





ISMP Medication SafetyAlert!®

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SafetyBriefs

 **Updated: ISMP's List of High-Alert Medications.** Based on a 2007 practitioner survey and review by ISMP and other medication safety experts, *ISMP's List of High-Alert Medications* has been updated (see page 4). Additions to the list include: epoprostenol (Flolan) IV, oxytocin IV, promethazine IV, and sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more. Warfarin, heparin, low-molecular-weight heparin, thrombolytics, and glycoprotein IIb/IIIa inhibitors were moved to a new category, *antithrombotic agents*, to which Factor Xa inhibitors and direct thrombin inhibitors were added. Amiodarone and lidocaine were also moved to a new category, *anti-arrhythmics IV*. Nesiritide was removed from the list due to a significant decline in use.

 **Scanning inconsistencies.** **BYETTA** (exenatide) is the first in a class of new antidiabetic drugs called incretin mimetics. The medication is available in a pen injector and is used mostly in outpatient settings to improve glucose control in adults with type 2 diabetes. Exenatide enhances glucose-dependent insulin secretion, increases B-cell growth/replication, slows gastric emptying, and may decrease food intake. Byetta is supplied as a sterile solution for subcutaneous injection containing 250 mcg/mL



The two Byetta pens deliver different doses.

of exenatide in a 5 mcg per dose, 60 dose, 1.2 mL prefilled pen (NDC 66780-210-07), and in a 10 mcg per dose, 60 dose, 2.4 mL prefilled pen (NDC 66780-210-08). The 5 mcg pen delivers 0.02 mL per activation, and the 10 mcg pen delivers twice that amount. One problem reported with this pen is related to the products' NDC numbers, which differ only by the last digit. The last two digits may not be read by some bar-code scanners used during the dispensing process in

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Progress with preventing name confusion errors

The August 9, 2007, issue of the *New England Journal of Medicine* contains a book review of *Medication Errors*, a 2007 American Pharmacists Association publication written by ISMP staff and invited experts, and the 2006 Institute of Medicine (IOM) report, *Preventing Medication Errors*. The reviewer wrote: "...filling a handwritten prescription could be the most dangerous of all medical procedures."



It's a timely message, as ISMP knows well that handwritten prescriptions combined with look-alike drug names are among the most risky conditions associated with medication use. Running closely behind is the combination of verbal orders and sound-alike drug names. In Pennsylvania, one in ten medication errors submitted to the state's reporting program is associated with providing the wrong drug to a patient; of those, one in three is due to confusion between medications with similar names.¹ The same findings have been reported for errors submitted to the United States Pharmacopoeia (USP)-ISMP Medication Errors Reporting Program.² With thousands of medications—most with both generic and brand names—on the market in the United States (US), it is easy to understand why mix-ups occur. The challenge to create new drug names that are not similar to existing drug names is great. Factor in handwritten orders—unfortunately still the norm in healthcare—and suddenly, the ability to differentiate between similar drug names poses an enormous challenge to the healthcare practitioner.

Managing the risks associated with name similarity is an industry wide obligation. It begins with the regulatory agencies and pharmaceutical companies when generic and/or brand names are selected, and spans the entire healthcare continuum, from practitioners to consumers. Below we offer a brief glimpse at what is being done in the

US to reduce the risk of look- and sound-alike drug names, along with additional steps that regulatory agencies, pharmaceutical companies, healthcare organizations, practitioners, and consumers should take to continue our efforts.

Regulatory agencies and pharmaceutical companies

Current efforts

When a newly marketed product turns out to have a name that is confused with an existing drug with a similar name, it may be tempting to believe that FDA and pharmaceutical companies are not doing enough to prevent drug name mix-ups. But, in recent years, there has been an increasing effort on the part of FDA and manufacturers to select and approve drug names that have been evaluated for safety. For instance, most major pharmaceutical companies currently use external safety testing companies to evaluate risks associated with potential trademarks (brand names) before launching new drugs. Unfortunately, many of the smaller pharmaceutical and biotech companies, and generic manufacturers and distributors have not yet adopted this practice. Occasionally, some of the larger companies that have had their trademarks evaluated do not follow the recommendations of a safety evaluation, downplaying the potential risk of an error and patient harm. Still, FDA evaluates all drug names presented for approval using an internal advisory committee and a computer software program known as POCA (phonetic and orthographic computer analysis).


