Human Factors Role and Considerations in Drug Labeling and Packaging

Institute for Safe Medication Practices
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Human Factors Role and Considerations in Drug Labeling and Packaging

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This activity is supported by **Novartis- Name Creation & Regulatory Strategy.**

1

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Nursing CE

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Objectives

Following completion of this activity, participants will be able to:

1. Differentiate between human errors and at-risk behaviors.
2. List factors that can degrade human performance and lead to human error.
3. Identify examples of unsafe drug product labeling and packaging.
4. Describe FDA's role in pre-marketing and post-marketing activities to prevent and address medication errors.

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Program Faculty

Matthew Grissinger

Mishale Mistry

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Latent and Active Failures

- Medication errors are almost never caused by a single element or by the fault of a single practitioner
- Catastrophic events are most often the result of the combined effects of latent failures in the system and active failures by individuals

9

Latent Failures (Blunt End)

- **Latent failures (blunt end errors)-** adverse consequences which lie dormant in a system and only become evident when combined with other factors to breach the system's defenses
- Often originate where organizational policies, procedures, and resource allocation decisions are made

10

Examples of Latent Failures

System Performance

- "Versed" vs. midazolam
- Ability to search drug names with only 2 letters
  - **"VE"**
- Overrides
  - **Ability to remove medication without pharmacist review of the order**
  - **Ability to remove medication without an order**

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Active Failures (Sharp End)

- Actions made by practitioners that contribute to error
- "Sharp End" errors
- Effects are felt almost immediately
  - **Slips, lapses (execution failures: action not as planned, or failure of memory)**
  - **Mistakes (planning failures; plan is inadequate)**
    - Decisions, choices made by individual
    - Failure in judgement

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Examples of Active Failures

Human Performance

- Human error
  - Did not see warnings on vial
  - Thought she was removing Versed, not vecuronium
- Behavioral choice
  - Use of overrides, but……

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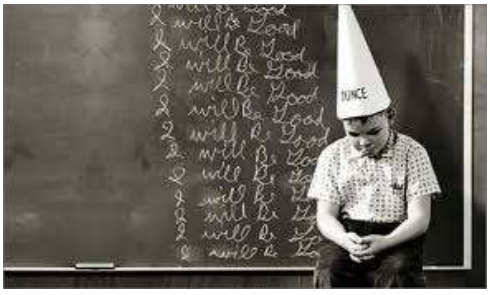
Why is this important?

- How we think about and respond to errors (both active and latent failures) reflects our healthcare culture



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Three Fundamental Beliefs in a Just Culture

- To err is human
- To drift is human
- Risk is everywhere

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Human Behaviors in a Just Culture

Human error—inadvertent action; inadvertently doing other than what was intended or what should have been done

At-risk behavior—behavioral choice that increases risk where risk is not recognized, or is mistakenly believed to be justified or insignificant

Reckless behavior—behavioral choice to consciously disregard a substantial and unjustifiable risk

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To Drift is Human

Drift: Behavioral Choices we make that unknowingly create unjustifiable risk

- Desire to accomplish more
- Fading perception of risk as we become more comfortable with the task

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Shaping Behaviors in a Just Culture

A nurse needs to administer a medication to a baby in the neonatal ICU. The ICU has an automated dispensing cabinet (ADC).

After accessing the baby's record and selecting the correct medication, the ADC opens a drawer with four bins. As he has always done, the nurse reaches into the second bin where the vial of medication has always been, confirms the blue cap on the vial, grabs the medication and takes it to the bedside to administer the medication.

