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ISMP 25 YEARS ADVANCING MEDICATION SAFETY

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Over-the-top risky: Overuse of ADC overrides, removal of drugs without an order, and use of non-profiled cabinets

Problem: Automated dispensing cabinets (ADCs) represent one of the most widely deployed forms of technology integrated with today's hospital medication use systems. ADCs were first introduced in hospitals in the 1980s to facilitate transition to a more decentralized medication distribution system. Originally designed as an automated unit stock system with the ability to support charge capture and automated replenishment, many medications were placed in open matrix drawers to which practitioners were allowed access without a pharmacist's review and/or verification of the medication order. Over time however, progressive changes to ADC hardware and software, as well as improvements in associated workflow processes, have given many organizations the ability to employ ADCs safely in a variety of locations outside the pharmacy.

Whether used as a full decentralized drug distribution model or for limited distribution of controlled substances, PRN (as needed) medications, and first doses only, ADCs today are often interfaced with electronic health record systems in both large and small healthcare settings. In most care areas, a pharmacist's verification of the medication order prior to removal of the drug is possible because of "profiling functionality" which requires a pharmacist to review and approve the appropriateness of each order prior to allowing access to the ordered drug. A pharmacist's review of each medication order is important to assess potential duplication in therapy, contraindications, unsafe dosing, allergies, and other medication-related concerns before a drug is removed from stock and administered. Well-designed cabinet configurations primarily employ individual locked or lidded pockets and drawers or other segregated storage options for medications, particularly high-alert medications, to prevent selection errors. Machine-readable (barcode) scanning is often available to verify the drug and dose in the pharmacy prior to distribution, upon ADC stocking, and at the bedside prior to administration. Label printers have been added to the current generation of ADCs to support safe practices after medication removal.

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Why ISMP Best Practice #10 (sterile water) is so important

We recently learned about a harmful medication error involving inadvertent intravenous (IV) infusion of sterile water for inhalation. As part of the process for in vitro fertilization, a young woman with no prior medical history went to an outpatient surgery center for egg retrieval. The procedure went well, and about an hour later, the medical team decided to administer one more liter of IV fluids prior to discharge. When the nurse went to hang the second liter of IV fluids, she noticed that the first liter administered was sterile water for inhalation. The entire liter of sterile water had infused, and unfortunately, the young woman developed hemolysis and eventually became anuric. She presently requires daily dialysis, and according to the person who reported the event, it is still unclear whether the woman will recover any renal function in the future.

It is notable that bags of sterile water for inhalation at the facility were kept on the same shelf as bags of IV normal saline, lactated ringer's solution, and other common IV fluids. Sterile water was used at this surgery center during cystoscopy procedures

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SAFETY briefs

HIGH-ALERT

Dosing card contributes to error. A stroke patient received the incorrect dose of **ACTIVASE** (alteplase) after a practitioner utilized the alteplase dosing card supplied by Genentech. The card expresses the weight in both pounds (lb) and kilograms (kg), side by side in a dosing window, as you

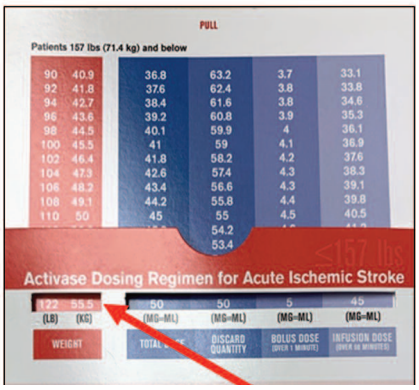

Figure 1. Patient weighing 122 kg received a dose appropriate for a 122 lb person.

slide the card up or down. "(LB)" and "(KG)" are both printed just beneath the window, so if one isn't careful, the proper unit of mass may be missed (**Figure 1**). In this case, the patient weighed 122 kg but the nurse administered a dose based on a weight of 122 lb. The patient received 50 mg, rather than the correct dose of 90 mg. Using the same dosing card, 3 nurses verified the dose prior to administration, all missing the error. Fortunately, the patient's stroke symptoms resolved and additional alteplase was unnecessary. This event took place in an inpatient area, but 2 emergency department (ED) pharmacists at the same hospital also experienced close call events.

