

ISMP Medication SafetyAlert!®

July 12, 2007 ■ Volume 12 Issue 14

SafetyBriefs

Warning! Exactacain straw must fit spray release button.

Some facilities are using EXACTACAIN Spray (benzocaine 14%, butamben 2%, tetracaine 2%) to numb patients' throats before endoscopy procedures. The metered-dose product is packaged with disposable applicator straws for each patient to help control the dose of spray, and it has a lower benzocaine dose than some competitors—factors that may reduce the risk of methemoglobinemia. However, there is a temporary safety risk with the product. A hospital pharmacist recently received a call from a nurse in the endoscopy suite, complaining that the tiny applicator straws were “popping off into patients' throats” during release of the spray. The nurse stated that “the old red straws don't do this, but the new clear ones do.” As a temporary fix, one of the pharmacists found some old red straws and gave them to her. He then called the manufacturer, Healthpoint, and learned that, about a year ago, it changed the spray release button (the white button on the container that you push down), which necessitated resizing the applicator straws that attach to it. Since the company ships the straws and the bottles as a kit, they assumed that practitioners would use the correct straws. But with boxes of both the old red and new clear straws available, nurses were sometimes trying to use an old straw with a new container, and a new straw with an old container.



Figure 1. Red straw should be used with older Exactacain containers. Clear straws will pop out if used with the older containers.

continued on page 2 ►

Requirement #1—Patch should stick to the patient!

PROBLEM: ISMP recently became aware of product quality concerns that may lead to errors with DAYTRANA (methylphenidate transdermal system) patches, the only transdermal system approved for the treatment of attention deficit hyperactivity disorder (ADHD). These patches are available in 10, 15, 20, and 30 mg strengths. Parents of children using Daytrana patches have posted complaints on several online message boards about the adhesive sticking to the protective liner, preventing the patch from sticking to the skin.¹⁻³ The extent of this problem is unknown, but the frequency of complaints on these online forums suggests that the problem is significant. A few examples follow:

“My son just started using the patch and I'm getting very frustrated because, every morning when it is time to put the patch on, I'm having problems with the adhesive sticking to the part I throw away... if I still put the patch on him, does he still receive the medicine?”

“Yesterday, I woke up early to apply the 15 mg patch [to my child] and I went through 4 patches because the backing of the patches would not come off at all, and when you finally pulled as hard as you could, the backing would come off but with all the med attached to it.”

To circumvent this problem, some parents have been refrigerating or partially freezing a patch before attempting to remove the backing. The manufacturer labeling states that the product should be stored at a temperature between 59 and 86 degrees.⁴ Colder temperatures may affect release of the drug and alter the onset of action. In fact, parents have reported that it seems to take longer for the patch to take effect when utilizing this work-around.

Parents have also been using other adhesives/overlays (e.g., tape or band aids) to hold the patch on the skin. Two problems

exist with this practice. First, the adhesive contains active drug, so taping a faulty patch to the skin that has all or part of its adhesive missing may reduce the amount of drug delivered to the child. Also, any loose adhesive may stick to the patient when the patch is removed and continue to release the drug beyond the intended treatment window. Next, if an occlusive overlay is used to help the patch adhere to the skin, the temperature at the site of application may be raised, thus increasing the absorption of methylphenidate. ISMP has previously alerted readers to serious harm that has occurred from over-delivery of transdermal medication due to raised body and skin temperatures.⁵ The risk of increased drug absorption with Daytrana could be serious because each patch contains more drug than the amount it delivers. For example, a patch intended to deliver 30 mg over 9 hours actually contains 82.5 mg of drug.

In addition to problems with the adhesive, some parents have been cutting Daytrana patches to titrate their child's dose of methylphenidate. These patches should never be cut. The DOT Matrix technology of Daytrana creates a suspension of tiny concentrated drug cells evenly dispersed through the adhesive layer. Cutting a patch can open the drug cells along the cut edges, interfering with the patch membrane and disrupting the delivery rate of the drug. According to postings on online forums, it seems some healthcare practitioners have contributed to this problem by erroneously advising patients that it is safe to cut the patches, as in the examples that follow:

“Our doc said that the patch is okay to cut...He explained that from a sheet of plastic the various [patch] sizes are punched out [by the manufacturer] so that the amount of medication is the same on all areas of the plastic.”

