




ISMP Medication SafetyAlert!®

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SafetyBriefs

 **Hazards of alcohol-based hand sanitizers.** Problems have come to light with the use of alcohol-based hand sanitizers recommended by the Centers for Disease Control and Prevention and others as alternatives to hand washing with antimicrobial soap. Two letters to the editor in last week's *New England Journal of Medicine* (356:529-31) described cases where the alcohol content (either ethanol or isopropanol exceeding 60% by volume) was intoxicating to people who purposely swallowed it for its effects. A recent *NBC Today Show* also reported that a 2-year-old child accidentally became intoxicated after swallowing hand sanitizer. The reports of intoxication noted that the risk of harm from these products should be addressed, especially with high-risk individuals. For example, hand sanitizing products might be sequestered at nursing stations and in medication rooms in behavioral health patient care areas and psychiatric crisis centers. The products also should not be used in areas where children might be exposed, including in the home. Alcohol-based products like **PURELL, GERM-X, NEXCARE, AVANT, PREVCARE** and **AVAGARD D** are also flammable. However, please be aware that a seemingly valid but fraudulent Chevron alert has been circulating about a man with severe burns on his hands, supposedly caused when residual amounts of Purell ignited while lighting a cigarette. Neither Chevron, the company that supposedly issued the alert, nor Johnson & Johnson, the maker of Purell, were involved in the alert's creation. The fraudulent alert also contained a photograph of hands with serious burns, but these injuries were unrelated to the use of Purell. Although the alert is fraudulent, ISMP has since verified that Purell and similar hand sanitizing products can ignite and should only be used as directed, which includes avoiding exposure to open flames.

(The above Safety Brief was revised and reissued on February 9, 2007.)

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Heed this warning! Don't miss important computer alerts

PROBLEM: Although pharmacists typically enter prescriptions and orders into the pharmacy computer, in some settings, specially trained pharmacy technicians or pharmacy interns perform this function. In these circumstances, a pharmacist later verifies that the order has been entered as prescribed at the same time he or she is assuring the appropriateness of the medication and verifying that the proper drug and dose has been prepared. The checking process is typically accomplished by comparing the order, pharmacy label, and the final product. As long as the original prescription or order is included in the checking process, this may seem to be a perfectly acceptable way to verify technician/pharmacy intern order entry and preparation of medications.

However, one glaring safety concern still exists with this process: the checking pharmacists may not know about alerts that were displayed during the order entry process and bypassed. As long as the order was entered as prescribed, the pharmacist may not be in a position to view computer alerts about a drug interaction, allergy, duplicate therapy, excessive or subtherapeutic dose, or other contraindications.

While bypassing alerts is often clinically appropriate, sometimes important warnings are inappropriately overridden. Bypassing alerts appears to be a rather common practice, especially if the significance of the alert is not valued by the viewer of the information. The alert systems used during order entry are often quite sensitive so users do not miss any critical information. This sensitivity comes at a cost: frequent 'false' alarms—or warnings that may not be clinically significant. Pharmacists can usually cite many examples of these false alarms. Besides being a nuisance, frequent false alarms can lead to alert fatigue and complacency—or the 'cry wolf'

syndrome.¹ Individual quirks in some pharmacy systems also contribute to missed alerts—conditions that should have given rise to an alert but did not. Thus, general annoyance and mistrust in the alert system could be one reason why it may seem perfectly acceptable to not worry about the alerts that technicians/pharmacy interns may bypass.

SAFE PRACTICE RECOMMENDATIONS: The problems described above are twofold: false alarms with pharmacy alert systems and the pharmacist's inability to view and assess alerts that may have been bypassed during order entry. While there are no silver bullets that can solve either problem quickly and effectively, a few suggestions are offered below to improve upon our valuable but imperfect alert systems.

Reduce sensitivity of alert system. The most direct way to curtail false alarms is to reduce the sensitivity of the alert system.¹ For example, many pharmacy systems allow users to choose the level of drug-drug interaction alerts (e.g., level 1-3) that will appear during order entry. While the existing level system is not perfect, it offers some relief from false, low significance alarms. However, keep in mind that reduced alert sensitivity leads to tradeoffs between false alerts and missed alerts.

