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ISMP

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

EPINEPHrine for anaphylaxis: Autoinjector or 1 mg vial or ampul?

Anaphylaxis is a medical emergency that requires immediate treatment with **EPINEPH**rine injection. These episodes are becoming more common both inside and outside of the hospital due to increases in food allergies and the use of contrast media, chemotherapy, monoclonal antibodies, and biosimilars. **EPINEPH**rine is available in autoinjector pen devices, ampuls, and vials; but which is preferable when treating a life-threatening condition?

EPINEPHrine autoinjectors

For anaphylactic reactions that occur in community settings, **EPINEPH**rine autoinjectors can be prescribed to provide patients and families with a ready source of the drug. Those at risk should carry an autoinjector and be properly trained to use it. Autoinjectors can also be found in outpatient healthcare provider settings such as office practices, clinics, and ambulatory surgical centers, as well as in hospitals emergency departments or other clinical areas in unit stock or automated dispensing cabinets (ADCs).

An intramuscular (IM) dose of 0.2 to 0.5 mg of **EPINEPH**rine is recommended for anaphylaxis in adults, but no comparative trials have been conducted to determine

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Are you ready to treat anaphylaxis?

Can you say for sure that healthcare professionals in your organization are always prepared to treat an anaphylactic reaction? A 51-year-old man died after he was not properly monitored or treated for an anaphylactic reaction that occurred when administering a dose of **INFED** (iron dextran injection) to the patient. While the INFeD package insert states that **EPINEPH**rine should be immediately available in the event of an acute hypersensitivity reaction, the **EPINEPH**rine was not near the bedside. The patient's nurse called a rapid response team but did not believe she was permitted to obtain **EPINEPH**rine from a nearby crash cart and administer it before the team arrived because it would require a physician's order. Waiting for a specific order risks the patient's life during a severe anaphylactic reaction.

Please review your policies, procedures, and/or protocols for treating anaphylaxis. When the risk of anaphylaxis is high, be sure **EPINEPH**rine is immediately available. Make sure that all clinicians are aware of the proper use of **EPINEPH**rine autoinjectors or kits. Be explicit in a medical staff-approved protocol about the conditions under which qualified professionals, including nurses, may administer a lifesaving IM or subcutaneous dose of **EPINEPH**rine without waiting for a specific order. In the absence of a protocol or order, as in the case above, a qualified clinician might still decide to administer a dose of **EPINEPH**rine using an available single-dose autoinjector, considering administration without an order is the lesser of two evils if the patient's life is hanging in the balance. Healthcare leaders should not put staff in a position where such a decision might be necessary—be sure you are ready to treat anaphylaxis! Please refer to **Best Practice 9** in the ***2016-2017 Targeted Medication Safety Best Practices*** listed in the right column for more information, or go to: www.ismp.org/sc?id=1645.

ISMP launches 2016-2017 Best Practices for Hospitals

ISMP has officially launched the ***2016-2017 Targeted Medication Safety Best Practices for Hospitals*** to identify, inspire, and mobilize widespread adoption of consensus-based best practices related to specific error-causing conditions that continue to harm patients or cause death. This is a follow up to the 2014-2015 document, which was used by hospitals nationwide as part of their patient safety improvement efforts.

The targeted best practices are realistic strategies upon which hospitals can focus their medication safety efforts over the next 2 years. The best practices have been reviewed by an external expert advisory committee, and each is accompanied by a rationale for its adoption. Related issues of ISMP's acute care newsletters are referenced in the web document to offer additional background information.

The ***2016-2017 Targeted Medication Safety Best Practices for Hospitals*** include 5 new strategies, numbered 7 through 11, which have been added to the 6 previous best practices for 2014-2015. The new strategies include:

Best Practice 7: Segregate, sequester, and differentiate all neuromuscular blocking agents from other medications, wherever they are stored in the organization.

Best Practice 8: Administer high-alert intravenous medication infusions via a programmable infusion pump utilizing dose error-reduction software.

Best Practice 9: Ensure all appropriate antidotes, reversal agents, and rescue agents are readily available along with directions for use and administration. Have standard-

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which dose is most clinically effective. Autoinjectors of 0.3 mg are available for adult use, and repeat doses are recommended at 5 to 15 minute intervals until symptoms improve. The autoinjectors are available in packages that contain 2 injectors in case a second dose is needed in outpatient settings before treatment is available from emergency medical personnel. For infants and children, a 0.15 mg **EPINEPH**rine autoinjector is available. The recommended dose for infants and children is 0.01 mg/kg; thus, the 0.15 mg autoinjector delivers a dose higher than recommended for children weighing less than 15 kg.