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At-Risk Behaviors

A behavioral choice

- Lose situational awareness
  - Don't see the risk
  - Faded perception of risk
  - Believe the risk is insignificant or justified

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At-Risk Behaviors

Behavior choice driven by the perception of consequences

- Positive rewards for taking shortcuts
  - Rewards are immediate, strong, positive
- Delayed, uncertain consequences are weak
- Rules are generally weak
- Successful violations frequent act as a reward

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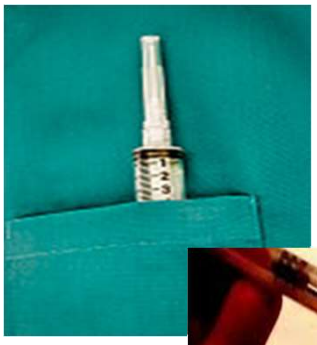
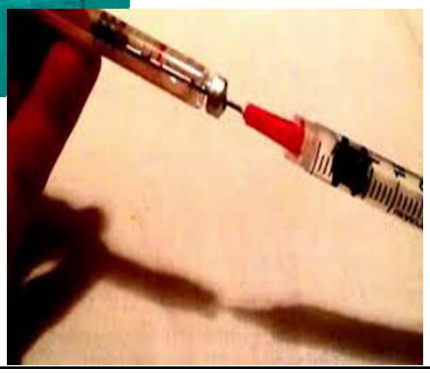
Examples of At-Risk Behaviors

- —Technology work-arounds
- —Rushed communication during shift change
- —Carrying medications in pockets
- —Unnecessary use of verbal orders/stat orders
- —Using a prefilled syringe as a vial
- —Grab and go drug selection





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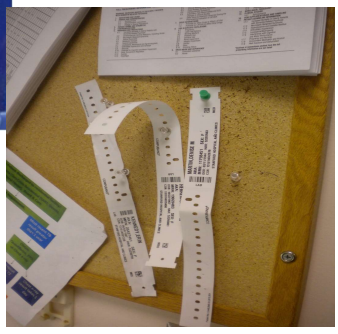
Examples of At-Risk Behaviors

- —Borrowing medications
- —Processing illegible orders
- —Using barcode bracelets not attached to patients
- —Preparing more than one patient's medications at once
- —Not labeling syringes



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Managing At-Risk Behaviors

Coach

- Change perceptions of risk

Change Systems

- Change systems that are causing behaviors

Address Rewards

- Change the consequences

Modify Barriers

- Reduce barriers that prevent compliance
  Add barriers to prevent noncompliance

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To Err is Human

– Human error is about **inadvertency:** it's not productive to describe or attribute all undesired human behavior to human error

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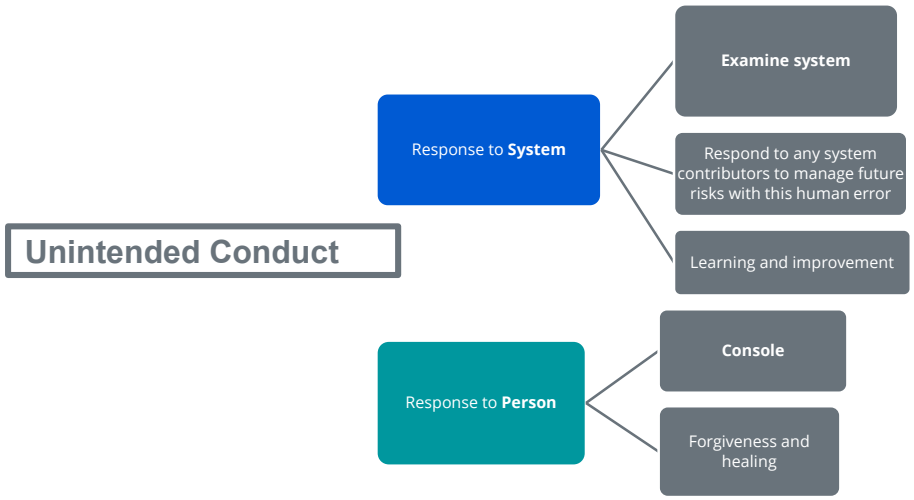
Management Human Error



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Human Error, At-risk, Reckless?

