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**USP Patient Safety
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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

Medication Errors Involving Neuromuscular Blocking Agents

Neuromuscular blocking agents (NMBAs) are commonly used to relax skeletal muscles during surgery that is conducted under general anesthesia. These agents are also used in emergency departments, intensive care units, interventional radiology areas, and even medical and surgical units. Because these agents paralyze respiratory muscles, misuse can lead to serious harm or death. Medication errors involving neuromuscular blocking agents have occurred in multiple areas within a hospital or health system.^{1,2} NMBAs

should only be administered by staff with experience in maintaining an adequate airway and respiratory support in facilities where intubation can readily be performed, oxygen can be administered, and respiratory support can be provided.

Between January 1, 2000 and December 2005, 651 medication errors involving NMBAs were reported to the United States Pharmacopeia's (USP) MEDMARX[®] program. One-third of the reported errors were intercepted (Category B) before reaching the patient (Table 1). However, 51% (n=332) of errors did ultimately reach the patient (Categories C-I) and 9.4% (n=61) resulted in some level of patient harm (Categories E-I). Among the harmful errors, 65% (n=40) resulted in temporary harm (Category E), and 11 were sentinel events (Categories G-I) including one fatality.

Table 1. Severity of Harm in Errors Involving Neuromuscular Blocking Agents

Error Category ^a	n	%
A	102	15.6
B	217	33.3
C	183	28.1
D	88	13.5
E	40	6.1
F	10	1.5
G	0	0
H	10	1.5
I	1	<1
Total	651	100

a. NCC MERP Error Category Index (A-I) www.nccmerp.org

Types of Error

There were 599 MEDMARX records in which at least one type of error was identified, with a total of 648 types of error selected (more than one type of error was involved in some cases). The most common types of error were *Improper dose/quantity* and *Unauthorized/wrong drug* which, when combined, accounted for 56% of the selections (Table 2).

Table 2. Types of Error Involving Neuromuscular Blocking Agents

Type of Error	n	% ^a
Improper dose/quantity	169	28.2
Unauthorized/wrong drug	166	27.7
Prescribing error	69	11.5
Drug prepared incorrectly	61	10.2
Omission error	51	8.5
Wrong time	37	6.2
Wrong patient	23	3.8
Extra dose	18	3.0
Wrong administration technique	14	2.3

Expired product	10	1.7
Wrong route	9	1.5
Mislabeled	8	1.3
Wrong dosage form	7	1.2
Deteriorated product	6	1.0

a. The percentages do not add up to 100% because more than one type of error was involved in some cases. There were 648 types of errors identified in 599 MEDMARX error records.

Causes and Factors Contributing to Errors

At least one cause of error was identified in 627 records, with 1,242 causes of error selected (more than one cause of error was identified in many cases). The single most common cause of error was *Performance deficit*; this factor was identified as a cause of error in 43.7% of the records involving neuromuscular blocking agents. Other common causes of error were *Procedure/protocol not followed* (22.5%), *Communication* (11%), *Calculation error* (10%), *Knowledge deficit* (9.6%), and *Documentation* (9.4%).

Two hundred and forty-three contributing factors were identified in 160 records. When a contributing factor was identified, *Distractions* was the most frequently reported selection (n=60) comprising 37% of the 160 records. *Emergency situation* and *Increased workload* each contributed to the error in 31% and 25% of the cases respectively. Inexperienced staff were thought to contribute to the error in 31 (19%) of the cases.

Products Involved in Errors

More than one third (35%; n=256) of medication errors involving NMBA's reported to MEDMARX involved Vecuronium. Fewer errors involved Cisatracurium (17.6%; n=128), Succinylcholine (15.9%; n=116), Pancuronium (14.4%; n=105), Rocuronium (10.2%; n=74), Atracurium (4.5%; n=33), Mivacurium (<1%; n=6), and Doxacurium (<1%; n=4). The reasons for these differences are unknown, although differences in volume of use of various products may be a determining factor.

Selected Case Reports

The following case reports are based on records in the MEDMARX database: They highlight several common risks associated with the use of neuromuscular blocking agents:

Case #1: A nurse administered an unauthorized intravenous (IV) admixture of vecuronium to the patient after mistaking it for a penicillin G IV admixture that was stored in the same refrigerator (the vecuronium was intended for another patient). The patient was already on life support and was receiving dopamine by IV infusion when the error occurred. The patient was monitored for adverse effects from the vecuronium. An increase in the fraction of inspired oxygen was required. The patient's heart rate increased and his blood pressure decreased, requiring an increase in the dopamine infusion rate for a short time. There were no long-term sequelae from the error.

Case #2: An order was written for Norcuron® (vecuronium), and the written order was then verbally relayed over the phone to the pharmacy. The pharmacy inadvertently prepared an admixture of norepinephrine, which was sent to the nursing unit and

administered. The patient's systolic and diastolic blood pressures increased to 198 mm Hg and 85 mm Hg, respectively. The blood pressure elevation was corrected by giving two doses of hydralazine 5 mg by IV push and labetalol 10 mg by IV push.

