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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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Examining Medication Errors Associated with Psychiatric Care Settings

Mental illness and mental-illness- type symptoms are not limited to any one population or age group. In a report published in 1998 in a psychiatric services journal, it was estimated that approximately 26% of all hospital admissions are for a psychiatric related diagnosis.¹ The use of psychotherapeutic medications in the treatment of mental illness and other associated psychiatric disorders has skyrocketed over the past several decades. This fact is evidenced in a recently-released study from the Centers for Disease Control (CDC) that provided data and information from the 2005 National Ambulatory Medical Care Survey.² The report documented that over 2.4 billion prescriptions for medications were either administered or prescribed during ambulatory medical care visits during 2005, of which antidepressants were the most widely prescribed therapeutic drug category, with 118 million prescriptions issued during the study year.²

Care of the psychiatric patient is largely dependent on the use of medications, many of which produce the desired beneficial effect, but come with significant side effects and the potential risk for adverse drug events.³ Antidepressants and antipsychotics are major subsets of the broad category of medications known as psychotherapeutic agents, which have become the cornerstone and most widely prescribed agents in treating a vast array of medical symptoms and diagnoses.

Accompanying the increased use of these agents is the increased risk of adverse drug events, including medication errors. In a 2003 literature review of ten studies related to preventable adverse drug events (pADEs), it was noted that psychotherapeutic and other CNS medications were second only to cardiovascular drugs as most frequently associated with pADEs. Drugs in this class that were associated with pADEs were antidepressants and antipsychotic agents, in addition to sedatives, hypnotics, benzodiazepines, and a variety of combination therapies.⁴ Therefore, the prescribing of antidepressants and antipsychotics, either alone or in combination with other medications, should be done with caution to ensure clinically appropriate and safe drug therapy.

During the period from January 1, 2000 through December 31, 2004, 796 facilities (including psychiatric specialty hospitals) reported 16,845 medication errors that occurred in a psychiatric care setting. A little more than 32% of the errors were intercepted before reaching the patient (Category B) (Table 1). However, 52.4% (n=8,838) did reach the patient (Categories C and D) but resulted in no harm. Less than 1% (n=141) resulted in some level of harm or death (Categories E-I).

Table 1. Severity of Medication Errors in Psychiatric Care Settings^a

Error Category	n	%
Potential errors		
A	2,407	14.3
Intercepted errors		
B	5,452	32.4
Non-harmful errors		
C	7,872	46.7
D	966	5.7

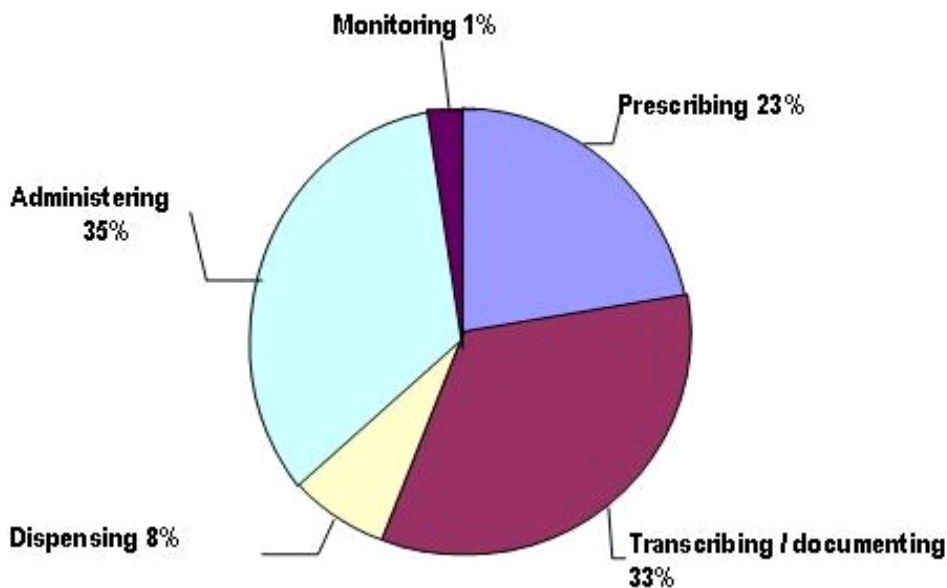
Harmful or fatal errors		
E	125	<1
F	19	<1
G	1	<1
H	2	<1
I	1	<1
Total	16,845	

^a For complete definitions of the Medication Error Category (Severity) Index from National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) see <http://www.nccmerp.org/pdf/indexColor2001-06-12.pdf>

Node (phase) Where Error Originated

The largest percentage of the error events (35%; n = 5,896) were reported to have originated during drug administration (Figure 1). Nearly as many (33%) indicated that the error began with transcribing or documenting activities which is one-third higher when compared to a five-year MEDMARX historical average of 24% for errors overall. This suggests that transcribing or documenting medication orders for psychotherapeutic agents may be more problem-prone than transcribing other types of medication orders.

