

FDA Drug Topics: ROLE OF FDA AND ISMP IN PREVENTING MEDICATION ERRORS



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Learning Objectives

- Describe FDA's role in pre-marketing and post-marketing activities to prevent and address medication errors.
- Outline strategies aimed to increase the safe use of drug products by minimizing use error that is related to the design, naming, labeling, and/or packaging of drug products.
- Review examples of recent medication error reports.
- Summarize how healthcare providers can help identify, prevent, and mitigate medication errors.

DMEPA's Premarket and Postmarket Activities in Preventing Medication Errors



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Center for Drug Evaluation and Research (CDER)



Office of Surveillance and Epidemiology (OSE)

Office of Pharmacovigilance and Epidemiology (OPE)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Division of Pharmacovigilance I, II (DPV I, DPV II)

Division of Epidemiology I, II (DEPI I, DEPI II)

Division of Medication Error Prevention and Analysis (DMEPA)

Division of Risk Management (DRM)

Overview of DMEPA

Division of Medication Error Prevention and Analysis

- CDER lead for medication error prevention and analysis for drug and therapeutic biological products
- Scientists and healthcare professionals with varied backgrounds

Mission:

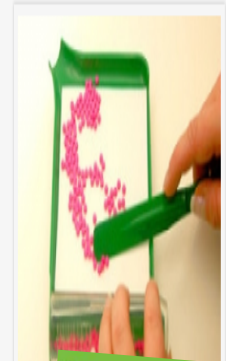
To increase the safe use of drug products by minimizing use error that is related to the *naming, labeling, packaging, or design* of drug products

Definition: Medication Error

- “A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer”
 - National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)
- Intentional or deliberate uses (e.g., abuse, misuse, off label use) are generally not considered medication errors



Medication Errors are a Global Public Health Burden



ISMP Canada Safety Bulletin
Psychiatric patient given wrong medication due to misspelling
 Inspection of Owencurra centre in Cork, found a 'serious medication error'
Death Associated with an IV Compounding Error
of Care in a Naturopathic Centre

Preventing Medication Errors: A \$21 Billion Opportunity



Spanish medicines regulator, AEMPS, the

Educating the Healthcare Community About Safe Medication Practices

WHO launches global effort to halve medication-

related errors in Dutch hospitals pay out millions in 5 years

tech™ (Quarter 3 2017)

medications using the Ellipta device,

ished in the Dutch Journal of

ge cl

News - Health

SAFETY briefs

Multivitamin injection label error: The vial label on the single dose INFINTE Adult multiple vitamins injection, manufactured

NHS medication errors contribute to as many as 22,000 deaths a year, major report shows

son to medication error

Medical errors under the spotlight at key forum in Riyadh

\$21 BILLION

Estimated annual cost of U.S. outpatient and inpatient preventable medication errors

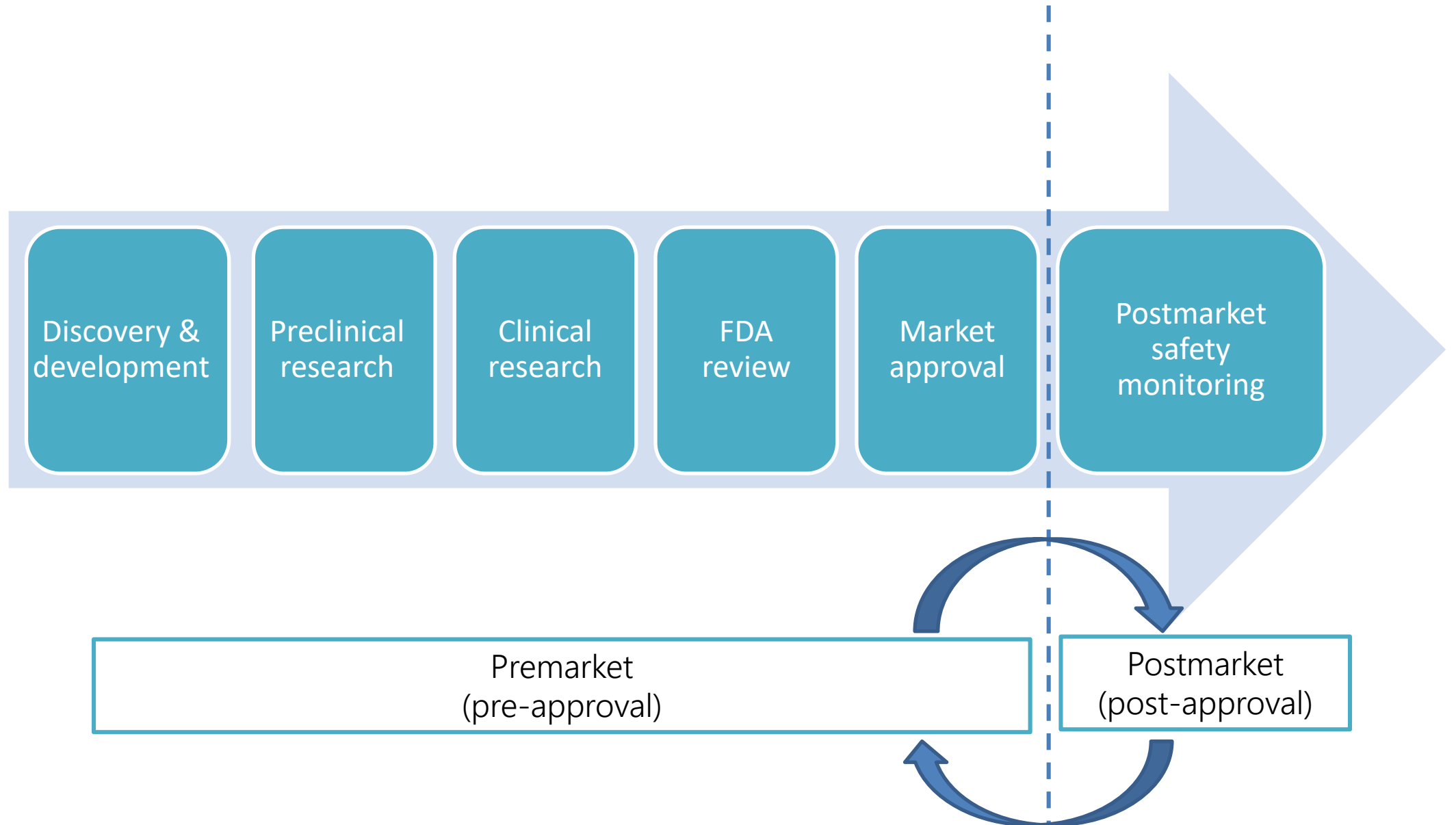
52%

Among adult outpatients...52% (95% CI: 42–62%) of adverse drug reactions were preventable

45%

Among inpatients...45% (95% CI: 33–58%) of adverse drug reactions were preventable [errors]

Medication Errors and Product Life Cycle



WHAT DO WE DO?

DMEPA Review Activities

Reviews take into account current federal regulations, applicable Guidance for Industry, USP Standards, and relevant postmarket experience.

-  **PROPRIETARY NAMES**
Primary/signatory authority on review of proprietary names.
-  **NONPROPRIETARY NAME SUFFIX**
-  **PRODUCT LABELING**
-  **PRODUCT PACKAGING**
-  **HUMAN FACTORS/ PRODUCT DESIGN**
Primary/signatory authority on human factors protocols.
-  **POSTMARKET PHARMACOVIGILANCE**

BEST PRACTICES IN DEVELOPING PROPRIETARY NAMES FOR DRUGS

DRAFT GUIDANCE FOR INDUSTRY
MAY 2014

Guidance for Industry

Best Practices in Developing Proprietary Names for Drugs

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov/>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis, Kellie Taylor at 301-796-0157, or (CBER) Office of Communications, Outreach and Development at 800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2014
Drug Safety



Safety assessment of proposed proprietary name for risk of drug name confusion that may lead to medication errors.

Considerations:

- **spelling** of the name
- **pronunciation** of the name when spoken
- **appearance** of the name when scripted throughout the medication use system

Look-Alike Sound-Alike Safety Assessment

BEST PRACTICES IN DEVELOPING PROPRIETARY NAMES FOR DRUGS

DRAFT GUIDANCE FOR INDUSTRY
MAY 2014



Proprietary Name Review



OPDP*

Conducts **misbranding** assessment of the proposed proprietary name

*For OTC products, the misbranding review is conducted by the Office of Nonprescription Drugs (ONPD)

OND

Provides **misbranding** and **safety** concerns with the proposed proprietary name based on clinical, chemistry, and/or pharmacology data that may impact acceptability

DMEPA

Conducts **safety** assessment of the proposed proprietary name for risk of drug name confusion that may lead to medication errors.

BEST PRACTICES IN DEVELOPING PROPRIETARY NAMES FOR DRUGS

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MAY 2014



Proprietary Name Review Misbranding Assessment

BEST PRACTICES IN DEVELOPING PROPRIETARY NAMES FOR DRUGS

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MAY 2014

DMEPA will **object** to a proposed name if it may **misbrand the product** for the following reasons:

- The proprietary name suggests that the drug is safer or more effective than has been demonstrated by scientific evidence.
- The proprietary name is “fanciful” and suggests that it has some unique effectiveness or composition when it does not. (21 CFR 201.10(c)(3)).



Proprietary Name Review Safety Assessment

BEST PRACTICES IN DEVELOPING PROPRIETARY NAMES FOR DRUGS

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MAY 2014

Focus: Prevent medication errors due to drug name confusion

21 CFR 201.10 (c.) The labeling of a drug may be misleading by reason (among other reasons) of:

(5) Designation of a drug or ingredient by a proprietary name that, because of *similarity in spelling or pronunciation*, may be confused with the proprietary name or the established name of a different drug or ingredient.



Proprietary Name Review Safety Assessment

BEST PRACTICES IN DEVELOPING PROPRIETARY NAMES FOR DRUGS

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MAY 2014

- Preliminary safety assessment:
 - United States Adopted Names (USAN) stems
 - other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors
- Similarity in printing, writing, and speech
- FDA Prescription Simulation Studies
 - handwritten prescriptions
 - verbal pronunciation of the drug name
 - computerized provider order entry
- Similarity of names by using FDA's Phonetic and Orthographic Computer Analysis (POCA) program and assessment of POCA scores

Proprietary Name Review Safety Assessment

Role of product characteristics in
proprietary name review



Coumadin 4 mg po qd

Coumadin 4 mg or Avandia 4 mg?

- Indications
- Strength
- Dose
- Dosage form
- Unit of measure, typical quantity or volume
- Route of administration
- Frequency of administration
- Instructions for Use
- Patient population
- Prescriber population
- Product Packaging
- Physical attributes
- Storage conditions
- Setting of use

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DEVELOPING
PROPRIETARY
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Proprietary Name Review Safety Assessment

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Considerations for Computerized Provider Order Entry

"Starts with"

Provides choices after typing
only a few letters

Brintellix
Brilinta

"Contains"

Provides all options that
contain what was typed

Ranexa
Tranexamic acid

SAFETY
CONSIDERATIONS FOR
CONTAINER LABELS
and
CARTON LABELING
TO MINIMIZE
MEDICATION ERRORS

DRAFT GUIDANCE FOR INDUSTRY
APRIL 2013

Guidance for Industry

Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

April 2013
Drug Safety



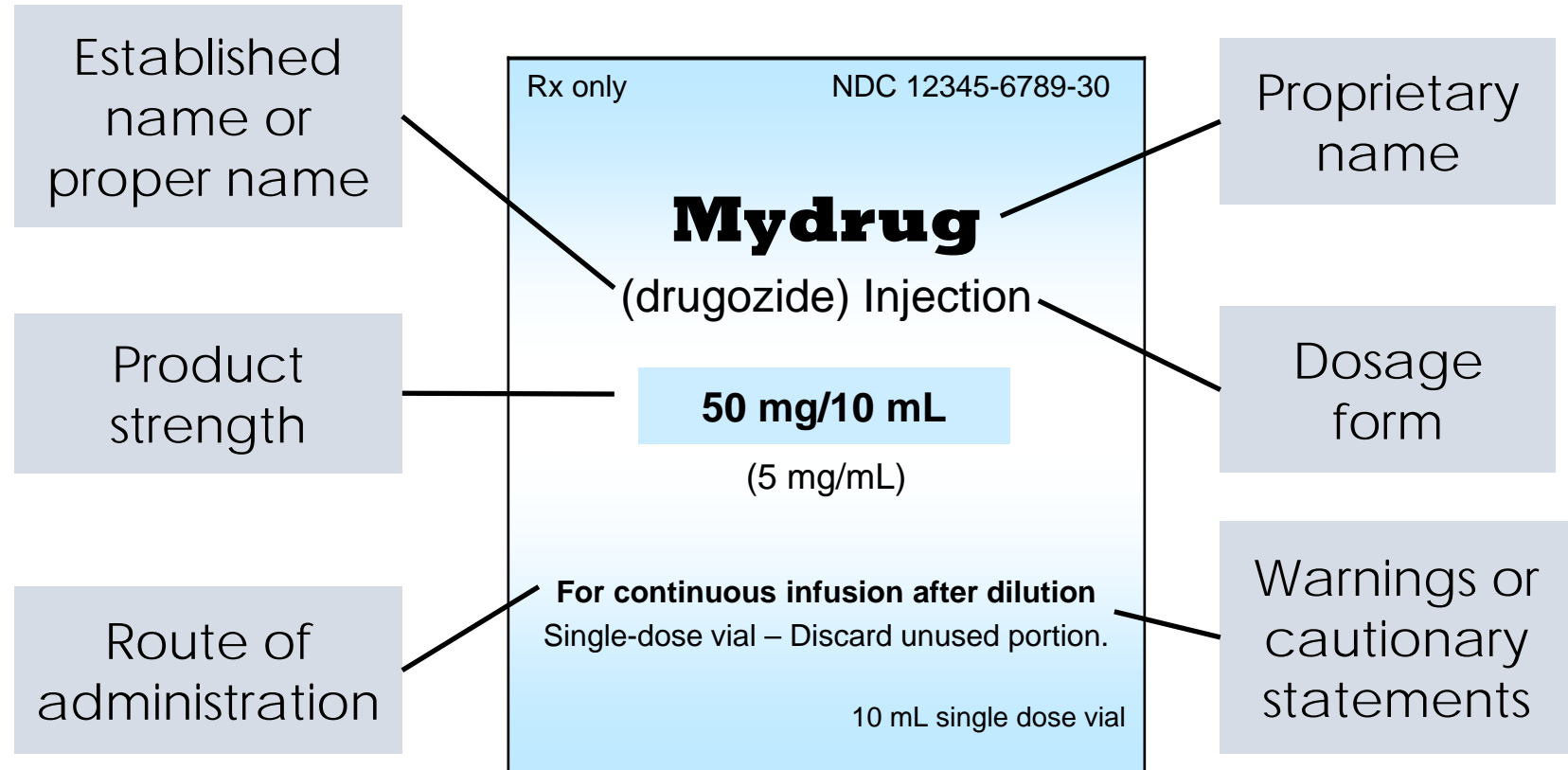
Product container labels and carton labeling should communicate information that is **critical to the safe use of a medication throughout the medication use system.**



