none"> • Brand/generic names look-alike 		
Communication-Related Causes: <ul style="list-style-type: none"> • Nonmetric units used • Verbal order • Prefix/suffix misinterpreted • Brand/generic names sound alike • Communication • Decimal point 	5,021	5.4

Selected Error Cases

Case #1–IV Pump Programming: A diabetic patient was receiving an IV of regular insulin one unit/mL at a rate of 10 units/hour titrated per sliding scale. Upon changing to a new bag of insulin, the IV pump was reset manually to clear prior totals and to enter the new volume to be infused. Shortly after the new bag was hung, a nurse noticed that the infusion pump was incorrectly set at 150 units (i.e., 150 mL/hour). The infusion was stopped and the patient was given Dextrose 50% in water and closely monitored for the next 8 hours. If the total volume of the bag (100 mL) had been infused at the rate of 150 units/hour, it would have taken only 40 minutes for the patient to receive 100 units of insulin, potentially causing irreversible brain damage and/or death from cerebral edema and insulin shock. The type of error was identified as Improper dose/quantity.

Case #2–Communication Failures: A patient who presented in the emergency room was given a heparin bolus and started on a heparin infusion. The patient was transferred to the coronary care unit where a physician, unaware that the patient was on a heparin infusion, ordered enoxaparin. Later, an on-call physician, unaware that the patient was receiving the enoxaparin, ordered another dose of the heparin infusion. The nurse who received the physician's call did not inform him of the patient's other medications. The patient received both heparin and enoxaparin for 15 hours, leading to a drop in the patient's hemoglobin and hematocrit, shortness of breath, and rales. The patient was given a blood transfusion and placed on a ventilator. The causes of error were reported as failures in communication and not following procedures and protocols.

Case #3–Dosage Form Confusion, Product Labeling Issues: A

loading dose of 500 mcg/kg of esmolol followed by a titrated IV infusion of 5,000 mg/500 mL was ordered for a surgical intensive care patient experiencing acute arrhythmias. Based on the patient's weight of 264 pounds (120 kg), the nurse correctly calculated the loading dose to be 60 mg. However, the noise and activity of the surgical intensive care unit distracted the nurse, and the nurse inadvertently retrieved an ampul of concentrated esmolol (250 mg/mL) instead of the ready-to-use product (10 mg/mL). The nurse drew up 3 mL (750 mg), mixed this amount with a small volume of normal saline, and administered the dose to the patient. The patient's condition soon deteriorated and he went into cardiac arrest resulting in brain hypoxia and death.

The complexity of ICUs, combined with the high acuity of the patients treated in these areas, creates an environment that is more susceptible to harmful patient outcomes when medication errors occur. The Agency for Healthcare Research and Quality (AHRQ) Evidence Report/Technology Assessment —*Making Healthcare Safer: A Critical Analysis of Patient Safety Practices*, identified several interventions that can reduce mortality in ICU patients.¹⁰ These include the following: reporting adverse events; staffing ICUs with physicians trained in critical care (i.e., intensivists); improving communications and the culture of safety among caregivers; and controlling blood glucose in critically ill patients. Other approaches to minimizing medication errors in ICUs include:

- Assigning a dedicated pharmacist to ICU areas
- Implementing a CPOE and bar-code system
- Reducing medical residents' work hours
- Ensuring adequate patient staffing patterns
- Simplifying and standardizing IV pumps, monitors, and IV catheters and
- Allowing adequate input on and training for new technology (e.g., IV pumps)

-
1. Joint position statement: Essential provisions for critical care in health system reform. Society of Critical Care Medicine. American Association of Critical Care Nurses. *Critical Care Medicine* 1994;22(12):2017-9.
 2. Groeger JS, Guntupalli KK, Strosberg M, et al. Descriptive analysis of critical care units in the United States: Patient characteristics and intensive care unit utilization. *Critical Care Medicine* 1993;21(2):279-91.
 3. Halpern NA, Bettis L, Greenstein R. Federal and nationwide intensive care units and healthcare costs: 1986-1992. *Critical Care Medicine* 1994;22(12):2001-7.
 4. Al-Asadi L, Dellinger R, Deutch J, Nathan S. Clinical impact of closed versus open provider care in a medical intensive care unit. *American Journal of Respiratory & Critical Care Medicine* 1996;153:A360.
 5. Bracco D, Favre JB, Bissonnette B, et al. Human errors in a multidisciplinary intensive care unit: a 1-year

