15 YEARS ISMP Helping You Keep Patients Safe
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Educating the healthcare community about safe medication practices
A federally certified Patient Safety Organization PSO
ISMP Medication Safety Alert!® Acute Care
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SafetyBriefs

Concentration change for Rugby iron sulfate drops. Clinicians who care for infants with iron deficiencies should be aware that at least one generic manufacturer, Rugby Laboratories (a subsidiary of Watson Pharmaceuticals, Inc.) has decided to change the concentration of its iron sulfate pediatric drops to 15 mg elemental iron per 1 mL from 15 mg/0.6 mL. According to Rugby, the change was not an FDA Center for Food Safety and Applied Nutrition (CFSAN) requirement; the change was made so that the strength would match Mead Johnson Nutritionals' **FER-IN-SOL** brand, which was changed to a 15 mg/mL strength in 2008. It is not known whether other generic manufacturers are planning similar changes. In the interim, the concentration changes have led to confusion in the market place since both concentrations remain on store shelves, with doctors, pharmacists, and parents largely unaware of the 40% dosing difference. For the new concentration, both Rugby and Mead Johnson used the same NDC number as the older concentration product, so there's no assurance that computerized drug databases or other drug indexes will reflect the correct concentration available in the pharmacy. To complicate matters with the Rugby product, it doesn't appear that the concentration is actually listed on the carton. We contacted the company to ask for the concentration to be added to

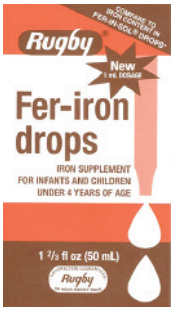

Figure 1. Product label lacks elemental iron concentration.

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Medication safety blog. ISMP president Michael Cohen contributes to a weekly guest blog on *Philly.com*, the Web site operated by the *Philadelphia Inquirer* and *Philadelphia Daily News*. Be sure to read the blog regularly and add comments about your experiences to enhance the medication safety-related postings for healthcare consumers. The blog pages' link is: www.philly.com/philly/health_and_science/97905324.html.

Preventing catheter/tubing misconnections: Much needed help is on the way

Catheter/tubing misconnections remain a serious problem in healthcare. Just a few weeks ago we learned of another fatal event. Over Memorial Day weekend, a 19-month-old child, who was receiving treatment for a chronic gastrointestinal disorder, died at a pediatric care center. A suspension of **QUESTRAN** (cholestyramine) was accidentally given via a central line intravenous catheter instead of through an enteral feeding tube.

In May 2010, another report was published about barium sulfate being administered via the superior vena cava during an upper gastrointestinal study (Soghoian S, Hoffman RS, Nelson L. Unintentional IV injection of barium sulfate in a child. *Am J Health-Syst Pharm*. 2010;67: 734-36). The patient, a 17-month-old child, had a central venous catheter (CVC) in place for antibiotic therapy. As the procedure began, approximately 3 mL of barium sulfate was injected into the CVC, which was mistaken as the child's gastrostomy tube. Fortunately, no respiratory distress developed and the child was discharged 4 days later.

Luer connector systems, common to many healthcare catheters, tubes, administration sets, extension sets, and syringes, have been at the heart of many catheter/tubing misconnections. At the center of one of the most commonly reported problems is the fact that some manufactured enteral catheters still have ports that only accept parenteral administration sets and syringes. So, even if a liquid medication is prepared in an oral syringe, the medication must be transferred to a parenteral syringe for administration via this type of enteral catheter port, risking the accidental administration of the drug via a parenteral line.

Below are examples of the type of reports we have received associated with catheter/tubing misconnections, all of which we've described in this newsletter since publication began in 1996:

- IV infusions connected to epidural lines, and epidural solutions connected to IV lines
- Syringe containing IV medication given via an intrathecal catheter
- IV tubing connected to inflation balloon port of endotracheal tube or tracheostomy tube
- Sequential compression device tubing or pneumatic blood pressure cuff tubing attached to port of IV administration set
- Oxygen tubing connected to port of IV administration set
- Breast milk intravenously infused into neonates
- Bladder irrigation solutions given IV, or TPN solutions administered via foley catheter port
- IV administration set spiked into enteral nutrition container, resulting in enteral nutrition administered IV.