Critical product information should appear the most prominent on the **Principal Display Panel (PDP)**

SAFETY CONSIDERATIONS FOR CONTAINER LABELS and CARTON LABELING TO MINIMIZE MEDICATION ERRORS

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APRIL 2013



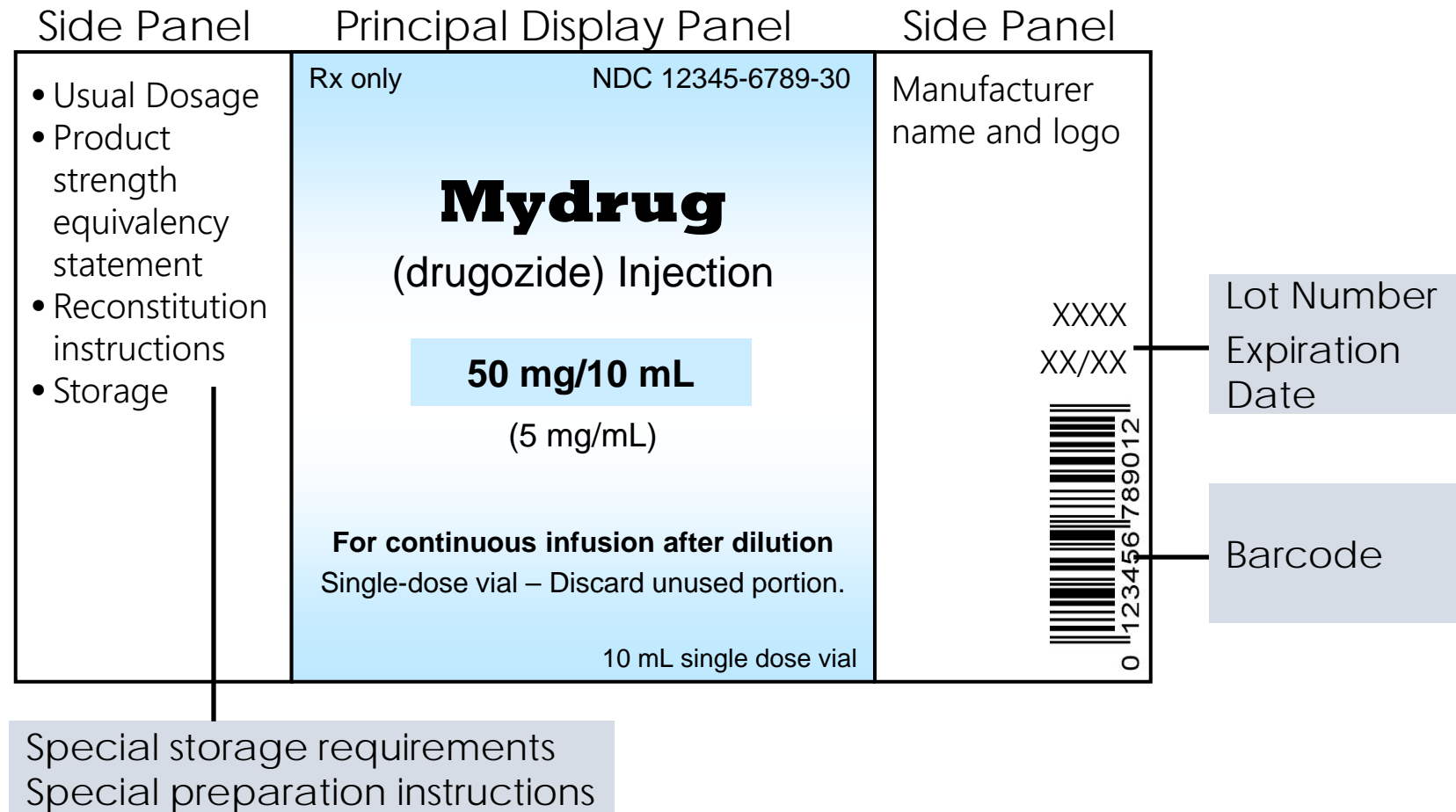
The Principal Display Panel is the portion of the container label or carton labeling that is most likely to be displayed, presented, shown, or examined by the user when the product is on a shelf



Product information on side and back panels

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Text *Size*, Font *Style*, and **Color** on the Principal Display Panel

SAFETY CONSIDERATIONS FOR CONTAINER LABELS and CARTON LABELING TO MINIMIZE MEDICATION ERRORS

- Use at least a 12-point sans-serif font (e.g., Arial)

ProprietaryName
(Established name)



- Choose text and background color to afford adequate legibility of text

Proprietary Name
(Established name)



- Avoid color combinations that do not afford maximum legibility of text

Proprietary Name
(Established name)



SAFETY
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Product Name

- The proprietary and established or proper name should be the most prominent information on the label
- The established name should be at least 1/2 the size of the proprietary name
- The established name should include the dosage form



Rx only NDC 12345-6789-30

Mydrug
(drugozide) Injection

10 mg/2 mL
(5 mg/mL)

For continuous infusion after dilution
Single-dose vial – Discard unused portion

Product Strength Expression

SAFETY CONSIDERATIONS FOR CONTAINER LABELS and CARTON LABELING TO MINIMIZE MEDICATION ERRORS

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140 mg per tablet

Use metric units of measure (e.g., mg, mcg, mL)

Nitroglycerin
Nitroglycerin in 5% Dextrose Injection
25 mg/250 mL
(100 mcg/mL)

The strength should match the units of measure in the Dosage and Administration section of the Prescribing Information

2 g/20 mL
(100 mg/mL)

Small volume parenteral products: Express strength as the quantity per total volume followed in close proximity by quantity per milliliter enclosed by parentheses

100 mg per vial

Dry powder parenteral products: Express strength as the amount per container

20 mg per tablet
Contains 40 mg total dose (2 x 20 mg tablets)

Blister packs: Express strength per unit; may also display the dose in certain instances

Product Strength and Net Quantity Statements

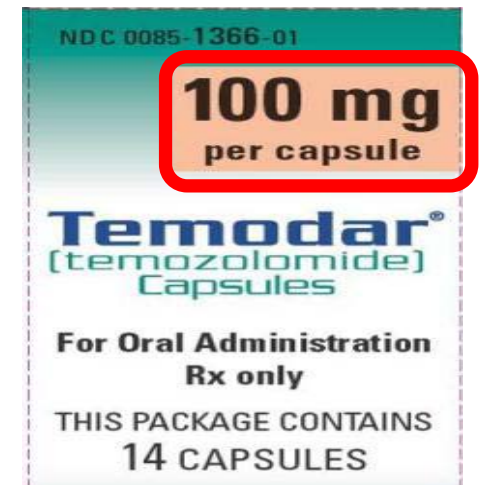
SAFETY CONSIDERATIONS FOR CONTAINER LABELS and CARTON LABELING TO MINIMIZE MEDICATION ERRORS



Note the placement of strength and net quantity



Note prominence of strength



Product Strength Differentiation




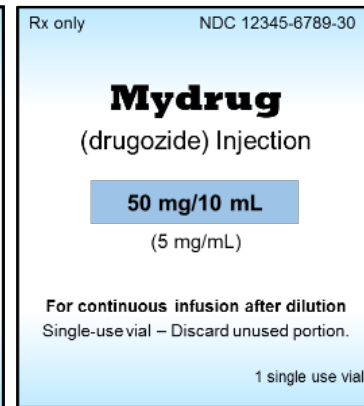
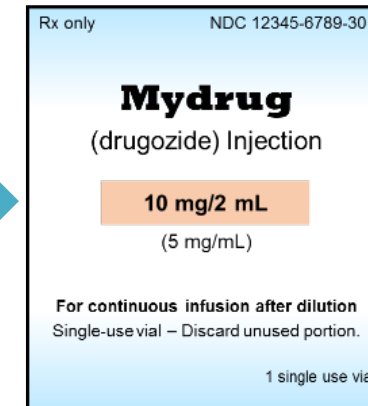
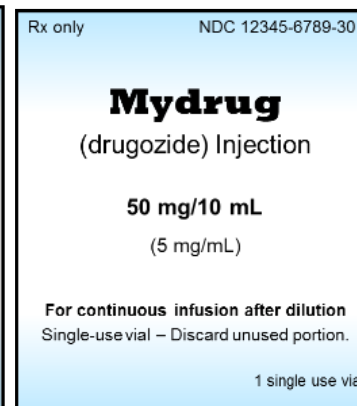
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Ensure the product strength stands out on the container label and carton labeling

Techniques include:

- Boxing 
- Prominent typeface or type weight
- Color differentiation



Route of Administration

- Must be present on the PDP for non-oral products per [21 CFR 201.100 \(b\)\(3\)](#)
- Avoid abbreviations
- Use affirmative statements (e.g., use “for irrigation” instead of “not for injection”) because “not” can be obscured or overlooked



FOR DEEP INTRAMUSCULAR INJECTION ONLY
WARNING: FATAL IF GIVEN BY OTHER ROUTES



SAFETY CONSIDERATIONS FOR CONTAINER LABELS and CARTON LABELING TO MINIMIZE MEDICATION ERRORS

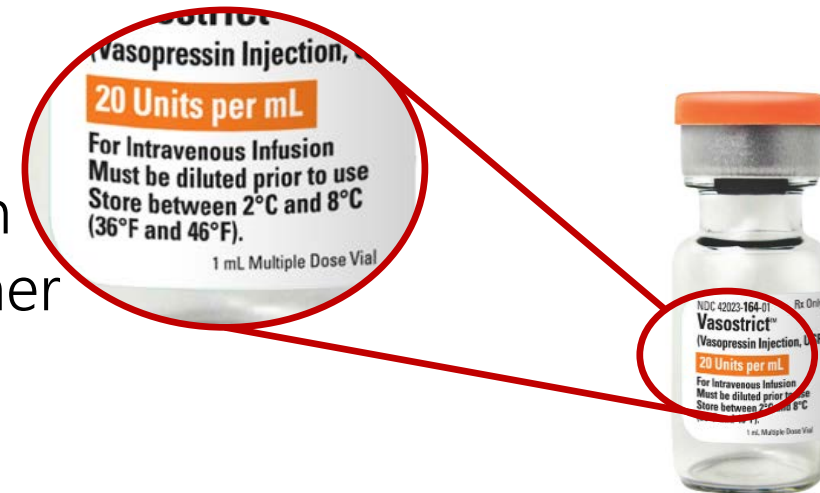
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 APRIL 2013

Warnings for Critical Information

SAFETY CONSIDERATIONS FOR CONTAINER LABELS and CARTON LABELING TO MINIMIZE MEDICATION ERRORS

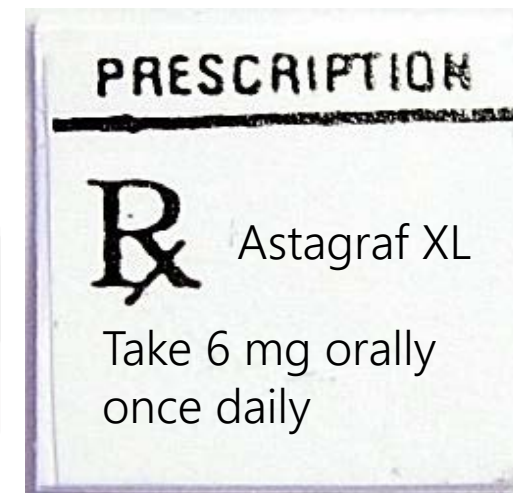
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- Use affirmative statements
 - For intravenous infusion
 - Fatal if given by any other route
 - Must dilute before use



- Consider whether the statement is helpful to ensure safe use

Patient: Took 1 mg orally once daily.
Patient stated she was following directions on the bottle





Avoid Crowding, Visual Clutter, Dangerous Abbreviations, and Acronyms

- Crowded labels/labeling may make important information difficult to read and/or easily overlooked
- Safety considerations:
 - Separate lines or blocks of text **with sufficient blank space**
 - Place **non-critical information on side/back panels**
 - Refer to ISMP's "List of Error Prone Abbreviations, Symbols, and Dose Designations"
 - Don't superimpose text over images or logos



SAFETY CONSIDERATIONS FOR CONTAINER LABELS and CARTON LABELING TO MINIMIZE MEDICATION ERRORS

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SAFETY
CONSIDERATIONS FOR
PRODUCT DESIGN
TO MINIMIZE
MEDICATION ERRORS

GUIDANCE FOR INDUSTRY
APRIL 2016

Safety Considerations for Product Design to Minimize Medication Errors

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

April 2016
Drug Safety



FDA EXPECTS MANUFACTURERS TO:

1. Investigate, understand and correct identified risks

Use analytical methods to develop drug products

2. Build safety into the product design

Apply these methods early in drug development and throughout the drug product's life cycle

3. Enable safe and correct use

Eliminate or reduce design elements that can cause use-related hazards

Drug product user interface

refers to all parts of a product a user interacts (e.g., sees and touches)

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CONSIDERATIONS FOR
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Most **effective strategies** focus on improvements to design of **drug product user interface**.



