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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.

New year, new beginning – USP is pleased to announce that its popular CAPSLink newsletter is returning to a regular monthly publication schedule after a temporary hiatus. We trust that our readers will continue to find this publication a valuable resource for current and relevant medication error information, analysis, and recommendations. As before, our goal is to provide healthcare practitioners, researchers, and the larger healthcare community with information that will support efforts to improve patient safety.

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Improving the Safety of Automated Dispensing Devices (ADDs)

The use of medication automated dispensing devices (ADDs) is rapidly becoming the norm within hospitals and health-systems replacing medication carts or open floor stock systems with automated devices. These devices can markedly improve the timeliness of drug distribution and administration - especially decreasing the time for first dose administration. These devices also dramatically limit access to medications by unauthorized individuals, thus improving medication security. However, as with any health care technology, there are patient safety implications that must be evaluated and monitored in order to decrease the risk of medication errors.

The tragic deaths of three neonates in an Indiana hospital this past September provides but one example that automated systems do not automatically prevent harmful medication errors.^{1,2} These events serve as an unfortunate reminder that additional safeguards (e.g., double check/redundant systems) must be in place when using ADD technology. A brief synopsis of the September fatal medication error follows:

1. A pharmacy technician restocked the pediatric nursing unit ADD with 1 mL vials of heparin (10,000 unit/mL) instead of the intended 1 mL vials of heparin (10 units/mL) vials. The two different concentrations of Heparin had very similar packaging and labeling.
2. There was no double check process or bar code scan used to ensure that the medication, which was replenished in the ADD by the pharmacy technician was correct.
3. Several nurses selected and retrieved heparin from the ADD, but apparently did not notice the higher concentration on the label (again given the similar labeling with the lower concentration) and administered a 1,000 fold overdose to the infants.

Errors involving the restocking of ADDs or the removal of the wrong drug from an ADD are not infrequent and have been reported previously to USP's MEDMARX[®] program and to the Institute of Safe Medication Practices (ISMP). The following case is very similar to the neonate fatalities in Indiana and was published in USP's MEDMARX 5th Anniversary Data Report³:

A pharmacy technician inadvertently mis-filled an automated dispensing device with 25 vials of Heparin 10,000 units per mL instead of Heparin 10 units per mL. Two doses were given to a pediatric patient during the night shift. On the day shift, a registered nurse recognized the discrepancy and removed the remaining 23 vials from the automated device. The infant became over anti-coagulated and had to be transferred to the Pediatric Intensive Care Unit for additional treatment. Similar drug product packaging/labeling and procedure/protocol not followed

were both cited as causes of error.

These errors can occur, in part, because of similar drug product packaging and/or labeling or if the medications are accidentally stocked in or returned to the wrong drawer/location within the ADD. Without some type of independent double check system (e.g., bar coding) the accuracy of restocking and drug retrieval will be at risk.

Between July 2001 and December 2005, there were 13,339 medication errors reported to the MEDMARX program involving ADDs. Approximately one-fifth of the reported errors were intercepted (Category B) before reaching the patient (Table 1). However, 33.8% (n=10,919) errors did ultimately reach the patient (Categories C-I) and 1.2% (n=383) resulted in some level of patient harm (Categories E-I). Among the harmful errors, 81% (n=310) resulted in temporary harm (Category E), and 19 were sentinel events (Categories G-I) including four fatalities.

Table 1. Severity of Harm for Errors Involving Automated Dispensing Devices^a

Error Category	n (%)
A	14,443 (44.7%)
B	6,977 (21.6%)
C	9,053 (28.0%)
D	1,483 (4.6%)
E	310 (1.0%)
F	54 (0.2%)
G	5 (0.0%)
H	10 (0.0%)
I	4 (0.0%)
Total	32,339 (100%)

^a Medication error categories are based on the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Error Category Index. Complete definitions of medication error categories can be found at: www.nccmerp.org

Types of Errors associated with Automated Dispensing Devices

By far, errors involving an Improper dose/quantity were reported more often (54%), followed by Unauthorized drug (20%) and Omission error (12%). These errors often resulted from mis-filling the ADD with an incorrect drug quantity, an incorrect strength of a drug, placing the product in the wrong drawer (or bin), or retrieving the wrong product.