Case #3: An order was written for cisatracurium 3 mcg/kg/min or 1.8 mg/hr for a child weighing 10 kg. The nurse calculated an administration rate of 18 mg/hr, which is a ten-fold overdose. The error was detected and corrected when the patient became agitated and short of breath. These symptoms resolved after the administration of oxygen.

Case #4: A physician removed vials of midazolam and rocuronium from a medication cart in the operating room, labeled two empty syringes with the respective drug names, and was interrupted while drawing up the two different drugs into the syringes. When the physician returned, he administered the content of one of the syringes (thought to be midazolam) to his patient in the pre-operative holding area. Shortly after, the physician was called away to answer a page and upon his return, found the patient unresponsive. The patient was resuscitated, given neostigmine to reverse the respiratory paralysis, and an airway was established and oxygen administered. The patient's surgery was canceled. It was later determined that the physician had administered the rocuronium in a syringe instead labeled as midazolam.

Recommendations to Improve the Safe Use of Neuromuscular Blocking Agents (NMBAs)

Certain packaging requirements for NMBAs are outlined within USP's official compendial standards and became mandatory for pharmaceutical manufacturers on October 1, 2005.³ These requirements mandate that both the ferrules (metal bands around the tops of vials) and overseals of neuromuscular blocking agents contain the words "Warning: Paralyzing Agent" or "Paralyzing Agent" (depending on the size of the closure system). Both the container cap ferrule and the cap overseal must bear the warning in black or white print (whichever provides the greatest color contrast with the ferrule or cap color).

USP's Safe Medication Use Expert Committee has published an extensive list of recommendations to improve safe use of neuromuscular blocking agents.² The following suggestions are based, in part, on those recommendations:

1. Conduct a failure mode and effects analysis (FMEA) on all NMBAs before they are added to the formulary to minimize the addition of products with poor labeling and packaging.
2. Avoid stocking neuromuscular blocking agents that are similar in appearance to other medications that are used in the institution.
3. Store neuromuscular blocking agents separately from other medications.
4. Limit the availability of NMBAs to the pharmacy and those selected patient care areas where mechanically-ventilated patients are treated.
5. Do not dispense NMBAs in unit-dose medication carts.
6. Do not allow NMBAs to be stored in a multi-cassette, automated dispensing device drawer. The storage drawer where the NMBA is located should only allow access to a single item.
7. Establish policies and procedures to ensure that medications in unlabeled syringes

are not administered, unless the dose is prepared and immediately administered. When preparing syringes, prepare one dose at a time.

8. Require that a brightly-colored alert label stating “Warning: Paralyzing Agent” appear on all syringes or infusion containers prepared by the facility.
9. Review the prescribing practices for ordering NMBAs and establish automatic discontinue orders when the patient is transferred out of the critical care areas.
10. Use bar code technology to improve the accuracy of identifying both the product and patient prior to administration.
11. Use sophisticated, programmable infusion devices (“smart pumps”) to deliver selected drug dosages when and where appropriate.
12. Educate health care professionals who administer neuromuscular blocking agents about the usual dosages and institutional policies and procedures for safe handling of these medications.

References

1. Phillips MS, Williams RL. Improving the safety of neuromuscular blocking agents: A statement from the USP Safe Medication use Expert Committee. *Am J Health-Syst Pharm*; 63; Jan 15, 2006; pp139-142.
2. Smetzer JL, Cohen MR. Preventing Errors with Neuromuscular Blocking Agents. *Joint Commission J on Quality and Patient Safety*; 32:1; Jan 2006; pp 56-59.
3. The United States Pharmacopeia–National Formulary (USP 29-NF 24), General Chapter <1> Injections; Packaging/Containers for Injections/Neuromuscular Blocking and Paralyzing Agents; 2457; 2006.



1. FDA Updates

GAO Report Finds Gaps in FDA Authority to Manage Drug-safety Issues: A recent Government Accountability Office (GAO) report criticizes the FDA's handling of drug-safety issues, claiming that the agency does not have effective processes for making decisions about drug safety and suggested that the agency be given more authority to force drug makers to complete post-marketing studies on the safety of prescription drugs. <http://www.gao.gov/new.items/d06402.pdf>

New Post Created to Focus on Drug Safety: The FDA has created a new position to bolster drug safety initiatives— associate director for safety policy and communication. Dr Paul Seligman was recently appointed to this new role within the FDA’s Center for Drug Evaluation and Research (CDER). Dr Seligman will provide oversight of drug safety issues and policies and the dissemination of safety information to healthcare professionals and patients through FDA's website.