- Consider **effect** of each design choice on end user
- Evaluate using **proactive risk assessments** before finalizing design
- Evaluate **how and why** problems have occurred with similar products
 - Identify error prone features and eliminate them from design
 - Prevent same errors from occurring
- Sponsors should consider **lessons learned** to minimize risks associated with their designs

Container Closure Design

- Is the container closure design:
 - safe for the route of administration?
 - appropriate for the intended users?
- Avoid use of a container closure that implies a route of administration other than the route intended, unless there are no other options available

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MEDICATION ERRORS

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Product Strength

- Review for inconsistency between drug product strength and dosing
 - Multiple units (e.g. tablets, capsules, vials, syringes) required to achieve a usual single dose?
- Dosing errors due to:
 - miscalculations
 - forgetting how much has already been administered



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Product Strength

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- Co-packaged dosage delivery device should be consistent with recommended dosing regimen/directions for use
- Printed matter appearing on dosage delivery device is considered labeling
 - Dose markings must be easy to read
- Dosing devices for oral solutions should use *metric unit markings*

Human Factors?

“...the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations...”

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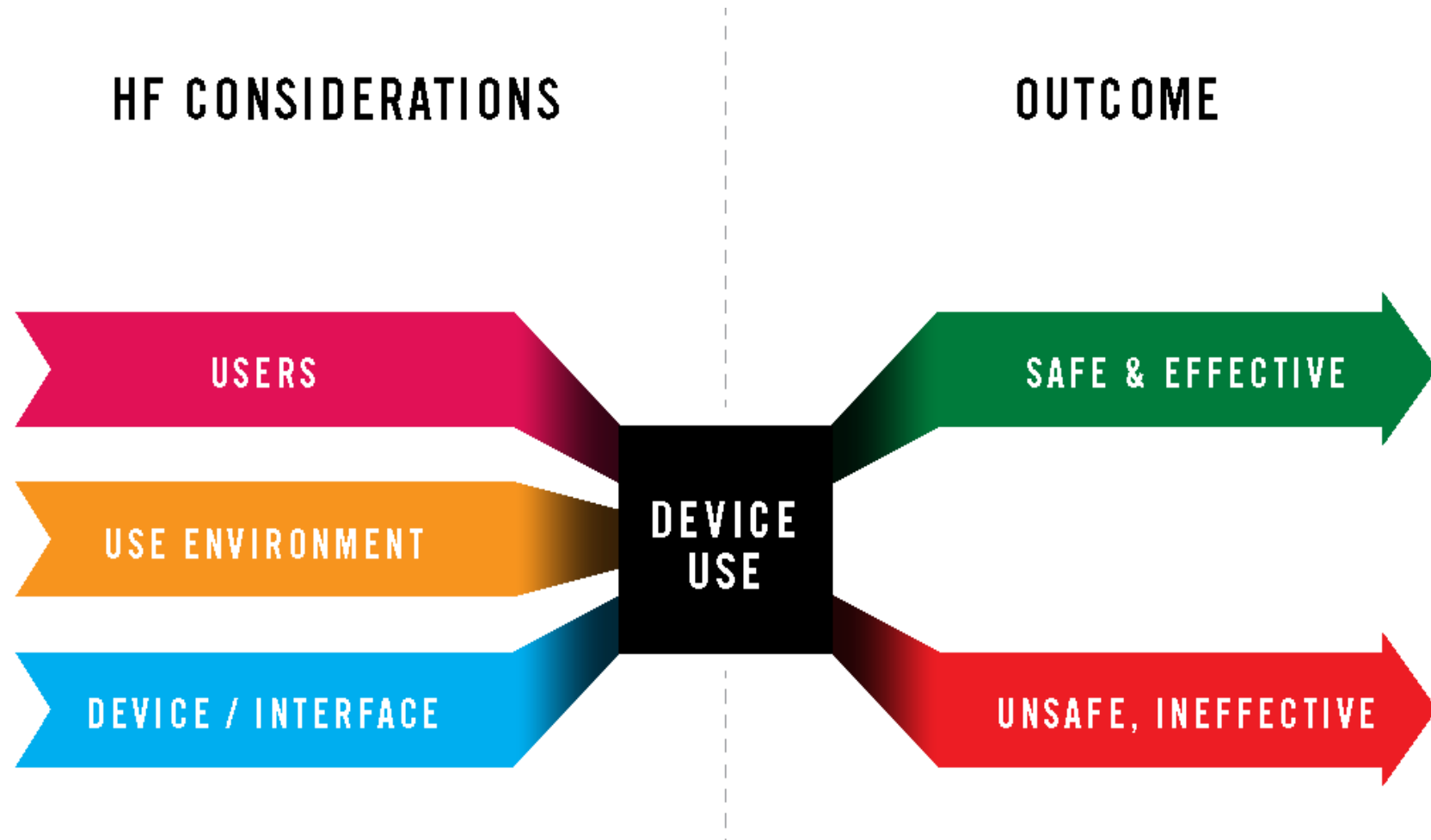
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Human Factors Considerations

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Human Factors Validation Studies



SAFETY CONSIDERATIONS FOR **PRODUCT DESIGN** TO MINIMIZE MEDICATION ERRORS

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- Systematic collection of data from representative participants in realistic situations
- Help determine whether users can safely and correctly perform critical tasks involved in using the product
- Results can be used to update the Failure Mode and Effects Analysis (FMEA)
- Should be conducted before product is submitted for approval, before any product modifications or additions to a product line
- Recommend that sponsors conduct human factors studies to characterize risks as well as develop mitigation strategies
 - Studies are generally small in size and short in duration (as compared to clinical studies that support drug approval)
 - Relatively small investment of resources early in product development can avoid the need to resolve issues post-approval

Postmarket Surveillance of Medication Errors

Why is postmarket surveillance necessary?

- Limitations of premarket clinical trials
 - Trials are conducted under controlled conditions, and may not use the final approved name, labels, labeling, and packaging
 - Numbers of patients tested is too small to detect serious but rare problems, and some errors may fall into this category
 - Trials are often of short duration
- FDA has a robust program to identify potential errors and address them prior to approval. However, medications errors remain a significant burden on public health*
- Allows us to monitor error reports and address those causes of errors that may be related to a drug's name, label and labeling, or packaging (before a product is widely distributed).

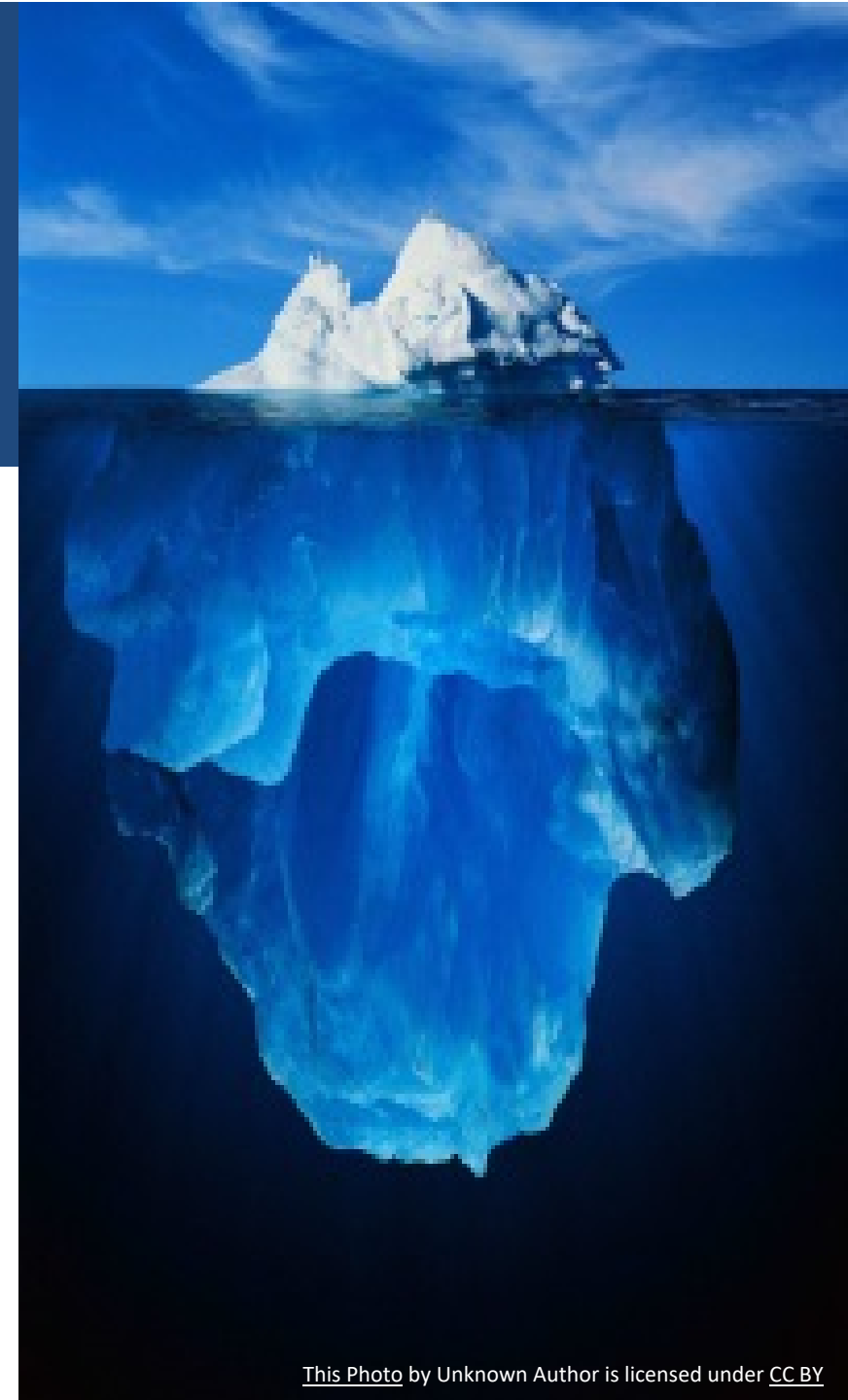
Medication error case reports

- FDA has Memorandum of Understanding (MOU) agreements with ISMP and other organizations to share publicly available medication error information
- The FDA Adverse Event Reporting System (FAERS) is FDA's primary source for monitoring medication errors, but we surveil other sources, including ISMP newsletters



Medication errors are *underreported*

- Extent of underreporting is unknown
 - Elliott, et.al., “estimated that **237 million medication errors occur** at some point in the medication process in England per year”
 - Prevalence and Economic Burden of Medication Errors in The NHS in England. 2018 (<http://www.eepru.org.uk/wp-content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf>)
- No U.S. requirement to report medication errors to FDA
- Likelihood of reporting medication errors *versus* adverse events



Barriers for reporting medication errors

- Fear of punishment or litigation
- Embarrassment of having been involved a medication error
- Different definitions for medication error
- Not knowing where, why, or what to report
- No allowance for anonymous reporting
- Organizational culture
- Workload/amount of time required for reporting

Original research

Identifying, understanding and overcoming barriers to medication error reporting in hospitals: a focus group study

Nicole Hartnell,¹ Neil MacKinnon,² Ingrid Skirrow³

ABSTRACT
Objectives: The under-reporting of medication errors can compromise patient safety. A qualitative study was conducted to enhance the understanding of barriers to medication error reporting in healthcare organisations.
Methods: Focus groups (with physicians, pharmacists and nurses) and in-depth interviews (with risk managers) were used to identify medication error reporting beliefs and practices at four community hospitals in Nova Scotia, Canada. Audio tapes were transcribed verbatim and analysed for thematic content using the template style of analysis. The development and analysis of this study were guided by Safety Culture Theory.
Results: Incentives for medication error reporting were thematised into three categories: patient protection, provider protection and professional compliance. Barriers to medication error reporting were thematised into five categories: reporter burden, professional identity, information gap, organisational factors and fear. Facilitators to encourage medication error reporting were classified into three categories: reducing reporter burden, closing the communication gap and educating for success. Participants indicated they would report medication errors more frequently if reporting were made easier, if they were adequately educated about reporting, and if they received timely feedback.
Conclusions: Study results may lead to a better understanding of the barriers to medication error reporting, why these barriers exist and what can be done to successfully overcome them. These results could be used by hospitals to encourage reporting of medication errors and ultimately make organisational changes leading to a reduction in the incidence of medication errors and an improvement in patient safety.

