



ISMP Medication SafetyAlert!®

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ISMP gains PSO status

The Agency for Healthcare Research and Quality (AHRQ) has notified us that our request for certification as a Patient Safety Organization (PSO) has been approved, effective November 5, 2008. ISMP is among the first group of entities granted PSO status. PSOs are organizations in which improvement of patient safety and quality comprise its primary mission and activities. They are being established under the Patient Safety and Quality Improvement Act of 2005. In the past, healthcare professionals and organizations have sometimes been reluctant to participate in external error-reporting programs and/or data sharing for safety and quality improvement purposes, for fear of legal liability. Since 1975 when our error-reporting program began, ISMP has never identified, or been forced to identify, any individual who has reported an error or an organization that has been involved in a reported error. Now, because reporting to a PSO confers both privilege and confidentiality to the information reported, ISMP's PSO status will afford an even higher level of protection when clinicians and organizations report to ISMP. Under our PSO status, practitioners should continue to report medication errors to us as they have in the past, and patient safety and quality committees in healthcare organizations can work with ISMP to analyze events and aggregate data to help reduce risks and hazards associated with patient care. ISMP can also work with other PSOs to provide expert analysis on behalf of services offered to their clients. For information, call (215-947-7797) or send us an email (mmandrack@ismp.org).



Using external errors to signal a clear and present danger

Chances are you've scanned the headlines and read many of the stories about medication errors published in the *ISMP Medication Safety Alert!*, particularly the tragic errors: the death of a young child who received a massive overdose of zinc due to a miscommunicated compounding process; the prolonged readmission of an elderly man with deep vein thrombosis and pulmonary emboli because he was not instructed to continue taking warfarin upon discharge a week earlier; the death of an infant who received 5 mg of morphine instead of the prescribed ".5 mg" dose when the naked decimal point was not seen. You've learned about many recurring errors: the death of *another* young man after intrathecal administration of IV vincristine; the death of *another* elderly patient from misprescribing of a fentanyl patch; the death of *another* young mother in labor after an intrathecal bupivacaine infusion was administered IV. There has been no shortage of harmful medication errors for us to relate in our newsletter.

saddened, anxious, unsettled, and perhaps even angry or frustrated. These initial gut feelings, which the airline industry has termed "leemers," cause you to feel "leery" about errors (thus, the term "leemers"), even if you can't put your finger on the exact cause of your unease.¹ Unfortunately, we have a tendency to gloss over these initial gut feelings and treat many errors as inconsequential in our own lives and work.¹ The stories you hear about tragic medication errors may be compelling but are perhaps felt to be irrelevant to your practice—a sad story, but not something that could happen to you or at your hospital. People tend to "normalize" the errors that have led to tragic events, and subsequently, they have difficulty learning from them.

There are several biases that lead to normalization of errors and thwart our learning from mistakes, particularly the mistakes of others. First, we have a tendency to attribute good outcomes to skill, and bad outcomes to sheer bad luck.² We have a relatively fragile sense of self-esteem and a tendency to protect our professional self-image (and the image of our workplace) by believing the same errors we read about could not happen to us. It

As you've read these stories, you've probably felt surprised or startled,

Table 1. Steps for Learning about External Errors¹⁻⁶

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Leaders should convey that high-profile, external events offer necessary learning and should be reviewed. ⁶
Define the types of events you should monitor and know about (e.g., serious event definition from the NQF). ⁶
Develop reliable sources of information (e.g., ISMP, FDA, TJC) to determine how and why the errors occurred. ⁵⁻⁶
Assign a specific professional(s) to routinely search the literature for published error experiences. ⁵⁻⁶
Establish group (unit-level, safety committees, administrative team, board) responsibility, with standing space on agendas, to ensure review of published external errors. ⁴⁻⁶
Establish a systematic way to review information about external errors and assess the organization's vulnerability to similar errors. ⁴⁻⁶
Ask yourself, "Could this event happen here?" ⁶
Listen to updated reports about events, particularly updates concerning why the errors occurred, and learn how the affected organizations are handling the events, if possible. ⁶
Determine a workable action plan to address vulnerabilities, and assign staff to ensure the action occurs. ⁵ Reassess vulnerabilities after the action plan has been implemented.
Use error stories as persuasive tools to drive improvements. ⁶
Let others know that you consider an external error to be a "clear and present danger" in your organization, and the steps you have taken to prevent such an occurrence. ⁶


SafetyBriefs

On the "do not use" list. The order below for **DDAVP** (desmopressin) was supposed to be given intranasally (IN) but was given intravenously (IV) in error. The order was written below another drug that was ordered IV. The abbreviation "IN" is on our list of abbreviations that should not be used. In addition to being mistaken as IV, "IN" has been mistaken as IM. To prevent errors, use intranasal, nasally, or NAS.