Following a 2003 public meeting on drug name similarities jointly sponsored by FDA, ISMP, and the Pharmaceutical Research and Manufacturers of America (PhRMA), the industry drafted *Good Naming Practices*. This effort, which has not yet been formally presented to FDA for endorsement, represents an industry commitment to drug name safety, and promising results are expected. PhRMA

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SafetyBriefs continued from page 1 some facilities, particularly community pharmacy settings. Additionally, most outpatient pharmacists use the middle segment of the NDC number to verify a prescription. As a result, the wrong size pen has been dispensed, mostly in outpatient settings where the risk of a patient injecting an incorrect dose is high. We've notified the manufacturer to request a distinctly different NDC number for each size pen. Meanwhile, pharmacists in outpatient settings should manually double-check these products to safeguard against dispensing the wrong pen.

Another problem with Byetta.

A nurse reported that she accidentally gave the entire contents of a Byetta syringe to a patient; this resulted in a 60-fold overdose. The nurse saw the prescribed dose of 5 mcg on the pen's label. However, there are no directions on the pen itself after the outer carton is discarded, and the nurse had missed the concentration designation and total volume listed in fine print. She'd never used Byetta and was unsure how to activate it, so she withdrew the entire contents (1.2 mL) from the pen's drug cartridge and administered that amount to the patient. According to the drug's labeling, patients who've experienced 10-fold overdoses have developed severe nausea and vomiting, rapidly declining blood glucose concentrations, and hypoglycemia that may require glucose administration. When the patient exhibited these symptoms, appropriate treatment was initiated, and the patient recovered. The wide variety of pen injector designs and activating mechanisms make it difficult for practitioners, particularly nurses, to learn how to use them properly and maintain competence. Nurses should receive adequate training, including hands-on use of a sample pen device, before they are expected to administer a drug using the device. Clinical and diabetic educators may be excellent resources for developing pen device-related training materials that can be quickly referenced when needed.

 **Favorable review.** Today's *New England Journal of Medicine* carries a very favorable review of the ISMP book, *Medication Errors* (2nd edition. 680 pp., illustrated. Washington, DC, American Pharmacists Association, 2007). The review notes that the book picks up where the 2006 Institute of Medicine (IOM) report, *Preventing Medication Errors*, leaves off, providing detailed information

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Drug names cont'd from page 1 has also funded a current project headed by ISMP to catalog all drug name suffixes and associated meanings, which will be widely available as a reference for health-care practitioners and consumers.

Additional steps for regulatory agencies and pharmaceutical companies

■ FDA should require all pharmaceutical companies to use an external, unbiased source for evaluating new trademarks, which includes input from practitioners who work in the areas where the drug will most likely be prescribed, stored, dispensed, and administered. The drug name evaluation report should be provided to FDA when the company requests trademark approval.

■ Companies should consistently accept the findings from external name evaluation companies to avoid potentially harmful mix-ups. Likewise, FDA authorities that grant final market approval to a new drug should give serious consideration to the recommendations from external name evaluation companies as well as the FDA's own internal advisory committee.

■ FDA, USP, and the United States Adopted Names (USAN) Council should work with PhRMA and other stakeholders to develop a standard evaluation method for nonproprietary names, to be employed at a specified point in their development.

■ FDA approval should be required for all new trademarks for drugs, including trademarks used for over-the-counter (OTC) products. (A loophole in the Code of Federal Regulations allows companies to market some designated products without FDA approval of the product names.)

■ The USP should provide a basis for some level of standardization of drug-name suffixes and associated drug release rates.

■ FDA should require companies to develop a risk management program that includes a name change provision for newer trademarks if post-marketing surveillance (including error reports) shows harmful or potentially harmful confusion with an existing brand or generic name.

■ The USAN Council should remain open to changing the generic name of a product if post-marketing surveillance (including error reports) shows harmful or potentially harmful confusion with another generic drug name.

Organizations, practitioners, and consumers

Current efforts

The Joint Commission's National Patient Safety Goal (NPSG) 3(c) requires accredited organizations to identify a list of look- and sound-alike drugs and to take action to prevent mix-ups among these drugs. While the latest Joint Commission statistics for this goal cite a 92% compliance rate, data from error-reporting programs indicate that drug name mix-ups are still common, even in accredited facilities. This may indicate that practitioners and organizations are not implementing the most effective risk-reduction strategies. One observer recently expressed concern that many organizations seem to simply rely on warning stickers to reduce the risk of mix-ups, when more effective measures are available and needed.