Figure 1. Medication Process Phase Where Errors Originated



Types of Error

Omission error was the most frequently reported type of error (28.5%; n=4,638), followed by *Prescribing error* (26.1%; n=4,243) (Table 2). These percentages are higher than the historical averages for omission and prescribing errors for the overall MEDMARX data set during the same 5-year reporting period. This suggests that some patients did not receive their intended medications and prescribing activities involving psychotherapeutic agents may be somewhat more problematic than prescribing drugs in other therapeutic classes.

Table 2. Types of Error Associated with Psychiatric Care Settings versus MEDMARX Overall^a

Types of Error	Psychiatric Setting		MEDMARX Overall %
	n	%	
Omission error	4,638	28.5	24.3
Prescribing error	4,243	26.1	20.5
Improper dose/quantity	3,124	19.2	23.4
Unauthorized /wrong drug	1,509	9.3	11.3
Extra dose	1,281	7.9	5.6
Wrong time	1,076	6.6	6.8
Wrong patient	757	4.7	4.9
Wrong dosage form	353	2.2	2.3
Drug prepared incorrectly	252	1.5	n/a
Wrong administration technique	83	0.5	1.4
Wrong route	68	0.4	1.6
Deteriorated product	29	0.2	<1
Expired product	15	0.1	<1
Mislabeling	1	0	<1

^a Based on 16,279 records with 17,429 documented selections during the period 01/1/00-12/31/04

When looking at harmful errors, *Omission* errors 31.2% (n=44) resulted in the highest percentage of overall harm followed by *Improper dose/quantity* at 24.1% (n= 34) and *Prescribing* errors at 15.6% (n=22) as documented in Table 3. An error involving “harm” is defined as resulting in the impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.⁵ For psychiatric patients, the harmful proportion for both omission and prescribing error types was slightly higher than the corresponding historical averages for the overall MEDMARX data set during the same 5-year reporting period. This suggests that psychiatric patients may be at greater risk of experiencing harm from an omission and prescribing error as compared to other patient populations.

Table 3. Types of Error by Harm for Psychiatric Care Settings versus MEDMARX Overall

Type of Error	Harmful Errors (Psychiatric Setting) ^a		Harmful Errors (Overall) ^b %
	n	%	
Omission error	44	31.2	26.3
Improper dose/ quantity	34	24.1	26.2
Prescribing error	22	15.6	10.8
Unauthorized /wrong drug	16	11.3	11.9
Wrong time	14	9.9	4.3

Wrong patient	11	7.8	3.2
Extra dose	9	6.4	5.2
Drug prepared incorrectly	3	2.1	4.0
Wrong administration technique	3	2.1	4.9
Wrong dosage form	2	1.4	1.0
Wrong route	2	1.4	1.9

^a Based on 141 records with 160 selections during the period Jan 1, 2000 - Dec 31, 2004

^b Based on 13,929 records during the period Jan 1, 2000– Dec 31, 2004.

Products Involved in Harmful Errors (Categories E-I)

Several other products in addition to psychotherapeutic drugs were involved with harmful outcomes (Table 4). This finding indicates that psychiatric patients are taking multiple medications to treat a variety of chronic medical conditions. Healthcare professionals involved in the care of this patient population have a responsibility to be aware of all components of the patient's medication therapy to avoid drug-drug interactions/contraindications that would impede appropriate and safe treatment.

Table 4. Products Involved with Harm in Psychiatric Care Settings^a

Product	n	% ^b
Insulin	15	10.5
Clozapine (Clozaril®, other)	10	7.0
Haloperidol (Haldol®, other)	8	5.6
Quetiapine (Seroquel®)	8	5.6
Oxycodone	7	4.9
Divalproex (Depakote®, other)	6	4.2
Methadone	6	4.2
Alprazolam (Xanax®, other)	5	3.5
Risperidone (Risperdal®)	5	3.5
Verapamil (Calan®, other)	5	3.5

^a Based on a total of 143 records with 183 selections reported to MEDMARX during the period January 1, 2000 – December 31, 2004. A total of 79 products were involved with harmful outcomes (Categories E-I).