Not all ADDs are alike and newer models have enhanced user safeguards. These models should reduce patient safety risks when they are combined with other emerging technologies such as machine-readable coding systems and direct interfaces with hospital information systems. Table 2 documents the ten leading types of medication errors associated with ADD technology.

Table 2. Types of Medication Errors for Automated Dispensing Devices^a

Error Type	n	% of Total Records
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Improper dose/quantity	16,463	53.9
Unauthorized /wrong drug	6,128	20.0
Omission error	3,419	11.2
Drug prepared incorrectly	1,602	5.2
Wrong time	1,354	4.4
Extra dose	899	2.9
Wrong patient	655	2.1
Wrong dosage form	603	2.0
Prescribing error	525	1.7
Wrong administration technique	488	1.6

^aBased on 30,565 records and 32,705 selections for the period 7/01 - 12/05.

Leading Causes of Medication Errors Associated with ADD Technology

The most frequently reported cause of error involving ADDs was *Drug distribution system* –recorded in about 54% of all records. When taken in context with two other leading causes, *Performance deficit* (34.3%), and *Procedure/protocol not followed* (21%), it suggests that the interface between staff and the ADD technology is not optimal and needs to be examined. Table 3 documents those leading causes of medication errors associated with ADDs.

Table 3. Leading Causes of Errors for Automated Dispensing Devices^a

Causes of Error	n	% of Total Records
Drug distribution system	14,836	53.8
Performance (human) deficit	9,453	34.3
Procedure/protocol not followed	5,604	20.3
Documentation	3,629	13.2
System safeguard(s)	2,203	8.0
Communication	2,193	8.0
Computer entry	2,174	7.9
Knowledge deficit	1,680	6.1
Transcription inaccurate/omitted	1,630	5.9
Monitoring inadequate/lacking	1,176	4.3
Workflow disruption	979	3.5
Similar packaging/labeling	953	3.5
Written order	863	3.1
Generic names look alike	779	2.8
Packaging/container design	729	2.6
Dosage form confusion	709	2.6
Incorrect medication activation	644	2.3
Equipment design	616	2.2
Brand/generic names look-alike	580	2.1
Information management system	570	2.1

^a Based on 27,581 records and 61,215 selections for the period 7/01 – 12/05.

Location of Errors Involving ADDs: General patient care units were identified as the

location where the majority of ADD-related medication errors occurred. This is logical given that these are the locations where the majority of ADDs are located within healthcare facilities (Table 4).

Table 4. Leading Patient Care / Medical Facility Locations Reporting Medication Errors for Automated Dispensing Devices^a

Location	n	% of Total Selections
Nursing (Patient Care) Unit	11,948	51.9
Pharmacy, inpatient	4,791	20.8
Emergency Department	916	4.0
Pharmacy, outpatient	896	3.9
Intensive Care Unit, Medical	727	3.2
Intensive Care Unit, Coronary	397	1.7
Maternity Unit	318	1.4
Intensive Care Unit, General	297	1.3
Labor/Delivery	287	1.2
Intensive Care Unit, Surgical	247	1.1

^a Based on 604 facilities reporting with 23,008 selections for the period 7/01 - 12/05.

Staff Involved with ADD Errors: Staff involved in medication errors associated with ADD technology goes beyond the disciplines of pharmacy and nursing. USP's analysis of MEDMARX data indicates that some of the errors were attributed to physicians and respiratory therapists. Several case reports indicated that unlicensed assistive personnel on the patient care unit accessed the machines as well.

Mis-fills of ADDs can impact personnel beyond pharmacy and result in errors. Some reports that involved nursing errors indicated that the nurse retrieved the product from the machine and administered the product without confirming the label. Reliance on technology for certain process functions does not abdicate professional responsibilities associated with medication dispensing and administration. Nurses and pharmacy technicians were implicated in more Improper dose/quantity, Unauthorized drug, and Omission errors than other staff members (Table 5).

