ISMP Update

November 8, 2017

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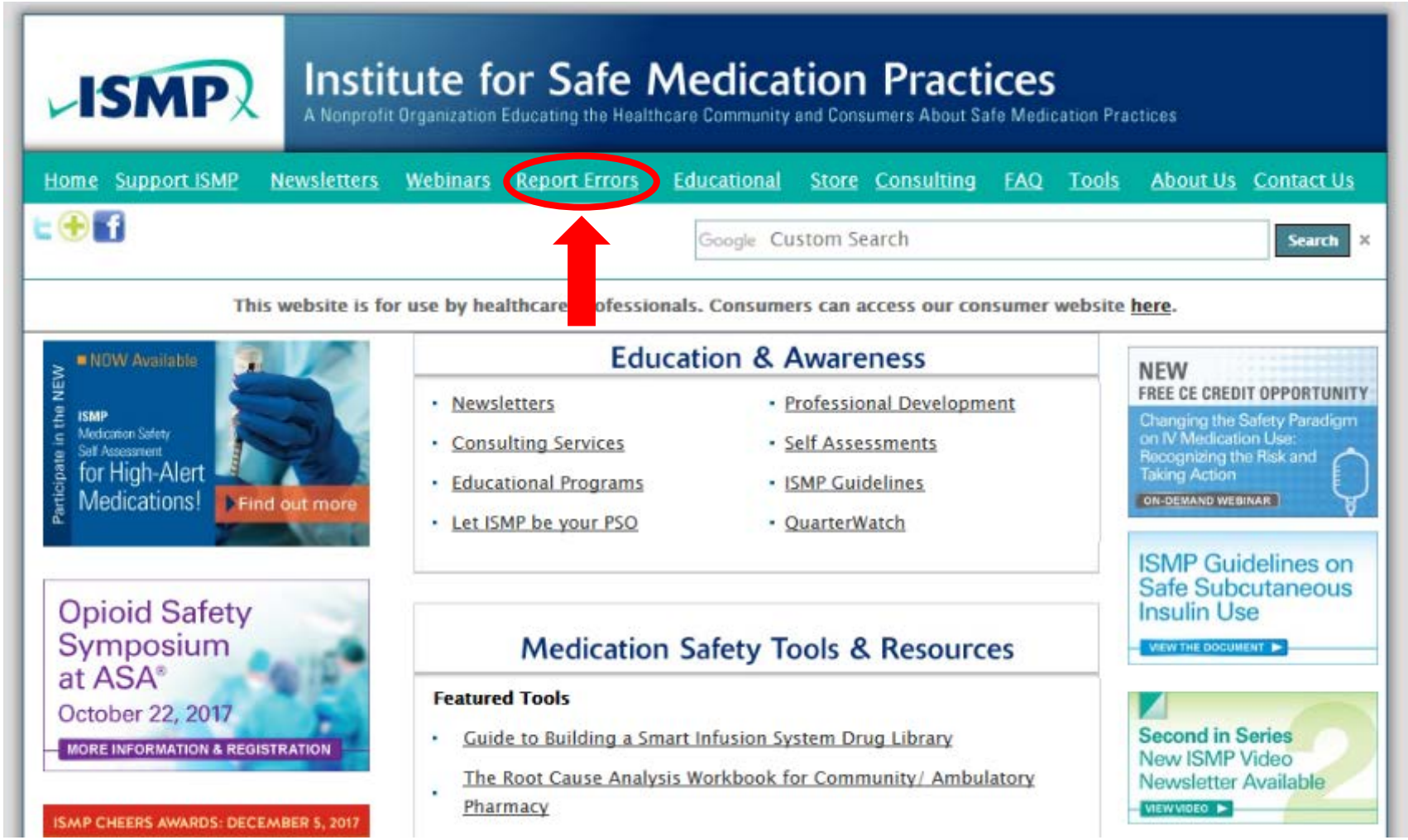
ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

ISMP National Medication Errors Reporting Program

Medication Error Reporting Program
Vaccine Error Reporting Program
Consumer Error Reporting Program

ISMP National Medication Errors Reporting Program (MERP)



National Medication Error Reporting System


ISMP

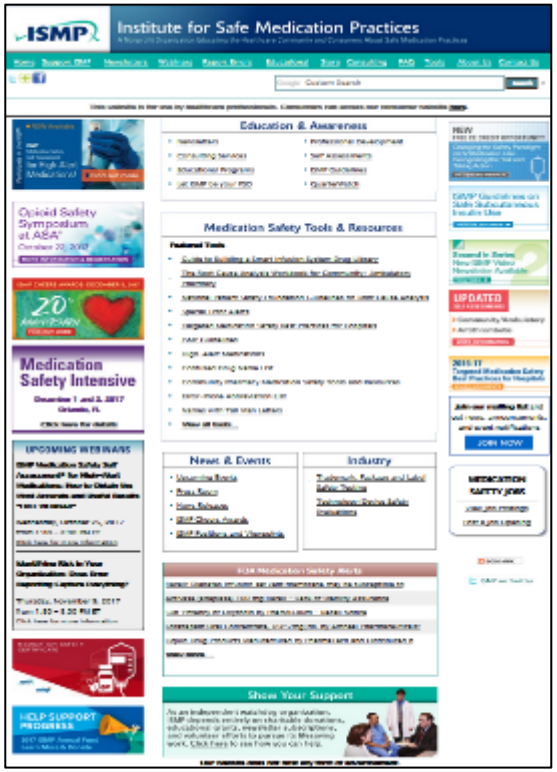
Acute Care

ISMP Medication Safety Alert!

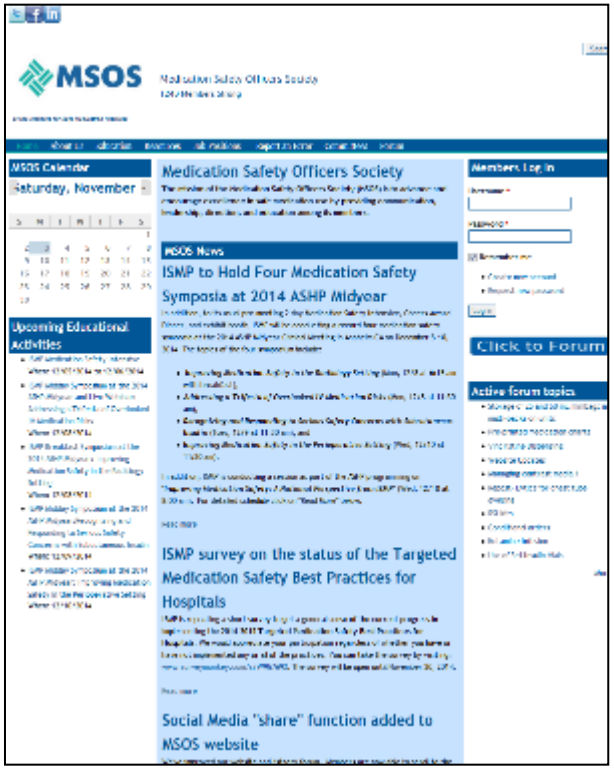
SAFETY briefs

- Issue nationwide hazard alerts and press releases
- Dissemination of information and tools
- Product nomenclature, labeling, and packaging changes, device design, practice issues
- Advocates for national standards and guidelines

ISMP Websites



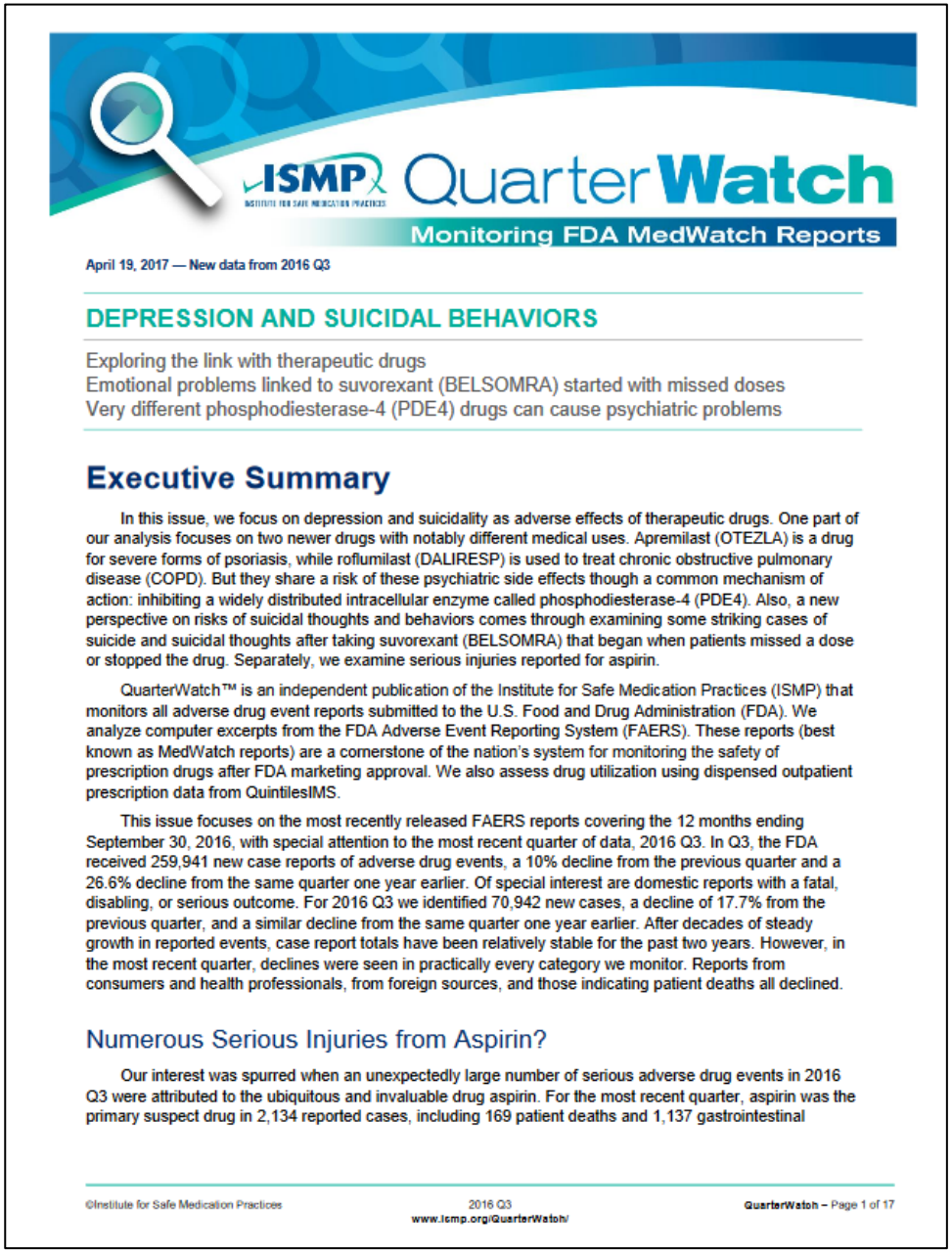
www.ismp.org



www.medsafetyofficer.org

www.consumermedsafety.org

ISMP Newsletters



ISMP QuarterWatch
Monitoring FDA MedWatch Reports

April 19, 2017 — New data from 2016 Q3

DEPRESSION AND SUICIDAL BEHAVIORS

Exploring the link with therapeutic drugs
Emotional problems linked to suvorexant (BELSOMRA) started with missed doses
Very different phosphodiesterase-4 (PDE4) drugs can cause psychiatric problems

Executive Summary

In this issue, we focus on depression and suicidality as adverse effects of therapeutic drugs. One part of our analysis focuses on two newer drugs with notably different medical uses. Apremilast (OTEZLA) is a drug for severe forms of psoriasis, while roflumilast (DALIRESP) is used to treat chronic obstructive pulmonary disease (COPD). But they share a risk of these psychiatric side effects though a common mechanism of action: inhibiting a widely distributed intracellular enzyme called phosphodiesterase-4 (PDE4). Also, a new perspective on risks of suicidal thoughts and behaviors comes through examining some striking cases of suicide and suicidal thoughts after taking suvorexant (BELSOMRA) that began when patients missed a dose or stopped the drug. Separately, we examine serious injuries reported for aspirin.

QuarterWatch™ is an independent publication of the Institute for Safe Medication Practices (ISMP) that monitors all adverse drug event reports submitted to the U.S. Food and Drug Administration (FDA). We analyze computer excerpts from the FDA Adverse Event Reporting System (FAERS). These reports (best known as MedWatch reports) are a cornerstone of the nation's system for monitoring the safety of prescription drugs after FDA marketing approval. We also assess drug utilization using dispensed outpatient prescription data from QuintilesIMS.

This issue focuses on the most recently released FAERS reports covering the 12 months ending September 30, 2016, with special attention to the most recent quarter of data, 2016 Q3. In Q3, the FDA received 259,941 new case reports of adverse drug events, a 10% decline from the previous quarter and a 26.6% decline from the same quarter one year earlier. Of special interest are domestic reports with a fatal, disabling, or serious outcome. For 2016 Q3 we identified 70,942 new cases, a decline of 17.7% from the previous quarter, and a similar decline from the same quarter one year earlier. After decades of steady growth in reported events, case report totals have been relatively stable for the past two years. However, in the most recent quarter, declines were seen in practically every category we monitor. Reports from consumers and health professionals, from foreign sources, and those indicating patient deaths all declined.

Numerous Serious Injuries from Aspirin?

Our interest was spurred when an unexpectedly large number of serious adverse drug events in 2016 Q3 were attributed to the ubiquitous and invaluable drug aspirin. For the most recent quarter, aspirin was the primary suspect drug in 2,134 reported cases, including 169 patient deaths and 1,137 gastrointestinal

https://www.ismp.org/quarterwatch/

NATIONAL ALERT NETWORK (NAN)

This alert is based on information from the National Medication Errors Reporting Program operated by the Institute for Safe Medication Practices.

NAN ALERT

September 15, 2016

Observe for possible fluid leakage when preparing parenteral syringes

The Institute for Safe Medication Practices (ISMP) has heard from three hospitals about occasional instances of medication leaking from syringes. Leaks have extended past the first and second rib on the black stopper on the parenteral syringe plunger rod into the surface of the syringe barrel that is exposed to air (**Figure 1**). The situation appears to occur as liquid is drawn into the syringe rather than after the syringe has been filled. In some cases, personnel said that it has happened rarely, and they may not have realized the situation was out of the ordinary, so instances may have gone unreported.

The reported syringes have been manufactured by BD, and both the company and the US Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) are aware of the situation. We are not certain if this issue may also involve syringes from other manufacturers. While syringes in the reported cases have been of varying sizes, BD reports that the syringes involved in its review have predominantly been the 10 mL size. There is a corrective action project underway to address the issue with the 10 mL syringes.

Figure 1. Medication or solutions drawn into this syringe have leaked below the black plunger (circled in red), which may pose a problem with sterility and safe handling of hazardous drugs.

In assessments BD has made, the company found that leakage into the area between the first and second ribs of the stopper retains the sterility of the fluid and in most instances has no impact on the volumetric accuracy of the delivery of the medication.

Proper user technique when preparing syringes can be helpful in preventing this situation, especially with larger syringe sizes (e.g., 30 mL and 60 mL). As a syringe is being filled with the vial inverted and the syringe below the vial, there may be a tendency to pull the plunger rod at an angle toward the user and not always maintain a vertical alignment with the syringe barrel. With an increased amount of fluid in the syringe, the ribs of the stopper may be angled enough to cause leakage past the stopper ribs. BD says that it is always important to ensure vertical alignment of the plunger rod with the syringe barrel when withdrawing a solution using this inverted vial technique.

