

ISMP Medication Safety Alert!® Acute Care ⚡

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Safety Briefs

⚡ Company comments on insulin pen safety. Based upon reports published by ISMP and FDA, sanofi-aventis has notified health professionals to exercise all necessary precautions to avoid the potential for risks to patients caused by using the same insulin pen for multiple patients, even if needles are changed before each use. Recommendations include prohibiting use of insulin pens as floor stock, providing reminders to staff that insulin pens are for single patient use only, and avoiding placement of labels on removable caps. The letter can be viewed in full at: www.ismp.org/newsletters/acute-care/articles/hcp-Letter.pdf. ISMP appreciates this action by the company.



⚡ Dosing mistake on 2007 Broselow Tape (pediatric crash cart tool). A pharmacist was about to reorder several Broselow Tapes (2007 Edition A) for her pediatric crash carts when she discovered that a new version (Edition B) was available. In order to determine whether or not tapes should be replaced hospital-wide, she contacted Armstrong Medical, the distributor, and was told that the change between A and B was in response to a “typo.” The “typo” consists of incorrect dosing for glucagon. Edition A lists the dose as 0.5 mg/kg/dose and 1 mg/kg/dose, rather than the correct standard doses of 0.5 mg or 1 mg, respectively. We are unaware of any public announcement about this problem or if all Edition A users have been made aware of the dosing error. We have a copy of a letter sent only in response to those who actively inquired about the changes, noting that there have been no dosing errors reported to the company. Among other things, the letter notes that using the mg/kg dose would require opening numerous vials, which would likely identify a probable error. While that is true, there are medications that may require preparation from several vials or ampuls, lessening the effect of this potential red flag. In fact, when glucagon is used in cases of beta-blocker or calcium channel blocker overdoses, adult patients and perhaps some children will require doses prepared from multiple vials (**DRUGDEX System** continued on page 2 ▶)

Shared MDIs: Can cross-contamination be avoided?

As a cost-savings measure, some respiratory therapy departments have been using a single metered dose inhaler (MDI) canister to administer medication to multiple patients. This practice, first described more than a decade ago,¹⁻³ employs a protocol in which the MDI nozzle (mouthpiece) is wiped with an alcohol prep pad and then inserted into a patient-specific aerosol cloud enhancer (ACE) spacer with a one-way valve before delivering the medication (see Figure 1). Most protocols also call for disinfecting the nozzle using an alcohol prep pad after the medication has been delivered. The MDI remains with the respiratory therapist and is used to deliver subsequent doses to other patients prescribed the same drug. The spacer remains with each patient and is not shared. This process, referred to as a common MDI canister protocol, is not used for patients on isolation precautions and is rarely used for patients being mechanically ventilated.



Figure 1. MDI with spacer device.

Proponents of this practice cite significant cost savings, staff efficiency, and fewer treatment delays, while advocating that cross-contamination among multiple users of the MDI is unlikely if the above-cited protocol is followed. Eliminating the need to retrieve and return each patient's MDI from patient-specific or unit medication supplies—particularly automated dispensing cabinets—has increased staff efficiency. Annual cost savings up to 55% have been documented, and the shared MDIs allow patients to be charged per puff of medication.¹⁻³ Treatment delays associated with pharmacy distribution of MDIs have been eliminated in many cases, and improvements in patient education have also been reported due to one-on-one time with respiratory therapists.

Opponents of allowing multiple patients to use the same MDI canister are not convinced that these benefits outweigh even a minimal risk of cross-contamination, particularly if the protocol for disinfecting the nozzle is not followed. Early findings from several hospitals that adopted the practice showed varying results. In one hospital, microbiological sampling of the canisters used to administer treatments showed no growth of organisms cultured from the mouthpiece after being swabbed with alcohol.¹ But cross-contamination was documented in two other cases.²⁻³

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⚠ Morphine oral concentrate no longer available unless companies submit a new drug application

Morphine (immediate release) oral solution concentrate (**ROXANOL** and generics) is being withdrawn from the market. Under a previously announced plan (www.fda.gov/cder/drug/unapproved_drugs/enforcement.htm) to ensure all US drugs are FDA approved, FDA sent letters on April 1 directing companies to stop making (within 60 days) and distributing (within 90 days) 14 narcotics in certain dosage forms that lack FDA approval, including Roxanol 20 mg/mL. Other opioids, including oxy**CODONE** and **HYDRO**codone, were listed in the letter

(www.fda.gov/cder/drug/unapproved_drugs/narcoticsQA.htm), but it's unclear whether **ROXICODONE**, the concentrated form of oxy**CODONE** (20 mg/mL), will remain available. It was not specifically mentioned in the FDA letter, and we have not reached the distributor, Xanodyne, for comment.