“My doc had this cool deal...where patients could get 40 patches free. The only thing is they are 30 mgs. He suggested I cut the patch to start

continued on page 2 ►

SafetyBriefs continued

The old straws do not fit tightly with the new container, and vice versa, thus, the difficulty with straws popping into patient's throats. Since spraying a patient's oropharyngeal mucosa with Exactacain takes away the gag reflex, this is a potentially dangerous situation. An anesthesia group at a different location also reported the same problem to us. If you use Exactacain, only the straws that come with the bottle should be used. Discard left-over straws when starting a new bottle. Be sure to press the straws firmly into the hole on the spray applicator. The usual dose is 3 sprays; more than 6 should never be administered. That's unrelated to this issue but a good refresher in light of past problems with methemoglobinemia (Moore TJ, Walsh CS, Cohen MR. Reported adverse event cases of methemoglobinemia associated with benzocaine products. *Arch Intern Med* 2004;164:1192-1196; also visit www.ismp.org/newsletters/acutecare/articles/20021003.asp for information).

**New ceftriaxone warning.** This

Monday, FDA and Roche published new information about a potential problem when **ROCEPHIN** (ceftriaxone) is used concomitantly with calcium or calcium containing solutions or products. Cases of fatal reactions with calcium-ceftriaxone precipitates in the lungs and kidneys in both term and preterm neonates were reported. Hyperbilirubinemic neonates, especially preterm babies, should not be treated with Rocephin. The drug must not be mixed or administered simultaneously with calcium-containing solutions or products (e.g., Ringers), even via different infusion lines, and calcium-containing solutions or products must not be administered within 48-hours of the last administration of ceftriaxone. For information, visit: www.fda.gov/medwatch/safety/2007/rocephin_DHCP_june2007.pdf.

Special Announcements...

Joint Commission Update. It's not too late to register for our teleconference, **Joint Commission Update: 2007-2008 Requirements Related to Medication Use**, to be held on **July 18** and repeated on **August 2**. Visit www.ismp.org/educational/teleconferences.asp for details about the 2008 safety goals and standards that will be discussed.

Employment opportunity. ISMP is seeking a full-time RN with clinical and managerial experience to support its consulting group. For details, visit: www.ismp.org/jobline/job11.asp.

Patch should stick continued

low, then increase as needed. I first cut it into thirds and just recently started cutting them in half for 15 mgs."

One final potential safety issue has come to light with Daytrana patches. To reduce skin irritation at the site of patch application, some parents have been applying corticosteroids such as **FLONASE** (fluticasone propionate) and **NASONEX** (mometasone furoate) to the application site *before* applying the patch. No studies evaluating the safety of this practice exist; thus, it is unknown if this increases or decreases the absorption of the drug. The use of corticosteroids in this manner may also mask hypersensitivity to methylphenidate or another component of the patch.

SAFE PRACTICE RECOMMENDATIONS:

ISMP has contacted FDA and the manufacturer of Daytrana, Shire Pharmaceuticals, about the adhesive problem. Shire representatives acknowledged the problem and stated that the company is developing a "thicker" liner that will allow easier removal from the patch adhesive. An expected release date is unknown. Until production problems have been corrected, warn parents about the possibility of the adhesive remaining on the protective liner, and suggest they call Shire's toll-free line (800-828-2088) to report problems. The company recommends avoiding use of patches from which the adhesive has stuck to the backing. Shire will send, within 7 business days of receiving a request, a free trial card for 40 patches to replace patches that may have been discarded due to backing problems.

This offer may not be helpful, as the same problem may still exist with the replacement patches, and obtaining the free supply of methylphenidate—a schedule II controlled substance—may be difficult. A new prescription will be needed for the trial

supply, since federal law prohibits refills. If the interim free supply is not available or effective, Shire recommends that parents contact their child's physician for alternative therapy until the patch adhesive problem is remedied.

Additional strategies for the safe use of Daytrana patches include the following:

- Educate parents about safe storage (e.g., recommended temperature, locked cabinet) and disposal of patches to protect children and pets from accidental exposure
- Inform parents that they should avoid contact with the adhesive, as it contains medication; and if contact occurs, wash the area with large amounts of water, but no soap, alcohol, or other solvents which may increase absorption of the drug
- Inform parents that skin irritation may occur with Daytrana and should be treated if necessary *after* the patch has been removed; and mention the child should be evaluated by a physician if skin irritation is accompanied by edema or other local reactions that do not improve within 24 hours of patch removal
- Educate parents and healthcare providers about the dangers of cutting Daytrana patches.