ISMP recommends sharing this information with sterile syringe production personnel and clinical personnel who prepare medications in parenteral syringes. Ask them to always observe prepared syringes for this situation. If leakage is observed beyond the first and second ribs of the stopper and into the area exposed to air, the syringe and medication may have been contaminated and should not be used. Additional precautions to avoid contaminating work surfaces and exposing personnel are required if leaking syringes contain hazardous drugs.

If a leaking syringe is identified, the syringe lot number should be identified and recorded, and such instances should be reported to the FDA MedWatch Program (www.ismp.org/sc?id=1660), the ISMP National Medication Errors Reporting Program (MERP) (www.ismp.org/MERP), and the syringe manufacturer.

The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP), distributes NAN Alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCC MERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication use system.

https://www.ismp.org/NAN/default.asp

NATIONAL ALERT NETWORK (NAN)

NAN ALERT 1

October 9, 2017

This alert is based on information from the National Medication Errors Reporting Program operated by the Institute for Safe Medication Practices.

Severe hyperglycemia in patients incorrectly using insulin pens at home

The Institute for Safe Medication Practices (ISMP) National Medication Errors Reporting Program (MERP) has received several reports of patients who failed to remove the inner cover of a standard insulin pen needle prior to attempting to administer the insulin. The latest event resulted in a fatality. A recently hospitalized patient with type 1 diabetes did not know to remove the standard needle cap from the insulin pen needle prior to administration. He was unaware that he was using the pen incorrectly and, thus, had not been receiving any of the insulin doses. The patient developed diabetic ketoacidosis and later died.

To protect staff from needlestick injuries and guard against the reuse of needles, many hospitals use insulin pen needles that automatically re-cover and lock the pen needle once injection has been completed and the needle has been withdrawn from the skin. Such products include **NOVOFINE AUTOCOVER** (Novo Nordisk) and **BD AUTOSHIELD DUO**. These safety needles are also recommended for some patients with manual dexterity limitations or if a caregiver is administering the injection to a patient.

Safety Pen Needle

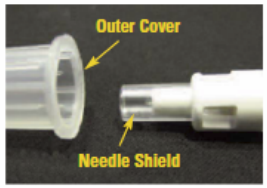


Figure 1. NovoFine Autocover is an example of insulin pen needle with a needle shield that automatically retracts upon injection and re-covers and locks over the needle when withdrawn from the skin. (BD AutoShield Duo, not pictured here, is another example of a safety needle used with pens.)

Standard Pen Needle

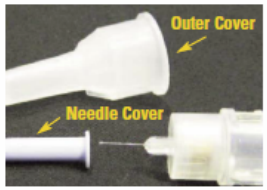


Figure 2. BD Ultra-fine III is an example of a standard pen needle. Both the outer cover and inner needle cover must be removed prior to injection.

With the NovoFine Autocover (**Figure 1**) safety needle, for example, the user holds the outer cover of the needle while it is attached to the insulin pen and then removes it, exposing a plastic needle shield that covers the needle. During administration, as the device is held against the skin and pressure is applied, the needle shield slides back to allow the skin to be punctured and the insulin to be injected once the button is pressed. As the needle is removed from the skin after administration, the shield slides back over the needle. The needle is hidden throughout the process so the patient will never see it.

The Autocover safety needle system is different from standard insulin pen needles widely used by patients in the home, which do not employ an automatic needle shield. These standard needles are available from brand and generic manufacturers. Because standard pen needles and those with an automatic needle shield look similar, patients may not be aware of the differences in preparation for administration. Both the automatic safety needle and standard needle systems have a larger outer protective cover that, when removed, exposes either a retractable needle shield (**Figure 1**) or a plain inner needle cap (**Figure 2**). The automatic safety needle shield is not

continued on page 2—NAN>

Quarterly Action Agendas

- 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.
- The ISMP Quarterly Action Agenda is prepared for leadership to use with an interdisciplinary committee or with frontline staff to stimulate discussion and action to reduce the risk of medication errors.
- http://www.ismp.org/Newsletters/acutecare/actionagendas.aspx

April - June 2017

ISMP Quarterly Action Agenda

ISMP 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 2017 issues of the *ISMP Medication Safety Alert!* have been prepared for leadership to use with an interdisciplinary committee or with frontline staff to stimulate discussion and action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue number to locate additional information. 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* (www.ismp.org/sc?id=479). The Action Agenda is also available for download in a Microsoft Word format (www.ismp.org/sc?id=2965) that allows expansion of the columns in the table designated for organizational documentation of an assessment, actions required, and assignments for each agenda item. Continuing education credit is available for nurses at: www.ismp.org/sc?id=480.

Key: ⚠ — ISMP high-alert medication

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Wholesaler totes may be a source of fungal contamination					
(8, 9) ⚠	Two hospitals reported aerosolized fungal contamination in cleanrooms believed to be caused by contaminated wholesaler totes. In one hospital, *Penicillium* was discovered in both the anteroom and a laminar flow hood. Soon after, practitioners noticed the tote covers from the drug wholesaler had visible mold growing on them. *Cladosporium*, *Aspergillus*, and *Penicillium* species were cultured from the totes. Bringing grossly contaminated totes into a pharmacy increases the risk of contamination in the cleanroom.	Regularly inspect arriving totes and other packaging, and take immediate action if needed, including follow-up with the wholesaler or supplier to resolve the issue. Follow best practices developed by CriticalPoint (www.ismp.org/sc?id=2903) that call for the use of a sporicidal agent when unpacking supplies from corrugated cardboard boxes before bringing them into a cleanroom. (Sterile isopropyl alcohol is ineffective in eradicating these types of microorganisms.)			
Missed heparin-induced thrombocytopenia (HIT) diagnosis from heparin-coated device					
(9) ⚠	During a procedure, a wire and catheter had been dipped several times in a solution containing heparin before insertion to prevent clotting. The patient developed thrombocytopenia 6 days later. A lab test for HIT was positive but ignored because the primary care physician did not know about the undocumented source of heparin. Once home, the patient suffered a thrombosis in his arm, requiring amputation. Hidden and undocumented sources of heparin exposure make a diagnosis of HIT difficult.	Compile a list of drug-eluting stents and commercially available and/or user-applied medication-coated catheters/devices used in the facility. Establish a system to document in the patient's record any exposure to medication-containing devices. Look for hidden sources of medications if symptoms arise in patients suggesting possible HIT, an allergic reaction, or other drug reaction. Discontinue all sources of heparin (including heparin-coated catheters and heparin flushes), and initiate treatment if HIT is suspected or diagnosed.			

Medication Errors:
The Year in Review

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Horsham, Pennsylvania

Preventing medication errors is an essential component of caring for patients and must be a core mission of every pharmacy. For medication error-prevention efforts to be effective, they must be a priority.

An error-reduction program begins by establishing a multidisciplinary team to improve medication use. To be effective, the team must be given reasonable time and resources to assess medication safety and implement systemwide changes that make it difficult or impossible for practitioners to make mistakes that endanger patients. This multidisciplinary team should accept ownership of the medication-use process and enthusiastically embrace the opportunity to improve medication safety.

The goals of the team should include the following:

- Promote a culture of safety to lower medication errors.
- Increase detection and reporting of medication errors and potentially hazardous drug-use situations.
- Explore and understand the root causes of medication errors.

Text continues on page 52

TECHNOLOGY

1 A fully integrated **computerized prescriber order entry (CPOE)** system includes the capability to build medication safety alerts and clinical decision rules. It should directly interface with the laboratory system and pharmacy, list drug-drug and drug-disease interactions, and offer clinical decision support.

2 **Barcode-enabled point-of-care systems** are designed to detect medication errors during medication administration. They verify and record all drugs administered to the patient through the use of a barcode scanner that matches the medication to the patient by scanning a barcode on the medication and the patient's wristband.

3 **"Smart" infusion pump** systems allow users to enter drug infusion protocols into a drug library with predefined dose limits. If a dose is programmed outside of established limits or clinical parameters, the pump halts or sounds an alarm. Some pumps can integrate patient monitoring and other patient parameters.

4 **Automated dispensing cabinets (ADCs)** are robust, point-of-use dispensing systems. ADCs should be integrated with the health care facility's information system and directly interface with the pharmacy system. Additionally, ADCs must be able to use barcoding technology for the restocking process to prevent medication errors.

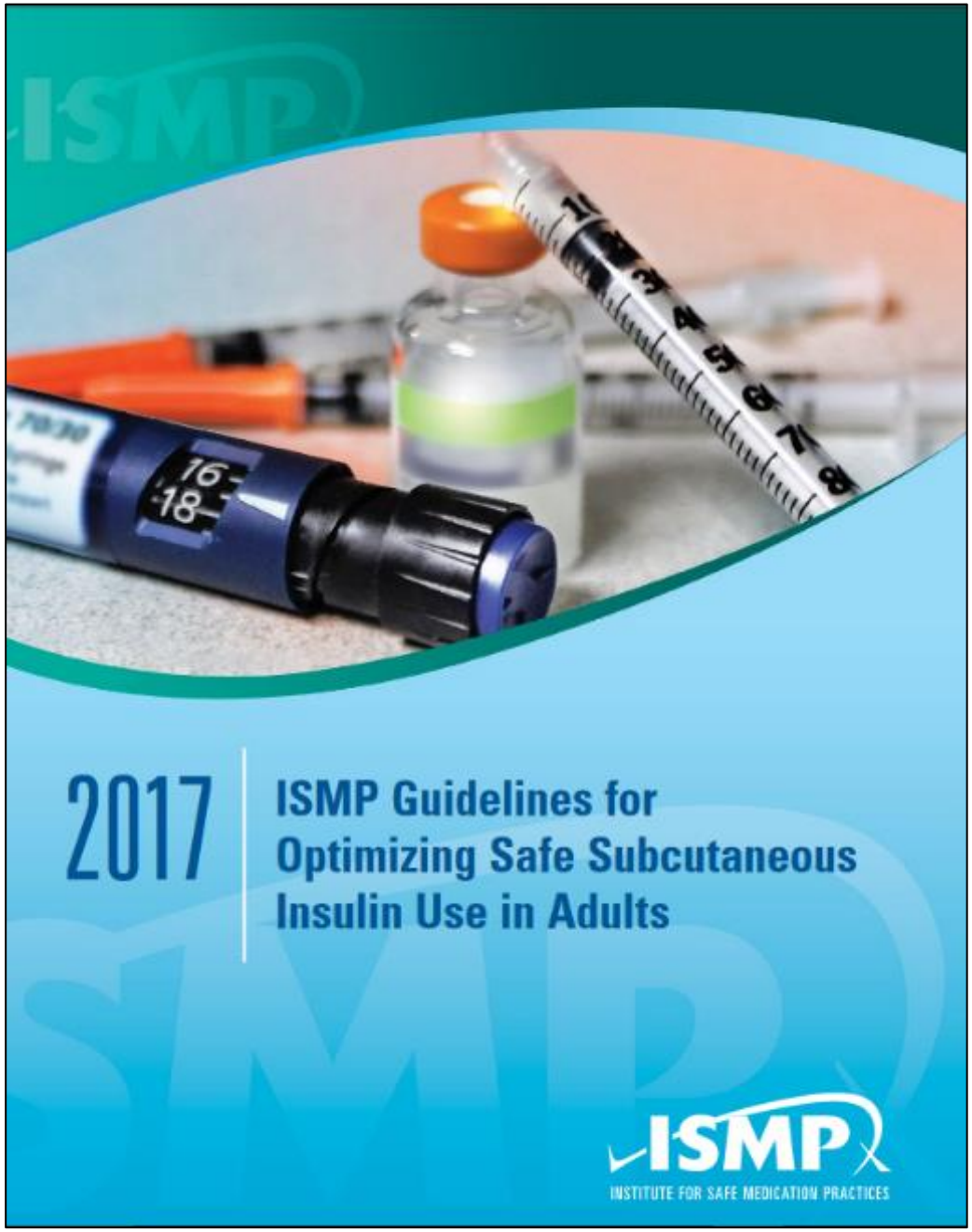
5 A **"robust" pharmacy order entry system** is fully interfaced with a CPOE system and must be able to produce medication safety alerts, directly interface with a health care facility's information systems, and generate a computerized medication administration record to be used by nurses while they administer medications.

6 **IV workflow technology** combines software and automated pharmacy workflow technology when compounding sterile products. It receives dose information from HIT systems and uses robotics, gravimetric analysis, and/or barcode scanning with video technology or digital images. Some can generate drug-specific administration notes and labels for point-of-care scanning by nurses.

http://www.pharmacypracticenews.com/download/MedErrors_ppnse1017_WM.pdf

ISMP Guidelines

- Formal guidance documents with recommendations on improving safe medication use in specific practice areas
  https://www.ismp.org/Tools/guidelines/default.asp
- Recent guidelines:
  - Subcutaneous Insulin (2017)
  - Adult IV Push Medications (2016)
  - IV Sterile Compounding (2016)
  - Building a smart infusion system drug library (2017)
  - Guidance on interdisciplinary safe use of automated dispensing cabinets (*Under revision*)


2017
ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults
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Cover photo taken by ISMP fellow Ghadeer Ranzasser.

ISMP Safe Practice Guidelines for Adult IV Push Medications

A compilation of safe practices from the ISMP Adult IV Push Medication Safety Summit

Prepared by the Institute for Safe Medication Practices (ISMP)

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Smart infusion pumps with drug libraries

Building a Smart Infusion System Drug Library

Introduction

A smart infusion system is designed to minimize programming errors and the related risk of patient harm. Each facility develops a customized infusion system drug library, which includes dosing ranges and other safety limits for individual drugs. During infusion programming the pump checks the entries against the drug library and alerts the clinician when a drug library limit is exceeded, preventing the patient from receiving an incorrectly programmed infusion.

A comprehensive drug library is critical for the effective and safe use of any smart infusion system. The effectiveness of a smart pump system's ability to detect programming errors before an infusion is delivered to a patient is dependent on how well the drug library is built and maintained.

Infusion systems with Electronic Health Record (EHR) system interoperability provide additional programming safety and facilitate clinical documentation.

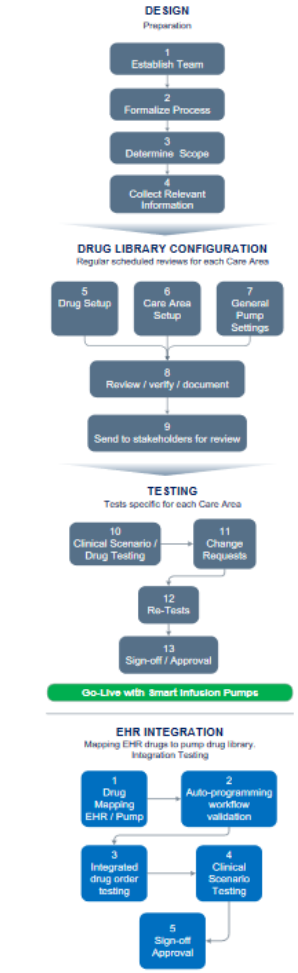
Figure 1 is an overview of the process to build an infusion system drug library, including steps to consider for EHR integration.

Design Phase

Step ONE – Establish the Team

One of the success factors for a well-built drug library is collaboration from all stakeholders.

Figure 1 Phases



http://www.ismp.org/tools/Building-Smart-Infusion-System-Drug-Library.pdf

Institute for Safe Medication Practices

ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations

Original Publication: 2013
Revised: 2016

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Note: *Words within the text of the document presented in all capital letters have a definition in the glossary section at the end of the document.*

Draft Guidelines for the Safe Electronic Communication of Medication Information

Safe presentation of drug nomenclature and dose expressions

1 List all medication-related products by generic name using all lowercase letters (unless using tall man letters as mentioned in item #8) as the primary expression of drug nomenclature, ensuring that each matches US Food and Drug Administration (FDA)-approved nomenclature so that electronic medication records agree with all package labels.