Identify priority alerts. Another option is to identify conditions that signal the most serious potential adverse drug events, and use the list to limit and customize computer alerts. For example, there is a relatively small, finite group of drug interactions that are clinically important from a pharmacodynamic or pharmacokinetic standpoint. Several health professionals have published lists of these priority conditions, which can be used to target customized drug-drug interaction alerts, or to serve as a resource for pharmacists who are checking orders.^{2,3} See Table 1 on the next page for examples. You can also

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SafetyBriefs continued**⚡ Drug shortage causes error.**

Once again, a drug shortage has contributed to a medication error. A patient being treated in a gastroenterology suite apparently received ketamine in a 50 mg/mL concentration instead of 10 mg/mL. According to a national drug shortage Web site provided by the American Society of Health-System Pharmacists (www.ashp.org), a shortage exists for ketamine in a 10 mg/mL strength. Therefore, the hospital had to stock the 50 mg/mL concentration in an OR automated dispensing cabinet. A nurse anesthetist prepared two syringes of the 50 mg/mL strength but only diluted one to 10 mg/mL. The error was recognized when the patient experienced unanticipated delirium and confusion. This error happened despite notifying anesthesia personnel about the shortage. This hospital now requires pharmacy to dispense only pre-diluted syringes. King Pharmaceuticals is the only manufacturer of a 10 mg/mL strength of ketamine. In mid-December 2006, the 10 mg/mL (20 mL) vials were recalled due to potential lack of sterility. King expects to be able to supply additional product by the end of February.

Message in our mailbox

In our January 25, 2007, article on an e-prescribing error involving accidental selection of U-500

instead of U-100 insulin, we emphasized the importance of building a hard stop into the computer for verification of all U-500 insulin orders. Pharmacist **Anne Lubischer** of the Portland, Oregon VA Medical Center wrote to let us know of an additional safety step they've added when prescribers electronically order the U-500 concentration. A flag tells them the order must be reviewed for appropriateness and that the patient will not immediately receive the medication. If the prescriber clicks "continue," he or she is taken to an endocrine consult order screen, which must be completed. If the endocrine team approves the order, the team will complete the order entry. If it is denied, the order will not be completed. The team notifies the prescriber of the results of the evaluation and the prescriber contacts the patient. These order screens help improve safety, formulary control, dosing, ease of ordering labs, and tracking of patients who are receiving U-500 insulin.

Heed this warning! continued

identify priority alerts by reviewing previous pharmacy interventions regarding drug-drug interactions, allergies, duplicate therapy, and so on, to learn the conditions that truly warranted a call to the prescriber and changes in drug therapy. Likewise, encourage clinicians to report encounters

Table 1: Examples of drugs with potentially serious drug-drug interactions**

cyclosporine
digoxin
lithium
monoamine oxidase inhibitors (MAOIs)
protease inhibitors
selective serotonin reuptake inhibitors (SSRIs)
warfarin

**Source: Drug Interaction Tip Sheet by Francis J. DeRoos, MD, from *Internal Medicine News*.²

of invalid warnings so they can be altered or removed from the pharmacy computer system. Once high-priority alerts have been identified, it should be impossible for order entry technicians/pharmacy interns to bypass these. Instead, these orders should remain in a queue for release by a pharmacist after viewing and responding to the associated problem. If a pharmacist eventually bypasses a high-priority alert, require documentation of the reason so it can be used for improvement activities.

Print a daily report of bypassed alerts.

Most computer systems will allow a report of bypassed alerts to be printed daily for a pharmacist to review. This may be during the nighttime hours in some locations, or there may be other recognized periods

when workload is lower, staffing is better, or someone is scheduled for this purpose. This is much more achievable if reports for bypassed *priority* alerts are created and reviewed. Otherwise, the length of the report may prohibit review and follow up. The exact process for follow up with problematic orders would also need to be described, especially if the review occurs at night. While retrospective review of bypassed alerts is not optimal, many drug-drug interactions, even some severe ones, will not harm patients until at least a few days after concurrent administration, so there is often time to take action before harm occurs. The same may not be true for some duplicate therapy, allergies, and dosing errors, but harm may be mitigated if the problem is discovered quickly.

Alerts on labels. Some order entry systems have the ability to print out any significant alerts on a label along with the other product labels that are produced. This way, the pharmacist will be able to view the bypassed alerts when checking the final product before dispensing. However, unless the labels with alerts are available in real time, the logistics of this option are impractical for inpatient settings, particularly if most medications are dispensed via automated dispensing cabinets.

References: 1) Wogalter MS ed. Handbook of Warnings. Lawrence Erlbaum Associates: Mahwah, NJ; 2006. 2) Splete H. Medical history holds clues to drug interactions. *Internal Med News*, 2005;38(22):42. 3) Hansten PD, Horn JR. The top 100 drug interactions: a guide to patient management, 2006 edition. American College of Clinical Pharmacy: Boston, MA; 2006.

Danger of giving topical thrombin intravascularly

PROBLEM: Topical thrombin has been available since the 1940s as a hemostat for use when oozing blood and minor bleeding from capillaries and small venules occurs. The product is provided as a powder for reconstitution in a vial, which can be mistaken as a parenteral drug (see photo on page 3). The manufacturer even provides the drug packaged with a syringe to ease preparation and withdrawal. Because of its action in the clotting mechanism, thrombin must not be injected systemically or allowed to enter large blood vessels. Extensive intravascular clotting and even death may

result. It is therefore applied only to the surface of bleeding tissue. Unfortunately, we're aware of several reports in which it was accidentally administered intravascularly, sometimes with a serious outcome.