DDAVP 5micrograms IN x1

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SafetyBriefs continued from page 1

 **New staff intimidation.** Many organizations are attempting to transform their culture and reverse their long-standing tolerance and indifference to intimidating and disruptive behaviors. In dealing with these issues, healthcare providers need to be sure not to overlook situations that seem to invite a reluctance to ask questions. To cite one instance, new staff, new graduates, and others may believe they need to “prove” themselves in order to gain and maintain the trust and respect of their coworkers. The following tragic error vividly brings this issue to light. A physician had prescribed a 1 liter “bicarb drip” for a hospitalized patient. The pharmacist who prepared the infusion was a new graduate who had just completed her orientation and competency verification. The prescriber’s order was not clear regarding the amount of sodium bicarbonate per liter, and the new pharmacist was too embarrassed and insecure to ask for help. While the prescriber intended to have 1 “amp” (8.4%, 50 mEq/50 mL per “amp” [which is really a vial]) of sodium bicarbonate in the 1 liter bag, the pharmacist dispensed a 1 liter bag of undiluted sodium bicarbonate solution (1 mEq/mL, 1,000 mEq/liter). The pharmacy technician who prepared the infusion per the pharmacist’s directions was also reluctant to ask questions when he had to empty a liter bag and pump 20 vials (50 mEq each) of sodium bicarbonate into the bag. Unfortunately, the nurse did not recognize the error and hung the infusion, which led to the patient’s death. While skills-based training and coaching in relationship-building and collaborative practice are certainly needed for leaders and managers, don’t forget to bring the frontline staff into the fold, particularly new staff/graduates. While our 2004 survey on intimidation (www.ismp.org/Newsletters/acutecare/archives/Mar04.asp#mar25) showed that new staff are often shielded from the intimidating behaviors of prescribers, we tend to forget that these staff may be intimidated by the very people who shield them. The code of conduct in an organization should promote an atmosphere where questions are expected and rewarded, regardless of staffs’ rank, experience, or education. Other important steps to help reduce intimidation in the workplace can be found in The Joint Commission’s July 2008 *Sentinel Event Alert* (www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_40.htm) and the 2004 March 11 and March 25 issues of this newsletter (found at the survey URL listed above).

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External errors continued from page 1

was just terrible luck that led to the bad outcome in another organization, soon to be forgotten by all except the few who were most intimately involved in the event.

Next, we have a tendency to be too optimistic and overconfident in our abilities and systems,² particularly when assessing our vulnerability to fatal events. We thirst for agreement with our expectations that the tragic errors we read about could not happen in our workplace, seeking confirmation about our expectations of safety while avoiding any evidence of serious risk.¹⁻² We may go through the motions of looking at our abilities and systems to determine if similar errors might happen in our organizations, but in the end, we tend to overlook any evidence that may suggest trouble (much like confirmation bias in which we view what we expect to see on a medication label, failing to see any disconfirming evidence). We subconsciously reach the conclusions we want to draw when it comes to assessing whether our patients are safe.²

To best promote patient safety, it is crucial to seek out information about external errors, to hold on to your initial feelings of surprise and uncertainty when you read about these errors, and to resist the temptation to gloss over what happened.¹ It is in the brief interval between the initial surprise and unease when reading about an external error, and the normalization of error—convincing yourself that it couldn’t happen to you—that significant learning can occur. If you wait too long, you can be easily convinced that there is nothing applicable to learn. Most opportunities for learning come in brief “ah-ha” moments that need to be frozen in time and remain connected to your initial feelings of surprise and unease in order to adequately learn from them and take action.