In a 2017 ISMP survey that looked at compliance with our *Targeted Medication Safety Best Practices for Hospitals*, 47% stated they had fully implemented Best Practice #3—to measure and document patient weights in metric units only—while, 44% had at least partially implemented the practice. At the hospital where the error

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We are now far more comfortable with the ability of ADCs to support the safety of the medication distribution system while allowing required drugs to be readily accessible in a variety of patient care areas. Nonetheless, ISMP continues to hear about limitations, unsafe practices, and pitfalls associated with ADC use, which can place patients in serious jeopardy. We have recently described some of these ongoing safety limitations, such as overutilization of open matrix drawer configurations, particularly for high-alert medications and controlled substances, and the ability to search for a drug in the ADC using only the first three (or less) letters of its name, which has sometimes led to fatal selection errors (e.g., entering "VE" for Versed and choosing vecuronium instead; www.ismp.org/node/1326). Our focus today is on three unsafe scenarios: overuse of overrides, removal of a drug from an ADC without an order, and removal of an ordered drug from a non-profiled ADC. Healthcare practitioners have used the term "override" loosely when referring to these circumstances, perhaps because each involves the removal of a medication from an ADC without a pharmacist's review of the order.

Overuse of Overrides

In our recently updated **Guidelines for the Safe Use of Automated Dispensing Cabinets** (www.ismp.org/node/1372), ISMP defines "override" as a process of bypassing the pharmacist's review of a medication order to obtain a medication from the ADC when assessment of the patient indicates that a delay in therapy would harm the patient. With this definition is a clear understanding that an order for the medication exists; that assessment of the patient indicates that a delay in therapy may be harmful; and that the drug is removed from the ADC before the order has been reviewed by a pharmacist.

One of the biggest challenges to the safe use of ADCs is the ease with which medications can be removed from the cabinets upon override—many times unnecessarily and with a lack of perceived risk associated with this process. Practitioners often view the override process as routine, rather than a risky step. They may fail to recognize that use of ADC overrides should be situation dependent and justifiable, and not based merely on an approved list of medications available on override. While organizations must identify the drugs with the potential to be obtained emergently, along with examples of situations that might require these drugs to be removed before a pharmacist's review, there will be many circumstances when there is enough time for the pharmacist to review even emergent medication orders prior to retrieving the drug from the ADC.

Another safety concern involves the process that should be in place for pharmacists and nurse managers to retrospectively review medications removed from an ADC via override. Too often, this review process is inadequate or absent; when it does happen, little can be learned from the menu-driven "reason" for the override, or important findings never reach nursing leadership with oversight of nursing practice at the ADC.

Removal of a Drug Without an Order

Sometimes, practitioners will obtain a medication from the ADC **WITHOUT** a specific verbal, telephone, written, or electronic order. Often, this is incorrectly referred to as an ADC "override;" however, all true "overrides" begin with an order and end with a decision to not wait for a pharmacist to review the order before obtaining the medication from the ADC.

In rare circumstances, a lifesaving medication must be removed from the ADC without a corresponding order due to a true emergency; even then, a protocol for rescuing a patient that requires a specific medication, an antidote, or reversal agent should serve as an order. However, most of the cases brought to our attention involved medications for which an order might be *anticipated*—fenta**NYL** and bupivacaine

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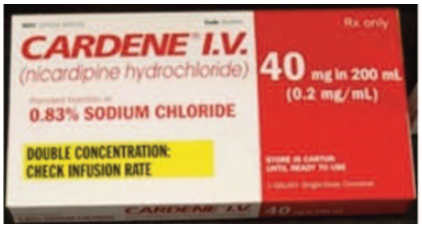
happened, the policy is to obtain metric weights only. Alteplase labeling also expresses dosing using the metric system. With that in mind, one must ask why the dosing card includes pounds? In fact, it might improve safety to block out the "LB" column on the slide with black tape to avoid potential mix-ups. Incidentally, given that 3 nurses missed the error while checking the dose, we hope the hospital will also examine its independent double-check process.

Amiodarone and niCARdipine mix-ups.

HIGH-ALERT

A hospital reported three errors involving Baxter's intravenous (IV) premixed bags of **CARDENE I.V.** (ni**CAR**dipine) 40 mg/200 mL, used for short-term treatment of acute hypertension, and **NEXTERONE** (amiodarone) 360 mg/200 mL, used for certain types of ventricular arrhythmias. Similar carton coloring (**Figure 1**), IV bag size, and bag appearance were contributing factors in each error. These two bags of IV medications were the only ones on the hospital's formulary that were packaged in cartons (to protect the medications from light). One incident was a close call, but the others reached patients, causing harm in one case.