Errors with EPINEPHrine autoinjectors

There are several brands of autoinjectors available in the US, but they are not interchangeable with respect to training or the way they are used. Given that anaphylaxis may not occur very often at any one location, remembering how to use different devices is difficult. Patients often forget how to use them within 3 months,[1] and many healthcare professionals have never been trained to use them at all.

EPIPEN is the most commonly used device, although it has been plagued by occasional misuse when people hold it upside down, press, and accidentally inject their thumb, or when a child gains access to the device. Both situations have been reported to ISMP, most recently a thumb injection by a nurse. **AUVI-Q** is another brand of autoinjector, which may be easier to use than the EpiPen since it provides digital voice instructions, but the device was recently withdrawn from the market because of potential inaccurate dosing or failure to deliver the drug. Amedra Pharmaceuticals markets an autoinjector, **ADRENACLICK**, and Lineage Therapeutics markets a generic autoinjector, which costs about 20% less than the other brand products. However, these devices may be more difficult to use. Last year ISMP informed Lineage Therapeutics that its pen device lacks a barcode, which the company promised to address.

Needle length and cost of EPINEPHrine autoinjectors

There are other potential drawbacks that have blocked full implementation of autoinjectors in clinical areas. For one, although giving **EPINEPH**rine by the IM route is most effective, there is no consensus about available autoinjector needle length. Clinicians may worry that the relatively short needle length (16.5 mm) on pen devices might not ensure that the drug reaches into the muscle when injected into the lateral thigh, especially in women.[2] On the other hand, autoinjectors have proved effective in treating anaphylaxis, and there is at least some evidence that the pressure exerted during the forceful injection is adequate enough to drive **EPINEPH**rine past the depth of the needle into the muscle.[3,4]

Although we believe that safety trumps cost, it's hard not to notice that the cost of an autoinjector has doubled in the past 3 years and is currently about $400-$500 for a 2-pack of the branded autoinjectors and about $200 for the generic. This is unfortunate because it may impact a patient's accessibility to autoinjectors. Insurance generally covers the partial cost of autoinjectors for consumers, but the associated copay may be high.[5]

For health systems that use autoinjectors and store them in numerous locations throughout their organization, hundreds of thousands of dollars may be needed annually to stock these devices, which can significantly affect the budget. **EPINEPH**rine autoinjectors have a shelf life of only 12-18 months. If the product is not monitored and rotated, it may not be used prior to expiration, thus requiring wastage and replacement. For this reason, some hospitals provide patient care units with 1 mg vials or ampuls of **EPINEPH**rine, which costs less than $5. Even with the addition of a syringe, alcohol wipe, needle, and so on, to make a ready-to-use anaphylaxis kit, the savings can still be significant.

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ized protocols and/or coupled order sets in place that permit their emergency administration when appropriate.

Best Practice 10: Eliminate the storage and use of all 1,000 mL bags of sterile water (labeled for "injection," "irrigation," or "inhalation") from all areas outside the pharmacy.

Best Practice 11: When compounding sterile preparations, perform an independent verification to ensure that the proper ingredients (medications and diluents) are added, including confirmation of the proper amount (volume) of each ingredient prior to its addition to the final container.

The best practices are fully described at: www.ismp.org/sc?id=1645. ISMP encourages hospitals that have not implemented the ***2014-2015 Targeted Medication Safety Best Practices for Hospitals*** (Best Practices 1 through 6) to do so as a priority, while implementing the new 2016-2017 best practices. Two of the ***2014-2015 Targeted Medication Safety Best Practices for Hospitals*** (Best Practices 2 and 3) have been revised for 2016-2017. The rationale for these revisions is included in the web document.

In February, we plan to hold a **webinar** to discuss the best practices in more detail. Information regarding registration will be available at: www.ismp.org/sc?id=349.

SAFETY wire

Could this happen at your hospital?

A used oxymetazoline nasal spray was inadvertently placed back in storage with unused oxymetazoline nasal sprays. The used product was almost administered to another patient. The error was identified when the patient's physician opened the cap and saw blood residue on the tip of the bottle. It appears that the used spray had been initially opened by twisting off the cap but leaving the tamper-resistant seal in place, then recapping it after use (**Figure 1**, on page 3). It was then inadvertently restocked in the medication room by a nurse or pharmacy technician who thought the product was unopened.