Help to avoid catheter/tubing misconnections is on the way. The International Organization for Standardization (ISO) has been working on a standard (ISO/IEC/FDIS 80369-1, "*Small-bore connectors for liquids and gases in healthcare applications*") that will result in making various healthcare catheter fittings and associated tubing sets or syringes incompatible with one another. The standards will include connectors for the flow of gases, enteral feedings, liquid medications via a gastric tube, limb cuffs (e.g., sequential compression devices, pneumatic tubes to blood pressure cuffs), urological access (e.g., bladder irrigation), and neuraxial access (epidural, intrathecal, intracranial). In addition, the current Luer connector standard (ISO 594) will be updated.

Designs for the connectors for enteral tubes and catheters, as well as containers, administration sets, and syringes, are

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the carton label. We continue to recommend that pharmacists contact prescribers to assure proper understanding of the amount of elemental iron patients should receive and to counsel caregivers who may be familiar with dosing of the former product. Prescribers should also write the dose in mg instead of mL.

IV fat emulsion shortage update. The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) has participated in ongoing communication with US suppliers of IV fat emulsions about the current shortage, which may last anywhere from 6 weeks to 6 months. A.S.P.E.N. recommends reviewing "Information to Use in the Event of an Intravenous Fat Emulsion Shortage" (available on the A.S.P.E.N. Web site at: www.nutritioncare.org/Index.aspx?id=5084) and implementing the strategies assembled by a group of experts to conserve the supply for the highest priority cases. Best estimates suggest that, if all facilities implement the shortage guidelines, the national supply will remain commensurate with national demand. During a period of a shortage, wastage is always a concern. However, any manipulation of an IV fat emulsion from its original container and preparation for infusion may potentially increase the risk of contamination and product instability. Facilities and practitioners need to observe and be compliant with the product labeling for storage and use, USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations, and applicable state board of pharmacy rules and regulations. Practices outside of these sources should not be implemented. Baxter Healthcare Corporation continues to allocate its national supply on a direct purchase basis. Should you have any questions, please contact your Baxter Sales Representative or Baxter's Center for Service at 1-888-229-0001.

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expected to be finalized by the end of this year or early 2011, with clinical testing by manufacturers accomplished during the standards development process. A final set of the standards should be completed by 2013. Although these will be voluntary, product vendors should have revised devices available soon after that.

As part of the new enteral standard, a female Luer connector will not be present on feeding tubes, except for the inflation balloon that anchors some long-term use feeding devices. In the past, such connectors on feeding tubes forced nurses to administer enteral feedings and liquid medications with a parenteral syringe or administration set. This, of course, made it possible for enteral substances to be accidentally connected to a Luer connector on an IV system or other systems with Luer connectors. Soon, only a compatible oral/enteral syringe will be able to be used to administer oral liquid medications via an enteral tube.

Until the standards are finalized, though, there is work to be done. It's important for organizations to perform a risk assessment to identify the various types of catheters and fittings now in use, identify the possibility for misconnections, assess the potential severity of misconnections, and address process changes that need to be made. For example, to start with, two easy-to-implement risk-reduction strategies common to most types of catheter/tubing misconnections include: 1) always trace the port and tubing back to its insertion site to verify the correct access/route of administration, and 2) never attempt to force or jury-rig a connection that does not fit easily and securely into an access port. For additional recommendations to avoid catheter/tubing misconnections, please review the articles we have compiled from prior newsletters at: www.ismp.org/sc?k=enteraladminsafety. Each article deals with one or more types of tubing/administration set/syringe misconnections.

On July 9, 2010, FDA sent a letter to product manufacturers, healthcare practitioners, and hospital purchasing departments (www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM218631.pdf) that offered advice regarding the prevention of catheter/tubing misconnections, which are similar to recommendations you will find in the compilation of ISMP newsletter articles we gathered in the link at the top of this column. FDA encourages manufacturers to assess the risk of misconnections associated with these devices, consider temporary and long-term options to mitigate risk, and to validate solutions they deem most appropriate. The FDA letter advises hospital purchasing departments to consider the safety of various systems and connections when purchasing new inventory.