Table 5. Staff Involved with Errors for Automated Dispensing Devices^a

Staff Involved	n (%)
Nurse, Registered	8,452 (47.7%)
Pharmacy Technician	4,196 (23.7%)
Pharmacist	2,461 (13.9%)
Nurse, Licensed Practical/Vocational	698 (3.9%)
Pharmacy Personnel, non-specific	576 (3.3%)
Physician	394 (2.2%)
Nursing Personnel, non-specific	347 (2.0%)
Unit Secretary/Clerk	211 (1.2%)
Respiratory Therapist	137 (0.8%)
Patient/Family Member/Caregiver	41 (0.2%)

Student	39 (0.2%)
Unlicensed Assistive Personnel	39 (0.2%)
Anesthesia Provider	31 (0.2%)
Nursing Assistant/Aide	29 (0.2%)
Radiology Technician	24 (0.1%)
Nurse Practitioner/Advanced Practice Nurse	11 (0.1%)
Other	25 (0.1%)
Total	17,711 (100 %)

^a Based on 17,711 total reported errors for the period 7/01 - 12/05.

Recommendations to Improve Safety When Using ADD Technology: In an effort to prevent medication errors, the following procedural safeguards should be considered for use with automated dispensing devices (ADDs):

1. Many manufacturers of ADD technology include the option of bar-code scanning and verification for restocking the devices. Hospitals and health-systems should seriously consider the inclusion of bar code scanning for drug replenishment and retrieval as an important component of ADD technology.^a
2. Consider using automated dispensing devices as part of a comprehensive automated medication-use system that requires pharmacy review and order entry before other staff can remove drugs from the device. ISMP recommends no overrides, but if allowed, the facility should develop a list of drugs or drug categories (e.g., antibiotics) that should not be removed without prior pharmacy notification and review.^a
3. Establish a standardized process for selecting the drugs for consideration to be stocked in ADDs relative to where these devices are located within the facility. When creating an ADD drug inventory the unique needs of each patient care unit must be taken into consideration in addition to staff expertise and familiarity with specific drugs on that unit, and the age and diagnoses of patients being treated^a
4. Establish maximum dose ranges for "high alert" medications and place this list on automated dispensing cabinets as a quick, readily accessible reference.^a
5. Educate staff on the importance of removing only a single dose (unit of use) of the medication ordered. If not used the drug should be returned to the pharmacy for appropriate disposition.
Nursing staff should never return unused drugs back into the ADD.^a
6. Develop a check system to assure the accurate stocking and restocking of medications to any ADDs. Checking could be accomplished by pharmacy staff members or by staff on patient care units if they are supplied with a daily list of the items added to the device for verification.^a
7. Create an interdisciplinary medication-use safety team to conduct a failure mode and effects (FMEA) analysis of the medication-use system specifically in critical care areas (e.g., ICU, pediatric and neonatology settings) to identify high-risk processes.^b
8. Dispense medications in ready-to-use (unit dose) form prepared by the pharmacy. An ASHP survey found that, for critical care beds, 64.3% of hospitals dispensed

75% or more of injectable medications in unit dose form.^{b,4}

9. Routinely assess staff competency on performing independent checks (double-checks) for all high-risk medications. This process should be used even if barcode bedside scanning is in place.^b
10. It is imperative that the judgment of educated and trained health care professionals serves as the initial and final authority regarding the safety of the patient. A reported 71% of hospitals use ADDs for drug distribution, therefore it should never be assumed that technology alone will prevent all errors and solve all problems in highly complex medication-use processes.^b
11. Pharmacists, nurses, medical staff and others as appropriate should develop comprehensive policies and procedures related to ADDs that include specific processes that ensure patient safety and the effective management and oversight of override medication dispensing.^c

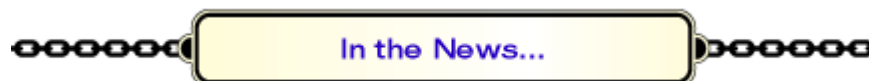
a Recommendation from ISMP (www.ismp.org/Newsletters/acutecare/articles/19981202.asp and www.ismp.org/Newsletters/acutecare/articles/20060921a.asp)

b Recommendation from ASHP (http://www.ashp.org/s_ashp/bin.asp?CID=1004&DID=6320&DOC=FILE.PDF)

c Kowiatek, J.G., Weber, R.J., Skledar, S.J., Frank, S., DeVita, M. Assessing and Monitoring Override Medications in Automated Dispensing Devices. *Joint Commission Journal™ on Quality and Patient Safety*. June 2006, Vol. 63, Num. 6: 309-317. The Joint Commission on Accreditation of Healthcare Organizations.