^b Percentages rounded.

Error Causes

Deficiency in performing assigned duties, failure to follow an established procedure or protocol, and inaccurate or omitted order transcription combined were cited as causes in over 80% of these error events. These findings should stimulate facilities to examine policies, procedures, and protocols and staff work patterns on psychiatric care units within the facility. Other frequently reported causes of error included lack of or incomplete documentation, ineffective communications, problems with the written order, knowledge deficit, and illegible or unclear handwriting.

Case Examples^a

1. A 43 year-old psychiatric inpatient fell causing bruising, which was believed to have resulted from a significant elevation in the Dilantin level after a psychiatrist added valproic acid to the drug regimen without checking for potential drug-drug interactions. This drug interaction has the strong potential of significantly raising serum concentrations of Dilantin to toxic Levels (>30mcg/mL).⁶ Additionally, the pharmacy did not catch and prevent this clinically significant drug-drug interaction. Although the patient experienced no additional clinical sequelae, observation was initiated and increased. This medication error resulted from an improper dose/quantity of an additional drug, with the contributing factor documented as inexperienced staff and failure to follow an established policy or procedure. Actions taken following the error included informing and educating the physician who ordered the valproic acid. This educational intervention included discussion and reminder that the facility policy contained a provision to check for drug interactions on all prescribed medications using the facility's on-line drug information program.

2. A 22 year-old inpatient in a specialty psychiatry facility, was experiencing acute pain. The patient was prescribed Oxycodone 40 mg every morning, to be titrated to 60 mg twice daily. On the first day of therapy, the patient was given 40 mg in the morning, 20 mg at noon and 60 mg at 5 pm. On the evening of the first day of the Oxycodone therapy, an oxygen saturation level was ordered, but never performed and the following morning, the patient was found unresponsive. Subsequently, a narcotic antagonist was administered with vital signs monitoring initiated. The emergency 911 number was called to transport the patient to an acute care facility, however, the patient expired. There is no documented free text as to exactly when or where the patient expired. A primary cause of this medication error was confusing and ineffective communications related to clarity of the drug order. Initial review of the error documented that there was inadequate communication related to the monitoring parameters and assessment of risk with associated respiratory depression. There were also inadequate guidelines for specifying when a dose of a medication should be held. Actions taken to avoid a reoccurrence included the physician(s) providing specific parameters and guidelines for monitoring and withholding a dose of a medication. Facility staffing policies and procedures were also modified to include new guidelines.

3. A physician's order for propranolol included criteria to withhold the drug if the patient was determined to be hypotensive. A licensed vocational nurse (LVN) failed to check the patient's blood pressure or the patient's chart (that indicated the patient was currently hypotensive) and inadvertently administered the drug to the 61 year-old patient. The patient later became obtunded and was sent to the emergency department of the servicing community hospital where she was admitted and later transferred to a specialty hospital resulting in a prolonged hospitalization of more than 10 days. This medication error was reported to be caused by a failure to follow procedure/protocol in addition to failure to properly monitor the patient. Actions taken following the error included an in-depth staff and physician analysis of the event and an examination of the causes and contributing factors. The patient's physician and the patient were informed. Policy

changes were made to communication procedures between physicians, nurses and nursing supervisors. Unit staffing practices and policies were modified to reflect the procedural revisions.

Suggestions to Improve Medication Safety in Psychiatric Care Settings

Based on a review of the error cases submitted to USP, there are several actions that healthcare facilities can take to improve medication safety in psychiatric care settings. First, organizations should develop protocols for medications with a narrow therapeutic index or that require ongoing monitoring or laboratory testing before initiation, or change in therapy (e.g. lithium carbonate, clozapine, divalproex, phenytoin).¹ Decision support or clinical rules specific for psychotherapeutic medications should be created within electronic prescribing and pharmacy information systems. Whenever possible, involve clinical pharmacists more directly in psychiatric patient care and where resources permit, have dedicated pharmacists who can participate in psychiatric patient care rounds or are readily accessible for consultation.¹ Periodically assess nurse, physician and pharmacist knowledge and understanding of medication management for psychiatric patients and finally, educate and involve patients in the appropriate use of their own medications.¹