FDA noted there are approved products and applications which contain the same active ingredients as the unapproved opioid analgesics; thus, a shortage is not anticipated. continued on page 3 ▶

SafetyBriefs continued from page 1 [Internet database]. Greenwood Village, CO: Thomson Healthcare. Updated periodically). We agree with the reporter that the company should proactively notify health systems of the error. Meanwhile, you should modify your tapes with the correct dose using a black pen to block out “/kg/dose” (see Figure 1). Please note: tapes may be kept in unlikely storage locations, so be sure you conduct a thorough search to uncover the entire supply of tapes in your facility. The publisher, Vital Signs, Inc., should consider making a label with the correct information available to users so it can be applied over the incorrect information.

OVERDOSE	
Dextrose 25%	0.5 g/kg/dose
Naloxone	0.1 mg/kg (max. dose 2 mg)
Flumazenil	0.01 mg/kg (max. dose 0.2 mg)
Glucagon	0.5 mg/kg/dose ←
	(3-4-5 kg thru white zones)
Glucagon	1 mg/kg/dose ←
	(blue thru green zones) (max. dose 1 mg)

Figure 1. Dosing errors (by arrows). To fix, cross out “/kg/dose” for both erroneous entries.

⚡ Baxa compounder alert. On March 23, 2009, Baxa Corporation issued an Exacta-Mix 2400 Compounder Safety Alert to warn users that interacting with the touch-screen while the pump door is open may cause an inaccurate ingredient delivery. If the user presses the “RESUME” button at any time while the door is open and the compounder is pumping or alarming, an over-delivery of an individual ingredient will result. The amount of the over-delivery can range from 0% to 100%, depending on the amount of ingredient delivered before the pump door was opened. The safety alert suggests communicating this information to all pharmacy personnel, and to reinforce the need to close the pump door before pressing “RESUME.” If “RESUME” is pressed while the pump door is open, the alert suggests placing an X on the bag label, clearing any bubble or occlusion, and discarding the bag. Pharmacy staff who check bags after production should also check the MixCheck Report for any bubble or occlusion alarm, and ensure the proper steps were followed. A warning label for the compounder will be provided by Baxa as soon as possible. Until then, pharmacies should post a warning where the compounder is located. The company is also working on a product upgrade to address the issue. To view the alert, visit: www.ismp.org/newsletters/acute-care/articles/Baxasafetyalert.pdf.

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In one case, cultures were taken of the MDI nozzle before and after disinfection with an alcohol prep pad, as well as after treatments were administered. Growth of *Staphylococcus epidermidis* occurred in at least 5% of the cultures with all three types of specimens, including those taken *after* the nozzle was disinfected with an alcohol prep pad.² In another case, the hospital assessed the failure to wipe the canister nozzle with an alcohol prep pad prior to patient use; 1 of 18 (5.5%) cultures resulted in growth of *Streptococci* Group D (*Enterococci*).³

Two more recent studies showed no adverse effects after implementing a common MDI canister protocol.^{4,5} In 2000, a study of 17 patients showed no contamination at 24, 48, or 72 hours when cultures were taken from the MDI mouthpiece after swabbing with an alcohol pad, after actuation and removal from the spacer, and after removing it from the spacer and swabbing it with alcohol.⁴ A similarly designed 2001 study also showed no growth in cultured samples from the MDIs after use with 50 patients.⁵

Contamination that might occur from a common MDI canister protocol would seem to come from the surface of the canister, not the medication itself. This risk could be mitigated by good hand washing, along with wiping down the canisters with alcohol swabs. But if staff are not compliant with hand hygiene between patients—and many are not—how compliant will they be with cleaning the mouthpiece after every patient use? The problem is less with the common MDI canister protocol itself and more so with the potential lack of carrying out proper infection control practices.

Hospitals that have successfully implemented the common MDI canister protocol state that compliance with disinfecting the MDI nozzle is key. But we know practitioners don’t always follow proper procedures. In one of our recent newsletters, we mentioned reports of transmitting blood-borne infections after reusing insulin pens, even after the needle was changed between patients.⁶ In 2008, the Centers for Disease Control and Prevention (CDC) found that more than 60,000 patients in the US during the last decade were at risk for blood-borne

diseases due to multiple lapses in infection control practices, including the failure to clean shared glucometers.⁷ More than 400 patients acquired Hepatitis B or C infections in patient-to-patient transmission due to a failure to follow fundamental infection control principles.⁷ Failure to properly disinfect stethoscopes between patient use has also been linked to nosocomial infections.⁸ The CDC and the American Medical Association recommend disinfecting stethoscopes between patient use,⁸ but as a practical matter, it does not happen.