2 Do not include the salt of the chemical when expressing a generic drug name unless there are multiple salts available (e.g., hydr**OXY**zine hydrochloride and hydr**OXY**zine pamoate). If the salt is used as part of the name (e.g., US Pharmacopeial Convention [USP]-approved abbreviations such as K [potassium], Na [sodium], HBr [hydrobromic acid], and HCl [hydrochloric acid]), it should follow the drug name, not precede it.

3 As appropriate, list associated brand names in a requisite field using an uppercase first letter (unless using tall man letters). Although the use of all uppercase letters is a standard convention for trademarks, mixed-case and lowercase letters are more unique and distinguishable than all block-like uppercase letters, which look similar especially in low lighting.[8] Trademark symbols (e.g., TM, ®) should not be used.

4 Express suffixes that are part of the drug name (e.g., SR, CD, CR) within both the generic name field and the brand name field (e.g., diltiazem CD, Cardizem CD).

5 Do not abbreviate drug names (e.g., MTX for methotrexate has been misunderstood as mito**XAN**trone; MSO_4 for morphine sulfate has been misinterpreted as magnesium sulfate).

6 Do not use outdated terminology when referring to medications or solutions (e.g., "heparin lock flush" for saline lock) or medical jargon that may not be as clear as familiar lay terms (e.g., "ophthalmic" and "otic" can be more clearly expressed as "eye" and "ear").

7 Avoid using drug protocol acronyms (e.g., CVP) without defining the protocol (cyclophosphamide, vin**CRIS**tine, predni**SONE**) at least once within the electronic communication.

8 Use tall man bolded letters (e.g., **DOBU**Tamine and **DOP**amine) to help distinguish look-alike products on screens to minimize the risk of selecting the wrong product when medication names appear alphabetically in look-up lists. See www.ismp.org/Tools/tallmanletters.pdf for ***FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters***. Pharmaceutical manufacturers are required to use tall man lettering for drug names on the FDA list.

9 Avoid the use of known error-prone abbreviations, symbols, and dose designations, including those on the ***ISMP List of Error-Prone Abbreviations, Symbols, and Dose Designations*** (www.ismp.org/Tools/errorproneabbreviations.pdf) that may cause confusion in electronic formats. Examples include:

a Do not use trailing zeros when expressing medication/solution doses (e.g., use 5 mg, never 5.0 mg).

b Use leading zeros for doses less than 1 measurement unit (e.g., 0.3 mg, never .3 mg).

c Spell out the word "units." Never use the abbreviation U, which easily can be mistaken as a zero, causing a 10-fold overdose. Never abbreviate international units as IU, which has been confused as IV (intravenous); this measure can be expressed as "units" alone.

d Include properly spaced commas for dose numbers expressed in thousands or millions (e.g., 5,000 units).

e Express weights and measures in a standard fashion and use USP standard abbreviations for dosage units as follows:

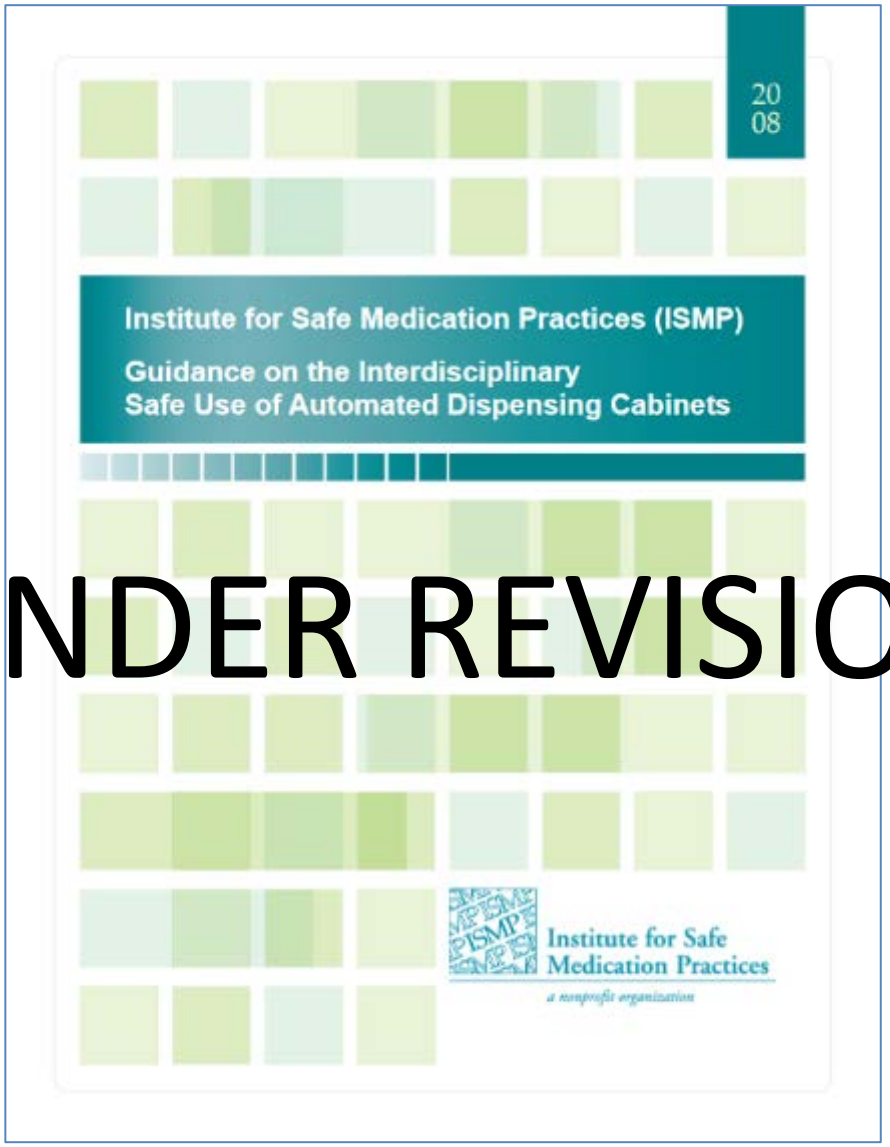
(1) cm = centimeter
(2) m (lowercase) = meter
(3) kg = kilogram
(4) g = gram
(5) mg = milligram
(6) mcg = microgram
(do not use the Greek letter mu [μ], which has been misread as mg)
(7) L (uppercase) = liter
(8) mL (lower-/uppercase) = milliliter
(do not use cc which has been misread as U or the number 4)
(9) mEq = milliequivalent
(10) mmol = millimole

f Do not include a period after dose designation abbreviations (e.g., mg.).

g Do not use apothecary system designations or symbols (e.g., grains, drams, minims), or household measurements (e.g., teaspoon, ounces).

h Do not use IN as an abbreviation for intranasal (may be confused with IV or IM); use "intranasal" or "NAS."

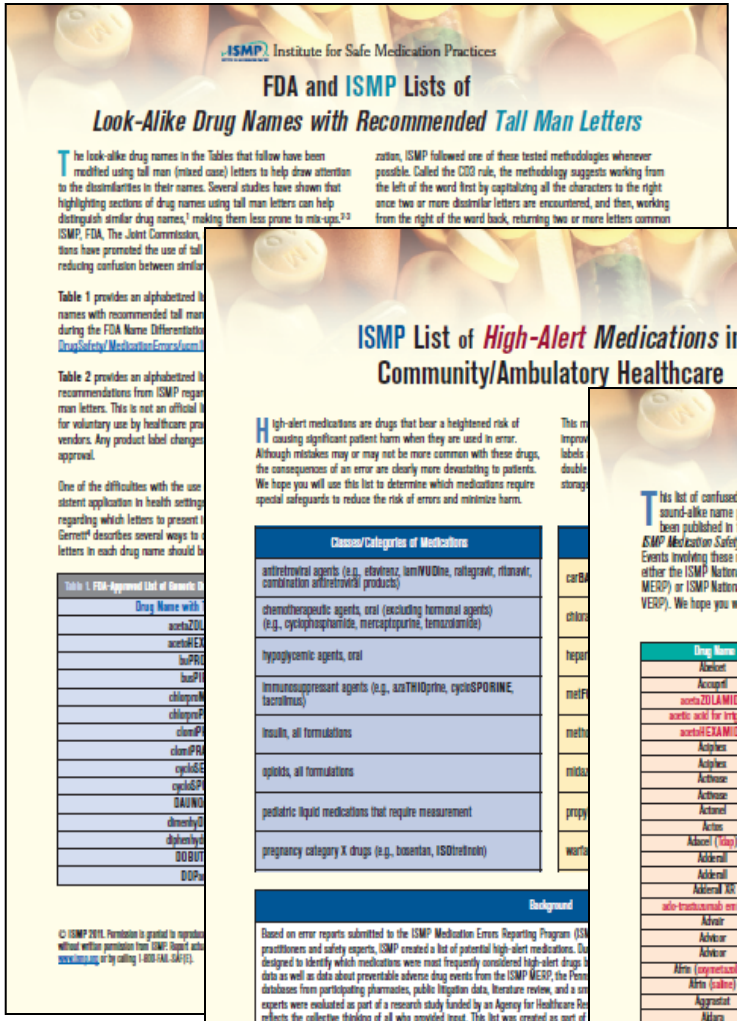
continued on page 5—Guidelines ▶



UNDER REVISION

http://www.ismp.org/Tools/guidelines/default.asp

ISMP Tools & Lists



ISMP Institute for Safe Medication Practices

FDA and ISMP Lists of *Look-Alike Drug Names with Recommended Tall Man Letters*

The look-alike drug names in the Tables that follow have been modified using tall man (mixed case) letters to help draw attention to the dissimilarities in their names. Several studies have shown that highlighting sections of drug names using tall man letters can help distinguish similar drug names,[1] making them less prone to mix-ups.[2,3] ISMP, FDA, The Joint Commission, and other organizations have promoted the use of tall man letters as a method for reducing confusion between similar drug names.

Table 1 provides an alphabetized list of look-alike drug names with recommended tall man letters, as determined during the FDA Name Differentiation

Table 2 provides an alphabetized list of look-alike drug name recommendations from ISMP regarding the use of tall man letters. This is not an official list of FDA-approved tall man letters for voluntary use by healthcare practitioners, organizations, and vendors. Any product label changes require FDA review and approval.

One of the difficulties with the use of tall man letters is the inconsistent application in health settings. Lambert-Kerzner[4] regarding which letters to present describes several ways to Gerrett[4] letters in each drug name should be

Drug Name with
acetaZOL
acetaHEX
buPRO
buPIV
chlorproMA
chlorproPE
clomiPHE
clomiPRA
cyclosPO
cycloSPO
DAUNO
dimenhyDR
diphenhyDR
DOBUT
DOPam

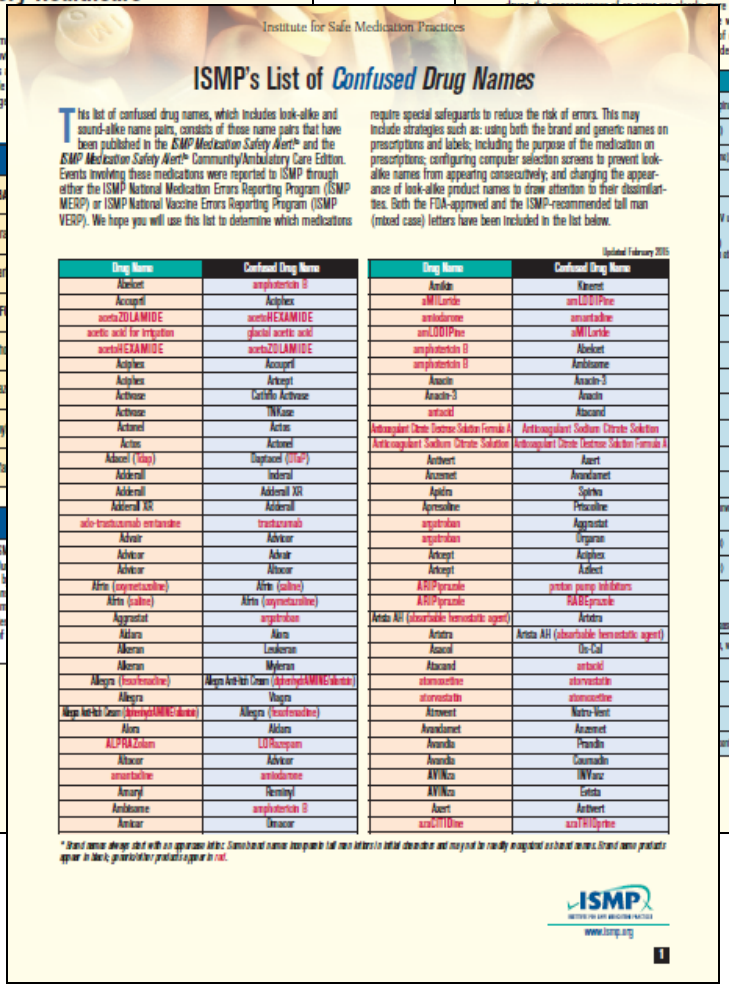
ISMP List of *High-Alert Medications* in Community/Ambulatory Healthcare

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 and minimize harm.

Classes/Categories of Medications
antiretroviral agents (e.g., efavirenz, lamIVUDine, raltegravir, ritonavir, combination antiretroviral products)
chemotherapeutic agents, oral (excluding hormonal agents) (e.g., cyclophosphamide, mercaptopurine, temozolomide)
hypoglycemic agents, oral
immunosuppressant agents (e.g., azaTHIOprine, cycloSPORINE, tacrolimus)
insulin, all formulations
opioids, all formulations
pediatric liquid medications that require measurement
pregnancy category X drugs (e.g., bosentan, ISOtretinoin)

Background

Based on error reports submitted to the ISMP Medication Errors Reporting Program (ISM practitioners and safety experts, ISMP created a list of potential high-alert medications. Da designed to identify which medications were most frequently considered high-alert drugs i data as well as data about preventable adverse drug events from the ISMP MERP, the Penn databases from participating pharmacies, public litigation data, literature review, and a sm experts were evaluated as part of a research study funded by an Agency for Healthcare Re reflects the collective thinking of all who provided input. This list was created as part of outpatient high-alert medications" (Grant # 1P20HS017107-01).



Institute for Safe Medication Practices

ISMP's List of *Confused Drug Names*

This list of confused drug names, which includes look-alike and sound-alike name pairs, consists of those name pairs that have been published in the *ISMP Medication Safety Alert!*® and the *ISMP Medication Safety Alert!*® Community/Ambulatory Care Edition. Events involving these medications were reported to ISMP through either the ISMP National Medication Errors Reporting Program (ISMP MERP) or ISMP National Vaccine Errors Reporting Program (ISMP VERP). We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as: using both the brand and generic names on prescriptions and labels; including the purpose of the medication on prescriptions; configuring computer selection screens to prevent look-alike names from appearing consecutively; and changing the appearance of look-alike product names to draw attention to their dissimilarities. Both the FDA-approved and the ISMP-recommended tall man (mixed case) letters have been included in the list below.

