



April 2004

# 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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#### Oncolytic Therapy Requires Special Vigilance

Errors involving oncology drug products are a concern because most oncolytic agents have a narrow therapeutic index and are toxic even at therapeutic dosages. An analysis conducted on reports submitted to USP's MEDMARX<sup>SM</sup> error reporting program revealed 3,871 errors involving oncology drug products reported during the 5-year period from September 1, 1998 to August 31, 2003. Fortunately, the majority (88%) of the actual errors (Categories B-D) did not cause harm, while nearly 3% did result in some level of patient harm ranging from temporary harm to death. (Table 1).

Table 1.

<b>Error</b>		
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<b>Category *</b>	<b>n</b>	<b>Percent (%)</b>
<b>A</b>	<b>353</b>	<b>9</b>
<b>B</b>	<b>1,700</b>	<b>44</b>
<b>C</b>	<b>1,488</b>	<b>38</b>
<b>D</b>	<b>226</b>	<b>6</b>
<b>E</b>	<b>75</b>	<b>2</b>
<b>F</b>	<b>25</b>	<b>0.60</b>
<b>G</b>	<b>3</b>	<b>0.08</b>
<b>I</b>	<b>1</b>	<b>0.03</b>
<b>Total records</b>	<b>3,871</b>	

\*See [www.nccmerp.org](http://www.nccmerp.org) for complete A-I Category definitions.

One or more types of error were selected for each of the reported errors involving oncology drug products (Table 2). Improper dose/quantity, prescribing error, omission error, wrong time, and unauthorized drug were the most common types of error reported.

Table 2.<sup>a</sup>

<b>Type of Error</b>	<b># Records Selecting Type</b>	<b>Percent (%)</b>
Improper dose/quantity	<b>884</b>	<b>25</b>
Prescribing error	<b>721</b>	<b>20.4</b>
Omission error	<b>656</b>	<b>18.5</b>
Wrong time	<b>441</b>	<b>12.5</b>
Unauthorized drug	<b>264</b>	<b>7.5</b>
Wrong drug preparation	<b>201</b>	<b>5.7</b>
Extra dose	<b>186</b>	<b>5.3</b>
Wrong administration technique	<b>163</b>	<b>4.6</b>
Wrong patient	<b>160</b>	<b>4.5</b>
Wrong route	<b>70</b>	<b>1.9</b>
Wrong dosage form	<b>41</b>	<b>1.2</b>
Expired product	<b>7</b>	<b>0.2</b>
Deteriorated product	<b>5</b>	<b>0.14</b>
(a) Based on 3,534 records that selected at least one Type of Error		

Performance deficit (43%) was cited as the most common cause of errors involving oncology products followed by a failure to follow procedures or protocols (20%) and transcription that was inaccurate or omitted (12%).

A variety of antineoplastic agents, hormonal agents (e.g., the progestin medroxyprogesterone), and adjunctive agents (e.g., type 3 serotonin receptor antagonists, which are used as antiemetic agents, and leucovorin calcium, which is used to prevent and treat toxicity associated with methotrexate and other folic acid antagonists) were identified in errors reported to MEDMARX. (Table 3).

Table 3.

<b>Generic Name</b>	<b># Records selecting product</b>	<b>Percent (%)</b>
<b>Ondansetron</b>	<b>1,256</b>	<b>30.4</b>
<b>Methotrexate</b>	<b>416</b>	<b>10.1</b>
<b>Dolasetron</b>	<b>285</b>	<b>6.9</b>
<b>Fluorouracil</b>	<b>220</b>	<b>5.3</b>

Cyclophosphamide	198	4.8
Cytarabine	183	4.4
Leucovorin	176	4.3
Doxorubicin	165	4.0
Etoposide	154	3.7
Paclitaxel	148	3.6
Carboplatin	123	3.0
Cisplatin	119	2.9
Vincristine	113	2.7
Azathioprine	95	2.3
Docetaxel	72	1.7
Ifosfamide	72	1.7
Gemcitabine	59	1.4
Bleomycin	29	0.7
Mitomycin	29	0.7
Mitoxantrone	28	0.7
Vinorelbine	28	0.7
Idarubicin	27	0.7
Dacarbazine	20	0.5
Daunorubicin	20	0.5
Topotecan	18	0.4
Fludarabine	17	0.4
Vinblastine	16	0.4
Irinotecan	15	0.4
Doxorubicin, Liposomal	14	0.3
Dactinomycin	3	0.1
Epirubicin	3	0.1
Lomustine	3	0.1
Teniposide	2	0.0
Total selections =	4,126	