References: 1) Suite 101- Special needs education forum. Daytrana patch chat. Discussion thread. Posted 12 February 2007. Available at: <http://specialneedseducation.suite101.com/discussion.cfm/1964>. 2) ADHD News.com-ADHD medication message boards. Daytrana anyone? Discussion thread. Posted 13 July 2007. Available at: www.adhdnews.com/forum/forum_posts.asp?TID=20458&PN=1. 3) Counseling Resource-Features. Problems with the Daytrana ADHD patch. Discussion thread. Posted 27 March 2007. Available at: <http://counselingresource.com/features/archives/2007/drugs/adhd-patch-problems/>. 4) Daytrana (methylphenidate transdermal system) patch prescribing information. Wayne, PA: Shire; 2007. Available at: www.daytrana.com/Consumers/PDFs/DaytranaPrescribingInfo.pdf. 5) ISMP. New fentanyl warnings: more needed to protect patients. *ISMP Medication Safety Alert!* August 11, 2005; 10(16):1-3.

ISMP Medication Safety Alert! Acute Care (ISSN 1550-6312) ©2007 Institute for Safe Medication Practices (ISMP). Permission is granted to subscribers to reproduce material for internal communications. Other reproduction is prohibited without written permission. Report medication errors to the USP-ISMP Medication Errors Reporting Program (MERP) at 1-800-FAIL-SAF(E). Unless noted, published errors were received through the MERP. ISMP guarantees confidentiality of information received and respects reporters' wishes as to the level of detail included in publications. **Editors:** Judy Smetzer, RN, BSN, Michael R. Cohen, RPh, MS, ScD, Russell Jenkins, MD. **ISMP, 1800 Byberry Road, Suite 810, Huntingdon Valley, PA 19006.** Tel. 215-947-7797; Fax 215-914-1492; E-MAIL: ismpinfo@ismp.org. This is a peer-reviewed publication.

ISMP Quarterly **Action** Agenda







One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and use that information to prevent similar problems at your practice site. To promote such a process, the following selected agenda items have been prepared for your senior leaders and an interdisciplinary committee to stimulate discussion and action to reduce the risk of medication errors. These agenda topics appeared in the *ISMP Medication Safety Alert!* between **April** and **June 2007**. Each item includes a brief description of the medication safety problem, recommendations to reduce the risk of errors, and the issue number in parentheses to locate additional information as desired. Many product-related problems can also be viewed in the *ISMP Medication Safety Alert!* section of our website. The Action Agenda is also available for download (www.ismp.org/Newsletters/acutecare/articles/actionagenda0703.doc) in a Word format that allows expansion of the columns in the table designated for organizational documentation of an assessment, actions required, and assignments for each Agenda item. Continuing education credit is available for nurses at: www.ismp.org/Newsletters/acutecare/actionagendas.asp.





Key: – ISMP high-alert medication

Issue No.	Problem	Recommendations	Organization Assessment	Action Required/Assignment	Date Completed
Unintentional acetaminophen overdoses					
(7) 	Unintentional acetaminophen overdoses are rooted in the failure of consumer education about potential harm from exceeding recommended doses, the variety of products that contain acetaminophen, confusing or incomplete labeling of prescription drugs that contain acetaminophen (e.g., APAP), and unknowing concomitant use of acetaminophen-containing products. Advertising campaigns that fail to prominently include “acetaminophen” as an ingredient also foster the risk of an overdose.	Educate patients about the potential for acetaminophen toxicity as well as how to identify acetaminophen as an ingredient in products. Inpatient medication administration records (MARs) should include the amount of acetaminophen in mg for each acetaminophen-containing drug prescribed. Advertisers should prominently list all active ingredients in products.			
Ongoing, preventable fatal events with fentanyl transdermal patches					
(13) 	Instances of significant patient harm, including death, continue to be reported when fentanyl transdermal patches are prescribed inappropriately to opiate-naïve patients and for acute post-operative pain. Despite changes to package labeling and efforts by the FDA, ISMP, and manufacturers to enhance provider education about safe prescribing, the incidence of harm-causing events remains unacceptably high.	Develop guidelines that address appropriate prescribing of fentanyl patches that are consistent with fentanyl patch package labeling, limit use of the patch to opiate-tolerant individuals with chronic pain, and include equianalgesic conversion tables. Measures to make these objectives operational include: setting pharmacy computer systems to provide hard stops if the initial dose is more than 25 mcg/hr; limiting prescribing privileges or requiring review by a pain management specialist; and scripted counseling to standardize patient education in outpatient settings.			
HUMAPEN MEMOIR and HUMIRA PEN (adalimumab) mix-ups					
(7) 	Humapen Memoir is a pen device that was recently launched for use with HUMALOG (insulin lispro injection [rDNA origin]). This product may be confused with Humira Pen used to treat immune-related disorders. The brand names look and sound very similar.	Be aware of the look- and sound-alike characteristics of these products. Prescribers should include the indication for these products, and practitioners should match the prescribed medication’s indication to the patient’s condition to help prevent errors.			