In the first case, the medications were stored in the intensive care unit (ICU) automated dispensing cabinet (ADC), on shelves above one another in an open matrix configuration. The patient was supposed to receive amiodarone, but the nurse removed a ni**CAR**dipine carton from the ADC. The error was quickly intercepted when the nurse scanned the product at the bedside.



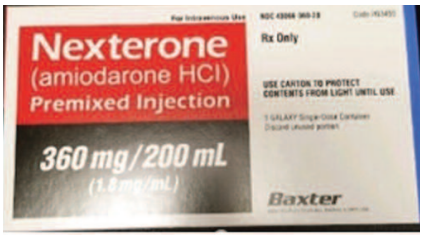


Figure 1. Cartons of Cardene I.V. (ni**CAR**dipine) and Nexterone (amiodarone) have been involved in several mix-ups reported to ISMP.

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for epidural analgesia in labor and delivery units; moderate sedation medications in endoscopy units; antibiotics in the emergency department (ED); premedication in ambulatory surgical units; and many others. Often done with the best intentions in anticipation of a specific order, removal of a drug from an ADC without an order is rarely perceived by practitioners as dangerous. Yet, not only has a pharmacist not reviewed the safety and appropriateness of the medication for the patient, but the prescriber has not yet ordered the medication. Furthermore, practitioners may fail to recognize that this action likely falls outside of their scope of practice.

Removal of an Ordered Drug from a Non-Profiled ADC

The use of an ADC in a profiled mode is an important safety feature as it attempts to direct practitioners to a patient-specific medication profile and limit access to medications that have been reviewed and verified by a pharmacist as appropriate for the patient. Use of a non-profiled ADC (which is not recommended), allows practitioner access to all medications contained within the cabinet, typically bypassing the pharmacist's review of the order prior to medication selection. Non-profiled ADCs are often located in diagnostic units, ambulatory care units, the ED, and surgical care units. In healthcare facilities without round-the-clock pharmacy services, sometimes profiled ADCs in both inpatient and ambulatory units are switched to a non-profiled mode once a pharmacist is no longer available.

Removing a medication from a non-profiled ADC may also be referred to as an "override;" however, keep in mind that a pharmacist may never even be notified about the medication order let alone have a chance to review the order, even retrospectively.

Safe Practice Recommendations: Now that ADCs have become a primary model for drug distribution in many healthcare facilities, and progress has been made with ADC technology and workflow processes, it is a good time to look at the issue of overrides, removal of drugs from an ADC without an order, and use of non-profiled cabinets again. Consider the following recommendations:

- Optimize the use of ADCs in a profiled mode that allows medication selection after orders have been reviewed and verified by a pharmacist. Use the profiled mode in both inpatient and outpatient areas (e.g., ED, preoperative care areas, post anesthesia care unit, procedural and ambulatory locations).
- Require a medication order (e.g., electronic, written, telephone, or verbal) prior to removing any medication from an ADC, including those available on override.
- Establish a policy that limits ADC overrides to the following situations:
  - ☐ When a licensed independent practitioner controls the ordering, preparation, and administration of the medication
  - ☐ When medications are required in emergent circumstances **AND** waiting for a pharmacist to review the order could adversely impact the patient's condition (e.g., antidotes, rescue agents, reversal agents; lifesaving medications; urgent comfort care measures to treat pain, intractable nausea and vomiting)
- Implement strategies that reduce the risk of an error when an override must be used (e.g., avoid stocking multi-dose containers; limit drug quantities available via override; require assessment of patient history, allergies, weight; provide a prompt for documentation of a witness when removing certain organization-identified medications via override from a profiled cabinet).
- Require documentation of override rationale. If menu-driven choices are available, ensure they will provide adequate information about the reason/circumstances for the override. Do not offer an option of "No order."

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In the second case, ni**CAR**dipine was found to be infusing in a patient who was supposed to be receiving amiodarone after transfer from a perioperative area. No patient harm was noted. In the third event, a physician gave a verbal order for an emergency bolus dose of amiodarone from a currently infusing bag of the drug. The nurse realized that there was not enough volume in the infusing amiodarone bag, so she rushed to the ADC to retrieve what she thought was a replacement bag of amiodarone. She was unable to scan the barcode at the bedside because the physician was using the computer. After administering a bolus dose from the new infusion bag, the patient became hypotensive and hemodynamically unstable. The infusion continued for a few hours until the oncoming nurse discovered that a bag of ni**CAR**dipine had been infusing.

