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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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### **Patient-Controlled Analgesia Pumps**

In noncritically ill patients, patient-controlled analgesia (PCA) has been shown to improve pain management with less sedation, less opioid consumption, and potentially fewer adverse effects (e.g., respiratory complications). PCA pumps offer several safety features to prevent the administration of excessive amounts of analgesic medication (e.g., a "lockout interval" that specifies the minimum amount of time between each dose and an established maximum allowable amount of drug during a predefined time period). Despite these advantages, medication errors involving PCA pumps continue to occur.

### **Data Analysis**

USP examined medication errors submitted to its MEDMARX<sup>SM</sup> and USP Medication Errors Reporting (MER)<sup>1</sup> Programs through August 31, 2003. To obtain PCA errors in MEDMARX, a text search for “PCA” in the *Error Description* field was conducted. Together, both programs yielded a total of 5,377 records. A total of 425 records (7.9%) were categorized as harmful (Category E-I<sup>1</sup>) (Table 1). Given that the average overall harm rate for error reports submitted to MEDMARX over the past several years has been approximately 2 percent, it appears that when PCA pumps are involved in medication errors, the chance for patient harm increases more than 3.5 times.

Table 1. PCA-Related Errors

| Error Category <sup>1</sup> | Count        | Percent (%) |
|-----------------------------|--------------|-------------|
| A                           | 474          | 8.8%        |
| B                           | 1,288        | 24%         |
| C                           | 2,568        | 47.8%       |
| D                           | 622          | 11.6%       |
| E                           | 387          | 7.2%        |
| F                           | 26           | 0.5%        |
| G                           | 0            | 0%          |
| H                           | 7            | 0.1%        |
| I                           | 5            | 0.1%        |
| <b>Total</b>                | <b>5,377</b> |             |

1. For complete Error Category definitions, visit [www.nccmerp.org/medErrorCatIndex.html](http://www.nccmerp.org/medErrorCatIndex.html)

The most common types of error involving PCA pumps were *Improper dose/quantity* (38.9%), *Unauthorized drug* (18.4%), and *Omission error* (17.6%) (Table 2).

Table 2. Types of Error<sup>1</sup>

| Type of Error                  | Count        | Percent (%) |
|--------------------------------|--------------|-------------|
| Improper dose/quantity         | 1,873        | 38.9%       |
| Unauthorized drug              | 887          | 18.4%       |
| Omission error                 | 846          | 17.6%       |
| Prescribing error              | 443          | 9.2%        |
| Wrong administration technique | 230          | 4.8%        |
| Extra dose                     | 227          | 4.7%        |
| Wrong drug preparation         | 203          | 4.2%        |
| Wrong time                     | 160          | 3.3%        |
| Wrong patient                  | 118          | 2.5%        |
| Wrong dosage form              | 79           | 1.6%        |
| Wrong route                    | 29           | 0.6%        |
| Deteriorated/Expired product   | 15           | 0.3%        |
| <b>Total</b>                   | <b>5,110</b> |             |

