



U.S. PHARMACOPEIA
The Standard of Quality™

USP Home | MER | MEDMARX® Demo | NCC MERP

November 2007

USP Patient Safety CAPSLink™

PROVIDED BY THE USP CENTER FOR THE ADVANCEMENT OF PATIENT SAFETY

Copyright © 2007 The United States Pharmacopeial Convention, Inc.

In this Issue

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.

Editor: John P. Santell, MS, RPh, FASHP
Contributor: W. Michael Heath, MBA, RPh

In this Issue:

Section I: Medication Error Analysis

Preventable Dangers Associated with Fentanyl Patches

Section II: In the News...

1. USP- ISMP Workshop: Using Data Effectively to Manage the Risks to Medication Safety
2. FDA Moves Forward with CDER Transformation
3. Medication Errors Make Up 23% of all Reported Events
4. Walgreen's Expands "In Store" Clinics
5. Serious Adverse Event Consortium Formed
6. Medication Reconciliation Toolkit Resource
7. Manufacturers Voluntarily Withdraw OTC Infant Medications
8. ISMP Issues Recommendations to Decrease Unlabeled Syringe Risks
9. Medication Therapy Management Codes for Pharmacists Approved



Preventable Dangers Associated with Fentanyl Patches

Continued reports of medication errors (some including patient deaths) related to the prescribing, dispensing and administering of fentanyl transdermal patches is deeply troubling. During the past several years, the FDA, along with several manufacturers and numerous patient safety agencies, have issued warnings about the inappropriate use of this product. Despite these warnings, reports that fentanyl patches are still prescribed for opiate-naïve patients in acute pain or inappropriately administered in combination with oral or intravenous opiates suggests that this is a persistent problem.¹ These errors have occurred in hospitals, physician offices, and in ambulatory surgery centers. Unfortunately, pharmacists often dispense fentanyl patches in both outpatient and inpatient (hospital) settings without complete information about the patient's diagnosis or condition, thereby limiting their ability to question the prescriber's order.

Additionally, nurses have applied the patches to patients without realizing that the product was inappropriately prescribed and dispensed.

In July of 2005, the FDA issued a Public Health Advisory to alert healthcare providers that deaths and overdoses had occurred in patients using both the brand name product Duragesic[®] and the generic product.² Despite these warnings, label changes, and the publication of prescribing problems, many healthcare practitioners still remain unaware of the dangers and proper prescribing guidelines with this potent narcotic product.¹ One example of a fatality involving a fentanyl patch error highlighted how an elderly, post-operative patient was discharged with both the patch and a prescription for oxycodone.³ Review of the case documented that the patient was opiate naïve with no chronic pain and was also being treated for sleep apnea and bronchopneumonia at the time of his surgery.

During the period from January 1, 2001 through December 31, 2006, a total of 2,215 medication errors related to fentanyl transdermal patches were reported to USP's MEDMARX[®] program. Approximately 27% of the errors were intercepted before reaching the patient (Category B, Table 1) which is lower than the historical MEDMARX average of 39.4%. Conversely, a larger percentage (61.2%) of the errors did reach the patient (Categories C and D) and a larger percentage (5.3%) resulted in harm or death (Categories E-I). This percentage of harm is more than 3 times higher than the percentage of harm seen for all errors reported to MEDMARX from 2001-2005. This suggests that errors involving fentanyl patches are more likely to result in patient harm compared to medication errors in general and this drug, therefore, should be considered a high-alert drug.

Table 1. Severity of Fentanyl Patch Errors^a

Error Category	n ^b	% ^c
Potential errors		
A	146	6.6
Intercepted errors		
B	596	26.9
Non-harmful errors		
C	1,186	53.5

D	170	7.7
Harmful or fatal errors		
E	101	4.6
F	11	<1
H	3	<1
I	2	<1
Total	2,215	

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>

b. Based on 2,215 medication error records reported to MEDMARX during the period 01/1/01-12/31/06.

c. Percentages may not total 100% due to rounding.