Currently, the medications in these strengths are not available from alternate suppliers. The hospital where the events occurred have segregated these products into different supply zones in the ADCs throughout the hospital. The importance of barcode scanning *prior* to drug administration, even during urgent situations, cannot be understated. Integration between smart infusion pumps and electronic health records is another way to prevent errors like these. ISMP also recommends avoidance of open matrix ADC configurations when possible, which may allow access to more than the intended drug. ISMP has previously received reports about mix-ups with these products and has contacted Baxter and the US Food and Drug Administration (FDA) for resolution.

OTC drug containers may lack a barcode. A pharmacist reported that the over-the-counter (OTC) oxymetazoline hydrochloride decongestant spray, 0.05%, that his hospital purchased, lacked a barcode and could not be scanned at the bedside (**Figure 1**, page 4). Instead, nurses had to scan the barcode on the product's carton, which is usually discarded after opening. The hospital purchased another brand of oxymetazoline and discovered no barcode on that bottle.

The US Food and Drug Administration (FDA) barcode rule requires certain human drug and biological product labels to have a barcode on the immediate container with, at a minimum, the National Drug Code (NDC)

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- Review and approve all medications for which overrides are permitted, clinical locations where they can be removed via override, practitioner types who can remove medications via override, and associated policies, through the Pharmacy and Therapeutics (P&T) Committee or equivalent interdisciplinary group. Ensure the list of medications that *can* be removed via override includes clear instructions about the need for patient assessment to first determine if the situation *requires* immediate removal of the drug, before a pharmacist has reviewed the order. Review the list of medications available by override at least annually.

- At least annually, review the drugs available in non-profiled ADCs to ensure they are routinely required in the setting and in the quantities needed. Keep in mind that all medications in a non-profiled ADC are accessible to practitioners without pharmacy oversight.

- Use an interdisciplinary group to routinely analyze override reports to identify if an order was obtained prior to removing the medication and whether the rationale for each overridden medication was appropriate. Trend override reports by medication, user, and area, and address barriers to the pharmacist's review of the medication order prior to drug removal. Discuss the results regularly with leaders and all disciplines with ADC access.

- For facilities **WITHOUT** around-the-clock pharmacy services, consider utilizing remote pharmacy services to support the use of profiled ADCs and facilitate order review before removal of medications. If remote pharmacy services are not feasible, consider allowing full access to all medications in ADCs to a single (or several) practitioner in the facility (e.g., nursing supervisor), rather than converting all profiled ADCs to non-profiled ADCs when the pharmacy is closed.

- For all practitioners who access ADCs, discuss these safety issues as a means of increasing their perception of the risk associated with overrides, removal of a drug without an order, and the use of non-profiled ADCs. Be clear about what constitutes an appropriate override, and how the use of override functionality strips away a layer of safety for their patients. Also remind frontline nurses that removing a drug from an ADC without an order is risky, and in some cases, has resulted in action against a practitioner's license.

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to fill the bladder, making it possible to then use special lenses to examine the lining of the bladder.

One of ISMP's *Targeted Medication Safety Best Practices for Hospitals* (#10) (www.ismp.org/node/160) calls for the elimination of 1,000 mL bags of sterile water of any type (injection, irrigation, or inhalation) from all areas outside of the pharmacy. We recommend using alternative size and/or shape containers of the product, such as 2,000 mL (2 liter) bags of sterile water for injection, irrigation, or inhalation (although there have been intermittent shortages); bottles of sterile water for irrigation; or vials of sterile water for injection. These containers vary greatly in appearance from 1,000 mL bags of common IV fluids and are much less likely to be confused as an IV solution than a 1,000 mL bag of sterile water.

Additional strategies to prevent errors include establishing a policy that 1,000 mL bags of sterile water can only be ordered by a pharmacy purchaser for pharmacy compounding purposes, and not stocking these 1,000 mL containers of sterile water in clinical locations. If sterile water (irrigation, inhalation) must be available in a clinical location, it should be purchased whenever possible in pour bottles or other plastic containers that are distinctly different in appearance from IV fluids that come in flexible plastic bags. Pharmacists should work with surgery center/operating room staff to establish guidelines regarding the safest way to provide large volumes of sterile water when needed for patient care.