Updated February 2015

Drug Name	Confused Drug Name
Abelcet	amphotericin B
Accupril	Aciphex
acetaZOLAMIDE	acetoHEXAMIDE
acetic acid for irrigation	glacial acetic acid
acetoHEXAMIDE	acetaZOLAMIDE
Aciphex	Accupril
Aciphex	Arimidex
Activase	Cathflo Activase
Activase	TNKase
Actonel	Actos
Actos	Actonel
Adacel (Tdap)	Daptacel (DTaP)
Adderall	Inderal
Adderall	Adderall XR
Adderall XR	Adderall
ado-trastuzumab emtansine	trastuzumab
Advair	Advicor
Advicor	Advair
Advicor	Altacor
Altris (oxymetazoline)	Altris (saline)
Altris (saline)	Altris (oxymetazoline)
Aggrastat	argatroban
Aldara	Alora
Alkeran	Leukeran
Alkeran	Mylleran
Allegra (fexofenadine)	Allegra Anti-Itch Cream (diphenhydrAMINE/allantoin)
Allegra	Viagra
Allegra Anti-Itch Cream (diphenhydrAMINE/allantoin)	Allegra (fexofenadine)
Alora	Aldara
ALPRAZolam	LORazepam
Altacor	Advicor
amantadine	amlodipine
Amaryl	Nemixyl
Ambisome	amphotericin B
Amikacin	Omnicor

Drug Name	Confused Drug Name
Amikin	Kineret
amILORide	amLODIPine
amiodarone	amantadine
amLODIPine	amILORide
amphotericin B	Abelcet
amphotericin B	Ambisome
Anacin	Anacin-3
Anacin-3	Anacin
antacid	Atacand
Anticoagulant Citrate Dextrose Solution Formula A	Anticoagulant Sodium Citrate Solution
Anticoagulant Sodium Citrate Solution	Anticoagulant Citrate Dextrose Solution Formula A
Anthrect	Avert
Anzemet	Avandamet
Apidra	Sporanox
Apresoline	Prinzoline
aripiprazole	Aggrastat
aripiprazole	Orgaran
Arixtra	Aciphex
Arixtra	Adalect
ARIPIprazole	proton pump inhibitors
ARIPIprazole	RABEprazole
Arista AH (absorbable hemostatic agent)	Arixtra
Arixtra	Arista AH (absorbable hemostatic agent)
Asacol	Bi-Cal
Atacand	antacid
atomoxetine	atorvastatin
atorvastatin	atomoxetine
Atrovent	Nutra-Vent
Avandamet	Anzemet
Avandia	Prandin
Avandia	Coumadin
AVINza	INVanz
AVINza	Estrata
Avert	Anthrect
azaCITIDine	azaTHIOprine

** Brand names always start with an uppercase letter. Some brand names incorporate tall man letters to help differentiate look-alike drug names. Brand name products appear in black; generic/other products appear in red.*

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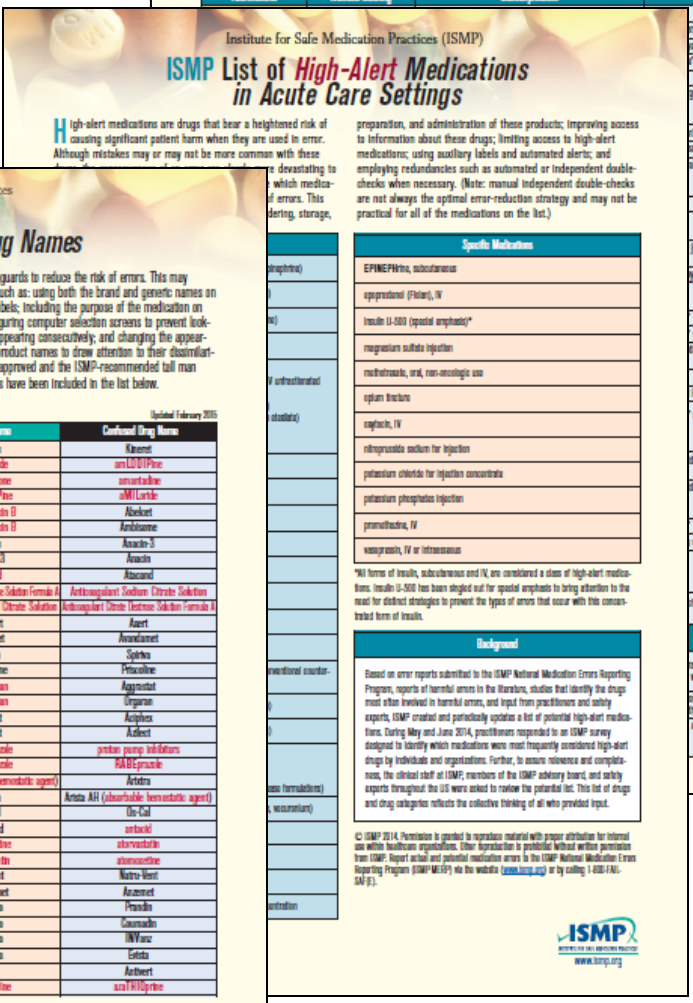

Institute for Safe Medication Practices

ISMP's List of *Error-Prone Abbreviations, Symbols, and Dose Designations*

The abbreviations, symbols, and dose designations found in this table have been reported to ISMP through the ISMP National Medication Errors Reporting Program (ISMP MERP) as being frequently misinterpreted and involved in harmful medication errors. They should **NEVER** be used when communicating medical information. This includes internal communications, telephone/verbal prescriptions, computer-generated labels, labels for drug storage bins, medication administration records, as well as pharmacy and prescriber computer order entry screens.

Abbreviations	Intended Meaning	Misinterpretation	Correction

Institute for Safe Medication Practices (ISMP)

ISMP List of *High-Alert Medications in Acute Care Settings*

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 [illegible] devastating to [illegible] which medica- [illegible] of errors. This [illegible]dering, storage, preparation, and administration of these products; improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; 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.)

Specific Medications
EPINEPHrine, subcutaneous
epoprostenol (Flolan), IV
insulin U-500 (special emphasis)*
magnesium sulfate injection
methotrexate, oral, non-oncologic use
opium tincture
oxytocin, IV
nitroprusside sodium for injection
potassium chloride for injection concentrate
potassium phosphates injection
promethazine, IV
vasopressin, IV or intraosseous

**All forms of insulin, subcutaneous and IV, are considered a class of high-alert medications. Insulin U-500 has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with this concentrated form of insulin.*

Background

Based on error reports submitted to the ISMP National Medication Errors Reporting Program, reports of harmful errors in the literature, studies that identify the drugs most often involved in harmful errors, and input from practitioners and safety experts, ISMP created and periodically updates a list of potential high-alert medications. During May and June 2014, practitioners responded to an ISMP survey designed to identify which 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 the ISMP 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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ISMP Self Assessments

These tools will help you assess the medication safety practices in your institution, identify opportunities for improvement, and compare your experience with the aggregate experience of demographically similar organizations.

http://www.ismp.org/selfassessments/default.asp

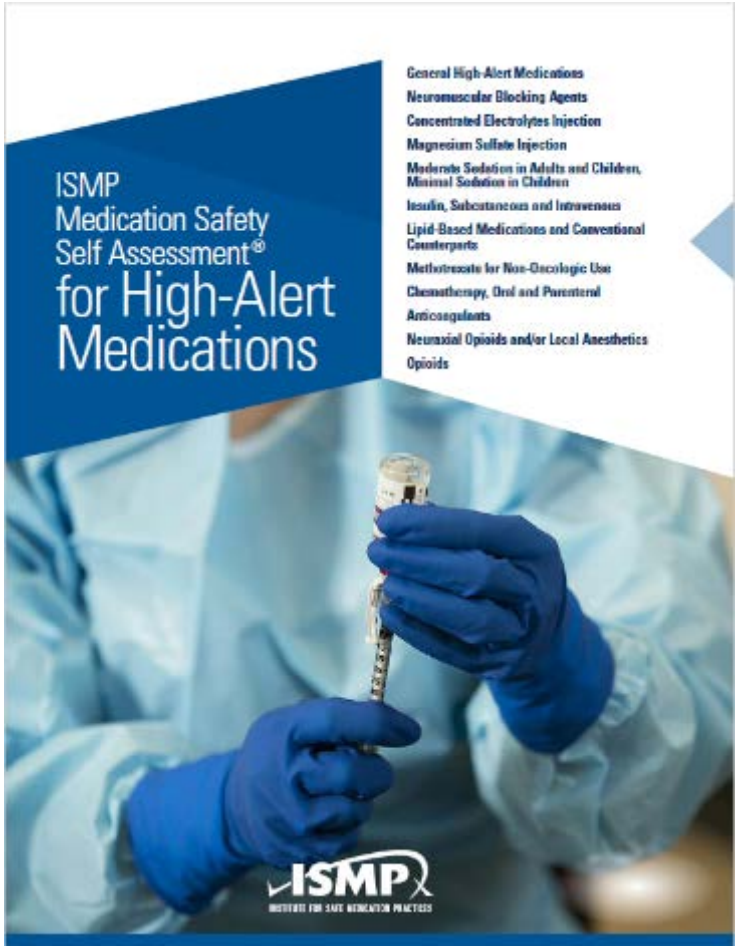
ISMP Medication Safety Self Assessment® for High-Alert Medications

ISMP Medication Safety Self Assessment for High-Alert Medications

Self-Assessment Tool

Help providers assess the safety of systems and practices associated with up to 11 categories of high-alert medications

- Heighten awareness
- Identify and prioritize
- Create a national baseline



High-Alert Medications

Medications bearing a heightened risk of causing significant patient harm when used in error

Targeted High-Alert Medications in the Self-Assessment

1. General High-Alert Medications
2. Neuromuscular Blocking Agents
3. Concentrated Electrolytes Injection
4. Magnesium Sulfate Injection
5. Moderate Sedation in Adults and Children, Minimal Sedation in Children
6. Insulin, Subcutaneous and Intravenous
7. Lipid-Based Medications and Conventional Counterparts
8. Methotrexate for Non-Oncologic Use
9. Chemotherapy, Oral and Parenteral
10. Anticoagulants
11. Neuraxial Opioids and/or Local Anesthetics
12. Opioids

Choose one or all of the targeted medications for evaluation!

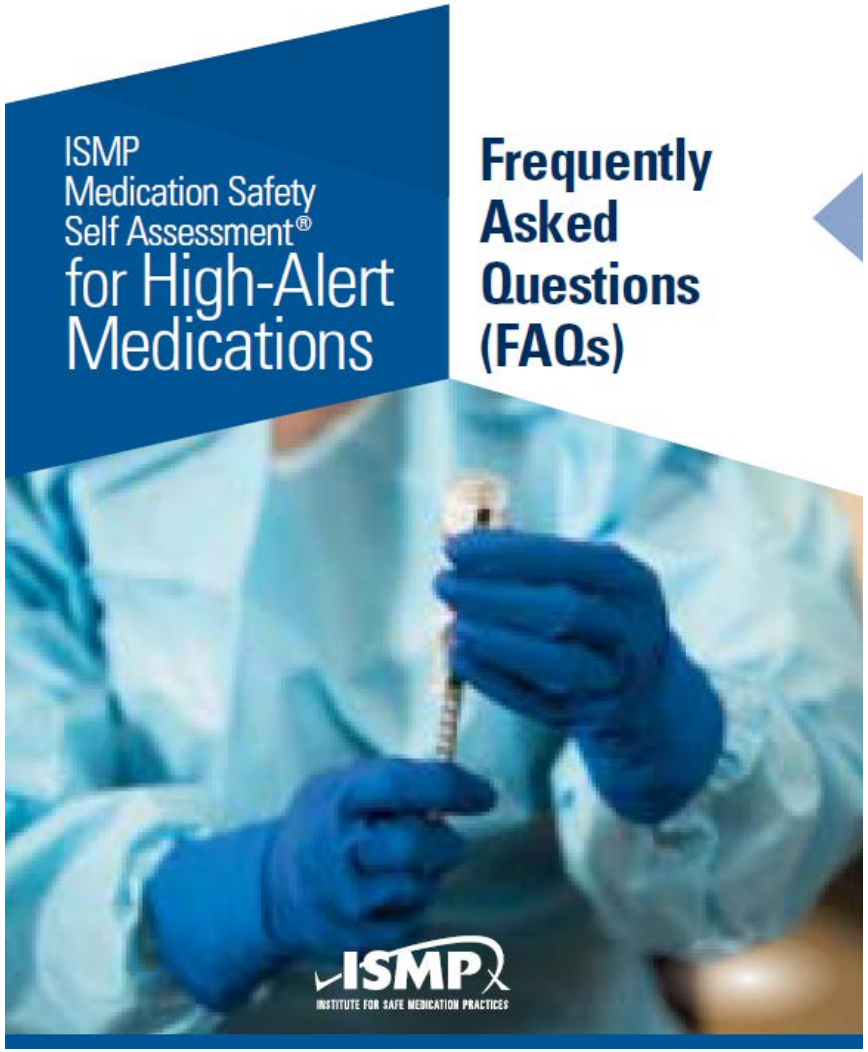
ISMP Medication Safety Self Assessment for High-Alert Medications

Participants

- Hospitals and LTC facilities
- Certain outpatient facilities
  - Ambulatory surgery centers
  - Emergency/urgent care facilities
  - Oncology clinics
  - Treatment centers
  - Dental surgery centers
  - Endoscopy centers
  - Diagnostic testing centers
- Choose one or more high-alert medication categories
- Encourage assessment of all categories of high-alert medications used in the facility

ISMP Medication Safety Self Assessment®
for High-Alert Medications

Contents



Workbook and Frequently Asked Questions

Acknowledgements

Funding and Sponsorship

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ISMP thanks the following members of our voluntary Advisory Group, who helped inform the content of the **ISMP Medication Safety Self Assessment® for High-Alert Medications**.

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Endorsing Organizations

Assessment Instructions

- Intended to be completed by interdisciplinary team
- About 250 items in total without demographics
- Complete sections applicable in their organization
- 5-point Likert-type scale from A to E for assessment
- Blind weighted scores for A through E
  - Items with no benefit for partial implementation will be weighted so choices below E will not provide any value
- Overall scores for each high-alert drug and the general items will be presented as a group
  - General items integrated into applicable groups
- Definitions and FAQs

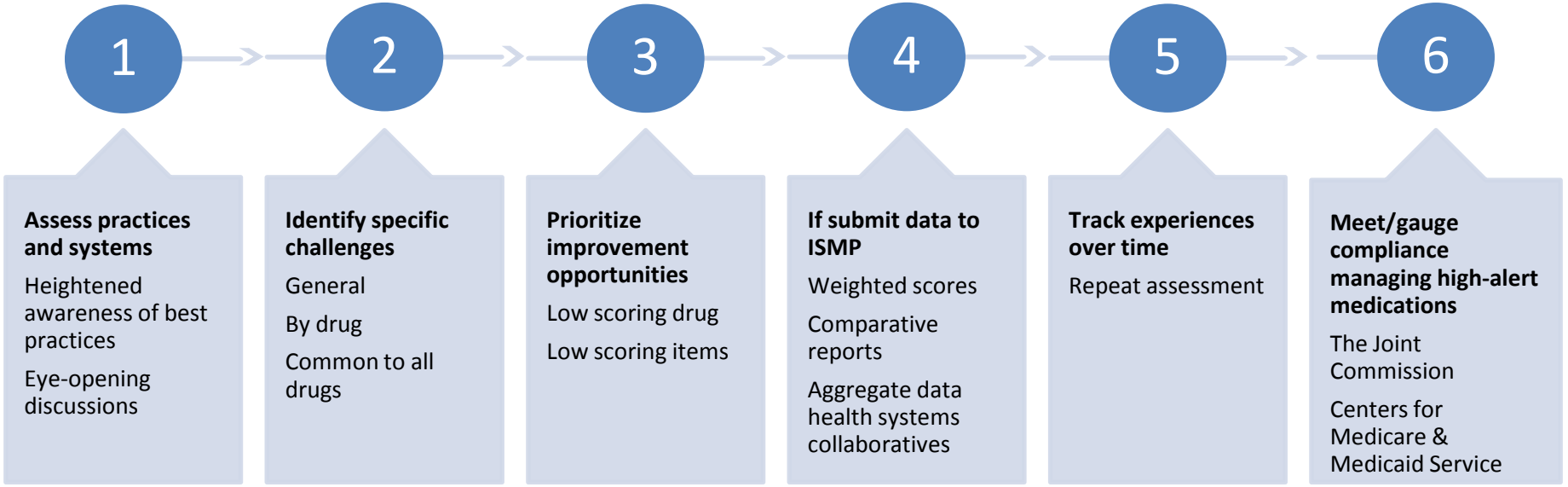
Data Analysis Plan

- Describes proposed approach for analyzing responses to assessment
  - Analytic methods
    - Weighting the items
    - Five scores
      - Weighted score for each medication
      - Maximum weighted score
      - Mean weighted score
      - Percent score
      - Mean percent score
    - Compare demographics to national profile
    - Descriptive statistics
    - Difficulty and cost with implementation

Collaboration with ISMP

- Contract with ISMP to establish a cohort of data for the system
- Each facility will enter a code when setting up an account
- ISMP will provide health system:
  - File of aggregate results
  - Comparative national data
  - Priority recommendations
- For information, contact selfassessment@ismp.org

Benefits of Participation



Other Project Outcomes

- Identify evidence-based practices to reduce the risk of errors with high-alert medications
- Identify error-reduction practices that are supported by expert opinion
- Heighten awareness of the distinguishing characteristics of a safe system for using the targeted high-alert medications
- Create a baseline of national efforts to enhance safe use of targeted high-alert medications
- Allow participants to compare their findings with demographically similar organizations

Assessment—General Demographics

- Basic
  - Bed size, location, ownership, scope of services
- Training programs
- Pharmacy services
  - 24 hours
  - Satellites
- Specialty staff
  - Medication safety officer
  - Hospitalists, intensivists
- Available technology

Insulin, Subcutaneous and Intravenous

Scope: Unless otherwise stated, these items pertain to all concentrations of insulin prescribed, prepared, dispensed, and/or administered by the subcutaneous, IM (rare), and/or IV routes of administration using a vial and syringe, pen, continuous subcutaneous insulin infusion device (insulin pump), and/or infusion.