- **Human Error:** Staff picked up the wrong pen for administration to a patient
- **At-risk behavior:** Insulin pens not always labeled per patient; staff unaware that the pen could not be used on a second patient after changing the needle
- **Reckless behavior:** A clinic physician instructs the staff to reuse the insulin pens even though is known to be against OSHA and CDC Guidance because it will save the clinic money

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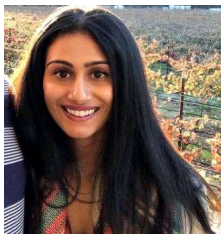
OSE's Premarket and Postmarket Activities in Preventing Medication Errors



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27

27

Disclaimer

- The views and opinions expressed in this presentation represent those of the presenter, and do not necessarily represent an official FDA position.
- The labeling examples in this presentation are provided only to demonstrate current labeling development challenges and should not be considered FDA recommended templates.
- Reference to any marketed products is for illustrative purposes only and does not constitute endorsement by the FDA.

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28

28

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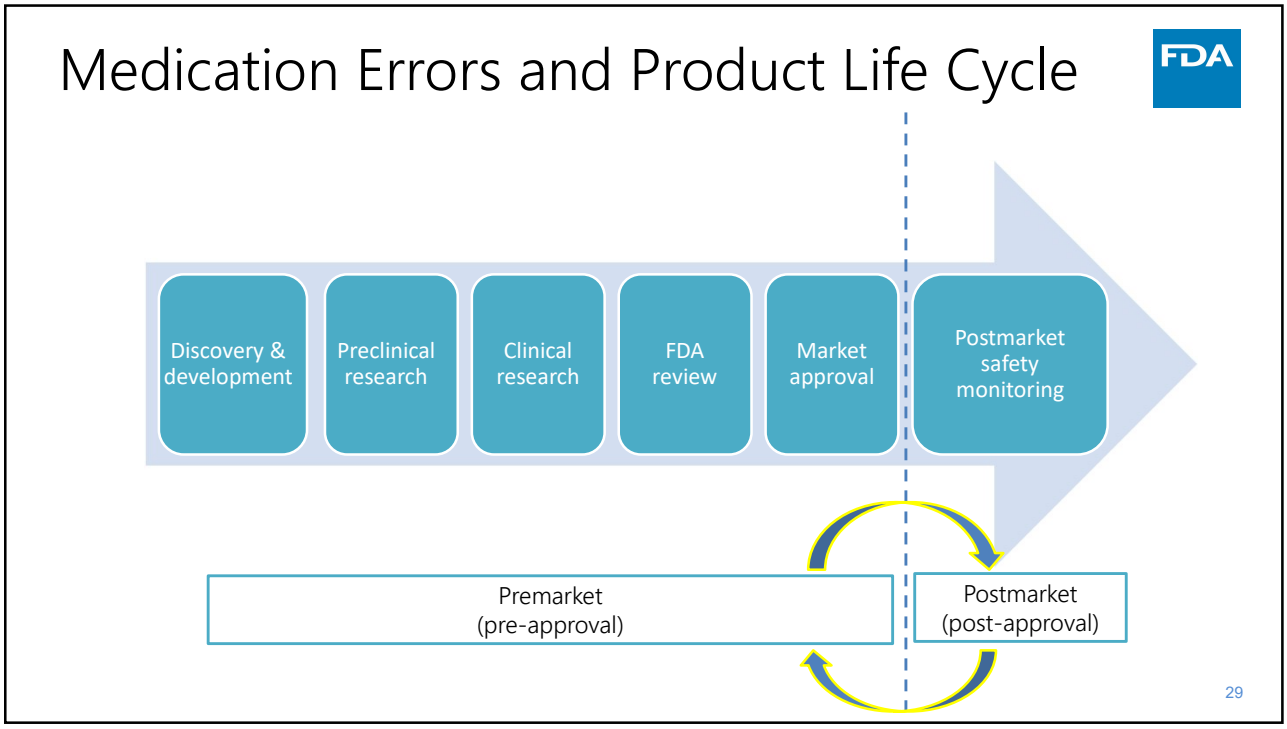