© ISMP 2007

Issue No.	Problem	Recommendations	Organization Assessment	Action Required/Assignment	Date Completed
Replacing outdated ACTIVASE (alteplase) and TNKASE (tenecteplase)					
(7) 	When the expiration date has been reached with Activase and TNKase, Genentech instructs hospitals to open the box, check if it's the diluent or drug that has expired, and if it's the diluent, to replace it and re-label the outer package with a new expiration date. An expired drug almost reached a patient after a pharmacist listed the new expiration date for the diluent, when the actual drug had an earlier expiration date.	While Genentech discourages return of the product if only the diluent has expired, ISMP confirmed with the company that they would allow pharmacists to return the entire box for replacement when the outer package expiration date has been reached, as ISMP has recommended.			
Fentanyl and midazolam bolus doses programmed in mcg, not mcg/kg					
(8) 	Several medication errors with a single infant occurred when the dose on the MAR was expressed in mcg while a smart pump prompted for a dose in mcg/kg. A total bolus dose of fentanyl was programmed as 12 mcg, without noticing that the smart Smiths Medical Medfusion 3500 Syringe Pump had prompted for the mcg/kg dose (4 mcg/kg). A soft dose-limit alert that appeared on the pump was overridden. The same type of error occurred when programming a bolus dose of midazolam.	Whenever possible, the dose of a medication should be prescribed and displayed on the MAR in the same way the information will be needed to program the pump. This will require nurses to communicate to prescribers about the format needed, and to ensure that pharmacy knows the way that bolus doses are typically delivered to patients (pump or syringe). Alerts, even soft alerts, from a smart pump should require close scrutiny before bypassing.			
RCA of chemotherapy error available					
(10) 	A woman with advanced nasopharyngeal carcinoma died after inadvertently receiving an infusion of fluorouracil over 4 hours instead of 4 days. Investigation showed that similar fatal errors have occurred at least seven times in North America.	The Alberta Cancer Board has published a RCA about this event, performed by ISMP Canada, on its website (www.cancerboard.ab.ca/NR/rdonlyres/4107CCF0-2608-4E4D-AC75-E4E812F94FD6/0/Incident_Report_UE.pdf) to promote learning. Review the RCA to evaluate and reduce the risk of this type of error in your facility.			
Error-prone drug concentration expression on ZEMURON (rocuronium) carton					
(8) 	A near-miss that could have resulted in a ten-fold overdose of Zemuron was reported, due to the prominent display of a mg/mL concentration (10 mg/mL) on the multiple-vial container, without listing the total amount of drug in each vial (100 mg/10 mL).	Providers should be aware of the labeling issue with Zemuron and exercise caution when dispensing and administering the drug. Pharmacy staff should highlight important information, such as the total dose of medication per vial, on carton labels to draw attention to it, or add auxiliary labels if the information is not available on the label.			