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1. Joint Commission Seeks Input on Proposed 2008 NPSGs

The Joint Commission released for review a list of DRAFT Goals and Requirements that will be considered for potential inclusion in the 2008 National Patient Safety Goals (NPSGs). The NPSGs, which are updated annually, are designed to require health care

organizations to protect patients from the negative impact of specific health care errors. The potential new Goals, Requirements and Implementation Expectations under consideration for 2008 implementation can be accessed on the Joint Commission website through the following link: [Click here to read more.](#)

2. FDA Updates

Efforts Against Marketed Unapproved Drugs: On December 11, 2006, the Food and Drug Administration (FDA) ordered firms to stop marketing unapproved drug products containing quinine, a drug used to treat malaria, citing serious safety concerns, including deaths, associated with quinine products. Although there is only one quinine product approved by the FDA, there are multiple unapproved products containing quinine currently marketed. For additional information see:

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01521.html>

MedWatch: The Centers for Disease Control and Prevention (CDC) issued an article describing three deaths in US infants aged less than 12 months associated with cough and cold medications. The cases underscore the need for clinicians to use caution when prescribing and caregivers to use caution when administering cough and cold medications to children aged less than 2 years. Complete MedWatch 2007 Safety summary:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#coughcold>

Proposed Labeling Changes to OTC Pain Relievers: The FDA recently proposed amendments to the labeling regulations on over-the-counter (OTC) Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) drug products. This includes important safety information regarding the potential for stomach bleeding and liver damage and when to consult a doctor.

<http://www.fda.gov/ohrms/dockets/ac/cder02.htm#NonprescriptionDrugs>

Comments on the current proposal, published in the December 26, 2006 Federal Register may be sent within 90 days to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/ohrms/dockets/default.htm>

3. ISMP Issues Alert on Use of IV Promethazine

The Institute of Safe Medication Practices (ISMP) recently alerted health care providers about the potential risk of serious tissue damage associated with the IV administration of promethazine. The alert provides information that injectable promethazine can be highly caustic to the lining of blood vessels and the surrounding tissue. Although promethazine can be administered either IM or IV, there is an increased risk of serious tissue damage associated with IV use. For a complete listing of recommendations, go to

<http://www.ismp.org/Newsletters/acutecare/articles/20061102.asp>

4. Patient Safety (High 5s) Initiative

The World Alliance for Patient Safety and the Commonwealth Fund recently announced a seven-country collaborative project that is designed to leverage the implementation of five standardized patient safety solutions to prevent avoidable catastrophic events in hospitals.

Complete story: http://www.jointcommission.org/Library/jconline/jo_01_07.htm#11

5. WHO Seeking Comments on Proposed Patient Safety Solutions

Health care professionals and patient advocacy groups from around the world are being invited to comment on nine proposed solutions for improving patient safety that have been developed under the aegis of the World Health Organizations Collaborating Center for Patient Safety.

<http://www.jcipatientsafety.org/14689/>

6. Free e-Prescribing Services for Physicians

The National ePrescribing Patient Safety Initiative (NEPSI) recently announced that it will offer free e-prescribing services to physicians in an attempt to eliminate hand-written prescriptions. The Web-based prescription system will reduce medication errors by forcing physicians to select proper dosages and by comparing medications for potentially harmful interactions. The technology automates safety checks, and includes drop-down menus that require physicians to confirm the proper dosage that they want for the patient. To read the complete release, click [here](#).

7. CMS Finalizes Regulations that Require Hospitals to Secure Medications

Hospitals participating in the Medicare and Medicaid programs must, as of January 26, 2007, keep all drugs and biologicals in a secure area "and locked when appropriate," lock Schedule II-V controlled substances in a secure area, and permit "only authorized personnel" to access locked areas. For more detailed information on this new requirement, [click here](#).

8. Roche Inadvertently Provides Wrong Tamiflu Dosage Information

The FDA announced recently through its MedWatch program that the package insert accompanying the Dear Healthcare Professional letter from Roche dated November 13, 2006, contained inaccurate information about the pediatric dosage of oseltamivir. The company has subsequently alerted recipients of that letter to the error in a December 26 follow-up mailing.

9. Safety Concern Broadens for Gadolinium Contrast Agents

On December 22, 2006 the FDA reported that a debilitating, potentially fatal skin disorder previously linked to Omniscan has the potential to occur in patients with moderate to end-stage kidney disease exposed to any gadolinium-containing contrast agent. [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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