Healthcare providers without Joint Commission accreditation, such as community pharmacies, may not be familiar with risk-reduction strategies related to look- and sound-alike drug names. Additionally, managing risks associated with look- and sound-alike drug names proved to be a low-scoring category in both the 2000 and 2004 *ISMP Medication Safety Self Assessment for Hospitals*. Similar results were found with an ISMP community pharmacy self-assessment tool.


Additional steps for organizations, practitioners, and patients


■ Maintain awareness of look- and sound-alike drug names as published by safety agencies, and provide updated information to professional staff regularly.

■ Identify a discrete list of look- and sound-alike drug names that may be problematic in your organization. A list of potentially harmful, problematic name pairs specific to different healthcare settings can be found at: www.jointcommission.org/NR/rdonlyres/C92AAB3F-A9BD-431C-8628-11DD2D1D53CC/0/LASA.pdf. ISMP *Quarterly Action Agendas*, internal error reports, and staff brainstorming sessions may also yield examples of similar drug name pairs that should be targeted for action. Ensure that

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SafetyBriefs continued from page 2 that is useful for clinicians and clinical pharmacists. The review also notes that the IOM report and ISMP book are thorough, well-written, authoritative, fact filled, visionary, and that they provide the most up-to-date and broadest coverage of the subject currently available.

 **ISMP errata.** The July 26, 2007, edition of the newsletter incorrectly stated that "amrinone," a nonproprietary drug that was renamed inamrinone (**INOCOR**), is an antiarrhythmic, and amiodarone (**CORDARONE**) is an inotrope. The opposite is correct: amrinone is an inotrope and amiodarone is an antiarrhythmic. We apologize for the error, which occurred during the final editing process.

 **Unintended consequences of CPOE.** A recently published article (Ash JS, Sitting DF, Poon EG, et al. The extent and importance of unintended consequences related to computerized provider order entry. *J Am Med Inform Assoc* 2007;14(4):415-23) described the results of a study on the unintended consequences of computerized provider order entry (CPOE) systems. A telephone survey was used to gather information from 176 US hospitals with CPOE about eight types of unintended consequences. The following consequences were ranked as most severe: new work/more work involving physician data entry; changes in workflow; "never ending" system demands on information technology staff for maintenance, upgrades, and more sophisticated functionality; reduced personal communication among CPOE users; overdependence on technology; and the need for good back-up systems to manage extensive downtime. Fast order entry and improved prescribing efficiency were among the most desirable consequences, along with fewer calls to physicians for order clarifications, and the ability for prescribers to access patient information from a remote site. Best practices to promote adoption of the technology were also identified, including providing one-on-one training sessions for physicians and ongoing support; tailoring order sets to physician preferences; customizing discharge instruction sheets; and grouping data entry elements by topic (e.g., care of ventilated patients). The study also found that unintended consequences—be they positive, negative, or both—continued to exist over the duration of use, and that aggressive detection and management of adverse consequences are vital for success. For details, visit: www.ismp.org/sc?k=ahrqCPOE.

Drug names cont'd from page 2 clinicians are aware of the name pairs targeted for action and the steps that should be taken to reduce confusion.

- The Joint Commission should further specify in its NPSG 3(c) how organizations should choose targeted name pairs, update the list, and monitor the medication-use process to determine if their risk-reduction efforts are successful.

- Prescribers should specify the dosage form, drug strength, complete directions, and purpose of medications on prescriptions and orders to help differentiate drugs with look-alike names. Pharmacists and nurses should match the drug's indication to the patient's condition before dispensing or administering it.

- Implement electronic prescribing to reduce the risk of mix-ups stemming from handwritten orders. When warranted for a particularly problematic drug name pair, install a computerized alert as a reminder during prescription processing.

- Use preprinted orders or prescriptions if electronic prescribing is not available.

- Use verbal or telephone orders only when absolutely necessary and never for chemotherapy. If used, verbal or telephone orders should be documented on the patient's record and read back, spelling the drug name and stating its indication.

- Use both brand and generic names when prescribing drug name pairs known to be similar. Also, list brand and generic names for problematic name pairs on medication administration records (MARs) and automated dispensing cabinet (ADC) computer screens.