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(21 CFR 201.25) (www.ismp.org/ext/266). However, the rule exempts manufacturers from having to print a barcode on the immediate container in certain situations, including with over-the-counter (OTC) drugs. The rule notes that a barcode is only required on the immediate container of OTC drugs that are "dispensed pursuant to an order and are commonly used in hospitals" or packaged or labeled for hospital use. Since "commonly used in hospitals" is open to interpretation, manufacturers of OTC drugs used in hospitals may not comply with printing a barcode on the immediate container.

We have contacted FDA and Major Pharmaceuticals about the situation. Since almost any OTC drug may be used in a hospital, we urge all drug manufacturers to comply with the rule even if not required to do so. Incidentally, the clear plastic overwrap that states, "SEALED FOR SAFETY" (**Figure 1**), isn't safe because it makes it difficult to read the product label.

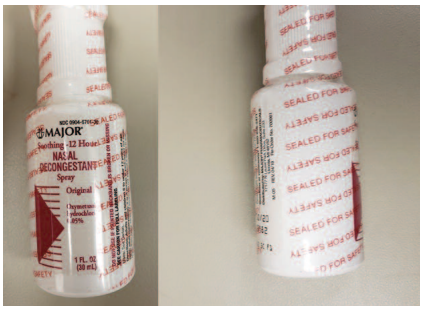

Figure 1. OTC products often lack a barcode on the immediate container label, as shown here with oxymetazoline nasal spray.

Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit our website at: www.ismp.org/MERP or www.ismp.org/VERP. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

Join ISMP on Tuesday evening, **December 10, 2019**, at 6:00 p.m. for the 22nd Annual **CHEERS AWARDS** at **Stoney's Rockin' Country** in Las Vegas. The gala will celebrate a group of health-care leaders who have gone all in to develop best practices and programs that prevent medication errors and protect patients.

Please Attend the Awards Dinner and/or Make a Donation to Support ISMP's Efforts

You can help honor this year's **CHEERS AWARD** winners as well as recognize **ISMP's 25th anniversary** by making a donation and/or attending the awards dinner. Your participation helps bring attention to safety advances and enables ISMP to continue the core of its lifesaving work—preventing medication errors. To make a donation and/or register for the dinner, please visit: www.ismp.org/node/938.

Keynote Speaker:
Marcus Schabacker, MD, PhD

President and Chief Executive Officer, ECRI Institute, Plymouth Meeting, PA

Lifetime Achievement Award Winner:
Rita Shane, PharmD, FASHP, FCSHP

Chief Pharmacy Officer and Professor of Medicine, Cedars-Sinai Medical Center, Los Angeles, CA

ISMP Activities at the 2019 ASHP Midyear Meeting in Las Vegas

Workshop *(preregistration required - please call 215-947-7797)*

Friday, December 6 & Saturday, December 7
Medication Safety Intensive
Maggiano's Little Italy
Fashion Show Mall, 3200 Las Vegas Blvd., Las Vegas, NV
To register, go to: www.ismp.org/node/1239

Symposia *(all at Mandalay Bay North Convention Center)*

Tuesday, December 10
Justifying Your Return on Investment with Integrated Medication Use Technology
11:30 a.m. – 1:00 p.m., Doors open at 10:45 a.m.
Room: Islander Ballroom G, Lower Level
To register, go to: www.ismp.org/node/12306

Wednesday, December 11
Transforming Smart Infusion Pump Safety: Paving the Way with the New ISMP Guidelines
11:30 a.m. – 1:00 p.m., Doors open at 10:45 a.m.
Room: South Pacific J, Lower Level
To register, go to: www.ismp.org/node/12610

Educational Sessions with ISMP Speakers

(all at Mandalay Bay South Convention Center)

Sunday, December 8
Small but Mighty: Improving Safety with High-Alert Medications
2:30 p.m. – 3:30 p.m.
Room: Oceanside B, Level 2

Tuesday, December 10
The Safety of Intravenous Drug Delivery Systems: Update on Issues Since the 2009 Consensus Development Conference
2:00 p.m. – 3:30 p.m.
Room: Lagoon F, Level 2

Managing the Crisis You Didn't Prevent: Leadership and Medication Safety
4:00 p.m. – 5:15 p.m.
Room: South Seas J, Level 3

Wednesday, December 11
ISMP Medication Safety Update for 2020
8:00 a.m. – 9:30 a.m.
Room: Oceanside B, Level 2

ISMP

For more information: www.ismp.org or call 215-947-7797
Visit ISMP at Exhibit Booth # 667