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

References:

1. Grasso BC, Bates D. Medication Errors in Psychiatry: Are patients being harmed? *Psychiatric Services* (Talking Points) <http://ps.psychiatryonline.org> May 2003; Vol 54 No. 5: 599.
2. Burt C, McCaig L, Rectsteiner E: Ambulatory Medical Care Utilization Estimates for 2005. *Advance Data from Vital and Health Statistics* Number 388, June 29, 2007. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.
3. Bates D. Examining the Evidence, Do we know if psychiatric inpatients are being harmed by errors? *Psychiatric Services* (<http://ps.psychiatryonline.org>). Dec 2003; Vol 54 No.12: 1599-1603.
4. Kanjanarat P, Winterstein A, Johns T, Hatton R, Gonzalez-Riothi R, Segal R. Nature of preventable adverse drug events in hospitals: A literature review. *Am J Health-Syst Pharm*. Sept 2003; Vol 60: 1750-1759.
5. National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). Index for Categorizing Medication Errors; Definitions (Harm). NCC MERP website <http://www.nccmerp.org/pdf/indexBW2001-06-12.pdf> accessed 10/4/07.
6. American Hospital Formulary Service (AHFS), 49th Edition, American Society of Health-System Pharmacists, 2007, (AHFS Category 28:12:12, Hydantoins: Phenytoin, Phenytoin Sodium; Cautions/ Adverse Effects).



1. USP-ISMP Workshop: Using Data Effectively to Manage the Risks to Medication Safety

This one-day interactive program is designed for pharmacy directors, risk managers, patient safety officers, medication safety officers, and other healthcare professionals seeking to enhance their ability to collect, analyze, and prioritize

medication error and other adverse drug event data. Participants will learn how to select effective risk reduction strategies based on proven medication safety principles, instead of relying on human vigilance alone. They also will learn the best way to report findings in an actionable format that will help drive medication safety efforts and show results from system improvements. The workshops include home study materials and will include breakout sessions with an opportunity to gain hands-on practice working with data. Pharmacy and Nursing CE credit will be available.

AGENDA TOPICS that will be covered during the program include:

- Risk identification: Data collection methods
- Risk analysis: Analysis of aggregate data for trending
- Risk control: Choosing effective error reduction strategies
- Case studies: Examining data, priority setting, and interventions

FEES AND REGISTRATION

Early registration: \$350.00 (up to 21 days before program date)

Regular registration: \$395.00

Group discounts: For more information and a group code number for online registration, call 301-816-8136

To register for the workshops visit <http://www.intellor.com/usp/ismp>

REMAINING WORKSHOP DATES

November 5, 2007

8:00 a.m.–4:30 p.m.

USP Headquarters

Rockville, MD

December 1, 2007

Before the ASHP MidYear Clinical Meeting

8:00 a.m. – 4:30 p.m

Imperial Palace Hotel

Las Vegas, NV

2. Joint Commission Publishes 2008 National Patient Safety Goals

The Joint Commission recently published the 2008 National Patient Safety Goals and related requirements for each of its accreditation programs and its Disease-Specific Care Certification Program. One major change in this sixth publication of the National Patient Safety Goals includes a new Requirement (3E) to take specific actions to reduce the risks of patient harm associated with the use of anticoagulant therapy. The new requirement has a one-year phase-in period that includes defined milestones, and unlike previous year the requirements will be phased in throughout 2008, with full implementation required by January 2009. The full text of the 2008 National Patient Safety Goals may be found at:

<http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/>

3. FDA Updates

a. FDA Strengthens Dietary Supplement Requirements: The FDA recently announced the final rule establishing regulations to require current good manufacturing practices (cGMP) for dietary supplements. The rule ensures that dietary supplements are produced in a quality manner, do not contain contaminants or impurities, and are accurately labeled. It also includes

requirements for recordkeeping and handling consumer product complaints. One significant result of this new rule is the requirement, by the end of 2007 for industry to report all serious dietary supplement related adverse events to FDA. The FDA is soliciting comments from the public on the interim final rule. A 90-day comment period, ended on September 24, 2007. The FDA Press Release is also available at: <http://www.cfsan.fda.gov/~dms/dscgmps6.html>