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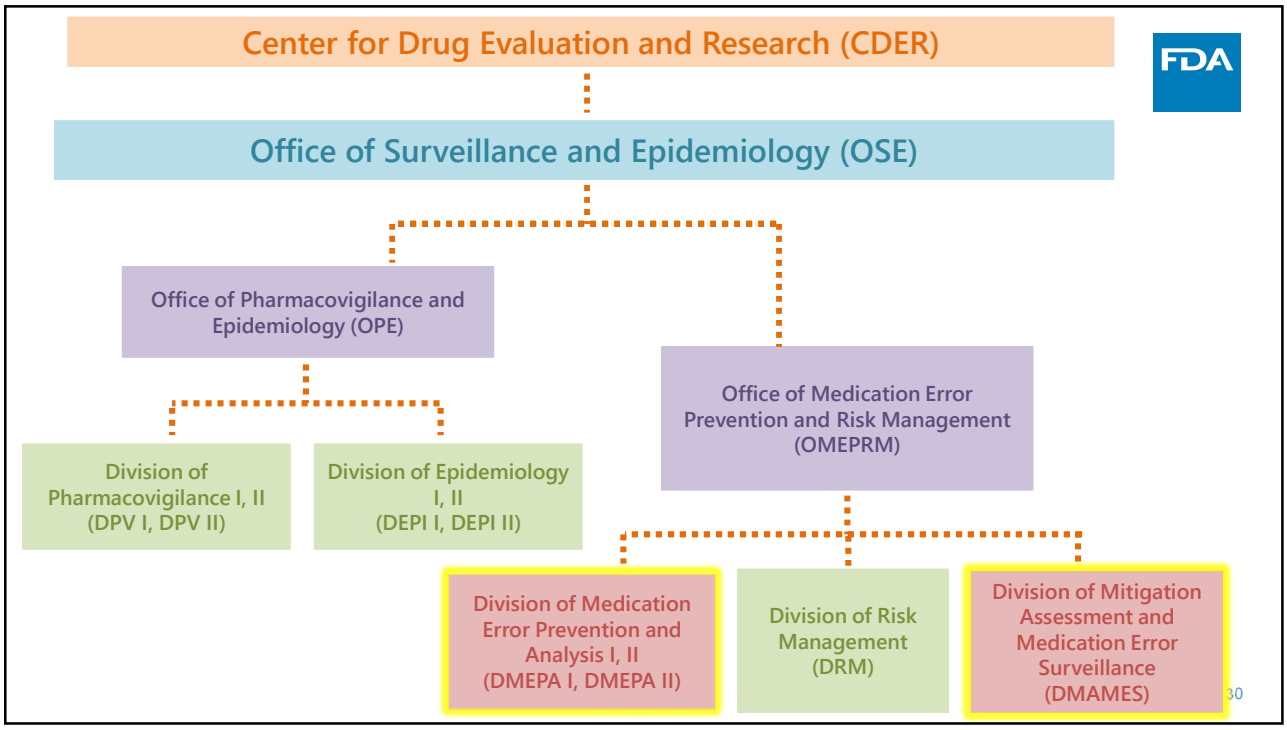

30

Overview of OSE's Medication Error Prevention and Surveillance

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Division of Medication Error Prevention and Analysis I and II (DMEPA I and DMEPA II)

- CDER Lead for **premarket** medication error prevention and analysis for drug and therapeutic biological products
- Evaluates weekly surveillance reports of medication errors submitted to the FDA Adverse Event Reporting System

Division of Mitigation Assessment and Medication Error Surveillance (DMAMES)

- CDER lead for postmarket medication error pharmacovigilance, including signal management
- CDER lead for assessing the effectiveness of risk evaluation and mitigation strategies (REMS) for drug products.
- Postmarket research and innovation

Both DMEPA and DMAMES consist of scientists and healthcare professionals with varied backgrounds

31

31

WHAT DOES DMEPA DO?

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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 (DMEPA & DMAMES)

32

32

Human Factors Role and Considerations in Drug Labeling and Packaging

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

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

33

33

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Human Factors?

"Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance."