FDA also mentioned that the agency is considering recognizing the ISO/IEC/FDIS 80369-1 standard when it is published, due to the significant impact it will likely have on the safety of these devices. If FDA recognizes the forthcoming standard, the agency will provide guidance to manufacturers regarding issues such as whether there will be a set period of time for currently marketed devices to come into compliance and the effect of the standard on new devices.

The standards will be a much-welcomed addition to improve patient safety. Coupled with additional safety measures, we are optimistic that patient harm from tubing misconnections will be greatly reduced.

Special Announcement . . .

Step Up Your Medication Safety Efforts with ISMP. Healthcare practitioners with medication safety oversight responsibilities have the opportunity to join ISMP experts for a 2-day interactive **Medication Safety INTENSIVE** workshop in **Orlando, FL, on November 4 and 5**. Participants will gain cutting-edge knowledge, tools, and strategies to establish an aggressive, focused medication safety program that is built on experience-based recommendations and strategies. For more details and to register, visit: www.ismp.org/educational/MSI/.

April - June 2010

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 to use that information to prevent similar problems at your practice site. To promote such a process, the following selected items from the **April-June 2010** issues of the ***ISMP Medication Safety Alert!*** have been prepared for an interdisciplinary committee to stimulate discussion and action to reduce the risk of medication errors. Each item includes a description of the medication safety problem, recommendations to reduce the risk of errors, and the issue number to locate additional information as desired. Look for our high-alert medication icon under the issue number if the agenda item involves one or more medications on the ***ISMP List of High-Alert Medications***. The Action Agenda is also available for download in a Word format (www.ismp.org/Newsletters/acutecare/articles/ActionAgenda1003.doc) that allows expansion of the columns in the table designated for organizational documentation of an assessment, actions required, and assignments for each agenda item. Many product-related problems can also be viewed in the ***ISMP Medication Safety Alert!*** section of our Web site at: www.ismp.org. Continuing education credit is available for nurses at: www.ismp.org/Newsletters/acutecare/actionagendas.asp.

Key: ⚠ – ISMP high-alert medication

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Common risks associated with heparin					
(7) ⚠	Since 1996, ISMP has published more than 100 reports about heparin errors. The latest event involved a child who died after receiving a large overdose of IV heparin due to an infusion pump setting error that was not detected during a verbal checking process. The pump was a smart pump with a drug library and dose-checking capabilities, but this feature was not utilized.	Identify and remove barriers to utilizing smart pump technology. Examine internal errors associated with heparin and common risks (e.g., programming errors, mix-ups with other drugs, compounding errors, concomitant administration of heparin-type products) listed in Table 1 (www.ismp.org/Newsletters/acutecare/articles/20100408.asp) to identify weaknesses. Implement key improvement strategies found in Table 1 and in the *ISMP Medication Safety Self Assessment for Antithrombotic Therapy* (www.ismp.org/selfassessments/asa2006/Intro.asp).			
Confusion between organ preservation solutions (i.e., VIASPAN and SPS-1) and IV containers					
(7) ⚠	Cold storage solutions used to preserve harvested organs are available in plastic bags that resemble IV bags and also contain a port that will accommodate IV tubing. An organ procurement team left a liter bag of ViaSpan in a hospital where it was later returned to the hospital's pharmacy with other IV solutions. Inadvertent IV administration of organ preservation solution would cause cardiac arrest due to the high amount of potassium.	Alert operating room staff of the possibility for mix-ups between organ preservation solutions and IV containers. If organ preservation solutions are routinely stored at your hospital, sequester the solutions away from other IV solutions and apply auxiliary warning labels to the outerwrap noting that this concentrated electrolyte solution is to be used only for the storage or flushing of harvested organs.			
Another fatal event with IV bupivacaine					
(10) ⚠	ISMP previously described an event involving a young pregnant woman who died after she accidently received an IV infusion of epidural bupivacaine and fenta**NYL**. More recently, news media from the United Kingdom reported that a hospital trust would be sentenced by a court after one of its own nurses died when she was given IV bupivacaine instead of saline shortly after giving birth.	Obstetrical units need to evaluate and address bupivacaine toxicity that results from accidental IV injection. Inherent risks associated with routinely prescribing, dispensing, storing, and administering both epidural and IV solutions, and other medications during labor and delivery should also be identified and addressed.			