Types of Error

Omission error was the most frequently reported type of error (33.4%) indicating that one-third of the patients did not receive their intended fentanyl patch. The second most frequently reported type was *Improper dose/quantity* (26.3%) followed by *Prescribing error* (13.1%) (Table 2). This suggests that administration and prescribing activities involving fentanyl patches are problematic and present opportunities for focused system improvement initiatives.

Table 2. Types of Error Associated with Fentanyl Patches^a

Types of Error	n	% ^b
Omission error	718	33.4
Improper dose/quantity	565	26.3
Prescribing error	281	13.1
Wrong time	266	12.4
Extra dose	179	8.3
Unauthorized /wrong drug	149	6.9
Wrong administration technique	65	3.0
Wrong patient	55	2.6
Wrong dosage form	28	1.3
Drug prepared incorrectly	19	<1
Expired product	12	<1
Deteriorated product	9	<1
Mislabeled	9	<1
Wrong route	5	<1

a. Based on 2,152 records with 2,360 documented selections during the period 01/1/01-12/31/06

b. Percentages may not total 100% due to rounding.

Error Causes

Performance deficit (46.1%) was the most frequently reported cause of all fentanyl patch errors (Table 3). When combined with errors caused by procedures or protocols not followed (26.8%) this accounts for almost 75% of all errors associated with fentanyl patches, which can be attributed to causes related

to human factors issues. These documented causes should serve as a reminder to facilities to examine policies, procedures, protocols, and staffing patterns. Other frequently reported causes of error related to fentanyl patches included knowledge deficit, ineffective communications, omitted or inaccurate order transcription, computer entry issues and inadequate patient monitoring.

Table 3. Common Causes of Errors Associated with Fentanyl Patches^a

Causes	n	%^b
Performance deficit	978	46.1
Procedure / protocol not followed	568	26.8
Documentation	263	12.4
Knowledge deficit	262	12.4
Communication	253	11.9
Transcription inaccurate/omitted	235	11.1
Computer entry	224	10.6
Monitoring inadequate/lacking	131	6.2
System safeguard(s)	98	4.6
Written order	88	4.1
Drug distribution system	65	3.1
Dispensing device involved	58	2.7
Computerized prescriber order entry	54	2.5
Workflow disruption	43	2.0
Computer software	38	1.8
Handwriting illegible /unclear	37	1.7
Dosage form confusion	31	1.5
MAR variance	31	1.5
Incorrect medication activation	29	1.4
Packaging /container design	23	1.1

a. Based on 2,121 records with 3,765 documented selections during the period 01/1/01-12/31/06

b. Percentages may not total 100% due to rounding.

Case Examples^a

1. An order was written for a fentanyl transdermal patch for a post-operative patient to control pain. The provider intended to order the 25 mcg/hr fentanyl patch, however inadvertently selected the first fentanyl drug product from the hospital's computerized medication pick-list, which was the 75 mcg/hr patch. The patient was then discharged and subsequently received the 75 mcg/hr patch and was found unresponsive at home the following day. The patient died as a result of the fentanyl overdose. Upon further review and analysis of the error, it was determined that the facility's computer system did not display the drug doses in an easy-to-read, ascending manner. The computer display was corrected with the additional implementation of a policy requiring the review for all new fentanyl orders by a pharmacist with specific instructions not to process any fentanyl orders for acute or post-op pain management or when the patient is determined to be opioid naive.

2. A patient was seen in the emergency department for intractable shoulder pain, and was given one fentanyl transdermal patch 75 mcg/hr with instructions to return the next day for follow-up and pain management instructions. The patient died at home, with the cause of death determined to be due to ventricular arrhythmia secondary to multiple drug intoxication. A root-cause analysis of the error determined that this fatal medication error occurred due to the inappropriate prescribing and dispensing of a fentanyl transdermal patch for the management of acute pain. The facility subsequently developed and implemented intensive education and training programs for all emergency department providers that focused on the appropriate indications and use of fentanyl transdermal patches.