International Ergonomics Association (IEA)

34

34

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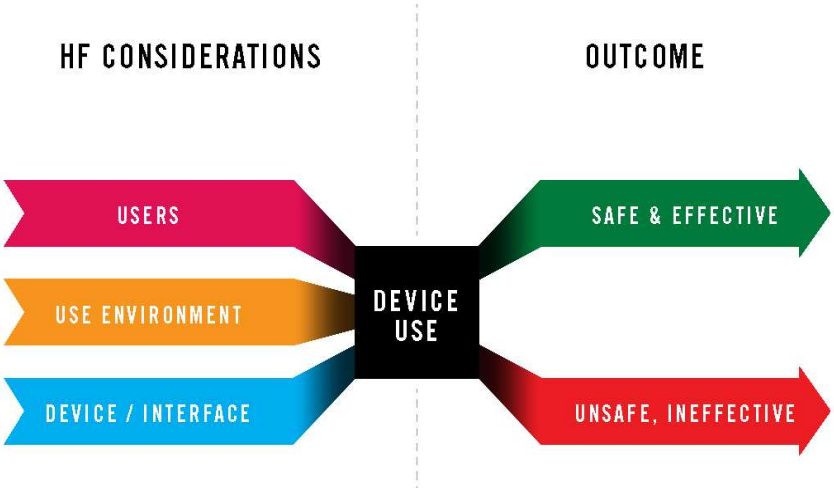
Human Factors Considerations



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Drug product user interface

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

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

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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

37

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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

38

38

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Product Strength

- 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 readable
- Dosing devices for oral solutions should use *metric unit markings*

39

39

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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

40 40

40

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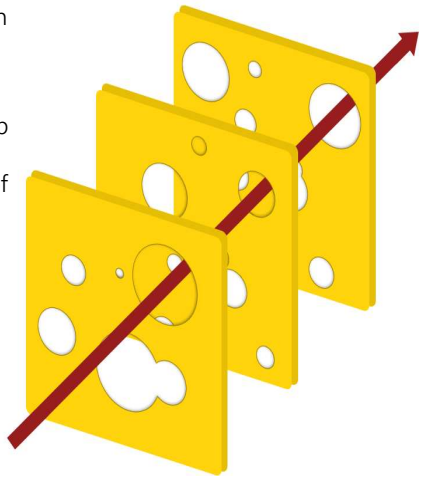
Failure Mode and Effects Analysis (FMEA)

- Analyze all steps involved in user interactions with the drug product in the anticipated use environments
- Identify potential use-related medication errors and system failures that could occur at each step of the medication use process
- Estimate probability of occurrence of identified potential medication errors and system failures
- Assess potential effects and severity of consequences of identified potential medication errors and system failures
- Identify mitigation strategies to address identified risks
- Evaluate success of mitigation strategies at reducing risk to acceptable level



41

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Human Factors Validation Studies

- 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
- Seeks to assess actual use
- Results can be used to update the 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

42

42

Human Factors Role and Considerations in Drug Labeling and Packaging

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

GUIDANCE FOR INDUSTRY
MAY 2022

Safety Considerations for Container Labels and Carton Labeling 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)
Center for Biologics Evaluation and Research (CBER)

May 2022
Drug Safety

FDA

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

43

43

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

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

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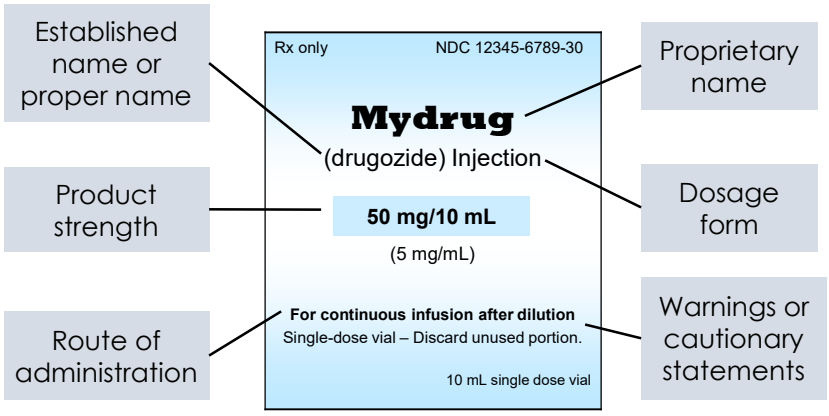