BACKGROUND
 Medication errors (any preventable event that may cause or lead to inappropriate medication use or patient harm while the

BMJ Qual Saf 2012;21:e81-88. doi:10.1136/bmjqs-2011-000299

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Student observations of medication error reporting practices in community pharmacy settings

Patricia L. Darbshire^a, Jessica C. Zhao^b, Angad Sodhi^c, Chelsea M. Anderson^{d,*}

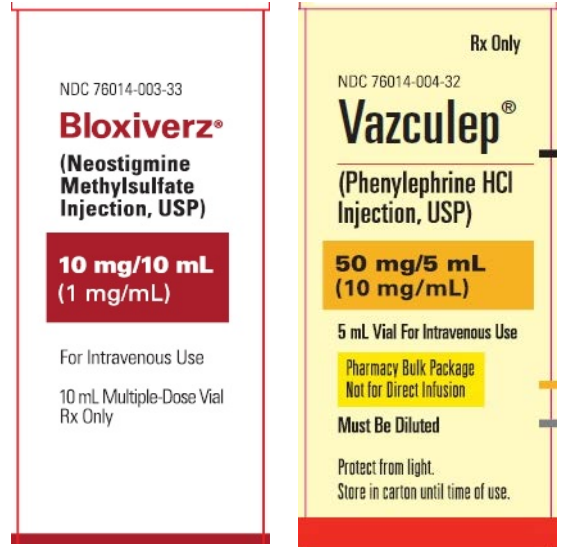
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^b Purdue University, 2334 NE 31st Street, Sammamish, WA, 98074, United States
^c Purdue University, 11 Branding Iron Lane, Glen Cove, NY, 11542, United States
^d Purdue University, 575 Stadium Mall Drive, RHPH G35, West Lafayette, IN, 47907, United States

ARTICLE INFO	ABSTRACT
<p>Keywords: Medication safety Community pharmacy Medication error reporting</p>	<p>Background: Medication safety practices and methods for reporting errors in community pharmacies are relatively unknown. Objective: (s) The primary objective of this study was to describe student-reported data on medication safety and error reporting practices in community pharmacies, and secondarily describe student learning from this assignment. Methods: Second professional year pharmacy students enrolled at Purdue University College of Pharmacy in the United States observed and recorded medication safety and error reporting practices as part of an experiential assignment. Data were collected from 170 unique pharmacy settings between the years 2016-2018 and analyzed using descriptive statistics and a paired t-test to assess student learning. Results: 51% of students reported documentation of 1-10 errors or near misses annually, with an additional 30% reporting 11-30. Near misses were only reported 26% of the time. Errors were most commonly reported to a pharmacy-specific reporting system (84%) and the Institute for Safe Medication Practices National Medication Errors Reporting Program (84%). The most frequently reported error types included wrong directions (34%), wrong drug (14%), wrong strength (13%), and wrong patient (12%). Pharmacists were observed to be interrupted approximately 19 times every hour. Anonymous error reporting was typically not allowed to the pharmacy's preferred error reporting system (71%). A policy requiring that the prescriber is contacted about errors was observed at 77% of the sites. The most common consequences of committing an error were education/training (72%) or progressive discipline (41%). Students reported a statistically significant increase in understanding of medication safety practices and methods for reporting errors in community pharmacies. (p < 0.01). Conclusion: This data supplements existing literature on medication safety practices and error reporting in community pharmacy settings, as well as highlights knowledge gaps outside the scope of this study.</p>

1. Introduction
 There is no current international consensus regarding the definition of a medication error. The United States National Coordinating

including workspace design, number of prescriptions filled, number of pharmacists on staff, or inadequate pharmacy technician training.^{3,4} Community pharmacies in the United States dispense over 4.1 billion prescriptions annually.^{5,6} Using a dispensing error rate of 3.2%

Example of Progression from Nonserious Event to **SERIOUS**



Summary

- We **encourage** healthcare providers to report all medication errors to MedWatch.
- If we are aware of potential problems, we can work to provide effective interventions that may help minimize further errors.
- Post marketing experience also helps us anticipate potential errors.
- We aim to identify and address the risk prior to marketing to help prevent medication errors.

Resources

Guidances for Industry:

- Best Practices in Developing Proprietary Names for Drugs (*Draft*) – May 2014
- Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors (*Draft*) – April 2013
- Safety Considerations for Product Design to Minimize Medication Errors – April 2016
- Applying Human Factors and Usability Engineering to Medical Devices – February 2016

We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database

<https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

Regulations*:

- 21 CFR 200s, 300s and 600s

*http://www.ecfr.gov/cgi-bin/text-idx?SID=c8497935ae0f040dfcfe06c6251ba507&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl

A Lot Happens When You Report A Medication Error or Hazard to FDA and ISMP



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ISMP National Medication Error Reporting System

June 14, 2018 • Volume 23 Issue 12

ISMP

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

ISMP National Vaccine Errors Reporting Program 2017 analysis (Part I): Vaccine errors continue with little change

Although vaccination ranks high among the greatest public health achievements of the twentieth century, the success of any individual vaccine relies on correct and widespread administration to the appropriate patient population. Vaccine errors threaten to undermine the protection immunizations provide and often leave patients inadequately protected against serious diseases such as hepatitis A and B, pertussis, diphtheria, cervical cancer, and many others. An analysis of 575 events submitted to the ISMP National Vaccine Errors Reporting Program (ISMP VERP) between January and December 2017 suggests that errors with vaccines continue to occur. Also, the number of error reports submitted to the ISMP VERP in 2017 increased by more than 100 reports compared to prior years since 2012. The most frequent types of vaccine errors reported during 2017 included:

- Wrong vaccine (23%)
- Wrong dose (19%)
- Expired vaccines or contamination/deterioration (19%)
- Wrong age (17%)
- Wrong time or interval (8%)
- Vaccine/component omission (e.g., only diluent or a single component of a two-component vaccine administered) (4%)
- Wrong route (2%)
- Wrong patient (1%)

continued on page 2—2017 analysis (Part I) >

Workbook of preliminary comparative assessment data available to participants

The Preliminary Comparative Data from the ISMP Medication Safety Self Assessment® for High-Alert Medications workbook is now available to participants who submitted their findings to ISMP. The workbook contains 4 tables and 9 graphs of aggregate data that can be used by participants to compare their results to the aggregate results of demographically similar US facilities. Inpatient, outpatient, and prioritization worksheets are also provided. To access the workbook and associated worksheets, log in to your account at https://ismpassessments.org/high_alert/, and click on the links titled "Results Workbook" and "Results Worksheets" in the top right corner of the page.

Help ISMP update its list of high-alert medications

It's been more than 4 years since we last surveyed readers and updated the ISMP List of High-Alert Medications in Acute Care Settings. Please take a few minutes to complete our 7-question survey (copy on pages 6-7) and submit your responses to ISMP at: www.ismp.org/exit/28. We would appreciate your opinion about possible deletions or additions to the list before we update it. We thank you for taking the time to provide your perspective on this important topic!

ISMP consulting services... Look what you may be missing

We're often asked if we provide medication safety consulting services to healthcare organizations; the answer is, yes! Because our only focus is medication safety, ISMP Consulting Services offers a unique, educational, and objective perspective on practice, technology, and system issues associated with all aspects of the medication use process. In addition to a full prospective risk assessment of the medication use system, ISMP consultants can offer an unbiased viewpoint when investigating medication-related sentinel events or conduct focused assessments of specialty services (e.g., pediatrics, oncology, ambulatory surgery). ISMP's expertise is also ideal to assist you when focusing on certain high-alert medications, technology implementation, optimization of error reporting and detection, management of safety data, and the creation of a medication safety infrastructure.

Tailored to the organization's size and scope of service, an interdisciplinary team that may include specialists in key areas (e.g., pediatrics, oncology, technology) directly observes current medication processes and meets with frontline practitioners, management and administrative staff, and medication-related safety committee members to learn their unique perspectives on current practice. At the completion of the onsite assessment, the team holds a summary conference, followed by a customized written report of recommendations and implementation tools that are specific to your organizational needs, capabilities, and culture. The team remains available post-consult for questions. In addition to the confidentiality of these services, ISMP is a Patient Safety Organization (PSO) and can structure its work to best protect your patient safety information. Inquire about our services via our website www.ismp.org/consulting-services, email cconsults@ismp.org, or by calling 215-947-7797. We are here to help!

- Early warning system
 - Issue nationwide hazard alerts and press releases
- Learning
 - Dissemination of information and tools
- Change
 - Product nomenclature, labeling, and packaging changes, device design, practice issues
- Standards and Guidelines
 - Advocates for national standards and guidelines

ISMP and ECRI Institute Join Forces

By joining together, ECRI Institute and ISMP create one of the largest healthcare quality and safety institutions in the world, driving greater value to the healthcare organizations they serve with unrivaled expertise, resources, and solutions.

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Consulting and Education

Tools and Resources

Publications and Alerts

Error Reporting

LOGIN



Our Reporting Programs

What We Do with Your Reports

Your Reports at Work

Who We Work With

Data Analysis and Coaching

Report an Error

Error Reporting for Practitioners

Error Reporting for Consumers

Report a Vaccine Error

By joining together, ECRI Institute and ISMP create one of the largest healthcare quality and safety institutions in the world, driving greater value to the healthcare organizations they serve with unrivaled expertise, resources, and solutions.

LEARN MORE

ISMP National Medication Errors Reporting Program

Thank you for for submitting a report to the ISMP National Medication Errors Reporting Program (MERP).

- Please provide as much detail as possible when telling us the story of what went wrong or could go wrong, the causes or contributing factors, how the event or condition was discovered or intercepted, and the actual or potential outcome of the involved patient(s).
- Be sure to include the names, dosage forms, and dose/strength of all involved products. For product-specific concerns (e.g., labeling and packaging risks), please include the manufacturer.
- Share your recommendations for error prevention.
- If possible, submit associated materials (e.g., photographs of products, containers, labels, de-identified prescription orders) that help support the report being submitted.

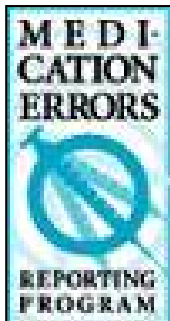
Please complete the form below and click on the "Submit" button to report the error or hazard to the ISMP National Medication Errors Reporting Program.

Name:	<input type="text"/>	(optional)
Email:	<input type="text"/>	
Confirm email:	<input type="text"/>	
Error Description:	Please describe the incident as best you can. This information will be handled in confidence.	
	<input type="text"/>	
Upload Images (optional)	<input type="text"/>	<input type="button" value="Select"/>
	Up to three images can be uploaded, Input area will appear after each image is selected up to 3.	
	<input type="button" value="Submit"/>	

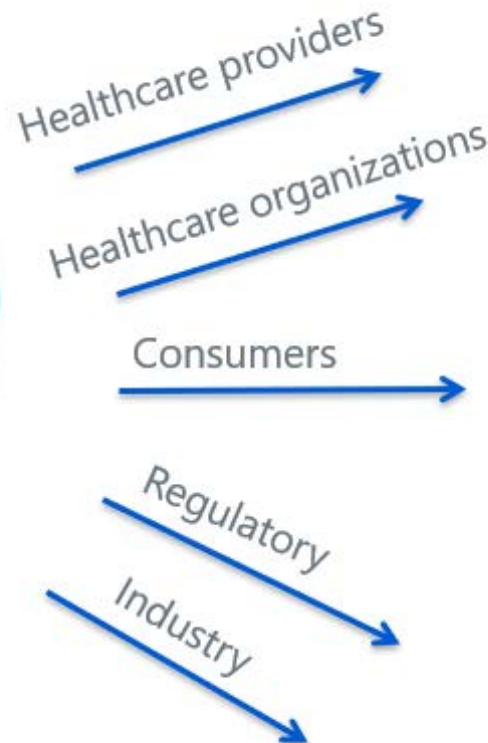
Reporting to ISMP as a PSO



Where does ISMP get its information? Where does it go?



ISMP Canada
 ISMP Spain
 ISMP Brazil
 IMSN



Process when you report a hazard or error to ISMP – Every report is indispensable!



Report received and entered into ISMP database



- Report entered into one of our databases and initially reviewed by ISMP nurse or pharmacy technician analyst
- ISMP sends an email to reporter to confirm receipt of the report and thank him or her for reporting

ISMP professional staff review every report and gather additional information if necessary



- Report redacted of identifying provider and/or facility information
- Nurse or analyst distributes reports and accompanying photographs, screen shots or attachments through secure portal to ISMP interdisciplinary professional staff
- Professional staff reviews every report, shares comments on topic with one another via the portal

ISMP professional staff review every report and gather additional information if necessary



- Similar hazards, errors identified
- Suggest questions to ask reporter to better understand the report, make recommendations for mitigating the risk
- Reports incite conversation among professional staff
- Gain understanding of the reported risks and underlying causes

Report identified as requiring further investigation for sharing the lessons learned



- Significant factor - is report actionable? Leads to further investigation and sharing of lessons learned
- Can patients, vendors, standards organizations and regulators take specific actions to prevent or reduce risk of similar error, or mitigate potential patient harm?
- Is hazard or error new? Has it caused or could it cause harm? Does it require action by FDA or manufacturer, state professional board, standards organizations such as USP or The Joint Commission?