3. An order was written for a 67-year old patient to change the fentanyl patch from 125 mcg/hr to 50 mcg/hr at noon. At 4:30 p.m. of the same day, a nurse documented the application of a 50 mcg/hr patch on the medication administration record. The next day, another nurse found the patient with one 50 mcg, one 100 mcg, and one 25 mcg patch all applied and indicating that the 125 mcg patch was not to be removed when the 50 mcg patch was applied. The patient was found to be comatose and transferred to the ICU requiring intubation, increased monitoring, and observation. The patient eventually recovered and was discharged. Review of this medication error determined that the nurse who applied the 50 mcg patch, was either unable to locate or did not try to locate and remove the 100 mcg + 25 mcg (i.e., 125 mcg patch) resulting in a potentially life threatening drug overdose, resulting in prolonged hospitalization.

a. Case reports reflect actual error descriptions reported to MEDMARX[®] but may have been modified for clarity.

Recommendations to Prevent Fentanyl Patch Medication Errors:

- Create specific prescribing and dispensing guidelines for fentanyl transdermal patches that are aligned with the product labeling and referenced during computer entry of the medication. Fentanyl patches should only be used by patients who are: (1) tolerant to opiates in the treatment of chronic pain and (2) not well controlled with shorter-acting analgesics.¹
- Develop policies that require verification of the indication. Pharmacists should be involved in the review of all orders for fentanyl patches prior to dispensing and administration. In situations when a pharmacist is not available to review the order prior to administration (e.g. in an emergency department), there should be a double-check by another licensed healthcare provider, who is knowledgeable on the appropriate prescribing of fentanyl patches.
- Task the Pharmacy & Therapeutics Committee or other appropriate committee with establishing dosing limits and include these limits in prescribing protocols, pre-printed order sets, and computer entry systems to ensure that fentanyl patches are always prescribed at the lowest dose necessary to effectively control pain.¹
- Assess the concomitant use of opiates. When the clinical appropriateness of

the patient's dose is evaluated, prescribers must take into consideration all other opiates prescribed for the patient with the goal of preventing an overdose.¹

- Restrict prescribing privileges for fentanyl patches to providers who are knowledgeable in the continuous administration of potent opioids, in the management of patients receiving potent opioids for treatment of pain, and in the detection and management of hypoventilation including the use of opioid antagonists.^{1,4}
- Only prescribe fentanyl patches for patients who are known to be tolerant to opioid therapy of comparable potency. Use in non-opioid tolerant patients may lead to fatal respiratory depression. Overestimating the fentanyl patch dose when converting patients from another opioid medication can result in fatal overdose with the first dose. The elimination half-life of the patch is 17 hours. Therefore, patients who have experienced serious adverse events, including overdose, will require monitoring for at least 24 hours after the patch is removed since serum fentanyl concentrations decline gradually and reach an approximate 50% reduction 17 hours after system removal.⁴
- Signs and treatments of overdose scenarios should be communicated and understood. All healthcare providers who prescribe fentanyl patches, and nurses and patients who apply the patches, should be aware of the signs of fentanyl overdoses, including respiratory distress; shallow breathing; tiredness, extreme sleepiness or sedation; inability to think, talk or walk normally; and feeling faint, dizzy or confused. If these symptoms occur, patients or their caregivers should fully understand the importance of immediately seeking medical attention.¹
- Aggressively monitor patients for hypoventilation, which may occur at any time during the use of fentanyl patches especially during the initial 24-72 hours. Because hypoventilation may occur following initiation of therapy and increases in dosage, patients with hypoventilation should be carefully observed for degree of sedation and their respiratory rate monitored until respiration has stabilized. The use of concomitant CNS active drugs requires special patient care and observation. Respiratory depression is the chief hazard of opioid agonists and is more likely to occur in elderly or debilitated patients, usually following large initial doses in non-tolerant patients, or when opioids are given in conjunction with other drugs that depress respiration. Respiratory depression from opioids is manifested by a reduced urge to breathe and a decreased rate of respiration, often associated with the “sighing” pattern of breathing (deep breaths separated by abnormally long pauses). Carbon dioxide retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids and should also be closely monitored.⁴
- Develop a mechanism or process to “flag” or mark where patches are placed on a patient (e.g., use a human body pictogram) to alert practitioners and