Demographic Questions

1) **If a patient admitted to the facility takes insulin at home in a higher concentration than 100 units/mL (U-100), how are these insulin doses typically provided during hospitalization, long-term care admission, or outpatient encounter?**
(select all that apply)
- ☐ Insulin doses of the same form and concentration are available and dispensed for the patient
- ☐ The patient is converted to U-100 insulin doses
- ☐ The patient is started on an insulin infusion
- ☐ The patient is asked to supply his or her own insulin from home for administration in the facility
- ☐ We never administer insulin in our facility
- ☐ Other: (please specify) _____

2) **Where is general (non-patient specific) unit stock of insulin pens and vials stored in patient care units/treatment areas?**

Insulin pens? (select all that apply)
- ☐ ADC in a matrix drawer containing multiple insulin types
- ☐ ADC in matrix drawers containing a single insulin type
- ☐ ADC in a single drug access drawer
- ☐ ADC refrigerator
- ☐ General medication refrigerator
- ☐ General stock at room temperature
- ☐ Non-patient specific insulin pens are not stocked in patient care units/treatment areas
- ☐ We don't stock insulin pens anywhere in our facility
- ☐ Other: (please specify) _____

Insulin vials? (select all that apply)
- ☐ ADC in a matrix drawer containing multiple insulin types
- ☐ ADC in matrix drawers containing a single insulin type
- ☐ ADC in a single drug access drawer
- ☐ ADC refrigerator
- ☐ General medication refrigerator
- ☐ General stock at room temperature
- ☐ Non-patient specific insulin vials are not stocked in patient care units/treatment areas
- ☐ We don't stock insulin vials anywhere in our facility
- ☐ Other: (please specify) _____

continued on page 49

Assessment—Insulin Demographics

- Demographics
  - Which insulins are used and methods of dispensing
  - Storage of insulin
  - Certified diabetic educator, endocrinologist

Option	U-200 insulin	U-300 insulin	U-500 insulin
Insulin doses of the same form and concentration are available from the pharmacy and dispensed for the patient			
Insulin doses of the same form and concentration are available from unit stock and removed and labeled for one patient			
The patient is converted to U-100 insulin doses when the patient's total dose of the concentrated insulin is below a hospital-defined dose			
The patient is converted to U-100 doses regardless of the patient's total dose of the concentrated insulin			
The patient is started on an insulin infusion to deliver appropriate doses of insulin			
The patient is asked to supply his or her own insulin from home for administration in the hospital			
Other: (please specify)			

ISMP Medication Safety Self Assessment®
for High-Alert Medications

Self-Assessment Items

A	There has been no activity to implement this item.
B	This item has been formally discussed and considered, but it has not been implemented.
C	This item has been partially implemented for some or all patients, orders, drugs, or staff.
D	This item is fully implemented for some patients, orders, drugs, or staff.
E	This item is fully implemented for all patients, orders, drugs, or staff.

		A	B	C	D	E
General Items						
Protocols and Order Sets						
1	Standard insulin protocols and/or order sets exist and are used to guide care when: (score each item individually)					
a	Converting from oral agents to insulin					
b	Managing insulin during planned and unplanned interruptions of oral and enteral nutrition					
c	Circumstances when a clinician other than the prescriber may adjust or hold an insulin dose					
d	Using **CONCENTRATED INSULINS**					
e	Managing pregnant and postpartum patients with pre-existing diabetes					
f	Managing patients receiving glucocorticoid therapy					
g	Treating hyperkalemia					
h	Treating calcium-channel blocker overdoses using high-dose insulin					
i	Treating clinically significant hyperglycemia and hyperosmolar hyperglycemic state					
j	Treating clinically significant hypoglycemia					
k	Monitoring patients via defined laboratory testing and bedside **POINT-OF-CARE** glucose monitoring, and communicating critical blood glucose values					
FAQ l	Managing patients when their symptoms are inconsistent with a current blood glucose value					
Prescribing						
2	An IV insulin infusion or scheduled subcutaneous insulin with **BASAL**, **NUTRITIONAL**, and **CORRECTIONAL INSULIN** doses is used to manage blood glucose levels in patients with diabetes; **and** patient blood glucose levels are not managed solely using sliding scale insulin.					
Expression of Drug Names, Concentrations, and Doses						
FAQ 3	The insulin concentration (e.g., U-100, U-200, U-300) does not follow the name of the insulin on the MAR/eMAR or other medication lists, with the exception of regular insulin U-500 (Humu**LIN** R U-500).					
FAQ 4	**TALL MAN LETTERING** with bolded text for the unique letter characters of look-alike insulin names (e.g., Huma**LOG** and Humu**LIN**; Novo**LOG** and Novo**LIN**) is used when displaying the names in computer order entry systems, order sets, protocols, guidelines, MARs/eMARs, ADC screens, infusion pump screens, drug storage bins, and pharmacy labels and/or **AUTOMATED SYSTEM LABELS.**					

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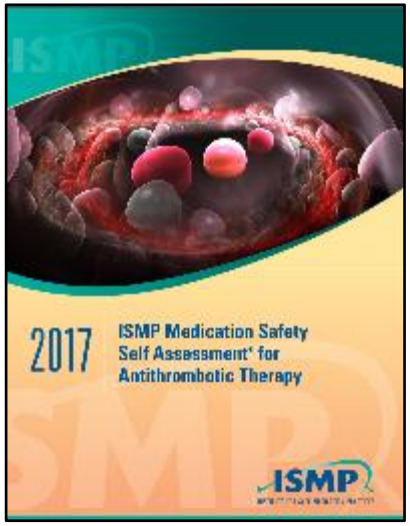
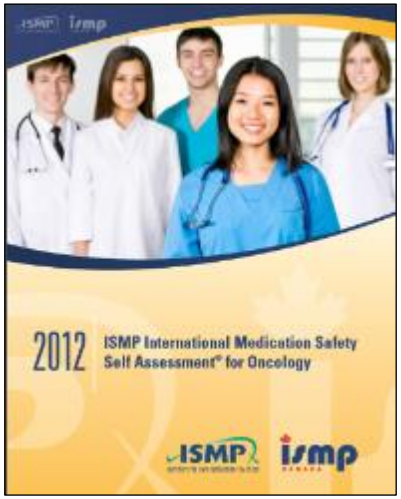
Assessment examples—Insulin Items

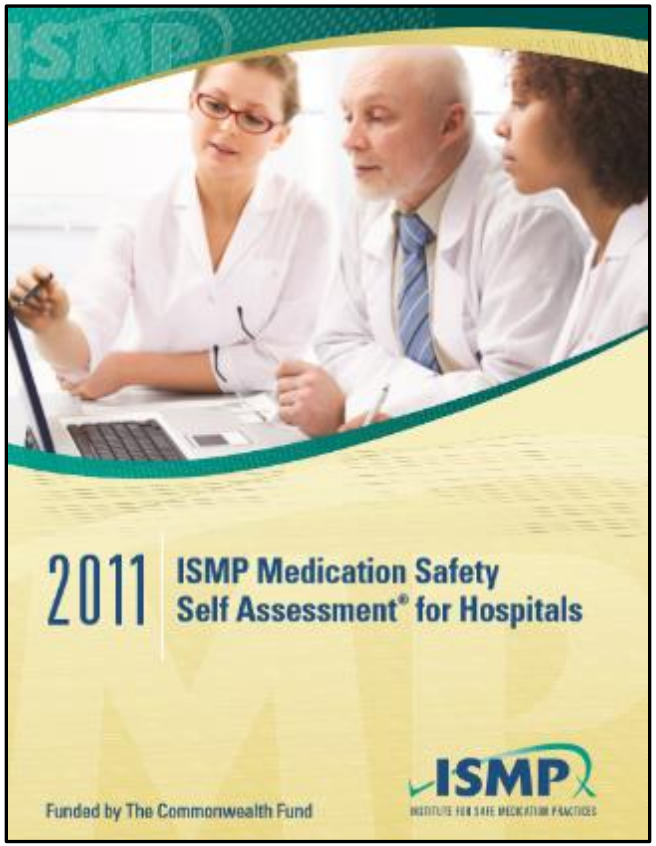
Protocols, P-D-A, Pens, Concentrated Insulin, IV Insulin, Diluted Insulin, Pumps, Hypoglycemia, Transitions, Patient Education

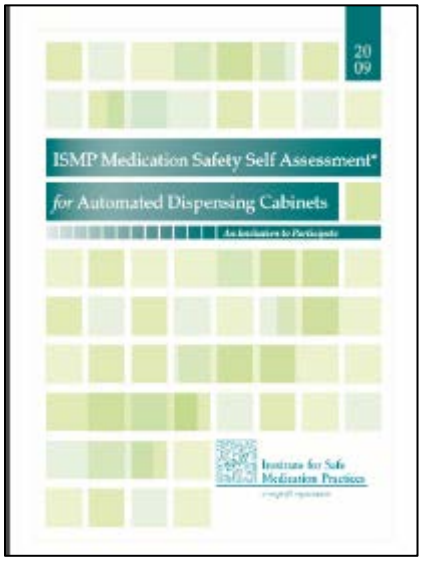
- Pharmacists confirm that the patient has an appropriate indication before approving initial insulin orders.
- The pharmacy prepares and dispenses patient-specific, prefilled syringes of basal insulin doses (if stability permits) for patients who are not using a patient-specific insulin pen device or insulin pump to deliver basal doses.
- Either U-500 insulin pens or U-500 insulin syringes are used when preparing, dispensing, and administering U-500 inulin to patients during hospitalization; neither a U-100 insulin syringe nor a tuberculin syringe is used in the hospital with U-500 insulin.
- U-100 insulin vials are not dispensed or stored as unit stock in neonatal intensive care units.

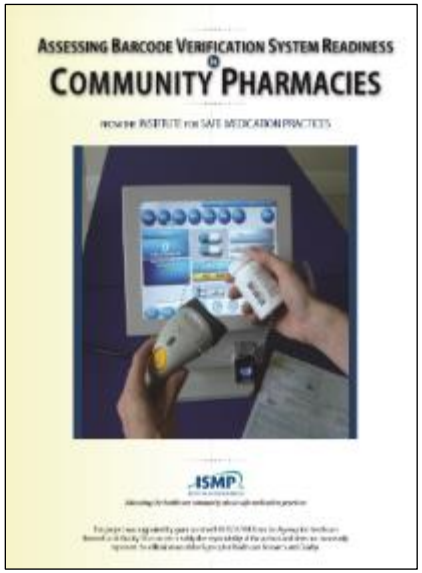
Background—Other ISMP Assessments





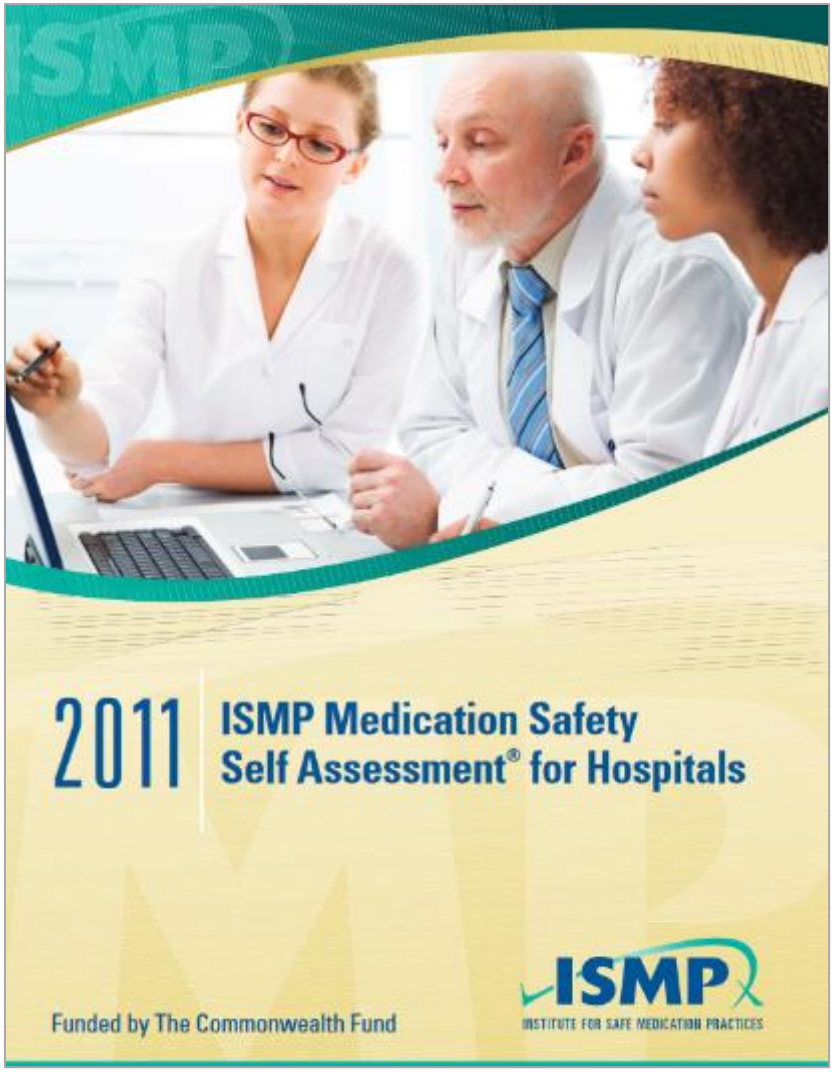






http://www.ismp.org/selfassessments/default.asp

2011 ISMP Medication Safety Self Assessment® for Hospitals



A	No activity to implement
B	Considered, but not implemented
C	Partially implemented in some or all areas
D	Fully implemented in some areas
E	Fully implemented throughout

VII. ENVIRONMENTAL FACTORS, WORKFLOW, AND STAFFING PATTERNS

Core Characteristic #12

Medications are prescribed, transcribed, prepared, dispensed, and administered within an efficient and safe workflow and in a physical environment that offers adequate space and lighting, and allows practitioners to remain focused on medication use without distractions.