In our February 25, 1998 and January 13, 2005 newsletters,³⁻⁴ we suggested making a New Year’s resolution to learn from published reports of errors, anticipating the same risks in your organizations, and making substantial improvements in patient safety. We repeated this recommendation in our November 29,

2007, newsletter⁵ after writing about repeated mix-ups between heparin vials of varying concentrations (10 units/mL and 10,000 units/mL), which led to the deaths of numerous infants. James Conway, senior vice president of the Institute for Healthcare Improvement, also published a recent article in *Healthcare Executive* outlining the importance of learning from other organization’s errors.⁶ Mr. Conway lists ISMP, FDA, The Joint Commission (TJC), the Pennsylvania Patient Safety Authority, and the National Quality Forum (NQF) as reliable sources of information on external errors. The ISMP and Conway articles outline the steps organizations can take to establish and maintain a system for ongoing learning from external tragic medical events. Table 1 (page 1) summarizes these steps.

The only way to make significant safety improvements is to challenge the status quo, inspire and encourage all staff to track down “bad news” about errors and risk—both internal and external—and to learn from the “bad news” so that targeted improvements can be made. We need to shatter the assumption that systems are safe until proven dangerous by a tragic event. No news is *not* good news when it comes to patient safety. Each organization needs to accurately assess how susceptible its systems are to the same errors that have happened in other organizations, and acknowledge that the absence of similar errors is not evidence of safety. Personal experience is a powerful teacher, but the price is too high to learn all we need to know from firsthand experiences. Learning from the mistakes of others is imperative.

References: 1) Weick KE, Sutcliffe KM. *Managing the Unexpected*. San Francisco: Jossey-Bass John Wiley & Sons, Inc. 2001. 2) Montier J. The limits to learning. In: *Behavioral Investing: A Practitioner’s Guide to Applying Behavioural Finance*. New York, NY: John Wiley & Sons, Inc.; pg. 65-77; 2007. 3) ISMP. It’s not too late for one more New Year’s resolution. *ISMP Medication Safety Alert!* 1998;3(4):1. 4) ISMP. Looking forward: make pro-change your New Year’s Resolution. *ISMP Medication Safety Alert!* 2005;10(1):1-2. 5) ISMP. Another heparin error: learning from mistakes so we don’t repeat them. *ISMP Medication Safety Alert!* 2007;12(24):1-2. 6) Conway J. Could it happen here? Learning from other organization’s safety errors. *Healthcare Executive*. November/December 2008;64,66-67.

SafetyBriefs continued from page 2**“Flag” insulin pen labels.**

We've mentioned it before, but once again, we heard about an insulin mix-up that happened when patient-labeled caps on insulin pens were accidentally switched. As a result, one patient received another patient's insulin before the error was detected. Given that short-acting and basal insulin analogs, as well as mixtures of intermediate and short-acting analogs, are available in pen devices with caps, mix-ups among these products could be harmful. The most recent report of a mix-up involved Novo insulins in **FLEXPEN** devices, which have caps. However the reporter was unable to tell us which Novo insulin was given incorrectly. Novo manufactures **LEVEMIR** (insulin detemir), **NOVOLOG** (insulin aspart), and **NOVOLOG MIX 70/30** (insulin aspart and insulin aspart protamine), which are all available in pens with caps. Other manufacturers also provide insulin pens with caps. For example, **LANTUS** (insulin glargine) basal insulin and the short-acting insulin **APIDRA** (insulin glulisine) are available in similar capped **SOLOSTAR** pens. To prevent errors, do not place labels on the caps. Although it's difficult to label the body of the pen, it can be done using a “flag” method (wrapping the label around the pen and folding the sticky ends together so the label looks like a flag on the pen).

ISMP Events at the ASHP Clinical Midyear Meeting

December 6

▶ *Using Data Effectively to Manage the Risks to Medication Safety*

To register, visit: www.ismp.org/education/al/ismpuspsworkshops.asp.

December 8

▶ *Safe Labeling of IV Drug Products and the Role of Bar-coding and Outsourcing in Enhancing Patient Safety*

To register, visit: www.ismp.org/pressroom/Symposium2008.asp.

December 9

▶ *11th Annual Cheers Awards Dinner*

See page 4 for details.

December 8-10

▶ *ISMP Exhibit at the Convention Center*

Please visit us at booth 1704.

Risk of IV administration of topical thrombin products

In our February 8, 2007 issue, we wrote about several cases of inadvertent intravascular injection of topical thrombin, including two fatal cases. This hemostatic product is meant only for application to the surface of tissues to stop oozing blood and minor bleeding from capillaries and small venules, or from areas surrounding vascular access sites, percutaneous tubes, or catheters. It is also employed in the treatment of epistaxis. After reconstitution, topical thrombin is used in conjunction with an absorbable gelatin sponge or may be sprayed on with an accompanying spray pump or syringe spray applicator (available in kits).