In one case, a physician reconstituted topical thrombin and instilled it into the track of a centrally placed catheter that had been removed and oozed blood. Within minutes of administration, the patient experienced breathing abnormalities, arrested, and died. In another case, a nurse administered topical thrombin

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Special Announcements...

ISMP teleconference. Please join us for our first teleconference of 2007, *Gaining Physician Compliance to Your Patient Safety Initiatives*, to be held on **February 22, 2007**, from 1:30-3:00 p.m. EST. ISMP medical director and trustee **Russell Jenkins, MD**, will explore how to win, not just enforce, physician compliance to key patient safety initiatives, including elimination of dangerous abbreviations and medication reconciliation. To register, please visit www.ismp.org/educational/teleconferences.asp.

Free FDA patient safety videos. The latest medication safety-related videos, developed by FDA in cooperation with ISMP, are available for free viewing or downloading on the ISMP Web site (www.ismp.org/Tools/fdavideos.asp). See the table below for the latest offerings.

February 2007	Possible Dosing Errors with the OptiClick Insulin Injection Device
	Dangerous Use of Saline Flush Syringes
January 2007	Preventing Dosage Errors with Diastat AcuDial
December 2006	Severe Tissue Injury with IV Promethazine
	Preventing Fatal Heparin Overdoses
November 2006	Danger in Administering Azathioprine and Mercaptopurine Together
	Vaccine Mix-ups: Adacel (Tdap) and Daptacel (DTaP)
October 2006	Nostril Errors with Nasal Sprays

PPAG meeting. The Pediatric Pharmacy Advocacy Group (PPAG) will be holding a conference, *Pediatric Medication Safety and Technology*, on **March 30 to April 1, 2007**, at the Renaissance Austin Hotel in Texas. Topics include barcode point-of-care systems, automated dispensing cabinets, computerized prescriber order entry, electronic medication administration records, smart pump technology, and more! Arrive early on Friday for a **bonus** pre-conference symposium on *Medication Safety and Technology*, co-sponsored by ISMP and PPAG! For more information, please visit www.PPAG.org.

Topical thrombin continued intravenously. Immediately following administration, the patient drew his left arm up to his chest, closed his eyes, and could not respond to voice commands. He subsequently experienced an apparent seizure. Supportive therapy was begun. Fortunately, within 10 minutes he was more responsive, and within 30 minutes, he was back to baseline status, talking and sipping water. The patient had no memory of the event or any residual effects.

In another case, a patient who was hospitalized for an unspecified operation was accidentally given thrombin 5,000 units intravenously. Soon after, the patient sustained a cardiopulmonary arrest, and resuscitation efforts were unsuccessful. In a fourth case, during cardiac surgery, a labeled thrombin syringe was placed in the warming pitcher along with heparinized saline syringes of similar volume. The thrombin was accidentally given intravenously instead of heparin. The patient survived but required additional monitoring and an extended hospital stay.



SAFE PRACTICE RECOMMENDATIONS: Topical bovine thrombin is available in the US only from King Pharmaceuticals. It is available as **THROMBIN-JMI** vials, spray kits, and syringe spray kits. In the above cases, some healthcare practitioners were not aware that the product is for topical use only. Thus, it should not be dispensed without verifying that the receiving staff understands the adverse consequences of an intravascular injection. In response to previous cases of misadministration, FDA had already asked the manufacturer to place a prominent, consistent warning on the carton labeling, "For topical use only—do not inject." The FDA also suggested that similar language be added to the warnings section of the package

insert (Gershon SK et al. Misadministration of topical bovine thrombin. *JAMA*. 1999; 282:1919). Similarly, an auxiliary label with the same warning should be affixed to any syringe holding topical thrombin.

During surgical procedures, it may be possible to delay preparation of thrombin and placement in the sterile field until parenteral products have already been administered. Sequester or separate topical thrombin from parenteral products once drawn into a syringe, and always communicate its presence when placing it in the sterile field. In various types of surgery, solutions of topical thrombin may be used in conjunction with an absorbable gelatin sponge for hemostasis. It may also be advantageous to use topical thrombin in a dry form on oozing surfaces.

Packaging of the product in kits can help prevent errors. With the spray kit, a syringe is used to reconstitute the product, then a pump with a protective cap is snapped onto the vial and the actuator is attached. With the syringe spray kit, thrombin is drawn into a syringe and a spray tip is attached. Reconstituted product should never be left in the syringe as an intermediary step. A label with a prominent warning against intravascular injection is provided. Consider having pharmacy prepare and label the drug whenever possible, especially if the operating room (OR) has a satellite pharmacist on site. If used outside of an OR environment, the unreconstituted vial should not be placed at the bedside for reconstitution by staff because it may be easily confused as a parenteral product.

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