Further investigation conducted, with additional resources accessed

Steps ISMP may take to investigate hazards or errors:



INVESTIGATE

- Reach out to reporter to ask clarifying questions, seek out additional information, graphics or examples
- Conduct professional literature, drug information and error-reporting database searches
- Seek out expert advice from established advisory groups or organizations with extensive knowledge in key subject areas

Further investigation conducted, with additional resources accessed



- Interact with other federally listed patient safety organizations (PSOs), such as our ECRI affiliate
- Interact with FDA Division of Medication Error Prevention and Analysis and others within the agency.
- Memorandum of Understanding with CDER

Further investigation conducted, with additional resources accessed



- Formal monthly calls and two face to face meetings annually
- Contact the pharmaceutical product manufacturer, device and technology vendors, drug information vendors and other service providers
- Conduct surveys to learn more about specific types of errors

Recommendations identified to drive further improvements



- Primary focus is on a few well-thought-out, high-leverage, long-term recommendations that are realistic, measurable, and attainable with reasonable resources
- Because ISMP is not a standards-setting organization, we sometimes make ambitious recommendations to drive practice, process, and technology improvements
- Many reports trigger FDA, manufacturer, device/technology vendors to further investigate and respond

Aggregate data from error databases analyzed and published periodically



2017-2018 BIENNIAL REPORT

The ISMP National Vaccine Errors Reporting Program (VERP)



www.ismp.org

<https://www.ismp.org/resources/2017-2018-vaccine-bi-annual-report>

February 13, 2020 • Volume 25 Issue 3

Acute Care
ISMP Medication Safety Alert!
Educating the Healthcare Community About Safe Medication Practices

ISMP
AN ECRI COMPANY AFFILIATE

**New Available from ISMP:
 Expanded Smart Pump Guidelines**
 We have just released revised and expanded *Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps* to provide strategies for addressing potential barriers and integrating this technology with other electronic systems. The expanded guidelines cover a broad scope of smart infusion pump usage in both inpatient and ambulatory settings, including perioperative, procedural, and radiology locations. The expanded guidelines also include recommendations to employ smart infusion pumps with dose error-reduction systems for plain IV fluid infusions. Also, there is a new set of guidelines associated with bi-directional smart pump interoperability with the electronic health record. For recommendations on reducing risks involving infrastructure, drug libraries, continuous quality improvement data, clinical workflow, and interoperability, visit www.ismp.org/node/1172.

Errors associated with oxytocin use: A multi-organization analysis by ISMP and ISMP Canada

PROBLEM: Intravenous (IV) oxytocin used antepartum is indicated to induce labor in patients with a medical indication, to stimulate or reinforce labor in selected cases of uterine inertia, and as an adjunct in the management of incomplete or inevitable abortion. Used postpartum, IV oxytocin is indicated to produce uterine contractions during expulsion of the placenta and to control postpartum bleeding or hemorrhage. However, improper administration of oxytocin can cause hyperstimulation of the uterus, which in turn can result in fetal distress, the need for an emergency cesarean section, or uterine rupture. Sadly, a few maternal, fetal, and neonatal deaths have been reported.

In October 2019, ISMP Canada published a multi-incident analysis¹ to identify opportunities to improve the safe use of this high-alert medication. A total of 144 reports of incidents associated with oxytocin were analyzed from voluntary reports submitted to ISMP Canada and the Canadian National System for Incident Reporting (NSIR) between 2000 and 2019. Maternal, fetal, or neonatal harm was reported in 12% of the oxytocin reports to ISMP Canada and 29% of the oxytocin reports to NSIR. Most of the incidents reported in both data sets occurred during drug administration.

In February 2020, ISMP analyzed an additional 52 voluntary reports associated with oxytocin submitted to the ISMP National Medication Errors Reporting Program (ISMP MERP) between 1999 and 2019. About 30% of the reports described more than one oxytocin error that had occurred. About 44% of the reported events originated during dispensing, with many relating to mix-ups between oxytocin and look-alike product vials. About a quarter (23%) originated during administration, and 13% during prescribing. Overall, about 8% of the reports were hazards that did not result in errors. A quarter (25%) of all events resulted in maternal, fetal, or neonatal harm.

Analysis of the 144 incidents reported to ISMP Canada and NSIR revealed 3 main themes, some with multiple subthemes. Analysis of the 52 reports submitted to ISMP revealed similar themes along with a few additional themes. The five themes from both ISMP Canada and ISMP analysis of oxytocin incidents are presented below.

THEME 1: PRESCRIBING ERRORS

Selection of wrong drug on order entry screen. Oxytocin errors related to prescribing were associated with selecting the wrong drug from a computerized prescriber order entry (CPOE) screen when searching using only 3 letters, "PIT", "OXXC" or "OXY10." Most recently, two errors were reported in which physicians had entered "PIT" for **PITOCIN** (oxytocin) in the CPOE system but accidentally selected **PITRESSIN** (discontinued brand name for vasopressin still found in some CPOE systems). When entering "OXY10" into the CPOE system, the following error occurred:

A physician intended to prescribe oral **OXYCONTIN** (oxycodone) 10 mg every 12 hours as needed for pain for a postpartum patient. He entered "OXY10" into the CPOE search field but accidentally selected "oxytocin 10 units IV" from the menu, resulting in an order for oxytocin 10 units IV every 12 hours as needed for pain. The pharmacist was concerned about the order but dispensed the medication as prescribed.

continued on page 7 — [Display](#) >

SAFETY briefs

Problems with containers with dual linear barcodes. We received a report about nurses scanning the wrong barcode on B Braun Duplex containers of ceftazidime injection (Figure 1). These and other B...
continued on page 7 — [SAFETY link](#) >

Figure 1. Nurses are confusing the two linear barcodes on B Braun Duplex containers.

<https://www.ismp.org/node/14240>

Hazard/error story & recommendations shared with FDA and via newsletters, interaction with manufacturers, vendors, other key stakeholders



- ISMP's primary vehicles are publication in one or more of our 5 subscription-based newsletters
- Urgent medication advisories requiring immediate notification of healthcare providers published first in a National Alert Network (NAN) bulletin to both ISMP email lists, ASHP members, ISMP website and member organizations of National Coordinating Council Medication Error Reporting and Prevention (NCCMERP)
- Error information contextually deidentified as necessary. Stories make information memorable

Long-Term Care AdviseERR™

Educating the Healthcare Community About Safe Medication Practices



A lot happens when you report a hazard or error to ISMP—there's no "black hole" here!

In 2019, ISMP celebrated its 25th anniversary with a year devoted entirely to medication error prevention. As we look back on our successes because bringing attention to signs and we want to assure never fall into a "black hole" been again. To demonstrate all that happens when you report a hazard or error to ISMP (summarized in Figure 1), whether it is via email or a phone call, reporting programs—the Reporting Program (ISMP), Vaccine Errors Reporting (ISMP), and the ISMP Consumer Medication Errors Reporting Program (ISMP-C-MERP).

Initial Review of Report
When ISMP receives a hazard or error report, it is entered into one of our databases: nurse or pharmacy technician or pharmacist report (ISMP), ISMP sends an email to the reporter and to thank him or her.

After redacting any identifying patient and/or facility information, our reports and any accompanying pictures or attachments through a secure portal professional staff. The professional staff review every report and often share comments on the topic with each other through the portal; identify similar hazards, errors, or related resources; suggest questions to ask the reporter to better understand the report; and make recommendations for mitigating the risk. Many reports incite conversation among ISMP professional staff so we can all understand the reported risks and underlying causes.

Depending on the level of detail provided in the original report, our nurse or analyst sends specific questions to the reporter so we can learn as much as possible about the event and its causes. In addition, each report is shared with the US Food and Drug Administration (FDA) and, if known, the manufacturer(s).

Supported by educational grants from Novartis and Fresenius Kabi

Nurse AdviseERR™

Educating the Healthcare Community About Safe Medication Practices



A lot happens when you report a hazard or error to ISMP—there's no "black hole" here!

In 2019, ISMP celebrated its 25th anniversary as the nation's organization devoted entirely to medication error prevention. As we look back on our successes because you have reported medication hazard bringing attention to significant medication safety issues. Even if we are unable to, and we want to assure you that the reports you submit never fall into a "black hole," irretrievably lost and never to be seen again. To demonstrate this, we want to share with you all that happens when you report a hazard or error to ISMP (summarized in Figure 1), whether it is face-to-face, via email or a phone call, or through one of our three error-reporting programs—the ISMP National Medication Errors Reporting Program (ISMP-NMER), the ISMP National Vaccine Errors Reporting Program (ISMP-NVER), and the ISMP Consumer Medication Errors Reporting Program (ISMP-C-MERP).

Initial Review of Reports

When ISMP receives a hazard or error report, it is entered into one of our databases and initially reviewed by an ISMP nurse or pharmacy technician analyst. Since most reports submitted to ISMP include the reporter's email address, ISMP sends an email to the reporter to confirm receipt of the report and to thank them for reporting.

After redacting any identifying patient and/or facility information, our nurse or analyst distributes all reports and any accompanying pictures or attachments through a secure portal to all ISMP interdisciplinary professional staff. The professional staff review every report and often share comments on the topic with each other through the portal; identify similar hazards, errors, or related resources; suggest questions to ask the reporter to better understand the report; and make recommendations for mitigating the risk. Many reports incite conversation among ISMP professional staff so we can all understand the reported risks and underlying causes.

Depending on the level of detail provided in the original report, our nurse or analyst (or another ISMP professional) sends specific questions to the reporter so we can learn as much as possible about the event and its causes. In addition, each report is shared with the US Food and Drug Administration (FDA) and, if known, the manufacturer(s).

Supported by educational grants from Novartis and Fresenius Kabi

ECRI Institute—ISMP affiliation creates one of the largest nonprofit

SAFETY wires
Abbreviations to avoid. Angiotensin II (GIAPREZA) injection for intravenous

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Educating the Healthcare Community About Safe Medication Practices



Medical abbreviations that have contradictory or ambiguous meanings

ISMP would like to thank Neil M. Davis, PharmD, MS, FASHP, for authoring this article. The author can be reached at neil@medlabrev.com for any comments or questions.

Introduction

Abbreviations are a convenience, a time saver, and a way of fitting a word or phrase into a restricted space or avoiding the possibility of misspelling words. However, a high price can be paid for their use. Abbreviations are sometimes not understood, misread, or interpreted incorrectly. Their use lengthens the time needed to train healthcare professionals; wastes time tracking down their meaning; sometimes delays the patient's care; and occasionally results in patient harm.

I published my first book of medical abbreviations, *Medical Abbreviations: 1,700 Conveniences at the Expense of Communication and Safety*, in 1983. To expand the list of abbreviations, I contacted hospitals and requested lists of abbreviations that were used at their facility, searched the literature, and solicited readers to send me abbreviations. Since then, I have published 16 editions of the book, which now contains 55,000 abbreviations. A web version of the book is updated with more than 30 new entries per week.²

One of the problems I noticed was that one abbreviation could have two or more contradictory or ambiguous meanings, which can create dangerous communications. I collected these meanings, and a partial list of medical abbreviations with contradictory or ambiguous meanings is shown in Table 1 (pages 3-5). It is obvious from an examination of this list that these abbreviations should not be used, as they fail to communicate with any certainty their intended meaning and present possible dangers to the health of patients.

The Joint Commission directs medical facilities to publish a Do Not Use List³ of abbreviations that must not be used (see ISMP's list at www.ismp.org/node/8). This list is a very important step in the right direction but does not solve the systemic problem of an abbreviation with contradictory or ambiguous meanings.³ The Joint Commission standards also state, if multiple abbreviations exist for the same term, the organization must identify which one will be used to eliminate ambiguity.⁴ This step is extremely difficult to achieve.

Two Possible Solutions That May Not Be Feasible

1) Create a national list of standard abbreviations. A simplistic approach to this problem is to create a national list of approved abbreviations, with each abbreviation having only one meaning. The problem with this approach is that all medical specialties, allied health professionals, health-related organizations, and government agencies would have to agree on one meaning for each abbreviation.

A recognized health-related organization, such as USP, the American Medical Association, the Council of Science Editors, ISMP, or ECRI Institute, would have to be funded to take responsibility for creating and maintaining such a list. The organization would have to reach out to all the health-related organizations to suggest abbreviations that should be on this list. Then, arbitration would be required between organizations if there is conflict with a suggested abbreviation that has more than one submitted meaning, such as PT

continued on page 2—Abbreviations >

Community/Ambulatory Care ISMP Medication Safety Alert!

Educating the Healthcare Community About Safe Medication Practices



Speaking up about patient safety requires an observant questioner and a high index of suspicion

SAFETY briefs
Mix-ups between Almostly strengths

SAFE Medicine™

Protect Yourself from Medication Errors



As approval of medical marijuana spreads state by state, labeling problems have led to errors

Columbia (Washington, DC) have legalized medical marijuana. In addition, several states have legalized recreational use of marijuana. This information can be different than the street product. With medical products' contents, so this information can be different. However, each state has its own regulations in a wide variety of medical marijuana products. The labeling of these products.

Medical marijuana is Cannabis sativa. Much like the different marijuana comes in many different strains called cannabinoids. These cannabinoids are part on the growing conditions.

Medical marijuana are tetrahydrocannabinol (THC) and cannabidiol (CBD). THC affects the mind, behavior, and coordination, such as euphoria (happiness), relaxation, and intensity of these effects tends to be dose-dependent. Marijuana with high levels of THC may make you feel high. Even when taken in small doses, symptoms include dizziness, increasing the risk of falls. THC use can lead to marijuana use disorder.

Studies suggest it may help reduce inflammation, and seizures on epilepsy. Unfortunately, side effects include headache, diarrhea, restlessness, and marijuana addiction.

Product labeling mentions various drug-related toxicities that require reduced strength. See **SAFETY briefs >**



Figure 1. Stivarga carton holds three 28-tablet bottles.



Sidebar:
Labeling issue with medical marijuana

A patient in the hospital told a nurse she takes medical marijuana at home for pain and to help her sleep. She showed the bottle of medical marijuana to the nurse. The dropper bottle had a wrap-around label on it (Figure 1). The label said it was a 330 mg tincture and listed the contents as a "hybrid" with a 1:10 ratio. Instructions for use were not on the label. The patient stated the bottle contained a 30-day supply and that she takes half a dropperful at bedtime. The dropper had 0.5 mL and 1 mL markings on it.

Brand X	
Medical Marijuana	
330 MG	Hybrid
TINCTURE	1:10

Figure 1. Wrap-around label on a dropper bottle of medical marijuana liquid (with the product name replaced with "Brand X").