- prospective study. *Intensive Care Medicine* 2001;27(1):137-45.
6. Donchin Y, Gopher D, Olin M, et al. Look into the nature and causes of human errors in the intensive care unit. *Critical Care Medicine* 1995;23(2):294-300.
 7. Herout PM, Erstad BL. Medication errors involving continuously infused medications in a surgical intensive care unit. *Critical Care Medicine* 2003;31(12 Suppl):S678-S86.
 8. Osman S, Harris CB, Dunagan C, Prentice D, Fraser VJ, Kollef MH. Reporting of medical errors: An intensive care experience. *Critical Care Clinics* 2004;32(3):727-33.
 9. Rothschild JM, Landrigan CP, Cronin JW, et al. The Critical Care Safety Study: The incidence and nature of adverse events and serious medical errors in intensive care. *Critical Care Medicine* 2005;33(8):1694-700.
 10. Shojania KG, Duncan BW, McDonald KM, Wachter RM, Markowitz AJ. Making health care safer: A critical analysis of patient safety practices. Evidence Report/Technology Assessment: Number 43. Rockville, MD: Agency for Healthcare Research and Quality; 2001.



1. FDA Updates

FDA to Improve Post-approval Monitoring of Medical Devices: Earlier this month, federal regulators from the FDA's Center for Devices and Radiological Health (CDRH) responded to criticism regarding FDA's monitoring of medical devices once they are approved. Dr. Daniel Schultz, director of the CDRH, stated the Agency was challenged by the size and growth of the device industry, but announced an initiative that was underway to better identify, analyze, and respond to post market data on product errors and malfunctions. Schultz acknowledged concerns regarding the quality and timeliness of the center's release of information on device safety and noted that the center will strive to develop a process that ensures safety to the same level as the pre market review process.

Black Box Warning for Nimodipine: Bayer and FDA notified healthcare professionals of changes to the prescribing information for nimodipine (Nimotop), including a boxed warning to notify prescribers about medication administration errors. Nimodipine is approved for oral administration to improve neurological outcome after subarachnoid hemorrhage. When administered intravenously or parenterally, it can cause serious adverse events, including death. Nimodipine must not be administered intravenously or by any parenteral route.

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Nimotop>

2. ISMP Issues Safety Action Priorities

The Institute for Safe Medication Practices selected items from its

Safety Alert newsletter that it believes are important areas for action for acute care practitioners to reduce the risk of errors. The items are listed in a chart format making it easy to share with an interdisciplinary patient safety, medication safety, or Pharmacy & Therapeutics Committee with the goal of stimulating discussion and developing actions to mitigate medication errors.

<http://www.ismp.org/Newsletters/acutecare/articles/AA2006Q1.pdf>

3. Study Examines Physicians' Adherence to Black Box Warnings

The objective of a study published this month in *Archives of Internal Medicine* was to determine how frequently clinicians prescribe drugs in violation of black box warnings and to determine how frequently such prescribing results in harm. About 7 in 1000 outpatients received a prescription violating a black box warning and few incidents resulted in detectable harm.

<http://archinte.ama-assn.org/cgi/content/abstract/166/3/338>

4. Call for Eisenberg Safety Award Nominations

The National Quality Forum and the Joint Commission on Accreditation of Healthcare Organizations are accepting nominations of individuals and organizations for the 2006 John M. Eisenberg Award for Patient Safety and Quality. Nominations are due by May 1. [Click here to read more.](#)

5. NQF Releases Patient Safety Classification System

The National Quality Forum (NQF) recently released a standardized classification system for patient safety data called the Patient Safety Event Taxonomy (PSET). NQF believes that the use of a standardized framework will lead to an improved understanding of medical errors.

The PSET will enable interoperability of reporting systems and comparability of information across systems and over time. The JCAHO developed the PSET with the assistance of a work group comprised of representatives of provider and health professional organizations and the federal government. The report contains four voluntary consensus standards derived from JCAHO's Patient Safety Event Taxonomy. The executive summary and portions of the report, *Standardizing a Patient Safety Taxonomy*, are available at <http://www.qualityforum.org>.

6. HRSA Finds Link Between Accreditation and Medication Safety Measures

A recent study funded by the Health Resources and Services Administration found that Joint Commission accreditation and the financial status of rural hospitals is related significantly to pharmacist staffing, use of technology and the implementation of four key medication safety activities: 1) a do-not-use abbreviations list; 2) a policy of using two patient identifiers for administering medications; 3) a policy of having two health professionals independently check doses of high alert medications; and 4) a high alert drug list. The study is available at http://www.uppermidwesthrhc.org/pdf/medication_safety.pdf.

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.

-
- Refer your colleagues to [subscribe](#) to this newsletter.
 - If you no longer desire or consent to receive this newsletter, you can [unsubscribe now](#).

USP does not sell or distribute email addresses. Questions about USP CAPSLink™ may be sent to caps@usp.org.

Copyright 2007, U.S. Pharmacopeia. All rights reserved