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Common pitfalls when conducting a root cause analysis (RCA)					
(8)	ISMP continues to observe common pitfalls encountered while conducting a RCA, often rendering the process less useful than intended. Common problems include: failing to establish a sequence of events; over-reliance on written policies and procedures to illustrate what normally happens when providing care; failure to conduct investigations for all at-risk behaviors and human errors identified; not seeking external information about similar adverse events; selecting weak error-reduction strategies; and others.	Ensure that the RCA includes an accurate sequence of events. Investigate "what normally happens" rather than just relying on "what policies and procedures require." Identify conditions that led to at-risk behaviors, and discover the deep system-based causes of events (see probing questions in Table 2 at: www.ismp.org/Newsletters/acutecare/articles/20100422.asp). Search professional literature for similar events, and choose error-reduction strategies which are more resistant to human error. Carry out action plans and measure your success.			
Propofol container labels highlight the percent concentration, not the mg/mL strength					
(8) ⚠	Propofol 5 mg (0.5 mL) was ordered for an agitated pediatric patient following extubation. The nurse accidently gave 5 mL (50 mg) of propofol. The propofol (**DIPRIVAN**) vial had a pharmacy label covering the mg/mL strength, so the only visible portion of the label stated "propofol 1%." Also, due to the propofol shortage, the imported product sold by APP Pharmaceuticals and manufactured by Fresenius Kabi, only highlights the strength as 1%, making it difficult to determine the mg amount.	To reduce the risk of calculation errors, hospitals using the imported product should add an auxiliary label to draw attention to the mg/mL strength. Pharmacy-applied labels, however, should never obscure critical information on the manufacturer's label.			
Prevent vinCRIStine wrong route injections					
(10) ⚠	More than 50 fatalities have been reported after administering vin**CRIS**tine via the intrathecal route; the few patients who survived this type of error have permanent neurological deficits. The most recent fatal event occurred in an adult patient who had been receiving IV vin**CRIS**tine as well as intracerebroventricular methotrexate through an Ommaya reservoir. The patient inadvertently received vin**CRIS**tine via the Ommaya reservoir.	Safety practices to prevent this error can be found at: www.ismp.org/Newsletters/acutecare/articles/20060223.asp and www.who.int/medicines/publications/drugalerts/Alert_115_vincristine.pdf. ISMP and the World Health Organization suggest dispensing and administering vin**CRIS**tine diluted in a minibag, and to separate IV and spinal medication delivery times. Medication safety teams/committees may want to view the free FDA Patient Safety Video on this topic at: www.accessdata.fda.gov/psn/transcript.cfm?show=68#7.			

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Safe practice with the once daily opioid EXALGO (HYDROmorphone extended-release)					
(10) ⚠	Recently FDA approved Exalgo, which is indicated for the management of moderate to severe pain in opioid-tolerant patients requiring continuous opioid analgesia for an extended period of time. Confusion between immediate- and extended-release products could result in an overdose, which may lead to serious adverse events such as respiratory depression and death, or an underdose, leading to poor efficacy.	When prescribing Exalgo, include the proprietary name, and if the established name is used, spell out "**HYDRO**morphone extended-release." If prescribing immediate-release **HYDRO**morphone, do not attach modifiers such as "IR." Before dispensing or administering Exalgo, verify that the patient is opioid-tolerant, counsel patients on how to properly take Exalgo, and encourage patients to read the Medication Guide.			
Failure to set a volume limit for a magnesium bolus dose leads to harm					
(11) ⚠	An obstetrician prescribed an IV magnesium sulfate bolus dose of 6 g/30 minutes followed by a continuous infusion of 2 g/hour for a patient in preterm labor. A nurse obtained a 20 g/500 mL bag of magnesium sulfate and programmed the bolus to be delivered as a continuous infusion at 12 g/hour with no volume limit. The nurse forgot to return to the patient's room in 30 minutes to reprogram the rate to 2 g/hour. The smart pump did not provide a hard stop to prevent the administration of an excessive dose of magnesium sulfate.	Never infuse an IV magnesium sulfate bolus dose from the maintenance solution unless: 1) The bolus dose is delivered using the bolus dose feature; 2) Separate dose limits are operational for bolus and maintenance doses; 3) These alerts are configured as a "hard stop," and 4) A qualified nurse remains at the bedside during infusion of the bolus dose to monitor the patient for signs of magnesium toxicity. If all these conditions are not met, administer the bolus dose from a separate container.			
Questionable safety with continuous inhalation albuterol infusion set-up					
(11)	Albuterol inhalation solution was added to an IV bag with tubing that was fit into a nebulizer to provide continuous respiratory therapy to status asthmaticus patients. A nurse discovered that a patient's IV medications had been infused into the IV tubing connected to the nebulizer. This practice could also lead to accidental IV delivery of inhalation drugs.	Avoid this risky practice by only adding the inhalation solution directly into a nebulizer cup as needed.			
The Centers for Medicare & Medicaid Services (CMS) 30-minute rule may result in unintended consequences					
(12)	The CMS regulation that requires medications to be administered within 30 minutes before or after their scheduled times, may be causing nurses to drift into unsafe work habits in order to meet the rule, such as pre-pouring medications, pre-charting medication administration, and removing medications for multiple patients at the same time.	Consider the risks inherent in the workarounds that may be taken to comply with the 30-minute rule, and remind nurses that exact timeliness with scheduled medications is frequently less important from a clinical perspective than making sure the correct patient receives the correct medication.			