Topical thrombin should never be injected or otherwise allowed to enter large blood vessels because extensive intravascular clotting and death may result. Surprisingly, in the above cases, some practitioners were not aware that the product is intended for topical use only. An FDA Patient Safety News video, produced in cooperation with ISMP, details proper use of topical thrombin (www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=78#4).

Earlier this year, a new topical thrombin recombinant product, **RECOTHROM**, was introduced. Unlike the other topical thrombin on the market, **THROMBIN JMI** (bovine thrombin), whose label expresses the concentration in “units,” Recothrom is labeled in international units with the abbreviation “IU” prominently listed throughout product labeling, including the carton label and vial (see figure 1), package insert, and promotional materials. ISMP and The Joint Commission list IU as an abbreviation that should never be used because it has sometimes been misread as IV (intravenous). To cite one example, our May 4, 2006 issue

detailed a case where a nurse misunderstood the abbreviation IU as IV in an order for vitamin E “200 IU.” With Recothrom labeled using “IU,” the risk of misinterpretation and a serious medication error is increased. We've contacted FDA and the company to ask that the “international unit” (“IU”) designation be changed to “units.”

We have an additional concern with thrombin products. Thrombin JMI and Recothrom vials are accompanied by a prefilled syringe for reconstitution. If the reconstituted product remains in the unlabeled syringe, it can be confused with another product. Thus, the reconstituted product should never be left in the syringe as an intermediary step. A label with a prominent warning against intravascular injection is provided and should be used on any syringe that contains topical thrombin.

Information about topical thrombin—including viewing the FDA Patient Safety News video and reviewing the indication, dose, route, administration, and safe storage of the drug—should be included in the initial and ongoing competency validation of all staff who work where this product might be used. It's also a good idea for pharmacists to visit various surgical procedure units and other applicable patient care locations to see firsthand how the drug is being used and to assure proper labeling. Consider having pharmacy prepare and label the drug when possible, especially if the operating room (OR) has a satellite pharmacy on site (reconstituted Recothrom is stable for 24 hours). 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 confused as a parenteral product.



Figure 1. Recothrom website shows carton and vial with IU abbreviation.

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11TH ANNUAL ISMP CHEERS AWARDS

*It's a Family Affair!
Help Us Cheer for the Medication Safety Stars*

Join us on Tuesday evening, **December 9, 2008**, in Orlando, FL, at Maggiano's Little Italy for a gala dinner as we honor this year's **ISMP Cheers Awards** recipients.

CHEERS AWARD WINNERS

FDA Patient Safety News Videos

www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm

US Food and Drug Administration (FDA) - Rockville, MD

www.HealthInfoTranslations.org

Mount Carmel Health System, OhioHealth, The Ohio State University Medical Center, and Nationwide Children's Hospital - Columbus, OH

Sebastian Ferrero Foundation

www.sebastianferrero.org - Gainesville, FL

ISMP VOLUNTEER AWARD WINNER

Debra Simmons, RN, MSN, CCRN, CCNS

Research Scientist, Texas A and M Health Science Center, Rural and Community Health Institute, and Associate Director, The Patient Safety Education Project - Houston, TX

ISMP MEDICATION SAFETY ALERT! SUBSCRIBER AWARD WINNERS

Community Health Network
Indianapolis, IN

UMass Memorial Medical Center
Worcester, MA

LIFETIME ACHIEVEMENT AWARD WINNER

Diane Cousins, RPh

*Vice President, Healthcare Quality and Information
United States Pharmacopeia (USP) - Rockville, MD*

SUPPORT THE AWARDS

The **ISMP Cheers Awards** would not be possible without the generous support of committed sponsors. We need your help to continue spotlighting heroes and trendsetters in the prevention of medication errors. Consider helping to ensure the future of the awards and the continuation of ISMP's lifesaving work by making a donation. For details, visit: www.ismp.org/Cheers/2008cheers_prospectus.pdf.

For more information about supporting the Cheers Awards,
please visit ISMP online at: www.ismp.org/Cheers or call 215-947-7797.



*Even
Aunt Clara
will be there!*