caregivers where to look for removing old patches (possibly multiple patches) which could be applied separately at several body surface area locations.⁵

- Mandate patient, family member and/or caregiver education. It is imperative that patients who are using a fentanyl patch (as well as their caregivers) are educated and assessed on the safe use of this product.¹

References:

1. Institute of Safe Medication Practices (ISMP) Acute Care Newsletter June 28, 2007, *Ongoing, preventable fatal events with fentanyl transdermal patches are alarming*. Accessed via internet from: <http://www.ismp.org>, November 26, 2007
2. FDA Public Health Advisory. Safety Warnings Regarding Use of Fentanyl Transdermal (Skin) Patches, July 15, 2005. Accessed via internet from: <http://www.fda.gov/cder/drug/advisory/fentanyl.htm>, November 26, 2007.
3. Institute for Safe Medication Practices (ISMP) Acute Care Newsletter – May 31, 2007, *Staff unaware of fentanyl patch starting doses*.
4. Janssen Pharmaceuticals Dear Healthcare Provider Important Drug Warning. Prescribing Information on Duragesic[®]. June 2005, Accessed via internet [Click here](#) on November 26, 2007.
5. Duragesic[®] (Fentanyl Transdermal System) product label, full prescribing information from Janssen Pharmaceuticals, available via internet [Click here](#). Accessed November 21, 2007.



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

This is the final opportunity to attend a 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 (Must be processed 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

Visit <http://www.intellor.com/usp/ismp>

ONE REMAINING WORKSHOP DATE

December 1, 2007

Before the ASHP MidYear Clinical Meeting

8:00 a.m. – 4:30 p.m.

Imperial Palace Hotel

Las Vegas, NV

2. FDA Moves Forward with CDER Transformation

The FDA recently announced the award of a two-year, \$1.5 million contract to the Center for Professional Development (CPD) to assist with the transformation of FDA's Center for Drug Evaluation and Research (CDER), with a particular focus on steps to improve workplace leadership, empower staff, and establish more effective business practices. The award is part of the FDA's ongoing response to a report issued in 2006 by the Institute of Medicine (IOM). The contract focuses on development of practical strategies that will strengthen CDER's organizational effectiveness and primary mission of advancing and protecting the public health. FDA Press Release on this subject available at [click here](#).

3. Medication Errors Make Up 23% of all Reported Events

In a recent Advisory, the Pennsylvania Patient Safety Authority documented that medication errors continue to rank high among reported events to the Pennsylvania Patient Safety Reporting System at 23% of all reported medical events. The primary reasons medication errors are so often reported relate to confusing medication labels and directions, and the use of look-alike, sound-alike drugs. Of the 23% of reported events, only 1% actually harmed a patient. Additional information on this topic available at: [Click here](#).