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Errors with EPINEPHrine 1 mg ampuls or vials

In the fall of 2014, the National Comprehensive Cancer Network (NCCN) sent a letter to member hospitals, calling for the use of **EPINEPH**rine autoinjectors in an effort to prevent wrong dose and wrong route errors when ampuls or vials are used to treat severe allergic reactions or anaphylaxis. The concern with 1 mg ampuls or vials of **EPINEPH**rine is that the contents must be drawn into a syringe, risking dosing errors or misadministration by the intravenous [IV] route instead of IM route. During a stressful emergency situation, clinicians have occasionally administered a full vial or ampul (1 mg dose) IV, which could prove harmful to some patients. In a review of more than 600 cases reported to the Pennsylvania Patient Safety Reporting System, wrong route errors involving IV administration instead of IM or subcutaneous injection were responsible for 25.4% of all **EPINEPH**rine adverse events and 63.3% of the harmful events.[6]

Autoinjector or 1 mg vial or ampul?

Deciding to stock patient care units with autoinjectors or 1 mg vials or ampuls of **EPINEPH**rine remains a tough choice. Some hospitals have decided that autoinjector manufacturers have priced themselves out of the market, making it difficult to allow use in all areas of the hospital. Instead, they have prepared anaphylaxis kits containing a 1 mg **EPINEPH**rine vial or ampul along with a syringe, needle, label with proper dose for IM injection, a warning not to administer the entire vial, and any other essential components. Still, we agree with NCCN that the presence of a vial or ampul of **EPINEPH**rine in the wrong hands invites accidental IV injection when the patient has an IV line established. So, an **EPINEPH**rine autoinjector is appealing as a properly labeled unit dose that can be employed within seconds to treat the emergency, and the contents cannot be administered IV.

To us, an autoinjector certainly makes sense in outpatient clinics and office practices. Examples would include outpatient areas where chemotherapy or contrast media is administered. If more than one ADC is available in these outpatient areas, the autoinjectors could be stocked in only one of them, with visual aids available on the others to guide staff to the correct ADC when it is needed. If you choose to use an autoinjector, staff training as well as periodic retraining about proper use of the autoinjector is still a requirement.

See the **Sidebar**: **Are you ready for anaphylaxis?** on the bottom of page 1 for further comments about administering **EPINEPH**rine during emergencies.

References

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To *The* Point

"Our lives begin to end the day we become silent about things that matter."

---Martin Luther King, Jr

> **SAFETY** wire continued from page 2

There is only about a millimeter of tamper-resistant seal that covers the space between the cap and the bottle. Once opened, the entire seal should be removed. In this case, most of the seal was



Figure 1. Part of the safety seal was removed, but it mostly remains intact on the cap.

allowed to remain. The pharmacy, at this hospital, is currently applying additional tamper-resistant stickers on top of the manufacturer's seal to easily distinguish opened nasal spray bottles from unopened bottles, similar to special seals that are often placed on IV container ports to distinguish used from unused products.

The hospital's medication error committee believes this incident and future incidents could be prevented by improving the product's tamper-resistant seal and how it is placed on containers during the packaging process, so the hospital sent a letter to Major Pharmaceuticals, the product manufacturer. ISMP has received similar reports involving ointments and other products where blood-borne pathogens might be transmitted because a used container was mistaken as an unopened container.

We would appreciate hearing about additional suggestions you might have to avoid potentially dangerous accidental product reuse. In the meantime, remind staff to completely remove the entire safety seal when the product is used, and to suspect a potential problem if the seal is very loose fitting over the cap, which may happen if only the bottom portion

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Mix-ups among "V" drugs

Confirmation bias likely played a role in a pharmacy admixture error in which **VFEND** (voriconazole) 200 mg diluted in 0.9% sodium chloride was prescribed but **VENOFER** (iron sucrose) 200 mg diluted in 0.9% sodium chloride was prepared and dispensed. Earlier in the day, an experienced pharmacy technician had correctly prepared a Venofer 200 mg dose for another patient, and a pharmacist had checked it prior to dispensing. Later in the day, the same technician picked up a newly printed label to begin preparing the next IV admixture. The label stated "voriconazole (VFEND) 200 mg in sodium chloride 0.9%," but the technician misread the label as Venofer 200 mg in sodium chloride 0.9%. She quickly noticed the letters common to both brand names—V, F, N, and E—and the 200 mg dose, and her mind immediately thought of the admixture, Venofer, which she had prepared earlier in the day.

Believing she had the correct product in mind, normal human cognition caused her to stick to her initial assumption (called an *anchoring heuristic*) and to avoid pursuing alternative thoughts on what the label said (called *premature closure*). Once confirmation bias kicked in, the brain rejected any disconfirming evidence that would have alerted her to the error.