		A	B	C	D	E
149	Lighting is adequate (illumination levels around 100 foot-candles) to clearly read labels and other important drug and patient information in pharmacies, patient unit medication rooms, patient rooms, and at ADCs.					
150	Workspaces where medications are prepared are orderly and free of clutter.					
151	Pharmacies and patient unit medication rooms (or areas) have adequate space for storage of drugs, IV solutions, and drug supplies.					
152	Medication preparation areas in the pharmacy and on patient care units are isolated and relatively free of distractions, interruptions, and noise (not greater than 50 decibels [dBA]).					
153	All phone calls to the pharmacy are triaged and forwarded to medication preparation and order entry areas only when necessary.					
154	Areas where drug orders are transcribed and/or entered into **COMPUTER ORDER ENTRY SYSTEMS** are isolated and relatively free of distractions, interruptions, and noise (not greater than 50 dBA).					
155	Medication refrigerators in patient care areas are of sufficient size to allow admixtures that require refrigeration to be stored in an organized manner.					
156	Nurses select medications for administration in medication rooms, at ADCs, or in other areas that are isolated and relatively free of distractions, interruptions, and noise (not greater than 50 dBA).					
157	Practitioners who administer medications prepare and/or select one patient's medications at a time, immediately before administering the medication.					
158	When new construction or renovation of an existing area where medications will be prescribed, dispensed, stored, or administered is planned, an interdisciplinary group of practicing staff involved in medication use is included in the decision-making process of the design of the area. *Scoring guideline: Choose NOT APPLICABLE if your organization has not built new space or renovated within the past 3 years.*					NOT APPLICABLE

A	No activity to implement
B	Considered, but not implemented
C	Partially implemented in some or all areas
D	Fully implemented in some areas
E	Fully implemented throughout

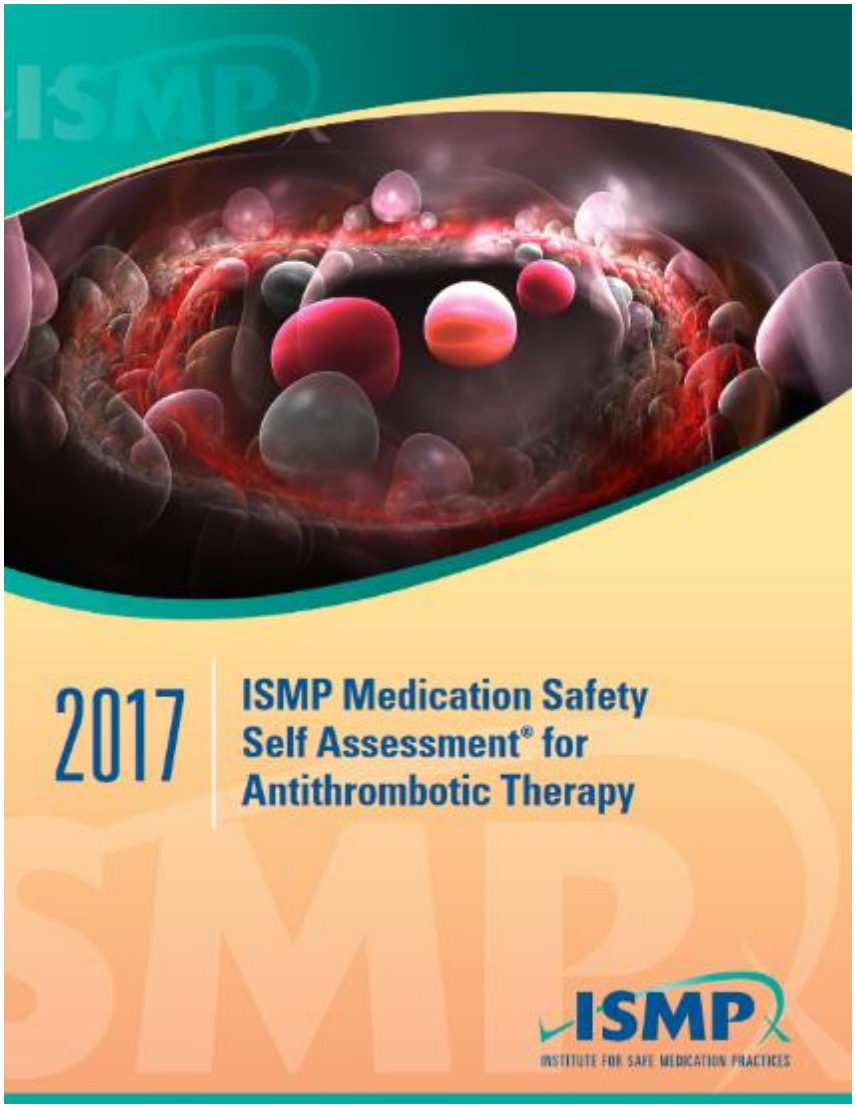
VI. DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION (continued)

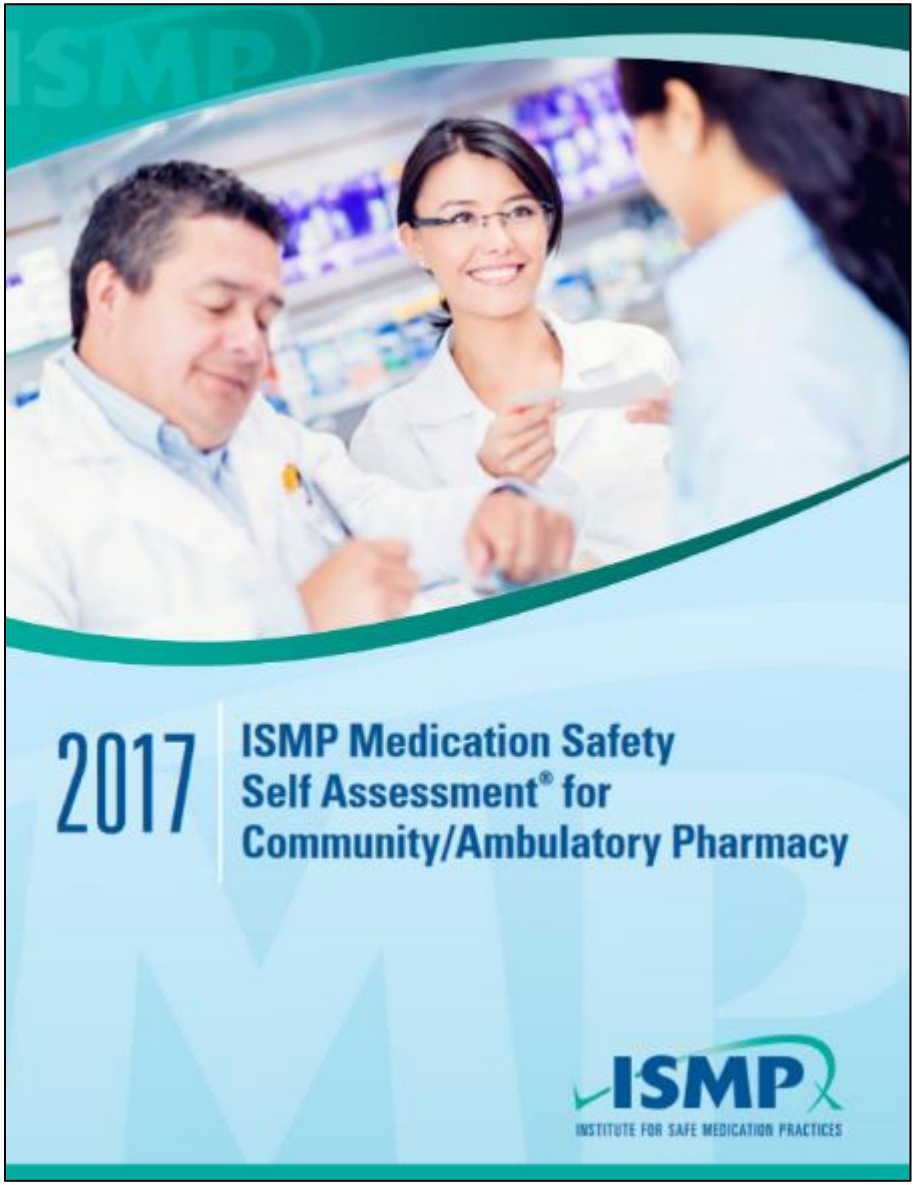
Core Characteristic #9

Unit stock is restricted.

		A	B	C	D	E
110	**PATIENT-SPECIFIC DOSES** are dispensed for at least 90% of all injectable products (including saline and heparin flushes) for adult, pediatric, and neonatal patients.					
111	All oral solid medications are dispensed to patient care units in labeled, ready-to-use **UNIT DOSES**.					
112	All oral liquid medications are dispensed to patient care units (including neonatal, pediatric, and critical care units) in labeled, ready-to-use **PATIENT-SPECIFIC DOSES**.					
113	IV solutions that are unavailable commercially are prepared in the pharmacy unless needed in emergent lifesaving situations.					
114	Pharmacy fills all elastomeric pumps and prepares all IV solutions and irrigations needed in the operating room or procedural areas (including interventional radiology, cardiac catheterization areas), unless needed in emergent lifesaving situations.					
115	Drugs stocked in patient care units (including in ADCs) are carefully selected by considering the needs of each patient care unit, staff expertise and familiarity with specific drugs, the risk of error with each drug, and the age and diagnoses of typical patients being treated on the units, and unit stock is reviewed at least semiannually to determine low usage medications that may be eligible for removal from inventory.					
116	Drugs stocked in patient care units are available in the least number of doses, concentrations, and forms that will meet essential patient needs between replenishment (not to exceed 72 hours).					
117	Medications are not removed from inpatient (including PACU) unit stock (including ADCs) before a pharmacist reviews the specific patient order and screens the order for safety. Exception: Urgent or lifesaving situations where a delay would harm the patient.					
118	Medications are not removed from outpatient (including the ED, ambulatory surgery, outpatient oncology) unit stock (including ADCs) before a pharmacist reviews the specific patient order and screens the order for safety. Exception: Urgent or lifesaving situations where a delay would harm the patient.					

2017 ISMP Medication Safety Self Assessment ® for Antithrombotic Therapy

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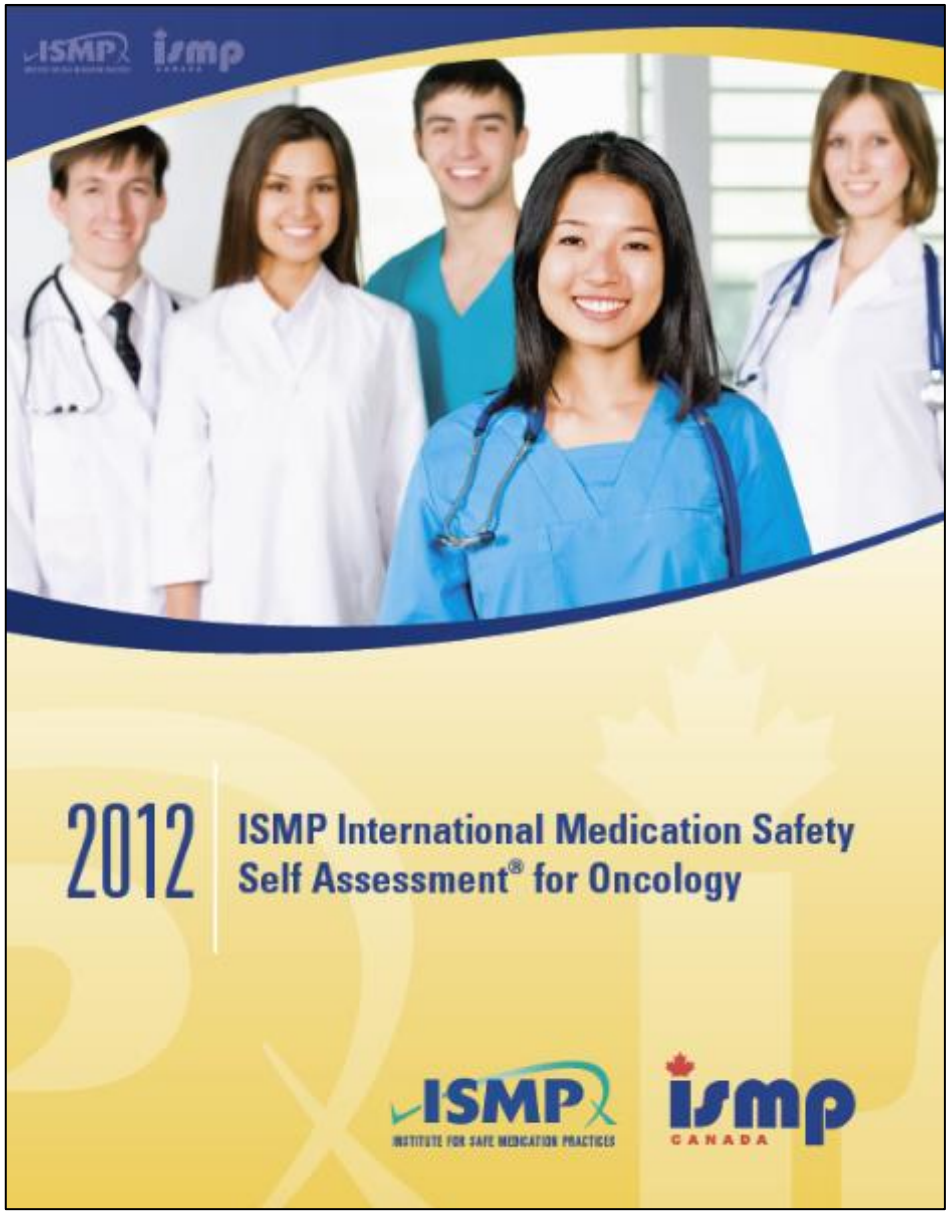
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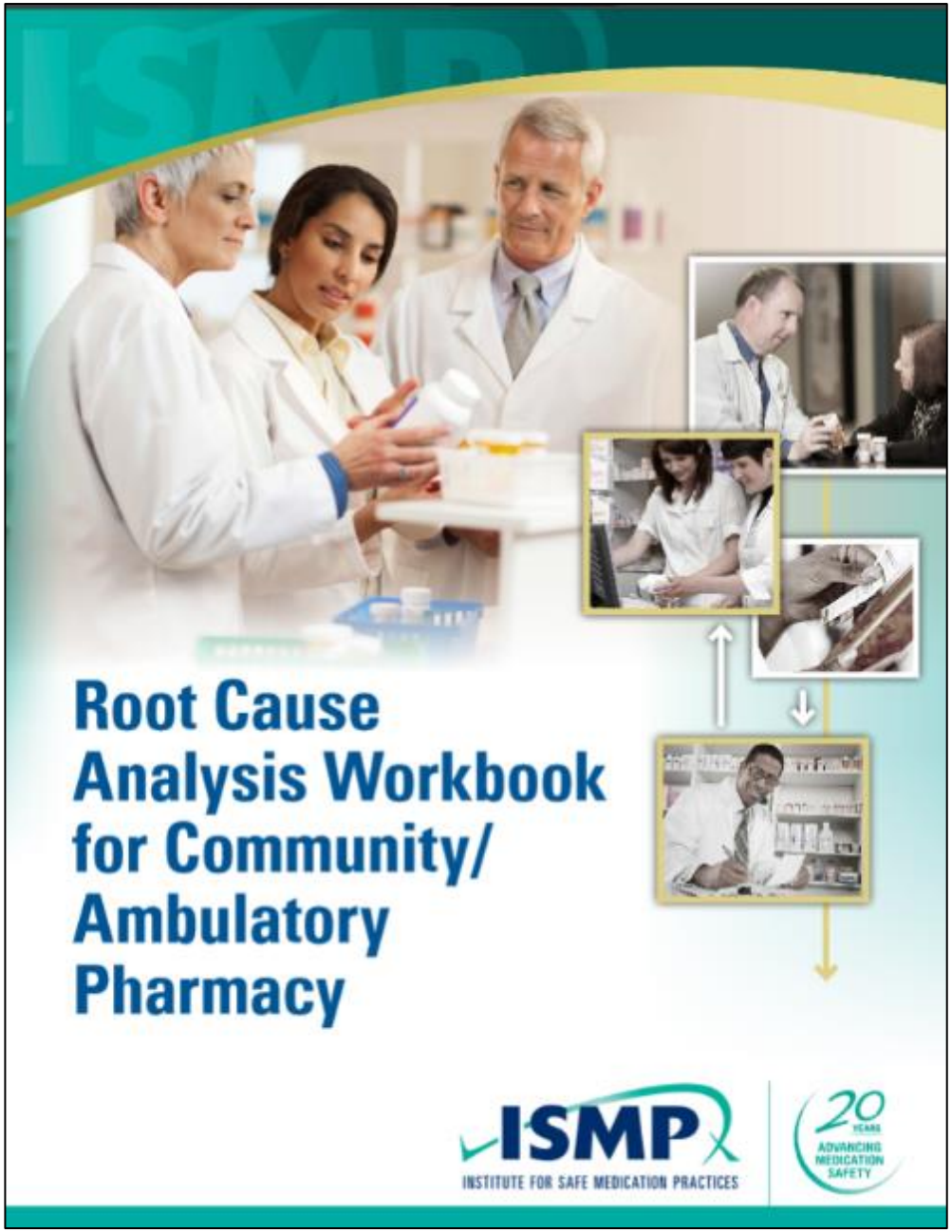
Root Cause Analysis Workbook for Community/ Ambulatory Pharmacy
ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES
20 YEARS
ADVANCING MEDICATION SAFETY