4. Walgreen's Expands "In Store" Clinics

Walgreen's will expand its drug store based clinics to be staffed by Nurse Practitioners and Physicians Assistants. The community based retail drugstore chain expects to triple the number of U.S. cities it serves by the end of the year. Currently, Walgreen has 63 clinics in four cities and is on pace to operate 400 clinics inside Walgreen's stores by the end of next year. The clinics, which generally are staffed by nurse-practitioners or physician assistants, tout their ability to offer same-day appointments plus weekend and evening hours for routine ailments such as sore throats and ear infections. Visits to the clinics are usually less expensive than trips to a doctor's office. Additional information available at: <http://www.walgreens.com/takecare/default.jsp>

5. Serious Adverse Event Consortium Formed

The International Serious Adverse Events Consortium (SAEC) has announced

plans to launch two initial research programs designed to identify genetic markers that may help predict which individuals are at risk for serious drug-related adverse events (SAEs). The two studies will address drug-related liver toxicity and a rare but serious drug-related skin condition called Stevens - Johnson syndrome (SJS). The SAEC is a nonprofit corporation comprised of leading pharmaceutical companies, and academic institutions with scientific and strategic input from the U.S. Food and Drug Administration (FDA). For additional information, [click here](#).

6. Medication Reconciliation Toolkit Resource

Consumers Advancing Patient Safety (CAPS) has developed and released two toolkits, [How to Develop a Community-Based Partnership Council](#) and [How to Create an Accurate Medication List in the Outpatient Setting Through a Patient-Centered Approach](#). The first toolkit outlines the process of developing the community based partnership council, while the second toolkit is geared toward improving the accuracy of a patient/consumer's medication list in the outpatient care setting. The council's work was targeted toward persons 55 years and older, who are among the most vulnerable to medication safety issues due to chronic medical conditions, multiple medications and multiple healthcare providers. CAPS Press Release available at: [Click here](#).

7. Manufacturers Voluntarily Withdraw OTC Infant Medications

On October 11, 2007 the Consumer Healthcare Products Association (CHPA) announced the voluntary withdrawal of oral infant medications from store shelves. The voluntary withdrawal of OTC oral infant cough and cold medicines was initiated by the makers of those medications out of an abundance of caution. This is not a mandatory recall or a safety issue. The voluntary withdrawal only affects oral infant cough and cold medications. It does not affect any other children's medicines. Because children under the age two are the most vulnerable to the harm caused by the misuse of oral, over-the-counter cough and cold medicines, the makers of these medicines have recommended strengthening their labels to state "Do Not Use" for children under two. This recommendation, as well as others, was discussed before a FDA advisory committee on October 18 and 19, 2007. Additional information may be obtained from: <http://www.otcsafety.org/>

8. ISMP Issues Recommendations to Decrease Unlabeled Syringe Risks

In its November 15, 2007 Newsletter, ISMP cited research that documents that the incidence of errors with injectable medications is higher than with other forms of medications. Unlabeled syringes are a significant risk associated with preparation of injectable products in all clinical areas. Although Joint Commission Standard MM.4.30 requires the labeling of all medications, it has been documented that the problem of unlabeled syringes continues to be observed in every patient care area. ISMP has issued recommendations to decrease the risk of patient harm related to unlabeled syringes: [Click here](#).

9. Medication Therapy Management Codes for Pharmacists Approved

The predominantly physician based *Current Procedural Terminology (CPT)* editorial panel has approved the following reimbursement codes for pharmacists who provide medication therapy management services beginning January 1,

2008. The three codes include the following:

99605—Initial 15 minutes of MTM services, including assessment and intervention, if appropriate, for a new patient (replaces 0115T, a temporary code),

99606—Initial 15 minutes of MTM services, including assessment and intervention, if appropriate, for an established patient (replaces 0116T), and

99607—Each additional 15 minutes; used in addition to 99605 or 99606 (replaces 0117T).

These permanent codes are only applicable to MTM services that a pharmacist provides during a face-to-face encounter with a patient. For additional information, see: [Click here](#).

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.

-
- Refer your colleagues to [subscribe](#) to this newsletter.
 - If you no longer desire or consent to receive this newsletter, you can [unsubscribe now](#).

USP does not sell or distribute email addresses. Questions about USP CAPSLink™ may be sent to caps@usp.org.

Copyright 2007, U.S. Pharmacopeia. All rights reserved

12601 • Twinbrook Parkway • Rockville • Maryland • 20852