1. Based on 4,812 records, making 5,110 selections for Type of Error

### **Selected Cases from MER**

1. A male patient was admitted with intractable back pain and a history of arthritis and diabetes and was also taking oral steroids. The patient was admitted after the pharmacy had closed for the night. For pain control, the patient was ordered morphine PCA with a loading dose of 10 mg, a PCA dose of 4 mg every eight minutes, plus a continuous infusion dose of 2 mg/hour, with a four-hour limit of 130 mg. The patient received 81.7 mg for the first 5.5 hours and 21.3 mg for the next four hours. Shortly thereafter, the patient was found to be unresponsive. A code was called and the patient died due to respiratory arrest. The patient had been checked for vitals every hour as per routine. It was discovered after the event that the patient may have had undiagnosed sleep apnea.
2. Settings and concentrations for morphine PCA were ordered per standard protocol. In 1.5 hours, the patient received 4 doses of morphine via the PCA device and was noted as being "talkative, eating, and drinking." Three hours later, a second nurse noted the patient as unresponsive but did not contact the physician. Over the course of the night, the patient received 3 more doses of morphine via the PCA device. Toward the end of the night shift, a third nurse noted that the patient was unresponsive and "gurgling" with lung crackles. The physician was contacted and ordered suctioning, naloxone, and furosemide. The patient's condition improved but again deteriorated later in the day. The patient later expired. When the nurse was cleaning the room, she turned off the PCA device and removed the morphine solution. She noted that the solution in the IV bag did not correlate to the pump. The pump indicated the bag should contain 20 mL with a dose of 8 mg delivered. The nurse calculated that the bag should contain at least 80 mL. The nurse contacted a supervisor, who reviewed the pump settings, and discovered that the pump had been incorrectly programmed to deliver 1 mg/mL instead of 0.1 mg/mL.
3. A PCA-related error occurred in a hospital and it was discovered that the error was not due to a wrong drug, dose, or programming error, but from the overdose of an opioid as a result of a practice-related error. The nurse, when assessing the patient's pain, would wake the patient to perform the assessment and then would push the PCA pump button on behalf of the patient. The nurse was attempting to assist the patient, but in reality was causing extreme over-sedation and the patient died.
4. A patient was ordered morphine PCA on the evening shift. A nurse mistakenly removed a meperidine PCA syringe from an automatic dispensing machine as an override medication. When the pharmacy reviewed the override medication removals the next morning, the error was discovered. The pump was checked and found to contain a meperidine PCA cartridge, but the dose settings were programmed for morphine. The patient received two doses of 10 mg meperidine instead of 1 mg morphine. In this case, the pump does not read the syringe bar code to verify the correct medication, which might have prevented this error.

## **Recommendations Based on Analysis of Medication Errors**

### **General**

- Conduct a Failure Modes & Effects Analysis (FMEA) for existing pumps, as well as for new pumps that are brought into the facility. Consider what

default settings are preprogrammed. Consider if the pumps can be programmed by drug (e.g., morphine PCA vs. hydromorphone PCA). Consider if the pump resets to a default (other than “000,” which would require active entry) after it turns off.

- Include bar codes on all PCA medications in facilities where point-of-care bar code systems or other item identification technology (i.e., Radio Frequency Identification, etc.) are implemented.
- Review policies concerning patient’s own pump being used in the hospital.
- Educate patients, family members, and staff (including physical therapists, X-ray technicians, etc.) on the use of the pumps.
- STAFF: Require proper and complete training and demonstration of competency before staff is permitted to work with pumps.
- PATIENTS AND FAMILY MEMBERS: Written instructions should be provided to patients. Instruct family members NOT to administer PCA doses—PCA by definition should be administered at the patient’s perception of need. Document education of patient and family members. . For issues related to PCA by proxy, visit <http://www.ismp.org/msaarticles/issue2.htm>
- Dosing errors are usually by a factor of 10. Errors include the following:
  - Underdoses when lockout is at 4 hours (default) instead of 1 hour.
  - Order calls for 1 mg/hour but the pump is set at 0.1 mg/hour.
  - Order calls for 0.05 mg but the pump is set at 0.5 mg.
  - Other errors include insertion of the wrong drug or wrong concentration in the PCA device.
- Pumps should have upstream occlusion alarms.
- Educate staff on sound-alike and look-alike drugs, especially when bar code technology is not part of the existing system. Many wrong drug errors with PCA pumps are due to name confusion (e.g., morphine vs. hydromorphone vs. meperidine). Auxiliary labeling or posted warnings could be used to highlight differences. Limit the number of products and strengths used/stocked in the facility. Create alerts in computer systems with dosing limits specific to the drug being selected. Do not store sound-alike or look-alike drugs together in a single drawer of the dispensing cabinet on the floor. To view USP’s list of similar drug names, [click here](#). USP also has a list of tips for using this resource. [Click here to view document](#).

## **Prescribing**

- Lockouts should be required with bolus dosing.
- Have standing orders for all medications used in PCAs. Be certain that standing order forms have complete information to avoid handwriting information or drug names. Include specific dosing guidelines and protocols for individualizing therapy to patients based on pain response. Standardize concentrations available for PCA drugs.
- If using preprinted order forms, prohibit writing over information on the form. For example, one provider using a PCA order form that was preprinted with “meperidine” crossed out the drug and wrote “hydromorphone” without changing the basal rate, loading dose, and lockout dose, which caused the patient to become unresponsive, requiring an antidote.
- Avoid duplication of pain management therapy when PCA is in use. Develop protocols to transition to oral therapy from PCA therapy.