ASSESS - ERR™

MEDICATION SYSTEM Worksheet

Patient MR# _____ Incident # _____

(if error reached patient) if no callback identified: ☐

Date of error: _____ Date information obtained: _____ Patient age: _____

Drug(s) involved in error: _____

Non-formulary drug(s)?	☐ Yes	☐ No
Drug sample(s)?	☐ Yes	☐ No
Drug(s) packaged in unit dose/unit of use?	☐ Yes	☐ No
Drug(s) dispensed from pharmacy?	☐ Yes	☐ No
Error within 24 hours of admission, transfer, or after discharge?	☐ Yes	☐ No
Did the error reach the patient?	☐ Yes	☐ No

Source of IV solution: ☐ Manufacturer premixed solution ☐ Pharmacy IV admixture ☐ Nursing IV admixture

Brief description of the event: (what, when, and why) _____

Possible causes	Y/N	Comments
Critical patient information missing? (age, weight, allergies, VS, lab values, pregnancy, patient identity, location, renal/liver impairment, diagnoses, etc.)		
Critical drug information missing? (outdated/absent references, inadequate computer screening, inaccessible pharmacist, uncontrolled drug formulary, etc.)		
Miscommunication of drug order? (illegible, ambiguous, incomplete, misheard, or misunderstood orders, intimidation/faulty interaction, etc.)		
Drug name, label, packaging problem? (look/sound-alike names, look-alike packaging, unclear/absent labeling, faulty drug identification, etc.)		
Drug storage or delivery problem? (slow turn around time, inaccurate delivery, doses missing or expired, multiple concentrations, placed in wrong bin, etc.)		
Drug delivery device problem? (poor device design, misprogramming, free-flow, mixed up lines, IV administration of oral syringe contents, etc.)		
Environmental, staffing, or workflow problems? (lighting, noise, clutter, interruptions, staffing deficiencies, workload, inefficient workflow, employee safety, etc.)		
Lack of staff education? (competency validation, new or unfamiliar drugs/devices, orientation process, feedback about errors/prevention, etc.)		
Patient education problem? (lack of information, noncompliance, not encouraged to ask questions, lack of investigating patient inquiries, etc.)		
Lack of quality control or independent check systems? (equipment quality control checks, independent checks for high alert drugs/high risk patient population drugs etc.)		

Did the patient require any of the following actions after the error that you would not have done if the event had not occurred?

☐ Testing ☐ Additional observation ☐ Gave antidote ☐ Care escalated (transferred, etc.) ☐ Additional LOS ☐ Other ____

Patient outcome: _____

https://www.ismp.org/Tools/AssessERR.pdf

FAILURE MODE AND EFFECTS ANALYSIS (FMEA):

A TOOL TO HELP GUIDE ERROR PREVENTION EFFORTS

Too often, marketing efforts, contractual agreements with purchasing groups or vendors, and cost serve as primary sources of information when making decisions about which medical products to purchase and use. Evaluation and input from those who would be using the products may not be sought and error potential may not be considered ahead of time. Later, this may lead to unforeseen problems in the hands of clinical users.

These pitfalls can be avoided by using a process known as Failure Mode and Effects Analysis (FMEA). FMEA is an ongoing quality improvement process that is carried out in healthcare organizations by a multidisciplinary team. It can be employed to examine the use of new products and the design of new services and processes to determine points of potential failure and what their effect would be – *before any error actually happens*. In this regard, FMEA differs from Root Cause Analysis (RCA). RCA is a *reactive* process, employed *after* an error occurs, to identify its underlying causes. In contrast, FMEA is a *proactive* process used to look more carefully and systematically at vulnerable areas or processes. FMEA can be employed *before* purchase and implementation of new services, processes or products to identify potential failure modes so that steps can be taken to avoid errors *before* they occur.

How can FMEA be used to reduce the risk of medication errors? To cite one example, a multidisciplinary committee could use FMEA to assess new drugs being considered for the formulary. Here's how the process would work .

- **Step 1**: The committee would explore how the intended product would be procured and used, from acquisition through administration. Who would prescribe the drug and for what type of patient? Where would the drug be stored? Who would prepare and dispense it? How would it be administered?

- **Step 2**: Potential failure modes (how and where systems and processes may fail) would be identified while considering how the product would be used. Could the drug be mistaken for another similarly packaged product? Does the label clearly express the strength or concentration? Does the name sound or look like another drug on the formulary? Are dosing parameters complex? Is the administration process error prone?

- **Step 3**: Once failure modes have been identified, staff would determine the likelihood of a mistake occurring and the potential consequences of an error. What would happen to the patient if the drug were given in the wrong dose, at the wrong time, to the wrong patient, by the wrong route, at the wrong rate or at the wrong time?

- **Step 4**: Staff would identify any preexisting processes in place that could help detect the error before it reaches the patient, and evaluate their effectiveness based upon knowledge of human factors.

- **Step 5** : If failure modes could cause errors with significant consequences, actions would be taken to prevent the error, detect it before it reaches the patient, or minimize its consequences. A few examples include using an alternative product; preparing the drug in the pharmacy; standardizing drug concentrations, order communication and dosing methods; using auxiliary warning labels or computer alerts; and requiring entry of specific data into computer systems before processing orders.

Although industries outside of medicine have developed elaborate FMEA scoring systems to rank items for action, the simplified FMEA process as described above can be an efficient proactive risk management tool, especially when organizations consider what is already known about error potential from past experiences or information available in the media such as the *ISMP Medication Safety Alert! ®* newsletters.

Adapted from: ISMP Medication Safety Alert! ® October 17, 2001. (6)21.

Sample FMEA

- Failure Mode and Effects Analysis (FMEA) Bibliography
- REDUCING MEDICATION ERRORS Through Failure Mode & Effects Analysis (Video; available at the ISMP Store)

Example of a Health Care Failure Mode and Effects Analysis for IV Patient Controlled Analgesia (PCA)

Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Prescribing							
Assess patient	Inaccurate pain assessment	Cultural influences; patient unable to articulate	Poor pain control	2	4	8	Standard scale to help assess pain; training on cultural influences
Choose analgesic/mode of delivery	Wrong analgesic selected	Clinical situation not considered (age, renal function, allergies, etc.); tolerance to opiates not considered; standard PCA protocols not followed (or not available); concomitant use of other analgesics not considered; drug shortage; knowledge deficit; improper selection of patients appropriate for PCA	Improper dosing; improper drug; allergic response; improper use of substitute drug	4	3	12	CPOE with decision support, clinical pharmacy program; standard PCA protocol with education on use; point-of-use access to drug information; feedback mechanism on drug shortages with information on substitute drugs available; selection criteria for PCA patients
Prescribe analgesic	Wrong dose (loading, PCA, constant, lock-out), route, frequency	Knowledge deficit; mental slip; wrong selection from list; information about drug not available	Overdose; under-dose; ADR	4	3	12	CPOE with decision support; clinical pharmacy program; standard PCA protocols
	Proper patient monitoring not ordered	Knowledge deficit; mental slip	Failure to detect problems early to prevent harm	4	3	12	Standard PCA order sets with monitoring guidelines
	Prescribed on wrong patient	Similar patient names; patient identifier not clear; name does not appear on screen when ordering medications	Wrong patient receives inappropriate drug and dose; ADR; allergic response	3	3	9	Match therapy to patient condition; alerts for look-alike patient names; visible demographic information on order form or screen
	No order received	Unable to reach covering physician	Poor pain control	2	2	4	Proper physician coverage and communication channels

Note: Hypothetical FMEA for typical hospital using patient controlled analgesia. Specific hospital issues and hazard scores will differ at each practice location

2016-2017 Targeted Medication Safety Best Practices for Hospitals

The purpose of the Targeted Medication Safety Best Practices for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices for specific medication safety issues that continue to cause fatal and harmful errors in patients, despite repeated warnings in ISMP publications. Hospitals can focus their medication safety efforts over the next 2 years on these best practices, which are realistic and have been successfully adopted by numerous organizations. While targeted for the hospital-based setting, some best practices may be applicable to other healthcare settings. The Targeted Medication Safety Best Practices for Hospitals have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

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 (number 2 and 3) have been revised for 2016-2017. Best practices number 7 through 11 are new for 2016-2017.**

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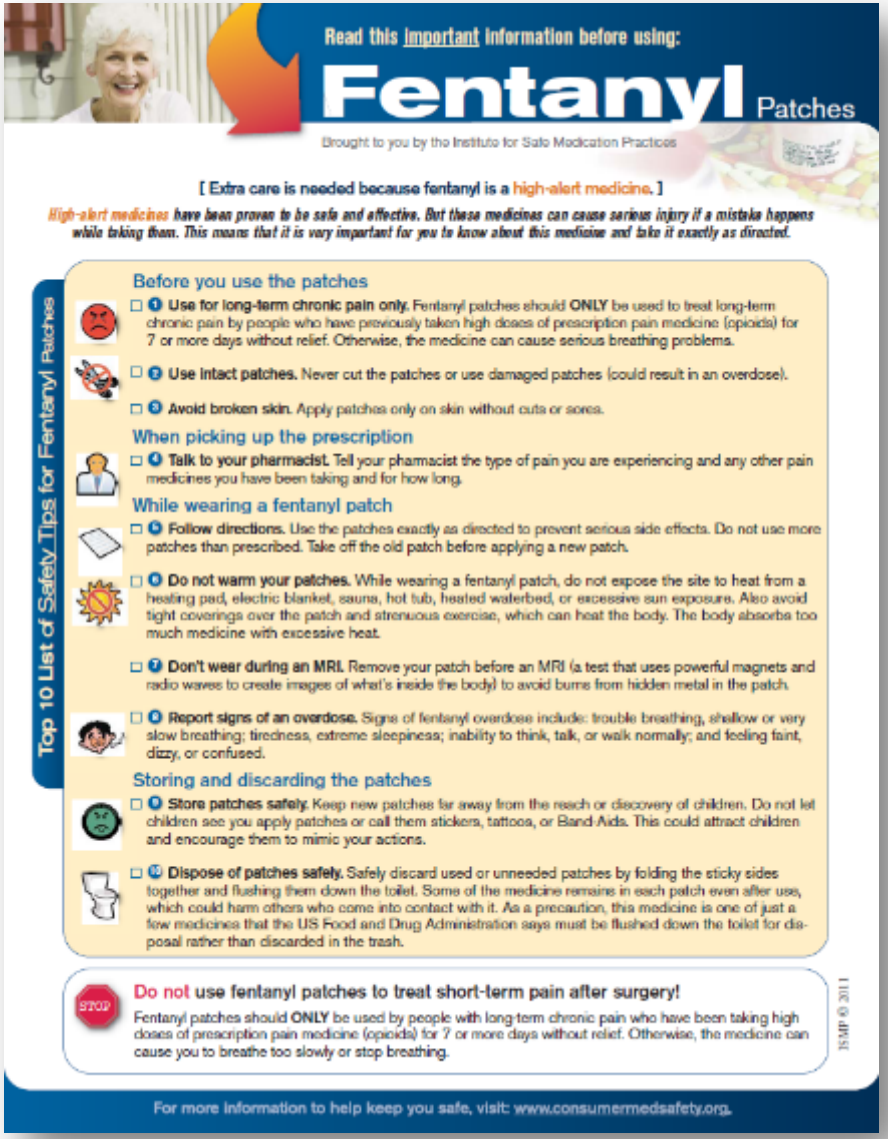
http://www.ismp.org/tools/bestpractices/default.aspx

2016-2017 Targeted Medication Safety Best Practices for Hospitals

- Purpose: inspire widespread adoption of consensus-based best practices on specific error-related issues that continue to harm patients and/or cause death
- Primary target areas:
  - IV vincristine
  - Oral methotrexate
  - Patient weights in metric units
  - Neuromuscular blocking agents
  - High alert drug via smart pumps
  - Availability of antidotes and rescue agents
  - Use of oral syringes
  - Oral liquid dosing devices
  - Glacial acetic acid
  - Eliminate liter bags of sterile water
  - Use of technology for IV admixture compounding

www.consumermedsafety.org

Importance of Consumer Involvement



Read this important information before using:

Fentanyl Patches

Brought to you by the Institute for Safe Medication Practices

[Extra care is needed because fentanyl is a high-alert medicine.]

High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is very important for you to know about this medicine and take it exactly as directed.

Top 10 List of Safety Tips for Fentanyl Patches

Before you use the patches

- ❶ **Use for long-term chronic pain only.** Fentanyl patches should **ONLY** be used to treat long-term chronic pain by people who have previously taken high doses of prescription pain medicine (opioids) for 7 or more days without relief. Otherwise, the medicine can cause serious breathing problems.
- ❷ **Use intact patches.** Never cut the patches or use damaged patches (could result in an overdose).
- ❸ **Avoid broken skin.** Apply patches only on skin without cuts or sores.

When picking up the prescription

- ❹ **Talk to your pharmacist.** Tell your pharmacist the type of pain you are experiencing and any other pain medicines you have been taking and for how long.

While wearing a fentanyl patch

- ❺ **Follow directions.** Use the patches exactly as directed to prevent serious side effects. Do not use more patches than prescribed. Take off the old patch before applying a new patch.
- ❻ **Do not warm your patches.** While wearing a fentanyl patch, do not expose the site to heat from a heating pad, electric blanket, sauna, hot tub, heated waterbed, or excessive sun exposure. Also avoid tight coverings over the patch and strenuous exercise, which can heat the body. The body absorbs too much medicine with excessive heat.
- ❼ **Don't wear during an MRI.** Remove your patch before an MRI (a test that uses powerful magnets and radio waves to create images of what's inside the body) to avoid burns from hidden metal in the patch.
- ❽ **Report signs of an overdose.** Signs of fentanyl overdose include: trouble breathing, shallow or very slow breathing; tiredness, extreme sleepiness; inability to think, talk, or walk normally; and feeling faint, dizzy, or confused.