So how much THC and CBD did the patient take with each dose? The label does not show how much liquid (mL) equals 330 mg. Since the bottle contained a 30-day supply, the nurse calculated that the full bottle likely contained 15 mL, 30 days times each daily dose of 0.5 mL. Thus, the strength of the product might have been 330 mg per 15 mL. But, this is an unreliable way to determine the product strength.

The label also does not say if the ratio of 1:10 is THC:CBD or CBD:THC. So how much THC and CBD are in each dose? When the patient's husband brought in the box that held the bottle, the label said there was no CBD at all in the product, even though the label said it was a 1:10 ratio of a "hybrid."

patient and community aware that the FDA's parts of dispensing errors (b-000) injection, antibody prophylaxis. The 70 mg or 140 mg once monthly, pre-filled syringe for patient self-



140 mg/ml

oved in May 2018, two containing injector (for the 70 mg/mL, 140 mg monthly injections to administer 140 mg dose, the 140 mg/mL as approved in lower, until the containing two's depleted, there packages on the 140 mg

SAFETY briefs >



Acute Care ISMP Medication Safety Alert!

Educating the Healthcare Community About Safe Medication Practices

COVID-19-related medication errors

H In our April 9, 2020 newsletter (www.ismp.org/node/15489), we shared an idea to add a question, “Is this event related to COVID-19 (coronavirus)?” to reporting systems to categorize COVID-19-related events, allow rapid analysis of quickly emerging risks, and reduce leadership’s reaction time in knowing about and addressing some of these issues. Since then, we have received several COVID-19-related medication errors each week and wanted to update you on a few important issues.

Remdesivir investigational drug labeling confusion

ISMP received a report last week about a hospital compounding issue due in part to label confusion with the investigational drug remdesivir. Some facilities have received this drug, manufactured by Gilead Sciences, under a compassionate use program during a period of expanded access and through an emergency use authorization (EUA) program issued by the US Food and Drug Administration (FDA). The hospital had implemented an investigational study using intravenous (IV) doses of remdesivir to treat patients with severe COVID-19. The adult protocol called for an initial loading dose of 200 mg, followed by subsequent 100 mg doses. Each vial of remdesivir contains a total of 100 mg. Instead of using 1 vial to prepare each 100 mg subsequent dose, 2 vials were used, thus providing 200 mg for each subsequent dose instead of the intended 100 mg.

Remdesivir is available for use in clinical trials in at least two different dosage forms: a lyophilized powder for injection and a solution for injection. Like many investigational drug container labels, the vials are not clearly labeled, and the information presented is crowded and in a small font (see our 2-part article about problems with investigational drug labeling: www.ismp.org/node/1048; www.ismp.org/node/1068). The vials of lyophilized powder have a label listing the total amount (100 mg) of drug in the vial (Figure 1). The vials of remdesivir injectable solution have a label that lists the per mL strength, “Remdesivir (GS-5734) Injection, 5 mg/mL” (Figure 2). Below the 5 mg/mL listing, the vial label notes the total volume in the vial, “Contents: 21.2 mL,” which may

continued on page 2 — COVID-19 errors >

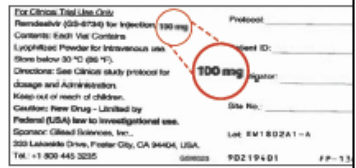


Figure 1. Label on vial of remdesivir lyophilized powder notes that it contains 100 mg.

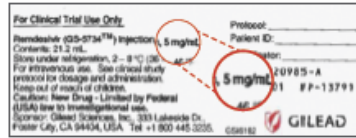


Figure 2. Label on vial of remdesivir injectable solution does not indicate the total amount (100 mg) of drug in each vial; instead, it lists a per mL amount (5 mg/mL) and below that, the total contents of the vial, 21.2 mL, which can be easily missed.

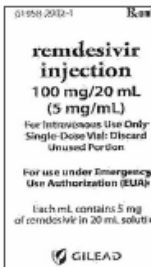


Figure 3. Another label from remdesivir injectable solution, which prominently lists the total amount of drug in each vial (100 mg/20 mL), with the per mL amount (5 mg/mL) in parentheses below it.

COVID-19 Collaboration

⚡ Double concentration (2%) propofol product becoming available
Fresenius Kabi received an emergency use authorization (EUA) on May 8, 2020, from the US Food and Drug Administration (FDA) to allow US marketing of

COVID-19 Collaboration

⚡ Double concentration (2%) propofol product becoming available
Fresenius Kabi received an emergency use authorization (EUA) on May 8, 2020, from the US Food and Drug Administra-

tion of patients 16 years and older who require mechanical ventilation in an intensive care unit (ICU) during the COVID-19 pandemic. Propoven 2% is expected to be available by mid-June. This will help address the unprecedented demand for propofol used to treat hospitalized patients with COVID-19, particularly given pending propofol shortages.

There is an obvious concern with Propoven 2% given its double concentration. Use of the product may lead to overdoses if practitioners are unaware of the different concentration. Propoven 2% should be carefully reviewed by an interdisciplinary committee including pharmacy, nursing, medical, anesthesia, critical care, and ambulatory care representatives. Prior to use, all critical care prescribers (including those redeployed to COVID-19 critical care units), nurses working in critical care units, and anesthesia providers should be alerted to the double concentration. Fresenius Kabi will be providing stickers that warn about the 2% concentration, which should be applied immediately upon receipt of the product in the pharmacy so that each

continued on page 2 — Collaboration >

Acute Care ISMP Medication Safety Alert!

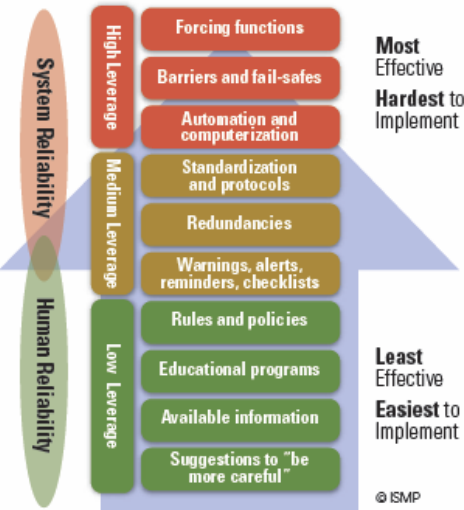
Educating the Healthcare Community About Safe Medication Practices

Education is “predictably disappointing” and should never be relied upon alone to improve safety

H A recent editorial in the May 2020 issue of *BMJ Quality & Safety* provides a noteworthy description of why education alone is a weak, low-value improvement intervention.¹ The editorial examines the impact of a national education program in Australia aimed at reducing outpatient proton-pump inhibitor (PPI) prescriptions, which found no significant changes in discontinuation of the intervention. The authors are unlikely to measure the impact of PPIs. They offer several salient reasons why education alone produces results. They first reviewed no improvements when examining the impact of education on clinical outcomes. Despite health system and clinical outcomes, the authors conclude that education alone is not sufficient, earning it a “necessary but not sufficient” intervention.¹

ISMP agrees that education alone is a weak improvement strategy. Education has its place as a basic prerequisite—it provides healthcare practitioners with the required knowledge (what they know) needed to develop the skills (applying that knowledge) to do their job well. For example, education about new medications, devices, automation, processes, and known risks is fundamental to forming a well-qualified complement of practitioners to manage medication safety. But while knowledge and skills are a necessary first step, education ranks among the least effective interventions in ISMP’s hierarchy of effectiveness of risk-reduction strategies (Figure 1), right below rules and policies, and far below more effective system-focused strategies such as forcing functions, barriers and fail-safes, and automation. ISMP has long noted that improvement strategies with the greatest impact on patient safety and the ability to sustain improvement are those that make it hard for practitioners to do their job wrong on page 2 — Education >

Figure 1. ISMP’s hierarchy of effectiveness of risk-reduction strategies. High-leverage strategies are most effective because they can eliminate the risk of errors and associated harm by “designing out” hazards; however, they often require complex implementation plans. Medium-leverage strategies, which are easier to implement, reduce the likelihood of errors or minimize harm; however, they may need periodic updating and reinforcement. Low-leverage strategies, which aim to improve human performance, are easy and quick to implement; however, they are the least effective strategies for error prevention although frequently relied upon.



© ISMP

Special Alert!

Prepare for vials of neuromuscular blocking agents without cap warnings
Due to the increase in demand for neuromuscular blocking agents for critically ill COVID-19 (coronavirus) patients on June 1, 2020, a significant shortage has occurred in the supply of these products, including vecuronium bromide (www.ismp.org/node/15489) and rocuronium bromide (www.ismp.org/node/15490). To assure availability of these two critical drugs, the US Food and Drug Administration (FDA) has no objection to the abbreviated labeling (ANDA) holder, Gland Pharma, Limited, to temporarily manufacture these drugs without the vial cap (seal) incorporating the usual statement, “Warning: Paralyzing Agent,” required by USP and FDA (Figure 1). Supply constraints prevent Gland from obtaining the products with the usual warning statements on the vial cap in time to address the shortage.

This temporary situation has obvious safety implications since the absence of the warning may make the vials look more like other medications in similar size vials and cap colors. **Neuromuscular**



Figure 1. Images of currently approved cap (left) and temporary cap (right) for vecuronium bromide injection 10 mg vial and 20 mg vial.

blocking agents are high-alert medications because of their well-documented history of causing catastrophic injuries or death when used in error. Staff awareness about the absence of the usual warning statement is critically important, as will be safe handling, as noted below.

continued on page 2 — Special Alert! >

ISMP Publications

— Regular Journal and Newsletter Features:

- *Pharmacy Practice News*
- *Nursing 2020*
- *Hospital Pharmacy*
- *Pharmacy Times*
- *Pharmacy Today*
- *US Pharmacist*
- *Journal of Emergency Nursing*
- *Home Healthcare Now*



INFORM

Error reporting outcomes

Reporter's Event Description

- "81 y.o. male admitted to hospital with slurred speech and gait change to R/O stroke. Blood glucose 57 mg/dL (Hgb A1C was 13.9% upon admission).
- **It was discovered that the patient had not been removing the inner cap of his pen needle for his insulin until the day prior to admission.**
- For over a year, the patient's physician was constantly increasing the patient's insulin dose to 150 units in the morning and 156 units at bedtime (plus 80 units insulin lispro before each meal).
- The patient described that when he injected his insulin, he would use a napkin to soak up the excess insulin that spilled when he injected himself.
- He confirmed he would use an entire pen per day. On day PTA **he realized he had not been removing the pen needle inner cap** as instructed during diabetes self-management education.
- Patient took off the inner cap and injected the prescribed amount of insulin resulting in hypoglycemia.
- The patient was treated and recovered. During hospital stay he required significantly less insulin (glargine 15 units subcutaneously hs and insulin lispro 4-6 units before meals)."

Hazard/Error Story & Recommendations Shared

February 26, 2009

Volume 14 Issue 4

Safety Briefs continued from page 2

Vaccine abbreviations. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) has provided a current list of standardized abbreviations for vaccines included in the immunization schedules for children, adolescents, and adults (www.cdc.gov/vaccines/recs/acip/downloads/vac-abbrev.pdf). These abbreviations are intended to provide a uniform approach to vaccine references used in ACIP Recommendations and Notices to Readers that are published in the *MMWR*, the *Pink Book*, the *American Academy of Pediatrics Red Book*, and other publications. However, ISMP discourages the use of vaccine abbreviations (or any drug name abbreviation) when communicating prescription information because some abbreviations on the CDC list have been confused with one another. For example, diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (DTaP) have been confused with tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine, adsorbed (Tdap). These are age dependent and are not interchangeable. Also, DT (diphtheria and tetanus toxoids adsorbed [children]) has been confused with Td (Tetanus and diphtheria toxoids adsorbed [adult]).

Special Announcement...

ISMP teleconference. Join ISMP and our guest speakers from Brigham and Women's Hospital and the Cleveland Clinic for our next teleconference, *Enhancing Medication Safety: The Role of Safe Labeling, Bar Coding, and Outsourcing of IV Products*, on March 12, 2009. You will learn how product labeling, bar-coding technology, and outsourcing IV products can reduce the risk of adverse drug events with IV products. For details, please visit: www.ismp.org/educational/teleconferences.asp.

ISMP Medication Safety Alert! Acute Care (ISSN 1550-6312) ©2009 Institute for Safe Medication Practices (ISMP). Permission is granted to subscribers to reproduce material for internal communications. Other reproduction is prohibited without permission. Report medication errors to the ISMP Medication Errors Reporting Program (MERP) at 1-800-FAIL-SAFE. Unless noted, published errors were received through the MERP. ISMP guarantees confidentiality of information received and respects reporters' wishes as to the level of detail included in publications. Editors: Judy Simetzer, RN, BSN, FISMP; Michael R. Cohen, BPh, MS, ScD; Russell Jenkins, MD. ISMP, 200 Lakeside Drive, Suite 200, Hershman, PA 19044. E-mail: administration@ismp.org; Phone: 215-947-7797; Fax: 215-914-1492. This is a peer reviewed publication.

Inattention blindness continued from page 2
enced by age and mental aptitude. From time to time, attention is also variable within an individual due to influences such as distractions, alcohol, drugs, and fatigue.

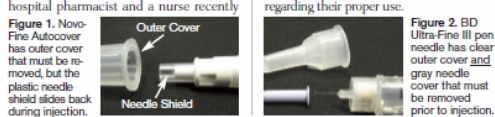
It is difficult to reduce the risk of inattention blindness, as it is an involuntary and unnoticed consequence of our adaptive ability to defend against information overload. Error-reduction strategies such as education, training, and rules are of little value. Instead, efforts should center on increasing conspicuity of critical information, and decreasing diversions of attention

Unusual explanation for hyperglycemia in patients on insulin

From a regulatory standpoint, hospitals are required by OSHA (CPL 2-2.69) to "use engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent." Whenever possible, that means using such things as safety needles in the hospital (preferably a passive system) to protect against needle stick injuries.