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
EPINEPHrine pre-filled syringe shortage: Safety concerns with available alternatives					
(12) ⚠	**EPINEPH**rine emergency syringes 1 mg/10 mL (0.1 mg/mL) are currently on backorder from the sole manufacturer of this product. Although injectable **EPINEPH**rine is still available in other forms, these products may not be safe alternatives.	Pharmacists should communicate information about the shortage and recommended substitute products to all potential areas where **EPINEPH**-rine emergency syringes are used. Conserve current supplies of syringes for code boxes and emergency responders where pharmacists would not be present during a code. Review the safety concerns associated with the available injectable products and corresponding error-reduction strategies at: www.ismp.org/NAN/files/NAN-201006.pdf.			
Preventing errors when administering drugs via an enteral feeding tube					
(7, 9, 10, 11)	Medication errors related to the administration of drugs via an enteral feeding tube can result due to the incompatibility of administering medications via a tube, improper preparation of medications, and/or using improper administration technique. Such errors can lead to an occluded feeding tube, reduced drug effect, or drug toxicity.	A team of nurses, pharmacists, nutritionists, and physicians should develop protocols for administering drugs through enteral feeding tubes that address using appropriate dosage forms, preparing drugs for enteral administration, administering each drug separately, diluting drugs as appropriate, and flushing the feeding tube. Protocol guidance is available at: www.nutritioncare.org/safety.			
Infusion pump safety issues with Baxter Colleague Volumetric Infusion Pumps and Hospira Symbiq					
(9)	FDA has ordered Baxter to recall and destroy all Colleague pumps because the company could not address known safety issues within an acceptable timeframe. The Hospira Symbiq infusion pumps may not detect air in the line if a clinician programs the pump to infuse more volume than in the bag/bottle. Also, unrestricted flow can occur with Symbiq, if the cassette is removed before the cassette carriage is in the fully-open position.	Continue to use Baxter Colleague pumps while Baxter works with the FDA to develop a transition plan. For strategies to mitigate risks with these pumps, visit: www.fda.gov/MedicalDevices/Safety/alertsandnotices/ucm210768.htm#1. If using Hospira Symbiq pumps, review the safety steps outlined by the company with your frontline staff (www.ismp.org/newsletters/acutecare/articles/clinical-bulletin.pdf and www.ismp.org/docs/Symbiq_Recall_Notification.pdf).			
The American Association for Respiratory Care (AARC) statement on inhaled medication dosing times					
(12)	AARC has a position statement on inhaled medication dosing times that differs from the CMS regulation requiring administration within 30 minutes of the scheduled time. CMS supports the AARC suggestion of an administration window that does not exceed 60 minutes before or after the scheduled administration time.	Keep on file a copy of the AARC position statement (www.aarc.org/resources/position_statements/inhaled_medication_administration.html) and CMS support language in case state surveyors or The Joint Commission question the timeframes for inhaled medications.			