Storing and discarding the patches

- ❾ **Store patches safely.** Keep new patches far away from the reach or discovery of children. Do not let children see you apply patches or call them stickers, tattoos, or Band-Aids. This could attract children and encourage them to mimic your actions.
- ❿ **Dispose of patches safely.** Safely discard used or unneeded patches by folding the sticky sides together and flushing them down the toilet. Some of the medicine remains in each patch even after use, which could harm others who come into contact with it. As a precaution, this medicine is one of just a few medicines that the US Food and Drug Administration says must be flushed down the toilet for disposal rather than discarded in the trash.

STOP

Do not use fentanyl patches to treat short-term pain after surgery!

Fentanyl patches should **ONLY** be used by people with long-term chronic pain who have been taking high doses of prescription pain medicine (opioids) for 7 or more days without relief. Otherwise, the medicine can cause you to breathe too slowly or stop breathing.

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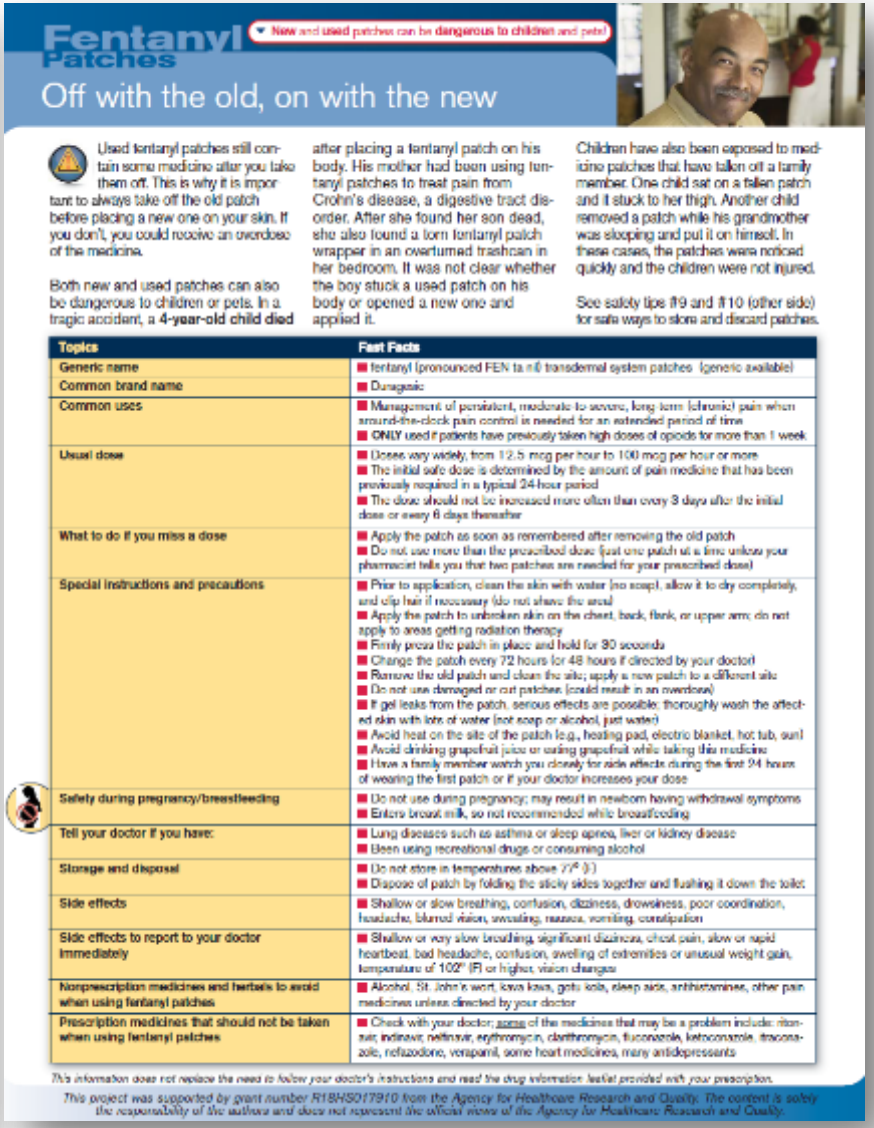
For more information to help keep you safe, visit: www.consumermedsafety.org.



Fentanyl Patches

New and used patches can be dangerous to children and pets!

Off with the old, on with the new

Used fentanyl patches still contain some medicine after you take them off. This is why it is important to always take off the old patch before placing a new one on your skin. If you don't, you could receive an overdose of the medicine.

Both new and used patches can also be dangerous to children or pets. In a tragic accident, a **4-year-old child died** after placing a fentanyl patch on his body. His mother had been using fentanyl patches to treat pain from Crohn's disease, a digestive tract disorder. After she found her son dead, she also found a torn fentanyl patch wrapper in an overturned trashcan in her bedroom. It was not clear whether the boy stuck a used patch on his body or opened a new one and applied it.

Children have also been exposed to medicine patches that have fallen off a family member. One child sat on a fallen patch and it stuck to her thigh. Another child removed a patch while his grandmother was sleeping and put it on himself. In these cases, the patches were noticed quickly and the children were not injured.

See safety tips #9 and #10 (other side) for safe ways to store and discard patches.

Topics	Fast Facts
Generic name	■ fentanyl (pronounced FEN ta nil) transdermal system patches (generic available)
Common brand name	■ Duragesic
Common uses	■ Management of persistent, moderate to severe, long-term (chronic) pain when around-the-clock pain control is needed for an extended period of time ■ **ONLY** used if patients have previously taken high doses of opioids for more than 1 week
Usual dose	■ Doses vary widely, from 12.5 mcg per hour to 100 mcg per hour or more ■ The initial safe dose is determined by the amount of pain medicine that has been previously required in a typical 24-hour period ■ The dose should not be increased more often than every 3 days after the initial dose or every 6 days thereafter
What to do if you miss a dose	■ Apply the patch as soon as remembered after removing the old patch ■ Do not use more than the prescribed dose (just one patch at a time unless your pharmacist tells you that two patches are needed for your prescribed dose)
Special instructions and precautions	■ Prior to application, clean the skin with water (no soap), allow it to dry completely, and clip hair if necessary (do not shave the area) ■ Apply the patch to unbroken skin on the chest, back, flank, or upper arm; do not apply to areas getting radiation therapy ■ Firmly press the patch in place and hold for 30 seconds ■ Change the patch every 72 hours (or 48 hours if directed by your doctor) ■ Remove the old patch and clean the site; apply a new patch to a different site ■ Do not use damaged or cut patches (could result in an overdose) ■ If gel leaks from the patch, serious effects are possible: thoroughly wash the affected skin with lots of water (not soap or alcohol, just water) ■ Avoid heat on the site of the patch (e.g., heating pad, electric blanket, hot tub, sun) ■ Avoid drinking grapefruit juice or eating grapefruit while taking this medicine ■ Have a family member watch you closely for side effects during the first 24 hours of wearing the first patch or if your doctor increases your dose
Safety during pregnancy/breastfeeding	■ Do not use during pregnancy; may result in newborn having withdrawal symptoms ■ Enters breast milk, so not recommended while breastfeeding
Tell your doctor if you have:	■ Lung diseases such as asthma or sleep apnea, liver or kidney disease ■ Been using recreational drugs or consuming alcohol
Storage and disposal	■ Do not store in temperatures above 77° F) ■ Dispose of patch by folding the sticky sides together and flushing it down the toilet
Side effects	■ Shallow or slow breathing, confusion, dizziness, drowsiness, poor coordination, headache, blurred vision, sweating, nausea, vomiting, constipation
Side effects to report to your doctor immediately	■ Shallow or very slow breathing, significant dizziness, chest pain, slow or rapid heartbeat, bad headache, confusion, swelling of extremities or unusual weight gain, temperature of 102° (F) or higher, vision changes
Nonprescription medicines and herbals to avoid when using fentanyl patches	■ Alcohol, St. John's wort, kava kava, gotu kola, sleep aids, antihistamines, other pain medicines unless directed by your doctor
Prescription medicines that should not be taken when using fentanyl patches	■ Check with your doctor; some of the medicines that may be a problem include: ritonavir, indinavir, nelfinavir, erythromycin, clarithromycin, fluconazole, ketoconazole, itraconazole, nefazodone, verapamil, some heart medicines, many antidepressants

This information does not replace the need to follow your doctor's instructions and read the drug information leaflet provided with your prescription.

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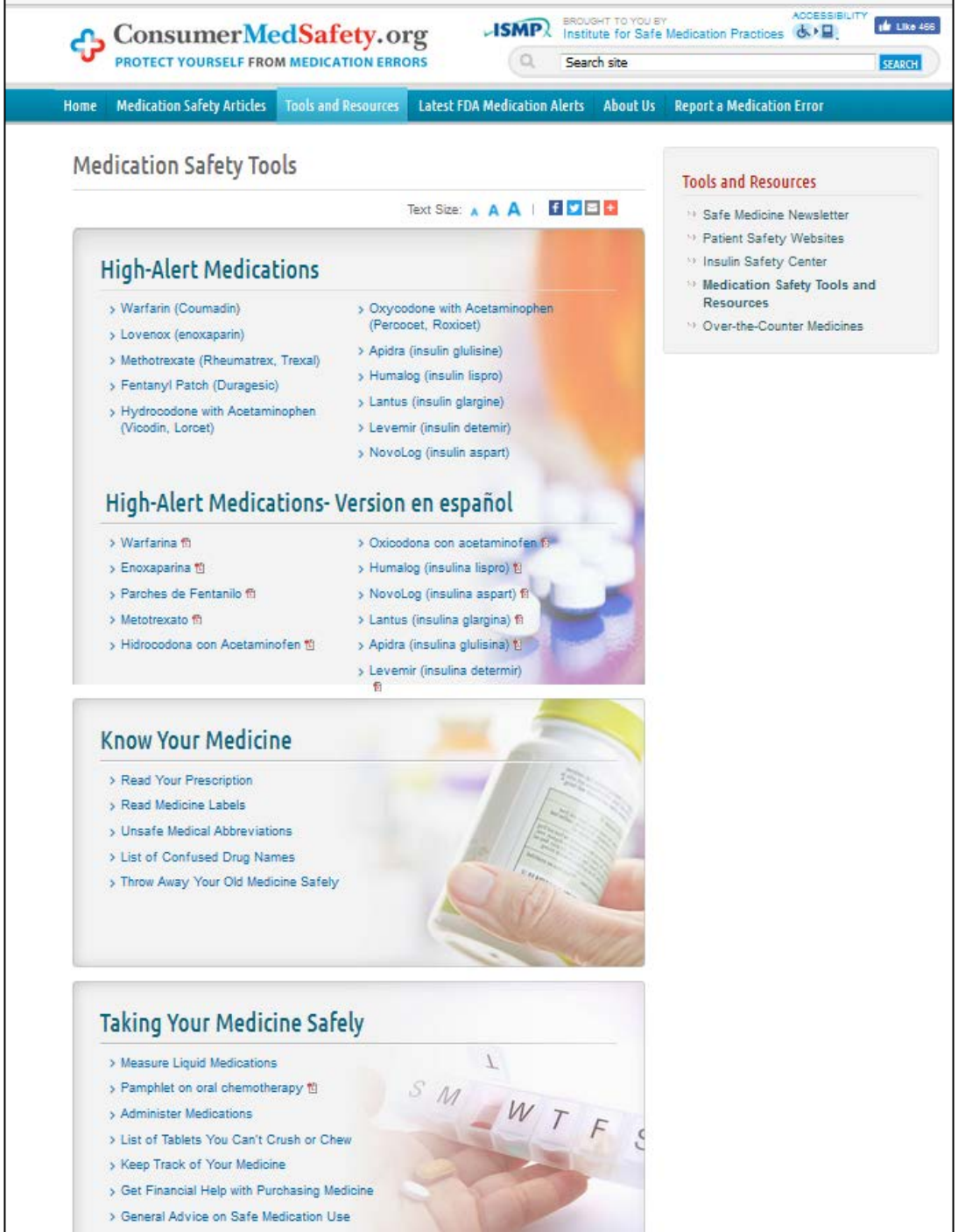
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Warfarin (Coumadin)
Lovenox (enoxaparin)
Methotrexate (Rheumatrex, Trexal)
Fentanyl Patch (Duragesic)
Hydrocodone with Acetaminophen (Vicodin, Lorcet)
Oxycodone with Acetaminophen (Percocet, Roxicet)
Apidra (insulin glulisine)
Humalog (insulin lispro)
Lantus (insulin glargine)
Levemir (insulin detemir)
NovoLog (insulin aspart)
High-Alert Medications- Version en español
Warfarina
Enoxaparina
Parches de Fentanilo
Metotrexato
Hidrocodona con Acetaminofen
Oxicodona con acetaminofen
Humalog (insulina lispro)
NovoLog (insulina aspart)
Lantus (insulina glargina)
Apidra (insulina glulisina)
Levemir (insulina determir)
Know Your Medicine
Read Your Prescription
Read Medicine Labels
Unsafe Medical Abbreviations
List of Confused Drug Names
Throw Away Your Old Medicine Safely
Taking Your Medicine Safely
Measure Liquid Medications
Pamphlet on oral chemotherapy
Administer Medications
List of Tablets You Can't Crush or Chew
Keep Track of Your Medicine
Get Financial Help with Purchasing Medicine
General Advice on Safe Medication Use
Tools and Resources
Safe Medicine Newsletter
Patient Safety Websites
Insulin Safety Center
Medication Safety Tools and Resources
Over-the-Counter Medicines

New!

< ISMP International >
Safe Medication Management Fellowship

ISMP is now accepting applications for a unique **2-year International Fellowship**

Sponsored by: Baxter International

Location and Term: The 2-year International Fellowship, sponsored by Baxter International, begins on **September 1, 2017**, at the Horsham, Pennsylvania (near Philadelphia) office of the Institute for Safe Medication Practices (ISMP). Relocation to the Horsham/Philadelphia area is required.

Qualifications: The International Fellow must:

- Have an advanced degree in healthcare (e.g., PharmD, master's degree)
- Have at least 1 year of experience in a clinical role in an acute care setting
- Be fluent in written and spoken English
- Be a US citizen or have official documentation that allows him or her to remain in the US for 2 years and travel internationally for a week or more at a time

Description: The International Fellowship will help train a medication safety leader seeking a long-term career at an international level. The Fellow will be involved in global medication safety initiatives, address worldwide safety issues, and help increase global reporting of medication errors. They also will work directly with international professional organizations and medication safety centers, and attend multi-country medication safety meetings and events. The Fellowship offers an unparalleled opportunity to learn from and work collaboratively with US and international experts in medication safety to assess and develop global medication error-prevention strategies.

How to Apply

Information, a course outline, and an application can be found at:
www.ismp.org/sc?id=2898.
Applications can also be requested by calling 215-947-7797.

The application deadline for the International Fellowship is June 30, 2017.

Advanced Education Opportunities

ISMP Fellowship

- 12 month experience
- Prepare practitioners for medication safety leadership positions
- Opportunities to network with pharmaceutical, healthcare, legislative, and regulatory professionals

Practitioner in Residence

- 1 week “rotation” tailored to each practitioner
- Includes didactic sessions and the opportunity to work with ISMP staff on a medication safety problems