One example of a safety needle for use with the NOVOLOG (insulin aspart) FlexPen is the NovoFine Autocover (Figure 1). The user holds the cover while the system is screwed onto the insulin pen. The cover is then removed, exposing a plastic needle shield that initially covers a 30-gauge needle. As the insulin is injected, the shield slides and allows the skin to be punctured, needle unseen (a demonstration can be viewed at: www.novonordisk.com/diabetes/public/needles/novofine_autocover/quickguide/view.asp?id=intro). When the needle is removed, the shield retracts and locks over the needle, which remains hidden, so it can't be used again.

The Autocover system is quite different from standard insulin pen needles that patients purchase at their pharmacy, which may not employ a shielded system. A hospital pharmacist and a nurse recently

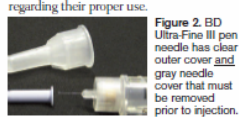


and secondary tasks when carrying out complex tasks.

References: 1) Green M. "Inattention blindness" and conspicuity. *Visual Expert* 2004 (www.visual-expert.com/?source=attentionblindness.html). 2) Angier N. Filed to change, even as it starts us in the face. *The New York Times* April 1, 2008 (www.nytimes.com/2008/04/01/science/01angier.html?_r=2&es=1207713600&em=204&omf=slain). 3) Federal Aviation Administration (FAA). FAA human factors awareness course. (www.hf.faa.gov/webtraining/intro/intro1.htm). 4) Arons B. A review of the cocktail party effect. MIT Media Lab; 1992. (www.media.mit.edu/people/papers/1992/aronb_AVI_05/92_cocktail_party_effect.pdf).

reported that some patients who became familiar with the NovoFine Autocover while in the hospital were later confused as they began to use a standard BD pen needle (BD Ultra-Fine III) after discharge. This needle also has a cover that, when removed, exposes a needle shield. However, the shield is actually just a **needle cap** that must first be removed to expose the needle for injection of the insulin (Figure 2). Some patients were confused and thought the cap would expose the needle when it was pushed against the skin, just as the Autocover shield did. After realizing that some patients' blood sugars were high, clinic nurses investigated and learned that patients were misusing the standard pen needles and, thus, not getting any insulin.

Patients who use Autocover devices and then switch to standard pen needles must be educated about the need to remove both caps. Removing the gray cap is an extra step that is not required with the NovoFine Autocover needles. If blood glucose levels are elevated after injection, the patient should be reminded to consult with their diabetes educator or physician, who should review injection techniques with the patient. Community pharmacists dispensing pen device supplies should also educate patients regarding their proper use.



NATIONAL ALERT NETWORK (NAN)

October 12, 2017

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 cover from the insulin pen needle prior to administration. She was unaware that she was using the pen incorrectly and, thus, had not been receiving any of the insulin doses. The patient developed diabetic ketoacidosis and later died.

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 dose 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.



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.

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 may 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 cover (Figure 2). The automatic safety needle shield is



continued on page 2—NAN >

The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP). 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. NCCMERP, 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.

Please encourage your patients and staff to visit www.consumermedsafety.org often. It may save a life!



September 26, 2018

LABELING CHANGE REQUEST

Dear Manufacturer,

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is aware of a postmarket safety issue associated with the use of pen needles used with pen injectors. These needles are regulated under the classification regulation 21 CFR [880.5570](#)¹ with product code FMI (Hypodermic Single Lumen Needle). Standard pen needles often have an outer cover and a removable inner needle cover, which are both removed before an injection. However, the FDA is aware that in some cases, the inner needle cover is not removed prior to use, resulting in non-delivery of the intended medication. The FDA has received some reports of hyperglycemia and diabetic ketoacidosis, including one death, associated with failure to remove the inner needle cover when a standard pen needle was used to inject insulin.

There are other safety pen needles which have an outer cover that is removed, and a fixed inner needle shield (sharps injury prevention feature) that is not removed before an injection. It is possible that patients could be taught using one type of pen needle, then receive the other type later. This could cause confusion about how to use the pen needle correctly, and may prevent the patient from getting the medicine they need. This issue was brought to our attention through the [Institute for Safe Medication Practices](#)² (ISMP), [National Alert Network \(NAN\)](#)³, Medical Device Reports (MDRs), FDA Adverse Event Reporting System (FAERS), and published [literature](#)⁴.

FDA reviewed the device labeling across standard insulin pen needle manufacturers to assess whether the Instructions for Use (IFU) adequately contain the necessary directions on steps to remove both covers, if applicable. While some manufacturers provide clear IFU to remove both the outer cover and the inner needle cover, the FDA found that some manufacturers do not provide this information, or the information may be confusing. For example, some manufacturers provide both written and visual graphics, while others provide only written instructions. Additionally, FDA found instances where removal of the outer cover and the inner needle cover were listed under one step in the IFU. Furthermore, there may be limited graphics supporting all necessary steps for safe use (e.g., the written information provided both steps but the graphic only showed one step).

It is important that the IFU for each device clearly and completely convey important information to device users. Therefore, FDA is requesting manufacturers who currently market pen needles cleared under product code FMI to review your most recent labeling (i.e., IFU) and training materials to assess the need for updates to clearly convey how to safely use your pen needle. In addition, FDA requests that all applicable standard pen needle manufacturers consider adding a warning in the labeling, similar to the following:

¹ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=880.5570>

² <https://www.ismp.org/alerts/severe-hyperglycemia-patients-incorrectly-using-insulin-pens-home>

³ <https://www.nccmerp.org/sites/default/files/nan-20171012.pdf>

⁴ Truong, T. H., Nguyen, T. T., Armor, B. L., & Farley, J. R. (2017). Errors in the Administration Technique of Insulin Pen Devices: A Result of Insufficient Education. *Diabetes Therapy*, 8(2), 221–226. <http://doi.org/10.1007/s13300-017-0242-y>

Your Reports at Work



FDA tells pen injector needle manufacturers to improve patient instructions

Thanks to your reporting about patients who failed to remove the inner pen needle cover prior to administering insulin, the US Food and Drug Administration (FDA) has asked needle manufacturers to update labeling and improve patient instructions for use.

Standard pen needles have outer and inner needle covers, both of which must be removed prior to injection. However, hospitals often use safety needles for medication pens. These have an outer cover that must be removed, but there is no inner cover to remove. An inner shield over the needle automatically retracts during injection and covers the needle after injection to prevent needlestick injuries. After discharge, patients may receive standard pen needles from their pharmacy and not know that the inner needle cover must be removed, especially if they have not been taught this step while hospitalized. If the inner cover of a standard pen needle is not removed, patients may not receive the medication. ISMP and the American Society of Health-System Pharmacists (ASHP) published a National Alert Network (NAN) Alert about this issue (www.ismp.org/node/44) in October 2017.

In response to these concerns, FDA has asked needle manufacturers to review their labeling and educational materials and to update and clarify the need to remove the inner needle cover/cap before injection. The agency also requested manufacturers to add a warning in the labeling, such as: "Remove both the outer cover and the inner needle cover before an injection. If both the outer cover and the inner needle cover are not removed before use, the medication or dose may not be injected, which may result in serious injury or death." The FDA labeling request can be accessed at: www.ismp.org/ext/155.

ISMP Medication Safety Alert! January 31, 2019

Working with industry to improve products



#	Report Date	Description	Product
74092	10/22/2019	Udenyca and Prolia have very similar packaging. A patient was dispensed Udenyca instead of Prolia. Luckily the error was caught by the RN before it reached the patient, but I feel like a change of the packaging is necessary to prevent this from happening in the future.	PROLIA
73744	7/19/2019	This error is in regards to the medications Prolia and Udenyca. The packages for both medications, from different manufacturers are very similar. Because of this, the medications were placed in the same bin in the refrigerator at XXXXXXXX XX XXXXXXXX Medical Center in XXXXX XXXXX, XXXXXXXXXXXXXXX. This could have potentially led to the wrong medication being given to a patient within the hospital.	PROLIA
73708	07/11/2019	Look alike packaging for Udenyca (biosimilar for Neulasta) made by Coherus and Prolia (Denosumab) made by Amgen. Udenyca is a newer biosimilar that has come to market. The box containing the product is, ironically, very similar looking to an AMGEN product, Prolia. Neulasta is also made by AMGEN. Both carry similar font and coloring including a green dot for the dosage/concentration. Udenyca is 6 mg and Prolia is 60 mg. If you contact me with an email address, I can attach a photo I took with them next to each other. Significant chance of staff grabbing 2 different medications with very different outcomes.	PROLIA
73678	6/28/2019	We encountered a look-alike packaging in our ambulatory clinics. Please see the attached photos of very similar packing of Prolia (denosumab) and Udenyca (pegfilgrastim-cbqv). These are both used in the same areas within in our clinics.	PROLIA
73674	6/28/2019	Our practice recently started purchasing pegfilgrastim-cbqv (Udenyca), a biosimilar product. When we received it, we noted that the packaging is very similar to denosumab (Prolia). The packages are of similar size, have similar coloring and other features. We are concerned that this is a potential safety issue and may lead to medication errors if the drug is incorrectly dispensed due to lookalike packaging.	PROLIA
73596	06/06/2019	I know ISMP often includes alerts in your newsletter regarding products with similar packaging. just found one that i haven't seen reported yet. Product packaging very similar on Prolia and Udenyca. Similarly sized box, same color scheme etc.	PROLIA
73550	5/22/2019	Medication safety issue with look-alike packaging between Udenyca and Prolia. Both are routinely use medications at an outpatient cancer center. See attached images.	PROLIA
73516	5/15/2019	While trying to obtain a Prolia injection from their unit's Omnicell they noticed that the wrong medication had been stocked in the cabinet. Udenyca had been stocked in the wrong location. Upon review by the pharmacy staff it was noted that the packaging was VERY similar despite having different manufactures. Both medications have green and white packaging with the concentration of the medication listed in a green circle in the same location.	PROLIA
73490	5/6/2019	Prolia syringes were found stocked in place of Udenyca syringes at an infusion site at my institution. No patient harm occurred. Contributed to this medication error is likely that their boxes are very similar in appearance in color and word placement, as well as their supply as a single-dose pre-filled syringe for subcutaneous administration (see image of both products side-by-side). It was thought that both items may have also been delivered in the same bag from our supplier in our order since they both require refrigeration, and that may have also contributed to the error. The very similar labeling and supply of these two commonly utilized medications at outpatient infusion centers may contribute to medication errors with these agents.	PROLIA

Working with industry to improve products



October 2019

IMPORTANT DRUG WARNING

Subject: Potential of carton confusion between UDENYCA® and Prolia® packaging associated with the risk of administration or dispensing error and adverse events

Dear Health Care Provider,

The purpose of this letter is to make you aware of the potential of carton confusion between the UDENYCA® (pegfilgrastim-cbqv) and Prolia® (denosumab) packaging which could lead to a risk of product administration or dispensing error and adverse events.

Potential of carton confusion between UDENYCA® and Prolia®

UDENYCA® and Prolia® have a similar carton appearance (Figure 1) which has led to product administration or dispensing errors and adverse events.

1. **Carton Appearance:** Both cartons look similar with a green/white color scheme and green horizontal bands across the top (Figure 1).
2. **Presentation and Strength:** Both cartons hold one single-dose prefilled syringe, and both medications are intended for subcutaneous administration. The UDENYCA® syringe contains 6 mg and the Prolia® syringe contains 60 mg.
 - a. The needle guard of UDENYCA® syringe is colorless while the Prolia® syringe is translucent green (Figure 2).
3. **Storage:** Both are refrigerated items and have the potential to be stored next to each other.

Figure 1: UDENYCA® (left) and Prolia® (right) Cartons



Figure 2: UDENYCA® (left) and Prolia® (right) Syringes



Coherus BioSciences, Inc. 333 Twin Dolphin Drive, Suite 600 Redwood City, CA 94065

Acute Care ISMP Medication Safety Alert!

Educating the Healthcare Community About Safe Medication Practices

New recommendations to improve drug allergy capture and clinical decision support

H The *Partnership for Health IT Patient Safety*, a national collaboration convened by ECRI Institute, has released a new report on drug allergy interactions and how clinical decision support (CDS) and health information technology (IT) can be used to improve safety.¹ The report, *Safe Practices for Drug Allergies—Using CDS and Health IT*, presents the findings of a multistakeholder workgroup composed of members from the *Partnership*, including healthcare providers, members from professional and patient safety organizations, safety and quality advocates, health IT developers, and academic researchers. The workgroup was co-chaired by ISMP President Michael Cohen and ISMP Medication Safety Specialist Christina Michalek and funded in part by the Gordon and Betty Moore Foundation. The report sets forth evidence-based safe practices and suggested implementation strategies for using technology to standardize allergy documentation, enabling CDS tools to provide more actionable allergy information, monitoring alerts for effectiveness, and engaging patients. A summary of key highlights from the report follows.¹

Importance of Drug Allergy Information and CDS Tools

Timely access to accurate, up-to-date drug allergy information is critical to avoid potentially life-threatening adverse drug reactions that can delay the delivery of appropriate treatment, necessitate additional treatments, increase care costs, and negatively impact patient outcomes. To facilitate the appropriate triggering of alerts, the information must be documented using the correct allergy terminology, coded properly, and captured in a standard location. Outdated allergy information must also be removed from the patient's list of active allergies.

continued on page 2—Drug allergy

22nd Annual ISMP Cheers Awards Nominations

In our ongoing effort to improve patient safety, ISMP takes great joy in recognizing others who share this same vision for the future. Each year, ISMP celebrates individuals, institutions, and groups that have demonstrated exemplary commitment to the continued science and study of medication safety through innovative and creative projects, educational efforts, standard setting, and/or research. The celebrated winners will receive an ISMP *Cheers Award*, which will be presented during an evening ceremony in early December of each year—more to follow on the gala!