b. Careful Use of Propofol Strongly Recommended: The FDA has cautioned health care professionals that patients may experience chills, fever, and body aches shortly after receiving propofol for sedation or general anesthesia. Recent data and information from researchers found no evidence that the propofol vials or prefilled syringes used were contaminated with bacteria or endotoxins. However, the FDA suggests that propofol vials and prefilled syringes be used within 6 hours of opening and that each vial be used for a single patient in order to minimize the potential for bacterial contamination. Patients who develop symptoms of acute febrile reactions after receiving propofol should be thoroughly evaluated for bacterial sepsis. For additional information, see: <http://www.fda.gov/cder/drug/infopage/propofol/default.htm>

c. FDA and Cephalon Warn of Deaths from Fentora: The FDA and Cephalon, Inc, the manufacturer of Fentora (fentanyl buccal tablets) recently announced that failures to strictly follow instructions in the product labeling resulted in recently reported deaths and other adverse events in patients who received the product. Fentora-related patient deaths have resulted from improper patient selection, improper dosing, and/or improper product substitution. Cephalon plans to revise the labeling for Fentora in the near future to clarify the appropriate patient selection criteria and dosage recommendations. The FDA Public Health Advisory on this subject is available at: http://www.fda.gov/cder/drug/advisory/fentalyn_buccal.htm

4. MSDS Collection Available Online from USP

USP has recently introduced the Material Safety Data Sheets (MSDS) Database Online, a fully-searchable online index of MSDS for USP's entire catalog of more than 2,000 Reference Standards. Unlike other collections that are periodically revised, MSDS Database Online will be updated each day to ensure that subscribers have anytime access to the most current safety information you need. MSDS will be in PDF format that you can download, save, and print. This product is available in 1-year English only subscription. For more information, contact USP Customer Service via phone at: 301-881-0666, via email: custsvc@usp.org or go to <http://www.usp.org/products/MSDS/>

5. Medication Errors and Syringe Safety Are Top Concerns for Nurses

Earlier this summer (June 2007), the American Nurses Association (ANA) announced the findings of the 2007 Study of Injectable Medication Errors, an independent nationwide survey of 1,039 nurses. The research concluded that the overwhelming majority of nurses (97 %) are "worried" about medication errors and more than two-thirds (68 %) believe errors can be reduced with more consistent syringe labeling. Nurses indicated that the most common factors

contributing to injectable medication errors are: Work environment being too rushed/busy, poor/illegible handwriting, missed or mistaken physician's orders, look/sound-alike medications and working with too many medications. The majority of nurses who participated in the survey (81 %) believe their healthcare facility should ensure sufficient staff is available for timely and efficient administration. For full text see:

<http://www.cnw.ca/fr/releases/archive/June2007/18/c5751.html>

6. Pharmacy Computer System Safety Workgroup Results Released

The Pennsylvania Patient Safety Authority recently released an Advisory with the results from a voluntary assessment of electronic pharmacy systems in Pennsylvania facilities. The objective of the survey was to assess the safety features and capabilities of pharmacy computer systems used in Pennsylvania hospitals. The study documented that pharmacy computer systems continue to allow users to override clinically significant warnings and are not detecting all unsafe drug orders. One key recommendation from the Advisory encouraged all facilities to test their pharmacy computer systems more frequently to ensure they are using the error-catching features to their full potential and to ensure that the systems are capable of preventing these errors. For complete story, see:

<http://www.psqh.com/enews/0607b.shtml>

7. Reports of Serious, Fatal ADEs Continue to Increase

Reports of serious adverse drug events and deaths that are routinely submitted to FDA have increased nearly threefold from 1998 through 2005, according to recent research reported in part by the Institute for Safe Medication Practices in a recent issue of *Archives of Internal Medicine*. Article abstract available at:

8. Ceftriaxone Labeling Revised Again by Manufacturer

Roche Laboratories, in a Dear Healthcare Professional letter dated August 2007, announced further changes to the labeling for Rocephin, (ceftriaxone) injection, which included revised information that Rocephin and calcium-containing solutions, including continuous calcium containing infusions such as parenteral nutrition, should not be mixed or co-administered to any patient irrespective of age, even via different infusion lines at different sites. Detailed information can be obtained from:

http://www.fda.gov/medwatch/safety/2007/Rocephin_HCP_august2007.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.

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