The Principal Display Panel is the portion of the container label or carton labeling that is most likely to be displayed, presented, shown, or examined by the user when the product is on a shelf

44

44

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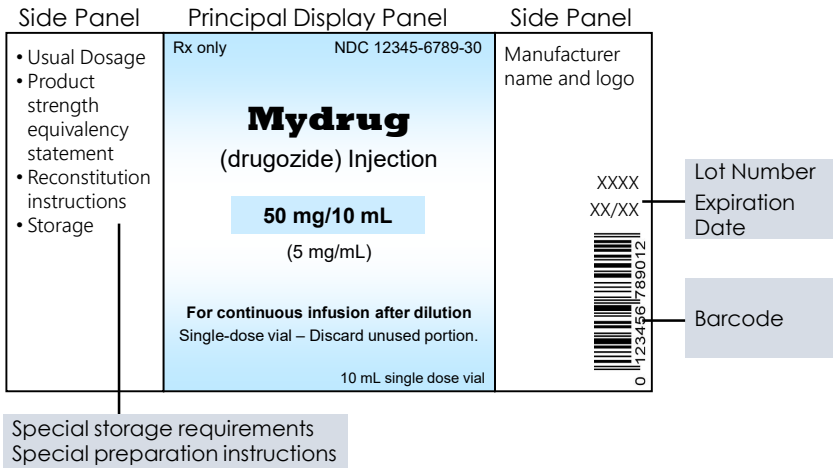
Product information on side and back panels



Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors. 2013. Available from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf

45

45

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

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

- Use at least a 12-point sans-serif font (e.g., Arial)
- Choose text and background color to afford adequate legibility of text
- Avoid color combinations that do not afford maximum legibility of text

ProprietaryName
(Established name)

Proprietary Name
(Established name)

Proprietary Name
(Established name)

46

46

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Avoid Crowding, Visual Clutter, Dangerous Abbreviations, and Acronyms

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- 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

47

47

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Product Name

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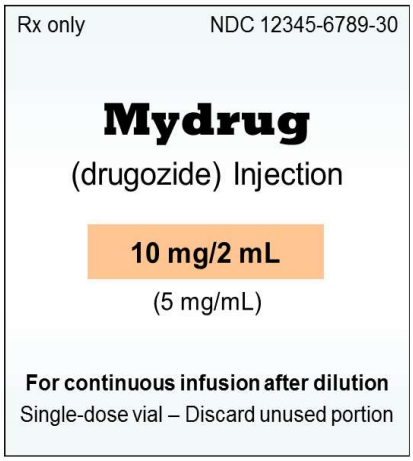
- The proprietary and established or proper name should be the most prominent information on the label
- The established name should be at least ½ the size of the proprietary name
- The established name for drug products should include the dosage form



48

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Product Strength Expression

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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 injection products*: Express strength as the quantity per total volume followed by quantity per milliliter enclosed by parentheses
100 mg per vial	*Dry solid injectable products requiring reconstitution*: Express strength as the quantity of drug per vial
5 mg/10 mg	*Fixed-combination drug products:* use slashes to separate the strength of each ingredient

49

49

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Product Strength and Net Quantity Statements

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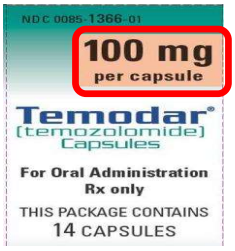
Note the placement of strength and net quantity

Note prominence of strength



50

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Route of Administration and Warnings or Cautionary Statement(s)

- The route(s) of administration should generally be described without abbreviations
- Use positive statements for route of administration, warnings or cautionary statements (e.g., *for intravenous use, give by subcutaneous injection*, or *must dilute before use*)
- Negative statements should generally be avoided because "not" can be overlooked