Deciding whether to implement a common MDI canister protocol requires thoughtful analysis and deliberation. If the results of earlier studies²⁻³ hold true, a 5% rate of potential cross-contamination may not be acceptable given the high-volume use of MDIs, frequency of repeated exposure to patients who use MDIs several times a day, and the heightened risk to immunocompromised patients. With shrinking reimbursements for care associated with nosocomial infections, cost-containment gains from employing a common MDI canister protocol may be quickly lost if an infection occurs. If a decision is made to move forward with a common MDI canister protocol, the Association for Professionals in Infection Control and Epidemiology (APIC) recommends carefully analyzing your processes to ensure handoffs between patients are not inadvertent sources of contact transmission, and emphasizing in the protocol the importance of hand hygiene and canister disinfection with alcohol after each use and prior to the next use.⁹ For hospitals that choose to dispense individual MDIs to patients, we encourage all manufacturers to provide smaller “institutional” containers of MDIs to prevent unnecessary costs and waste.

ISMP also suggests further research involving larger and more diverse patient samples from varied settings to better demonstrate any risks associated with cross-contamination among patients. Studies that show the level of staff compliance with the common MDI canister protocol over time and describe facilitators and detractors related to compliance would also be useful.

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Special Announcements...**Unique 2-day program.**

Attend ISMP's **Medication Safety INTENSIVE** workshop, a one-of-a-kind, interactive program that will teach you how to approach medication safety "through the eyes of ISMP." The workshop will be held in three locations during 2009. For details, visit: www.ismp.org/educational/MSI/default.asp.

Two ISMP teleconferences.

Join us for the next two teleconferences we are offering this spring. The second of ISMP's four-part teleconference series on high-alert medications, **Reducing the Risk of Patient Harm from Anti-coagulation Therapy**, will be held on **April 16, 2009**. This teleconference will focus primarily on preventing life-threatening events with heparin and warfarin.

On **May 18, 2009**, we will be presenting **Pediatric Medication Safety: High-Leverage Strategies for a High-Risk Patient Population**. During this teleconference, you will learn why pediatric patients are at high risk for medication errors and strategies to decrease that risk. Some of the topics that will be covered include pediatric adaptation of bar-coding technology, tips on compounding pediatric solutions, issues with standardized doses, and the use of resuscitation cards.

For more information and to register for the teleconferences, visit: www.ismp.org/educational/teleconferences.asp.

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pated. However, we believe the withdrawal of morphine oral concentrate will create problems for cancer patients, especially intermittently conscious patients near the end of life who require large doses of this drug to control pain. These patients may have difficulty swallowing the volume required using lower morphine concentrations.

It's unlikely that morphine oral concentrate will go away entirely, as compounding pharmacies can prepare the drug. However, quality control standards in some pharmacies may not be equal to standards in the pharmaceutical industry, thus risking calculation, preparation, packaging, labeling, and dropper calibration errors. Some patients might be switched to morphine via injection or suppository—less comfortable for the patient and more difficult to administer. Others might be switched to another opioid, but miscalculation of equianalgesic doses, temporary intolerance to the new drug, or inadequate analgesia may result.

Under a grandfather clause, a drug marketed prior to the 1938 Federal Food, Drug, and Cosmetic Act, and labeled with the same conditions of use as prior to the Act, was not considered a *new drug*. These drugs did not require an approved new drug application, but many thought tacit FDA approval was implied. It's the drug company's burden to prove an assertion that its product is grandfathered. But FDA believes few drugs are entitled to grandfather status because many differ from previous versions in some respect (e.g., formulation, strength, dosage form, route, indications, intended population).

Confusion between morphine oral concentrate (20 mg/mL) and conventional concentrations (20 mg/5 mL) has led to fatalities, as the concentrated version is without prominent warnings. Approved versions of opioids include labeling that reflects the risks, benefits, and safe use of these drugs. If morphine oral concentrate had undergone an FDA-approval process, there might have been labeling, packaging, or product changes to maximally protect against user error. For example, a required FDA-approval process may have led to labeling the concentrate as 100 mg/5 mL to help distinguish the high concentration from the lower 20 mg/5 mL strength. This is precisely the reason FDA is taking the current action—to compel submission of a new drug application and ensure safe use of unapproved opioids.

Although FDA had announced it was going to address unapproved drugs, the withdrawal of these opioids was unexpected, particularly given a FDA directive earlier this year that led pharmaceutical companies to create risk evaluation and mitigation strategies (REMS) for these opioids (www.fda.gov/cder/drug/infopage/opioids/default.htm). It's unfortunate that the move by FDA couldn't wait until the planned meetings about REMS were completed, allowing the pharmaceutical industry, medical community, and public a chance to interact with FDA. Hopefully, FDA and the companies will be able to collaborate so that morphine oral concentrate can remain on the market (with improved labeling). In fact, we understand that manufacturer-FDA communication is underway regarding this issue.

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