- Change the appearance of look-alike product names on computer screens, storage areas (including ADCs), pharmacy product labels, and MARs using bold face, color, or tall man letters for the parts of the names that are different (e.g., hydrOXYzine, hydrALAZine). Configure all computer screens to prevent look-alike drug name pairs from appearing consecutively.

- Store products with look-alike names in different locations. Use shelf stickers to help locate products that have been moved.

- Alert patients to the potential for mix-ups with known, problematic drug names.

- Encourage patients to question nurses or pharmacists about medications that look or sound different than expected.

- Require mandatory counseling in outpatient settings before dispensing one of the drugs from a problematic name pair.

- Explore and implement drug-specific risk-reduction strategies for problematic name pairs. For example, stock a different strength of morphine (2 mg/mL) and hydromorphone (1 mg/mL) to reduce the risk of confusion. (Visit the URL in the first bulleted item in this section for more examples.)

- Consider the risk of name confusion when adding a new drug to the formulary.

- Encourage reporting of actual and potential errors with look- and sound-alike product names, and use the information to establish error-reduction strategies.

To further national efforts to manage drug name confusion, ISMP will be hosting an invitational summit on October 9-10, 2007, in Philadelphia. This meeting will bring together a full range of pharmacy professionals and representatives from standard-setting organizations, regulatory agencies, the pharmaceutical industry, and the payer community. During the meeting, ISMP will discuss post-marketing strategies to identify and reduce name confusion and ways to improve upon their scope and effectiveness. ISMP believes that the healthcare industry can significantly reduce the risk to patients from otherwise preventable product mix-ups due to look- and sound-alike names.

References: 1) Pennsylvania Patient Safety Authority. Medication errors linked to drug name confusion. *Patient Safety Advisory* 2004; 1(4):1-3. 2) Smetzer JL, Cohen MR. Medication error reporting systems. In Cohen MR, ed. *Medication Errors*, 2nd ed. 2007; Washington, DC: American Pharmacists Association.

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ISMP's List of *High-Alert Medications*

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies like improving access to information about

these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; standardizing the ordering, storage, preparation, and administration of these products; and employing redundancies such as automated or independent double-checks when necessary. (Note: manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list).

Classes/ Categories of Medications
adrenergic agonists, IV (e.g., epinephrine, phenylephrine, norepinephrine)
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)
antiarrhythmics, IV (e.g., lidocaine, amiodarone)
antithrombotic agents (anticoagulants), including warfarin, low-molecular-weight heparin, IV unfractionated heparin, Factor Xa inhibitors (fondaparinux), direct thrombin inhibitors (e.g., argatroban, lepirudin, bivalirudin), thrombolytics (e.g., alteplase, reteplase, tenecteplase), and glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)
cardioplegic solutions
chemotherapeutic agents, parenteral and oral
dextrose, hypertonic, 20% or greater
dialysis solutions, peritoneal and hemodialysis
epidural or intrathecal medications
hypoglycemics, oral
inotropic medications, IV (e.g., digoxin, milrinone)
liposomal forms of drugs (e.g., liposomal amphotericin B)
moderate sedation agents, IV (e.g., midazolam)
moderate sedation agents, oral, for children (e.g., chloral hydrate)
narcotics/opiates, IV, transdermal, and oral (including liquid concentrates, immediate and sustained-release formulations)
neuromuscular blocking agents (e.g., succinylcholine, rocuronium, vecuronium)
radiocontrast agents, IV
total parenteral nutrition solutions

Specific Medications
colchicine injection
epoprostenol (Flolan), IV
insulin, subcutaneous and IV
magnesium sulfate injection
methotrexate, oral, non-oncologic use
oxytocin, IV
nitroprusside sodium for injection
potassium chloride for injection concentrate
potassium phosphates injection
promethazine, IV
sodium chloride for injection, hypertonic (greater than 0.9% concentration)
sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more

Background

Based on error reports submitted to the USP-ISMP Medication Errors Reporting Program, reports of harmful errors in the literature, and input from practitioners and safety experts, ISMP created and periodically updates a list of potential high-alert medications. During February-April 2007, 770 practitioners responded to an ISMP survey designed to identify which of these medications were most frequently considered high-alert drugs by individuals and organizations. Further, to assure relevance and completeness, the clinical staff at ISMP, members of our advisory board, and safety experts throughout the US were asked to review the potential list. This list of drugs and drug categories reflects the collective thinking of all who provided input.

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