Nominations for this year's *Cheers Awards* will be accepted through **September 6**. ISMP accepts external nominations, including self-nominations. The prestigious *Awards* spotlight efforts from all healthcare disciplines, and winners have included representatives from hospitals, health systems, long-term care, ambulatory care, community pharmacies, professional associations, federal and state agencies, as well as individual advocates. *Cheers Award* winners demonstrate a willingness to share learning beyond the organization (e.g., professional presentations; articles in peer-reviewed publications; tools shared on the internet; willingness to share learning in ISMP newsletters). To submit a nomination, visit: www.ismp.org/node/1036.

SAFETY briefs

4 **Prolia-Udenyca look-alike update.** We continue to receive reports about potential look-alike mix-ups between cartons of PROLIA (denosumab; Amgen), an osteoporosis drug, and UDENYCA (pegfilgrastim-cbqv; Coherus BioSciences), a biosimilar leukocyte growth factor associated with the reference pegfilgrastim product, NEULASTA. The US Food and Drug Administration (FDA) initially approved Prolia in 2010. Udenyca was approved in November 2018, and since its launch in January, we have received 12 reports of potential mix-ups. None of the reports have mentioned an actual error involving a patient. However, as reported in our May 23, 2019 issue, we have received reports of dispensing and drug storage errors. In several cases, a Prolia syringe carton was stocked in place of Udenyca, and vice versa, in automated dispensing cabinet refrigerators in outpatient infusion sites.



Figure 1. Package similarity has led to dispensing and storage errors.

The reports all indicate that the similar appearance of the outer cartons of these medications increases the risk of a medication error (Figure 1). Each carton holds a single syringe. Each outer carton has similar green and white coloring, and the packaging appears to be of similar size and dimension. Both medications are marked “for subcutaneous use.” The concentration for each drug is listed in a green circle in the same location. Both concentrations include the numbers 6 and 0, which one continued on page 2—SAFETY briefs >

Your Reports at Work



Thanks to your reporting, Coherus BioSciences submitted a revised carton label to the US Food and

Drug Administration (FDA) for its product, UDENYCA (pegfilgrastim-cbqv), a biosimilar leukocyte growth factor associated with the reference pegfilgrastim product, NEULASTA. The revision was recently approved. ISMP had received several reports last year about the potential for confusion with PROLIA (denosumab; Amgen), an osteoporosis drug. Two actual errors were reported in which patients received the wrong drug. Figure 1 shows the carton label similarities between Udenyca and Prolia while Figure 2 shows the revised carton label. While the company works to implement the new packaging, cartons of Udenyca will be shipped with a bright orange-red warning sticker affixed to the carton (Figure 3).

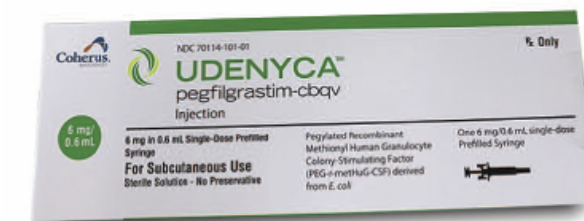


Figure 1. Former green carton label for Udenyca (bottom) led to confusion with Prolia cartons (top).

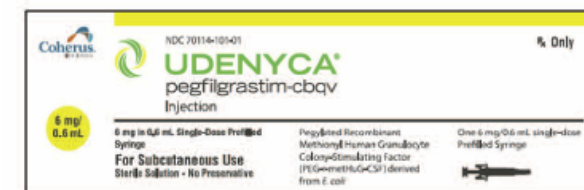


Figure 2. Recently approved color change for Udenyca contrasts with Prolia carton label above.

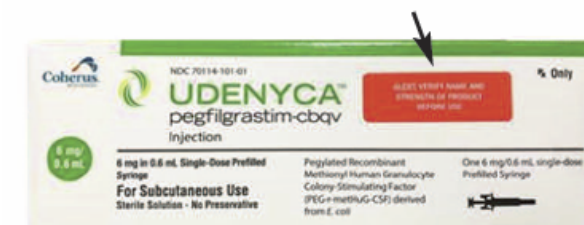


Figure 3. An orange-red sticker will be affixed to the original Udenyca carton until the new packaging is available. The sticker reminds practitioners to verify the product name and strength before use.

Error reporting outcomes

- Improvements in patient safety as a result of hundreds of specific product-related changes
 - Drug naming, labeling, packaging, medication-related device design, measuring devices, infusion pump safety issues.
- Some products withdrawn from market due to medication error issues
- Thousands of product label and labelling changes as a result of new FDA requirements or changes in USP standards (USP <7>) due to reported medication errors.
 - Dangerous abbreviations and dose designations, ratio expression, expression of drug concentration, certain new drug packaging requirements, etc.
- Practice-related standards (CMS, Joint Commission, etc.)

USP Standards

(7) LABELING

INTRODUCTION

This general chapter provides definitions and standards for labeling of official articles. Labeling standards for an article recognized in *USP-NF* are expressed in the article's monograph and applicable general chapters. It is intended that all articles in *USP* or *NF* will be subject to the labeling requirements specified in this chapter by means of a provision in *General Notices, 10 Preservation, Packaging, Storage, and Labeling*, unless different requirements are provided in a specific monograph. As with compendial standards for naming, identity, strength, quality, and purity, compendial requirements for labeling have a role in the adulteration and misbranding provisions of federal law [see the Federal Food, Drug, and Cosmetic Act (FDCA) sections 501(b), 502(e)(3)(b), 502(g), and 502(h)]. Exceptions or additional requirements specific to animal drug products and compounded preparations are provided in separate sections. Vaccine labeling is not included in this general chapter.

DEFINITIONS

The term "labeling" includes all labels and other written, printed, or graphic matter on an article's immediate container or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" is that part of the labeling on the immediate container.

A shipping container that contains a single article, unless the container also is essentially the immediate container or the outside of the consumer package, must be labeled with a minimum of product identification (except for controlled substances), lot number, expiration date, and conditions for storage and distribution.

Beyond-use dates (BUDs) and expiration dates are not the same. An expiration date identifies the time during which a conventionally manufactured product, active ingredient, or excipient can be expected to meet the requirements of a compendial monograph, if one exists, provided it is kept under the prescribed storage conditions. The expiration date limits the time during which the conventionally manufactured product, active pharmaceutical ingredient (API), or excipient may be dispensed or used. Expiration dates are assigned by manufacturers of conventionally manufactured products based on analytical and performance testing of the sterility, chemical and physical stability, and packaging integrity of the product. Expiration dates are specific for a particular formulation in its container and at stated exposure conditions of illumination and temperature.

The beyond-use date (BUD) is the date or time beyond which a compounded preparation must be discarded. The date or time is determined from the date the preparation was compounded.

LABELS AND LABELING FOR DRUG PRODUCTS AND COMPOUNDED PREPARATIONS EXPRESSED AS ACTIVE MOIETY IN NAME AND STRENGTH

The names and strengths of drug products and compounded preparations formulated with a salt of an acid or base are to be expressed in terms of the active moiety on the label (see *Nomenclature* (1121), *Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations*).

Labeling

The labeling clearly states the specific salt form of the active moiety that is present in the product or preparation because this information may be useful to practitioners and patients. The names and strengths of both the active moiety and specific salt form (when applicable) are provided in the labeling.

Exceptions

In rare cases in which the use of the specific salt form of the active moiety in the title provides vital information from a clinical perspective, an exception to this policy may be considered. In such cases, when the monograph title contains the specific salt form of the active moiety, the strength of the product or preparation is also expressed in terms of the specific salt form.

LABELS AND LABELING FOR INJECTABLE PRODUCTS

The labels¹ and the labeling state the following information:

- Name of the product
 - In the case of a liquid, the quantity or proportion of each active moiety or drug substance in a specified volume
 - In the case of any product to which a diluent must be added before use, the quantity or proportion of each active moiety or drug substance, name and volume of diluent to be added, the concentration after the diluent is added, directions for proper storage of the constituted solution, and a BUD (see *Expiration Date and Beyond-Use Date*)
- Route(s) of administration

¹ If there are space limitations, see 21 CFR§ 201.10(i), 21 CFR§ 201.105(b), 21 CFR§ 610.60.

FDA Guidance Statements

Guidance for Industry

Best Practices in Developing Proprietary Names for Drugs

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis, Kellie Taylor at 301-796-0157, or (CBER) Office of Communications, Outreach and Development at 800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2014
Drug Safety

Safety Considerations for Product Design to Minimize Medication Errors

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

April 2016
Drug Safety

Public Health Advisories

reduce the risk of errors. We look forward to the New Year and our continued service to you as we work together to protect patients from medication errors.

Your Reports at Work



FDA Public Health Advisory.

Thanks to your reports, FDA published a Public Health Advisory late Wednesday to warn US citizens traveling abroad or buying prescription drugs via the Internet about risks when obtaining medications from foreign sources (www.fda.gov/oc/opacom/reports/confusing_names.html). The advisory noted that some FDA-approved products have the same brand names as foreign drug products with completely different ingredients. They also found that 105 US brand names are dangerously close to foreign brand names used for different products; patients who fill prescriptions abroad may get the wrong drugs. FDA noted that the advisory builds on recognition of the problem as published in our January 13, 2005 newsletter. The advisory was accompanied by tables to identify the involved products. [continued on page 2](#) ▶



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FDA drug safety communications

FDA Drug Safety Communications for Drug Products Associated with Medication Errors

- FDA Drug Safety Communication: FDA approves brand name change for antidepressant drug Brintellix (vortioxetine) to avoid confusion with antiplatelet drug Brilinta (ticagrelor)
- FDA Drug Safety Communication: FDA cautions about dosing errors when switching between different oral formulations of antifungal Noxafil (posaconazole); label changes approved
- FDA Drug Safety Communication: FDA cautions about dose confusion and medication error with antibacterial drug Avycaz (ceftazidime and avibactam)
- FDA Drug Safety Communication: FDA cautions about dose confusion and medication errors for antibacterial drug Zerbaxa (ceftolozane and tazobactam)
- FDA Drug Safety Communication: FDA Alerts Pharmacists and Health Care Professionals to Potential for Injury when Dispensing the Similar-Sounding Drugs Durezol and Durasal
- FDA Drug Safety Communication: FDA requires label warnings to prohibit sharing of multi-dose diabetes pen devices among patients
- FDA Drug Safety Communication: FDA requiring color changes to Duragesic (fentanyl) pain patches to aid safety—emphasizing that accidental exposure to used patches can cause death
- FDA Drug Safety Communication: FDA warns about potential medication errors resulting from confusion regarding nonproprietary name for breast cancer drug Kadcyla (ado-trastuzumab emtansine)

FDA Advise-ERR in ISMP Medication Safety Alert! publications and FDA website

ISMP FDA Advise-ERR Articles

- [FDA Advise-ERR: Taking Crysvida with active vitamin D analogs is contraindicated](#) 
- [FDA Advise-ERR: Covers still being applied without the cloNIDine patch](#) 
- [FDA Advise-ERR: Lumoxiti has unique preparation instructions!](#) 
- [FDA Advise-ERR: Vyxeos: Verify Drug Name and Dose to Avoid Errors!](#) 
- [FDA Advise-ERR: Concomitant use of Entresto and ACE inhibitors can lead to serious outcomes](#) 
- [FDA Advise-ERR: Veterinary Drug and Human Drug â A Drug Name Mix-up](#) 
- [FDA Advise-ERR: Avoid using the error-prone abbreviation, TPA](#) 
- [FDA Advise-ERR: MefloquineâNot the same as Malarone!](#) 

ISMP educational programs



AN EVENT CONDUCTED AT THE AMERICAN ORGANIZATION OF NURSE EXECUTIVES (AONE) 2019 ANNUAL CONFERENCE

Manage the Safety Risks Associated with IV Push Medication Use

Working Together to Address Global Drug Safety Issues with Packaging and Labeling

- Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon) FASHP
- President, Institute for Safe Medication Practices
- Chairperson, International Medication Safety Network



Institute for Safe Medication Practices


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Just Culture

Training for Managers


Judy Smetzer, RN, BSN, FISMP
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ISMP Practice Guidelines



Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps




www.ismp.org

2020-2021


ISMP Targeted Medication Safety Best Practices for Hospitals



www.ismp.org



ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults



Guidelines for the Safe Use of Automated Dispensing Cabinets

Recommendations for the Safe Management of Patients with an External Subcutaneous Insulin Pump During Hospitalization

Please note: These recommendations were compiled and written by ISMP after reviewing current policies and procedures that have been tested through experience in several large and small US hospitals, a review of the professional literature, the results of the 2015 ISMP survey on this topic, and analysis of reports of errors related to insulin pumps submitted to ISMP or published in the literature. Examples of some of the recommended documents mentioned in the recommendations (e.g., patient consent/agreement, insulin pump order set, patient bedside worksheets/legals) are provided in several of the references**** listed at the end of the recommendations.

I. Initial Assessment Process

Admission Assessment

- 1) As part of an initial patient admission assessment, nurses should be prompted to specifically ask all patients if they are using an insulin pump.
- 2) If the patient is using an external insulin pump, the nurse conducting the initial patient assessment should notify the patient's admitting physician. They should not wait until a nurse is admitted to the unit to determine whether or not the nurse can remain in place and be responsible for the patient's care.