### Selected Case Examples

Case #1: Paclitaxel 375 mg/m<sup>2</sup> IV over 3 hours was ordered to treat metastatic breast cancer. A pharmacist with little experience in preparing chemotherapy and unfamiliar with normal dosing regimens prepared the order without question. The patient's nurse administered the product without questioning the physician or pharmacist regarding the dose. The patient became unresponsive about 2-1/2 hours after the infusion was started. The correct dose for this and other patients with metastatic breast cancer is 175 mg/m<sup>2</sup> (i.e., the patient received a more than twofold overdose). The patient developed neutropenia, fever, and sepsis, which were attributed to the error (the frequency and severity of hematologic toxicity from paclitaxel increase when the dosage exceeds 190 mg/m<sup>2</sup>).

Case #2: A patient was ordered Ondansetron (Zofran®) and Dexamethasone for prevention of nausea and vomiting associated with their chemotherapy regimen. A review of the patient's medication administration record by nursing staff the next day showed that these two medications had not been administered. Further investigation revealed that the night shift staff was unaware that dexamethaxone was available from the unit's automated dispensing cabinet and pharmacy-prepared IV piggybacks for Ondansetron were stored in the unit's refrigerator. As a result, the patient suffered with nausea and vomiting throughout the night.

Case #3: A daily IV infusion of cytarabine 200mg in 1 liter of sodium chloride 0.9% to be given for 7 days was prescribed for a patient with acute myeloid leukemia. After three

days of treatment, the patient was transferred to a different patient care unit and the order was rewritten exactly as it was written initially for 7 days of therapy. Several days later, a pharmacist noticed that 10 doses had been billed despite the 7-day duration of therapy ordered. The pharmacist contacted the patient's nurse who determined that the dose currently infusing was indeed the tenth dose (i.e., it was the seventh dose given after the transfer, and three doses had been given prior to the transfer). The nurse immediately stopped the infusion and notified the attending physician. The patient experienced a worsening of sepsis, and the error may have contributed to this outcome.

### **Implications and Recommendations**

There is a high frequency of improper dose/quantity errors involving oncology drug products and, given that many antineoplastic agents have a narrow therapeutic index and are toxic even at recommended dosages, serious patient harm can occur.

- Include oncolytics among the list of high-risk/high-alert medications and, per the Joint Commission standards, develop processes (i.e., policies and procedures) for selecting, procuring, storing, ordering, transcribing, preparing, dispensing, administering, and monitoring these agents.

Many errors involving oncology drug products were reported to be caused by performance deficit and failure to follow procedures and protocols .

- Examine and enhance efforts to ensure the competency of health care professionals involved with the prescribing, dispensing, and administration of oncology medications. Require all involved staff to undertake specific training that demonstrates their competence with verifying and processing orders for oncolytic drugs. Adequate and concerted instruction on the proper use of infusion devices should be part of this training for those personnel involved in the administration of these products.
- Examine and revise (if necessary) the procedures and protocols used for antineoplastic treatments.
- Ensure that staff are aware of existing policies and procedures and can demonstrate their familiarity with their content.

Many of the reported errors involving oncology drug products were attributed to misinterpretation of handwritten orders.

- Use standardized preprinted order forms for commonly used chemotherapy regimens or computerized prescriber order entry (CPOE) systems with built-in approved protocols and alerts. Do not permit the use of verbal orders for oncolytic drugs.
- Do not use abbreviations, acronyms, or "nicknames" when prescribing treatment regimens.
- Establish a list of required elements, including patient-specific data, that each oncology medication order must contain.

Numerous errors with oncology products were attributed to similar labels and/or packaging and extreme caution is needed in handling and preparing these agents.

- Review the oncolytic products on formulary and assess the potential for errors due to look-alike product labeling and packaging. Minimize look-alike containers and limit the availability of different vial sizes for parenteral medications.

- Standardize methods for reconstituting, diluting, admixing, and labeling these products.
- Establish a double-check system to verify the accuracy of the preparation methods.