© ISMP 2007

Issue No.	Problem	Recommendations	Organization Assessment	Action Required/Assignment	Date Completed
HydromorPHONE (DILAUDID) and morphine mix-ups					
(11) 	An advisory was issued about harmful and fatal overdoses associated with hydromorPHONE and morphine, many of which were attributed to lack of practitioner awareness of what constitutes an equianalgesic dose of hydromorPHONE, as compared to morphine; and confusion between the names hydromorPHONE and morphine.	ISMP has formally requested changing the name of hydromorPHONE to clearly differentiate it from morphine. Provide equianalgesic dosing charts in all areas where the drugs are prescribed, dispensed, and administered, and use tall man letters when referring to hydromorPHONE.			
Action needed to prevent dangerous heparin-insulin confusion					
(9) 	Inadvertent mix-ups between heparin and insulin have caused grave patient harm. In one case, insulin was added instead of heparin to TPN for a neonate resulting in serious hypoglycemia. Non-diabetic patients have also received insulin instead of heparin during catheter flushes and as a result of transcription and order entry errors. Mix-ups are generally attributed to similar product packaging and/or mental slips, particularly since both drugs are dosed in units and may share a similar 100 units/mL concentration.	Reduce the risk of mix-ups by: segregating heparin and insulin vials; using prefilled heparin syringes; differentiating heparin from insulin by dispensing insulin in pen devices; retrieving and adding insulin to an IV admixture in the pharmacy, and then returning unused stock to its storage area immediately after use; matching the indication for heparin or insulin to the patient's diagnosis; and requiring independent double-checks for TPN additives. In cases of unexplained hypoglycemia, always consider the possibility of a medication error.			
Look-alike heparin vials					
(9) 	A pharmacist who was checking medications destined for an automated dispensing cabinet found 10 mL vials of heparin 5,000 units/mL mixed in with 10 mL vials of heparin 1,000 units/mL, both manufactured by Abraxis. The labeling and caps on the vials are similar, and the products may be difficult to differentiate, especially if lighting is low.	Abraxis plans to investigate relabeling these products. Meanwhile, consider purchasing one product from another vendor to reduce similar appearance. In the pharmacy, do not store concentrations of heparin used to prepare IV infusions near those used to maintain vascular catheter patency. Limit floor stock heparin to 5,000 units per vial or prefilled syringe.			
Oral solution given IV					
(11) 	Two patients received IV infusions containing oral ondansetron liquid. The automated dispensing cabinet (ADC) from which the drug was removed contained oral and injectable ondansetron, but the screen did not designate "oral" beside the oral preparation. The product's clear appearance led the nurse to believe she had an injectable drug, so she withdrew the solution from an oral syringe into a parenteral syringe and gave it IV.	Apply auxiliary labels "For oral use only" to preparations in oral syringes. The ADC product selection screen should state "oral" for oral solutions, especially if injectable agents of the same drug are available in the cabinet. Ensure that nurses receive education about the safety design and purpose of oral syringes. The need to remove an agent from one syringe to another should signal a potential error.			

© ISMP 2007

Issue No.	Problem	Recommendations	Organization Assessment	Action Required/Assignment	Date Completed
Smart pump not used smartly to detect misprogrammed heparin infusion					
(8) 	A nurse programmed a smart pump to infuse heparin 1,000 mL/hour instead of the prescribed 1,000 units/hour. The dose-checking mode had been bypassed, and the smart pump had been programmed in the standard mode. Investigation revealed that the majority of nurses in the facility were using the standard programming mode instead of the dose-checking mode.	Consistently use the dose-checking features built into smart pumps and evaluate all alerts that arise. Measures to promote full utilization of dose-checking technology include: pre-implementation readiness assessment; post-implementation analysis of pump logs to track overrides; adjusting the pump library to minimize unnecessary alerts; and setting up pumps to default to the dose-checking mode.			
IV tubing misconnected to tracheostomy collar					
(12)	A patient's IV tubing was accidentally connected to the Luer connection on his tracheostomy collar. Fluid further inflated the tracheostomy collar balloon, causing an airway obstruction. The patient became cyanotic, but the error was quickly noticed. The IV line was disconnected from the tracheostomy collar, and the fluid was withdrawn from the balloon.	Conduct a failure mode and effects analysis (FMEA) on existing medical tubing and when introducing new tubes, connectors, and catheters, to uncover and manage risks of misconnections. Limit tasks that involve disconnecting and reattaching tubes to trained professional staff. Label lines and trace tubing from insertion to source before making connections.			
AHRQ releases its first report on hospital safety culture					
(10)	The Agency for Healthcare Research and Quality (AHRQ) has released the results of a 2007 Patient Safety Culture Survey (www.ahrq.gov/qual/hospsurveydb/). Findings of concern include widespread perception that mistakes would be held against those involved in the errors. As a result, more than half of respondents failed to report a single error or safety concern to their hospital during the past 12 months.	Consider administering the AHRQ Patient Safety Culture Survey in your hospital and comparing your results to the first nationwide database of findings. Use the results to pinpoint cultural issues that need to be remedied to enhance patient safety, particularly error and safety reporting.			
NORCURON (vecuronium) prescribed electronically for wrong patient					
(11) (12) 	Norcuron was electronically prescribed for the wrong patient from a remote location and administered to a non-ventilated patient on a medical-surgical unit.	Investigate how prescribing software may be configured to limit the prescribing of a neuromuscular blocking agent to patients on units where mechanical ventilation occurs. Before dispensing these agents, have pharmacists verify that patients who are not in an ICU or ED are mechanically ventilated. Smart pumps with unit-specific drug libraries would not have these drugs on units where patients are not mechanically ventilated.			