## **Dispensing**

- Standardize the strengths/concentrations available in your facility. Be sure physicians are aware of the standard concentrations in use. If higher concentrations are needed for a particular patient or certain settings, conduct FMEA to ensure additional safeguards are in place.
- Separate PCA syringe locations in automated dispensing systems to prevent selection of the wrong drug.

## **Administering**

- Double-check clamp (to open position) before closing the pump.
- Check that the pump is turned on.
- Check whether connections are to IV or epidural lines to prevent wrong-route errors.
- Check for kinked tubing in the pump door. Despite a kink in the tubing, at times no alarm may sound and the volume may be counting down.
- Perform double checks for initial setup and maintenance, and dose changes/change orders.
- Standard orders should be on the medication administration record.
- Conduct staff education on the importance of not administering oral medications (i.e., narcotics and controlled substances) to a patient with a PCA in use unless specifically ordered.
- Temporary nurses (agency or supplemental staff) need to review and be familiar with policies and protocols regarding PCAs and demonstrate competency in the use of this technology.
- Do not accept defaults blindly.
- Set pumps to be programmed in mg, NOT mL.
- Pumps should be assessed on a regular basis.

## **Monitoring**

- If patient complains of pain, reassess pump settings. Check that the basal rate has been entered. Also check that the tubing is not kinked.

1. The MER program is presented in cooperation with the Institute for Safe Medication Practices.

*Acknowledgment is given to the following members of the USP Safe Medication Use Expert Committee, who provided review and comment on these recommendations:*

Mark Sullivan, PharmD, MBA, BCPS — Vanderbilt University Medical Center  
Marjorie Shaw Phillips, RPh, MS, FASHP — Medical College of Georgia Health System  
Philip Schneider, MS — Ohio State University



### **1. USP Launches Revolutionary MEDMARX ADR Module**

MEDMARX now has the capability to document, search and analyze Adverse Drug Reactions (ADRs) making this the first, real-time repository of ADRs available to health care practitioners. The ADR module works similarly to the current medication error module in that participating hospitals and health systems

can see ADR reports from other facilities. MEDMARX version 6.0 allows health care practitioners to

- Collect data dynamically thereby creating a unique knowledge base that is immediately accessible to all participants
- Use an objective and validated causality assessment—the Naranjo probability scale
- Automatically populate the FDA MedWatch form thereby supporting professional responsibility and compliance with Joint commission standards
- Easily maintain an ongoing system to track and retrieve both preventable and non-preventable adverse drug reactions
- Capture and consistently document actions taken in response to adverse drug reactions; and
- Link ADRs that result from medication errors

Backed by the U.S. Pharmacopeia's 180 years of public health leadership and more than thirty years of voluntary pharmacovigilance programs, MEDMARX version 6.0 offers comprehensive features and unparalleled support. See for yourself how MEDMARX can assist you in all your medication management improvement initiatives. Call 1-800-MEDMARX (1-800-633-6279) and ask for a demonstration of MEDMARX v6.0.

## 2. JCAHO Updates

Questions related to the use of *abbreviations* (patient safety goal 2b) clarified: Until the end of 2004, the prohibited abbreviations requirement applies only to handwritten orders and other handwritten, patient-specific documentation. However, the long-term objective is to eliminate all ambiguous and other dangerous forms of notation from all forms of clinical documentation. Therefore, this requirement will continue as part of the 2005 Safety Goals and will include orders that are handwritten, printed, or electronic. [Click here to read more](#)

Interpreting the 2005 National Patient Safety Goals: JCAHO has posted a document entitled, *Rational and Interpretive Guidelines for the 2005 National Patient Safety Goals*, that provides insight into how surveyors will be interpreting the Goals next year. [Click here to read more.](#)

CMS and JCAHO issue technical manual for hospital quality measures: Each of the quality measures that are used by both the National Voluntary Hospital Reporting Initiative and for JCAHO accreditation are outlined and defined in a standardized manner in a new manual. Hospitals will use these common definitions to report on their quality beginning in January, 2005.