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

51

51

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

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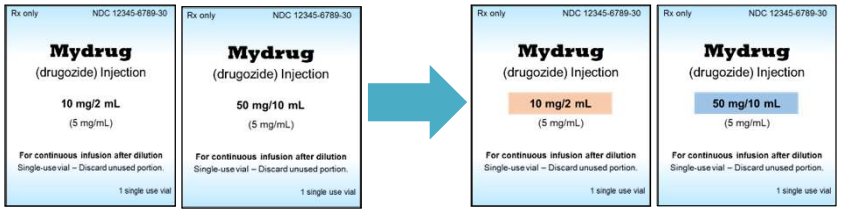
Product Strength Differentiation

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

Techniques include:
- Boxing
- **Prominent** typeface or type weight
- Color differentiation



52

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Use of Color:
Color Differentiation vs. Color Coding

- **Color differentiation** is a tool that may help:
  - —Differentiate products within a manufacturer's product line
  - —Differentiate strengths within a manufacturer's product line
  - —Highlight certain aspects of the label, such as important warning or cautionary statements
- **Color coding** uses color to designate a specific meaning
- FDA generally recommends avoiding color coding in most instances (identifying products by color may discourage reading labels)
  - — Reserved for special circumstances or after appropriate human factors testing data or information has been received and evaluated by FDA prior to use

53

53

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

GUIDANCE FOR INDUSTRY
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Use of Color: Color Coding

Certain applications of color coding may be appropriate

- Certain drug product strengths (e.g., warfarin, levothyroxine) are universally color coded across all manufacturers

- In other cases, color coding can lead to confusion

Different strengths

Different products

54

54

Human Factors Role and Considerations in Drug Labeling and Packaging

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

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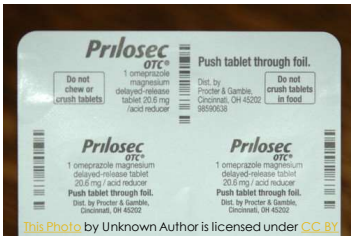
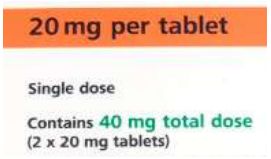
Blister Pack Presentations



Unit Dose Blister Cell Labels:
The barcode and other required or critical information (e.g., proprietary and established or proper name, dosage form, strength, lot number, expiration date, manufacturer) should appear over each blister cell

The product strength should describe the milligram amount of drug per single unit (e.g., tablet, capsule).



For products where a blister pack or carton contains 1 dose, if the total dose requires more than 1 unit (e.g., 1 tablet), then the PDP should include *both* the mg amount of drug per single unit AND the total dose contained in the blister pack or carton.

55

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

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Blister Pack Presentations

- Sponsors should carefully consider the overall design of a blister pack label to prevent confusion and dosing errors.
- The packaging configuration should make sense for the dosage and administration of the drug product and the intended patient population
- If multiple configurations of blister packs will be introduced, there should be adequate differentiation between the configurations to ensure that they can be distinguished and correctly selected *throughout* the medication use process (e.g., prescribing, dispensing)

56

Postmarket Surveillance of Medication Errors

57

57

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 the causes of errors that may be related to a drug's name, label, labeling, or packaging

*Preventing Mediation Errors: A $21 Billion Opportunity. Network for Excellence in Health Innovation (NEHI); 2011. https://www.nehi.net/bendthecurve/sup/documents/Medication_Errors_%20Brief.pdf