Similarly, the pharmacist checking the product suffered from confirmation bias. He immediately saw the brown-tinted solution in the bag and thought of the Venofer infusion he had checked earlier in the day. Thus, when reading the label, he too saw Venofer, not Vfend, 200 mg. People have a tendency to judge the likelihood of properly identifying products by how easily the idea sprang to mind (called *availability heuristic*). In this case, the brown-tinted solution quickly sealed the pharmacist's belief that the label said Venofer, not Vfend. Multitasking was another factor that contributed to confirmation bias. In this case, the pharmacist was trying to cover two very busy areas in the pharmacy during a staff lunch break.

This patient was critically ill, and omission of the antifungal medication could have been serious. Also, administration of unintended iron could have resulted in a hypersensitivity reaction. Fortunately, an astute nurse questioned why the antifungal medication was brown. She called the pharmacist to confirm that the right product was prepared. It was then the error was detected before the wrong medication was administered to the patient. Pharmacy prepared and dispensed the correct antifungal medication (Vfend) to treat the patient's infection.

Pharmacy errors made when preparing infusions may be impossible for nurses to detect if the label lists the correct medication and base solution, as in this case. Thus, raising questions when the appearance of a medication looks different than expected is a key error-detection strategy for nurses. Pharmacists are human and will make occasional mistakes. So remember, don't ever hesitate to speak up if something looks or feels amiss.

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has been removed. We would also like to know what kinds of checks are made when products are returned to unit stock or the pharmacy. Please email us at: ismpinfo@ismp.org.

Special Announcements

ISMP webinar

Please join us for our first webinar in 2016, ***Measuring Risk with Medications In Your Organization: Using the Right Data to Identify Risk***, on **January 27**. Medications are the most common interventions used to treat medical conditions, and adverse drug events can result in injury leading to patient harm. While we have a goal to prevent patient harm and to have reliable processes, how do we know we are being successful? This webinar will introduce a variety of methods available to measure medication safety within your organization. For more information and to register, please visit: www.ismp.org/sc?id=349.

CE credit now available

One hour of **free Nursing CE** credit covering the July – December 2015 issues of **Nurse AdviseERR** is available. Go to www.ismp.org/nursingce.

Kudos to nurses!

Nurses have again earned top honors in the annual Gallup poll on honesty and ethical standards when compared to other professions. Nurses ranked highest (85%) among the healthcare professions included in the poll—17 points higher than pharmacists, and 18 points higher than physicians (www.gallup.com/poll/187874/americans-faith-honesty-ethics-police-rebounds.aspx).

If you would like to subscribe to this newsletter, visit: www.ismp.org/sc?id=384

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Safe Medication Management Fellowships

ISMP is now accepting applications for two unique Fellowship programs

ISMP Safe Medication Management Fellowship

Location and Term: The 12-month Fellowship commences summer 2016 at the Pennsylvania (near Philadelphia) office of ISMP. Relocation to the Philadelphia area is required.

Description: The Fellowship **offers a nurse, pharmacist, or physician with at least 1 year of postgraduate clinical experience** an unparalleled opportunity to learn from and work with some of the nation's experts in medication safety. Now in its 24th year, the Fellowship allows the candidate to work collaboratively with practitioners in various healthcare settings to assess and develop interdisciplinary medication error-prevention strategies.

FDA/ISMP Safe Medication Management Fellowship

Location and Term: The 12-month Fellowship commences summer 2016. The Fellow will spend 6 months at the Pennsylvania (near Philadelphia) office of ISMP and 6 months at the Maryland (near Washington, DC) office of the US Food and Drug Administration (FDA). Relocation to the Philadelphia and Washington, DC, area is required.

Description: The Fellowship, **open to a healthcare professional with at least 1 year of postgraduate clinical experience**, is a joint effort between ISMP and FDA's Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, and Division of Medication Error Prevention and Analysis. The Fellowship allows the candidate to benefit from ISMP's years of experience devoted to medication error prevention. At FDA, valuable regulatory experience is gained by working with the division focused on medication error prevention.

A competitive stipend, paid vacation, and health benefits are provided with all Fellowship programs.

How to Apply

Information and applications can be found at: www.ismp.org/profdevelopment/.
Applications can also be requested by calling 215-947-7797.

Speak to ISMP's Current Fellows

Please join us on **February 10, 2016**, at **2:00 p.m.** ET for a special, live conference call about the Fellowship programs. Current and past Fellows will describe their Fellowship experiences as well as their post-Fellowship careers. They will also be available to answer any questions you may have about the Fellowship. To attend, please send an email to: fellowship@ismp.org.

The application deadline for all Fellowship Programs is March 31, 2016.