The manual is posted in two parts and may be accessed on the Internet at:

Part 1:

[http://www.cms.hhs.gov/quality/hospital/Specifications\\_Manual\\_PDF\\_pt1.zip](http://www.cms.hhs.gov/quality/hospital/Specifications_Manual_PDF_pt1.zip)

Part 2:

[http://www.cms.hhs.gov/quality/hospital/Specifications\\_Manual\\_PDF\\_pt2.zip](http://www.cms.hhs.gov/quality/hospital/Specifications_Manual_PDF_pt2.zip)

Two Remaining Workshops on Medication Errors: There are only two remaining, one-day workshops titled - "Transforming Medication Error Data into Meaningful Information". This interactive program will be offered on the following dates in **2004:**

- **November 1 in Oakbrook Terrace, IL (at JCAHO Headquarters)**
- **December 4 in Orlando, FL (Preceding the ASHP meeting)**

The program is designed for nurses, pharmacists, risk managers, medication/patient safety officers, physicians, and quality improvement staff and will teach participants methods to categorize error events by severity, determine thresholds to signal performance problems, and evaluate the impact of actions taken. 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=7032&site=5&return=5933>

### **3. USP Practitioners' Reporting News**

Tips for Using USP's Similar Names List: In April 2004, USP released its updated resource of [similar drug names](#).

In addition to meeting the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) [National Patient Safety Goals](#), this resource can also be used by healthcare settings other than hospitals to meet patient safety efforts. At first glance, this extensive list might appear daunting and one might question how best to use this resource in their practice. For this reason, USP's Center for the Advancement of Patient Safety (CAPS) has developed some tips to help practitioners use this resource efficiently. [Click here to view document](#).

Summary of Recent Cases: View a summary of cases received through the USP Medication Errors Reporting Program between February-July 2004. This summary include the following the following cases: Reference Book Error; Broselow® Tape Changes; Vials ≠ Syringes; Dangerous Concentration Expression. [Click here to view summary](#).

### **4. Survey Finds Some Physician Behavior Disruptive**

The *Los Angeles Times* recently reported on the findings of a survey published by the American College of Physician Executives. The vast majority of hospital managers and managers of clinics stated they regularly encounter situations of "disruptive physician behavior" including rudeness and condescension toward hospital staff. Only a small number of physicians were responsible for most of the incidents which were primarily committed against nurses or physician assistants. The study found that the disruptive behavior is more likely to occur in "stress-filled units" such as oncology wards and emergency departments. Researchers involved in the study suggest that repeat offenders should be disciplined or punished and have deductions in their pay. It was also suggested that hospitals and large clinics put in place policies that outline codes of conduct. Hospital administrators cite various problems in disciplining offending physicians including difficulty in penalizing contracted physicians and those who generate significant revenue for the organization.

### **5. AHRQ Finds Harmful Drugs Prescribed to Pregnant Women**

A new study funded by the Agency for Healthcare Research and Quality examined prescription drug use in pregnant women from 1996-2000. The study found that almost half of the women were potentially taking drugs that the FDA classifies as having no human evidence of safety for use during pregnancy, or which have been shown to cause harm to a developing fetus. The results appear in the August 2004 issue of the *American Journal of Obstetrics and Gynecology*. [Click here to read more.](#)

## 6. Consultant Relays Experience with Bedside Bar-Code Scanning

A pharmacist consultant for the Veterans Health Administration National Bar Code Medication Administration Joint Program shares her experience and provides advice on the successful implementation of bedside bar-code scanning. <http://www.ashp.org/news/ShowArticle.cfm?id=7674>

## 7. Proper Medication Upon discharge Improves Patient Outcomes

A study recently published in the *Annals of Internal Medicine* indicates that a relatively simple reminder to physicians using a standard hospital form is an inexpensive and potentially effective way to ensure that patients with heart disease are discharged on the appropriate drugs. Hospitals that implement "discharge medication programs" to improve physician and patient adherence to recommended standards of care see reduced readmissions and lower mortality rates. Among congestive heart failure patients in the program, researchers saw a 23% reduction in mortality and a 9% drop in readmissions. <http://www.annals.org/cgi/content/full/141/6/I-43>

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### USP Medication Error Reporting Programs:



**MEDMARX<sup>SM</sup>**—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.
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