58

58

Medication error case reports

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

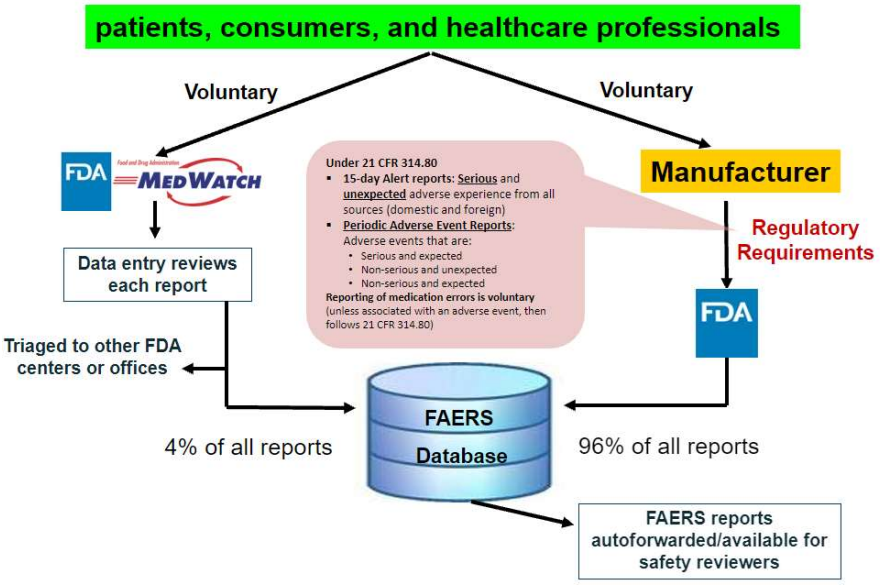
ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

59

*Preventing Mediation Errors: A $21 Billion Opportunity. Network for Excellence in Health Innovation (NEHI); 2011. https://www.nehi.net/bendthecurve/sup/documents/Medication_Errors_%20Brief.pdf

59

How Postmarket Reports Get to FAERS



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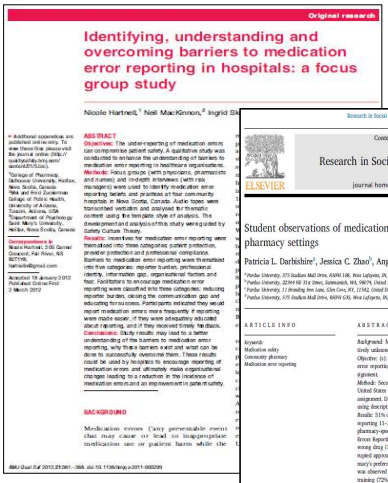
Medication errors are *underreported*

- Extent of underreporting is unknown
- No U.S. requirement to report medication errors to FDA
- Likelihood of reporting medication errors is lower *versus* adverse events

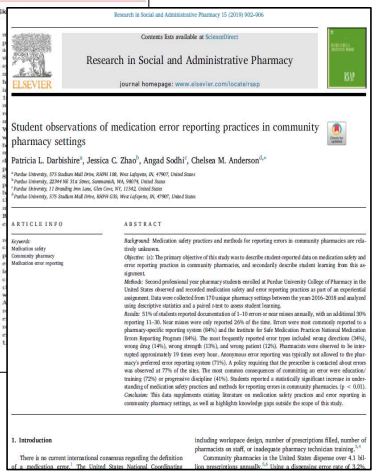
61

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



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



Research in Social and Administrative Pharmacy

Student observations of medication error reporting practices in community pharmacy settings

62

62

Example of Progression from Nonserious Event to SERIOUS

FDA

Report warning of potential look-alike container and cartons

DMEPA performs risk assessment, notifies FDA review division and company

Multiple reports of "near miss"

Company issues safety alert, distributes stickers, prepares to revise labeling

First serious report received (patient received wrong drug)

Labels and labeling urgently revised

63

Summary

FDA

- 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.

64

64

Resources

Guidances for Industry:

- Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors – May 2022
- 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

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Online Evaluation, Self-Assessment and CE/CME Credit

- Login at www.ProCE.com
- Select the following link: https://proce.com/CE-CME/pharmacy/human-factors-role-and-considerations-in-drug-labeling-and-packaging/11419
- Enter the attendance code
- Complete online post-test & evaluation
- Deadline: Thursday, October 27
- Pharmacists/Technicians: CE credit uploaded to CPE Monitor

Attendance Code
HFR927

66


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Questions?
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67