### 1) JCAHO Updates

2005 National Patient Safety Goals Under Review: The proposed 2005 Goals have been posted on JCAHO's web site and are open for comments until April 30, 2004. Some previous goals and requirements have been incorporated into JCAHO standards (e.g., wrong-site) while other goals have been clarified or had new requirements added (e.g. requirement for the use of bar coding to identify patients for medication or other treatments by 2007).

[http://www.jcaho.org/accredited+organizations/05\\_npsg\\_fr.htm](http://www.jcaho.org/accredited+organizations/05_npsg_fr.htm).

Helpful tips regarding compliance with prohibited abbreviations: Suggestions on how to comply with the National Patient Safety Goal related to dangerous abbreviations are now available on the JCAHO website.

<http://www.jcaho.org/accredited+organizations/patient+safety/04+npsg/tips.htm>

### 2) USP's *Practitioners' Reporting News and Quality Review*

Cases Submitted to USP's Medication Errors Reporting (MER) Program: View cases involving Fluzone's® misleading labeling; FiberCon's® poor packaging design; new reconstitution volumes for Augmentin® suspension; and misunderstood abbreviations on morphine sulfate's packaged dispensing spoon.

[Click here to read more.](#)

USP Quality Review No. 79: Use Caution—Avoid Confusion: USP's Center for the Advancement of Patient Safety has **updated the similar drug names resource**. Quality Review (QR) No. 79 will be posted at

<http://www.usp.org/patientSafety/briefsArticlesReports/qualityReview/archive.html>

Practitioners on the QR mailing list can expect to receive the newsletter over the next few weeks. Wall posters and pocket references of this resource will be available in June 2004 for purchase at <http://store.usp.org>.

### 3) New Report Cites Benefits of Electronic Prescribing

A report released today by the eHealth Initiative reviews e-prescribing techniques and is designed to help health care providers understand what to expect from system vendors and provides a basis for comparison in purchasing decisions. Although there has been a significant increase in electronic prescribing over the past several years, only 5% to 8% of physicians are currently using some form of an e-prescribing system. The eHealth Initiative is a council of health care leaders working to improve the quality, safety and efficiency of health care through information and information technology.

<http://ccbh.ehealthinitiative.org/highlights.aspx?Document=270>

#### **4) Pharmaceutical Manufacturers Explore Measures to Fight Counterfeits**

Drug manufacturers are responding to FDA recommendations and exploring how to use technology to combat the growing number of counterfeits entering the U.S. market. [Click here to read more.](#)

#### **5) Presidential Committee Drafts Health Care IT Recommendations**

The President's Information Technology Advisory Committee recently issued draft recommendations for the use of information technology in the delivery of health care services. The Committee recommended accelerating the adoption of information technology in health care in order to reduce medical errors and unproductive health care expenditures. The Committee called for increased federal support of studies that estimate the major costs and benefits of electronic health records, computer-assisted decision support, electronic order entry, and federal support for developing a single set of data standards for the most common forms of clinical data. A final report is expected in June.

[http://www.itrd.gov/pitac/meetings/2004/20040413/20040413\\_draft\\_hit.pdf](http://www.itrd.gov/pitac/meetings/2004/20040413/20040413_draft_hit.pdf).

#### **6) Study Examines CPOE Systems Strengths and Weaknesses**

According to a study in the *Archives of Internal Medicine*, computerized prescriber order entry systems (CPOE) need to have a substantive, clinical decision support reference built-in if they are to prevent the most harmful errors.

The study looked at over 17,800 inpatient and emergency department medication orders and found prescribing errors in 6.2% of all orders— 30.8% of which were rated as "clinically significant," meaning they either were likely to have caused patient harm or were likely to have required patient monitoring. The study concludes that CPOE in combination with clinical pharmacist involvement and an advanced clinical decision support system is vital for improving medication safety.

#### **7) New IOM Report Examines Health Literacy**

*Health Literacy: A Prescription to End Confusion* is the title of a new Institute of Medicine (IOM) report that claims that nearly half of all American adults have difficulty understanding and using health information. The report recommends that health care systems should develop programs that will reduce the negative effects of limited health literacy. <http://www.iom.edu/report.asp?id=19723>

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USP operates two complementary error reporting programs; the Medication Errors Reporting Program presented in cooperation with the Institute for Safe Medication Practices and MEDMARX. MEDMARX™ is an Internet-accessible, anonymous medication error reporting program and quality improvement tool used to track and trend medication errors.

For more information, visit [www.usp.org](http://www.usp.org)

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