Black-box warnings added to labels of two asthma medications: GlaxoSmithKline's Advair and Serevent asthma medications will now bear revised black-box warnings that caution users of an increased risk of asthma-related death. <http://www.fda.gov/cder/drug/advisory/LABA.htm>

Concern Continues on Safety of Drug Patches: An article last month in the *Philadelphia Inquirer* states that the FDA is further investigating the safety of transdermal drug-delivery systems, especially cases in which users exposed the patches to heat.

<http://www.philly.com/mld/inquirer/living/health/14022261.htm>

Tougher Approval Process for Naming Drugs: FDA is placing more focus on its review procedures for naming drug products in an effort to reduce medication errors that result from confusion between drug names. In 2004, the FDA's name-review board rejected 123, or 36%, of the proposed drug names it received, up from 29% in 2003 and 31% in 2002. Currently, the Agency uses several techniques to "test" potential problems with proposed drug names including checking proposed new names against a list of already marketed brand names and checking the use of the name in "real-world conditions" (e.g., presenting the drug name in prescription or voice-recorded form to a team of 130 physicians, pharmacists, and nurses). Proposed names are typically rejected if they look or sound too similar to existing drugs, are similar to names that have caused problems in the past, or if they "imply that the drug can do more than it really does."

Hospital Bed Design Guidelines: According to the FDA, there were 691 patient bed entrapments between 1985 and 2006. Of these, 413 patients died, 120 were injured, and 158 were near miss events. Entrapment is when patients become stuck or jammed in a part of the bed and cannot escape on their own. A new set of guidelines that identify potential hazards and outlines types of entrapments should help to reduce instances of these events. To read the complete press release, click [here](#). To view the new guidelines, click [here](#).

2. ISMP Uncovers Gaps in Facilities' Vincristine Safety Efforts

Findings from a survey conducted by the Institute for Safe Medication Practices (ISMP) revealed that nearly half of respondents' facilities did not package intrathecal medications in a manner obviously different from the packaging used for vincristine and other intravenous drugs. ISMP has compiled several strategies that facilities can undertake to prevent health care providers from administering vincristine by intrathecal injection.

<http://www.ismp.org/Newsletters/acutecare/articles/20060223.asp>

3. Joint Commission Updates:

Mid-2006 JCAHO Changes: Several recent revisions were made to JCAHO's medication management standards and go into effect July 1, 2006.

http://www.jcaho.org/NR/rdonlyres/83C5AC77-4BCC-4B6E-A2C5-5217A6F5FD6A/0/hap_stdrev_706.pdf

(hospitals)

http://www.jcaho.org/NR/rdonlyres/51831FFF-3C6F-4B08-AFEE-0E953B4D1FD4/0/CAH_stdrev_706.pdf

(critical access hospitals)

http://www.jcaho.org/NR/rdonlyres/22C6F437-1756-4613-AA48-DBDE9CC67EEF/0/ome_stdrev_706.pdf

(home care)

http://www.jcaho.org/NR/rdonlyres/DB152D6D-02F5-4592-9D5E-43B5F2750B25/0/ahe_stdrev_706.pdf

(ambulatory care)

Dangerous Tubing Misconnections: A *Sentinel Event Alert* was recently published urging

health care organizations to closely examine how tubes and catheters are connected to patients and challenges the manufacturers of these devices to redesign them in ways that will make dangerous misconnections much less possible. Reports to the Joint Commission, ECRI, the Food and Drug Administration (FDA), the Institute for Safe Medication Practices, and United States Pharmacopeia show that tubing and catheter misconnection errors occur frequently and, in some cases, lead to fatalities. [Click here to read more.](#)

4. VHA Issues QC Monitors for Bar Codes on Medications

To ensure that the bar codes on medication packages can be scanned at the point of care, the Veterans Health Administration recently issued a directive that contains six pages of quality-control monitors.

http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1380

5. Pharmacists' Counseling Reduces Adverse Drug Events

Prior to medication reconciliation standards, a randomized controlled study at Boston's Brigham and Women's Hospital found that pharmacist-provided medication review and patient counseling upon discharge followed by a phone call three to five days later resulted in a significantly lower rate of preventable adverse drug events.

<http://archinte.ama-assn.org/cgi/content/abstract/166/5/565> (abstract)

6. Electronic 'Tags' Improve Communication Handoffs

Breakdowns in communications between specialists and primary care physicians have led to serious patient harm, but a recent report in the *American Journal of Roentgenology* suggests that an inexpensive electronic tag can reduce lapses in communications. [Click here](#) to read more.

7. Error Risk Still Present with Computerization

A recent error event published in an article in the *Annals of Internal Medicine* highlight how computerized entry systems, like bar coding, can lead to new types of patient safety errors. The article describes how a diabetic patient was given the wrong bar code-enabled bracelet leading to the administration of a near-fatal dose of insulin to a non-diabetic patient. The article acknowledges that computerization can reduce many errors, but it cautions that the systems may weaken a caregiver's vigilance in following patient safety procedures. [Click here](#) to read the abstract.

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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