

Managing Pharmaceuticals to Reduce Medication Errors

August 26, 2003

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Subsidiary of ISMP

(www.med-errs.com)



Mission of ISMP

- Translate errors into education
- Encourage voluntary reporting
- Help prevent medication errors by productively interacting with:
 - Regulatory agencies
 - Professional organizations
 - Practitioners
 - Healthcare institutions
 - Pharmaceutical industry

Med-E.R.R.S.

- Wholly-owned subsidiary of the Institute for Safe Medication Practices (ISMP), incorporated in 1997
- Med-E.R.R.S. Board of Trustees
- Works with the pharmaceutical industry in pre-market phase to evaluate product labeling, packaging, and nomenclature for safety
- Works in post-marketing phase to help monitor and evaluate potential and actual medication errors that have been reported

Who can help manage pharmaceuticals to reduce medication errors?

**Should be collaborative approach
between:**

- Government (FDA and other healthcare agencies)
- Pharmaceutical industry
- Practitioners and healthcare systems

The **FDA** should work with drug manufacturers, distributors, pharmacy benefits managers, health plans and other organizations to assist clinicians in identifying and preventing problems in the use of drugs.

Recommendation 7.3

The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre- and post-marketing processes through the following actions:

- **develop and enforce standards for the design of drug packaging and labeling** that will maximize safety in use.
- **require pharmaceutical companies to test** (using FDA-approved methods) **proposed drug names** to identify and remedy potential sound-alike and look-alike confusion with existing drug names
- **work with physicians, pharmacists, consumers, and others** to establish appropriate responses to problems identified through post-marketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients

New FDA proposed guidances

- FDA is in the process of eliciting responses for several new proposed guidances relating to medication safety:
 - Safety reporting requirements (“The tome”)
 - Pre-marketing risk assessment
 - Risk management programs
 - Pharmacovigilance practices

New FDA proposed guidances

Most of these proposed guidances have an aspect related to safety and medication error reduction:

- pre-marketing risk assessment of product's name and packaging/labeling
- post-marketing surveillance as part of risk management program
- increased medication error reporting

Medication Error

(Based on NCC MERP definition)

- 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 or consumer.
 - Potential error (Category A)
 - Actual error (Categories B – I)

Medication Error (cont.)

Actual medication error

- Involves an identifiable patient, whether or not the product was administered or, if administered, whether or not the error results in a serious suspected adverse drug reaction (SADR), non-serious SADR or no SADR

Category E error

An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
(from *ISMP Medication Safety Alert! May 15, 2003*)

A covering physician admitted a patient with Hodgkin's lymphoma to a medical unit. At home, the patient had been taking hydromorphone (**DILAUDID**) 2 to 4 mg orally for pain. The covering physician prescribed the same medication, but also wrote an order for hydromorphone 2 to 4 mg IV every 3 hours for pain if the patient was unable to tolerate oral fluids. Like the physician, the nurses on the unit did not recognize that oral and IV dosing of this product, as with most opiate analgesics, is quite different.

Category E error (cont.)

In converting an oral hydromorphone dose to IV, the generally accepted equianalgesic dose is between 3 to 1 and 5 to 1. A nurse administered 4 mg IV and **the patient developed respiratory depression and became unresponsive. Two doses of naloxone IV reversed the effects of the medication.** The following morning, a pharmacist investigated the use of naloxone to uncover whether an error or other adverse drug event had occurred. He discovered the problem and corrected the dosing error.

Category I error

An error occurred that may have contributed to or resulted in the patient's death.

(from ISMP Medication Safety Alert! May 15, 2003)

An ED physician prescribed labetalol 20 mg IV push for a patient experiencing a hypertensive crisis. A nurse retrieved the drug quickly, but the patient was in the process of being transported to radiology. On the way, the nurse administered the medication in a matter of seconds. **The patient immediately arrested and was unable to be resuscitated.** Later, staff discovered several other cases where rapid IV push of labetalol may have contributed to patient harm.

Medication Error (cont.)

Potential medication error

- Does not involve a patient but rather describes information or complaint about a product name, labeling or packaging similarities

Examples of potential medication errors (nomenclature)

“The new drug Emend sounds like M-End Liquid, which is made in Tennessee and often used in the surrounding area. They will sound the same on a called in Rx.”

“New medication just released: "Cardizem LA." This will cause a lot of errors, being confused with Cardizem CD and Cardizem SR. Another sound alike error.”

Example of potential medication errors (packaging)

“I am writing about my concern over 2 look alike labels for lidocaine. Lidocaine 1% and lidocaine 2% have similar labels. They are both blue and white and both have blue tops. They are both 20 ml. There have been a few instances where these drugs have been stocked incorrectly by pharmacy personnel due to the similar appearance of the labels. I don't know of any instances where patients were harmed, but the potential is definitely there. I suggest that the manufacturer change the color of one of the labels, so there is less chance of a mix-up.”

Pharmaceutical Industry

One of the most frequent causes of pharmacy medication dispensing errors is failure to accurately identify drugs, most prominently due to look-alike and sound-alike drug names.

Leape et al. JAMA 1995; 274:35-43

Approximately 45- 50% of medication errors reported to the USP-ISMP Medication Error Reporting Program (MERP) and FDA MEDWatch Program are related to problems with product labeling, packaging or nomenclature.

Require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names

Nomenclature Related Problems

Look or Sound Alike

- Celebrex-Cerebyx
- Chlorpromazine-
Chlorpropamide
- Avandia-Coumadin
- Atgam-
Thymoglobulin
- Isordil-Plendil
- Zyprexa/Zyrtec
- Arthritis/Seizures
- Antipsychotic,other/
Diabetes
- Diabetes/Anticoagulant
- Different Doses
- CHF/Blood Pressure
- Antipsychotic/
Antihistamine

The Med-E.R.R.S. Process

- A two-part process to test potential trademarks using the ERRS™ model, a variation of Failure Mode and Effects Analysis (FMEA)
- Takes into account practitioner input and expertise of the Med-E.R.R.S. staff

Key Points of Trademark Safety Testing Process

- Importance of practitioners, experts
- Analysis of product in its clinical setting through the use of Failure Mode and Effects Analysis (FMEA)
- Review of medication error literature
- Qualitative process

(5)

Begin Forward + BID

Carix doing good

Develop and enforce **standards for the design of drug packaging and labeling** that will maximize safety in use.

NDC 0009-7529-01 5 mL Vial



irinotecan hydrochloride
injection

20 mg/mL

(on basis of trihydrate)

Caution: Federal law prohibits
dispensing without prescription.

Warning: For intravenous use
only—must be diluted before use.



Pharmacia & Upjohn

NDC 0009-7529-01 5 mL Vial



irinotecan hydrochloride
injection

100 mg/5 mL
(20 mg/mL)

— on basis of trihydrate

Caution: Federal law prohibits
dispensing without prescription.

Warning: For intravenous use
only—must be diluted before use.



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Practitioners and Healthcare Systems

Medication errors have much more to do with breakdown in the system than with anyone's competency



1-20

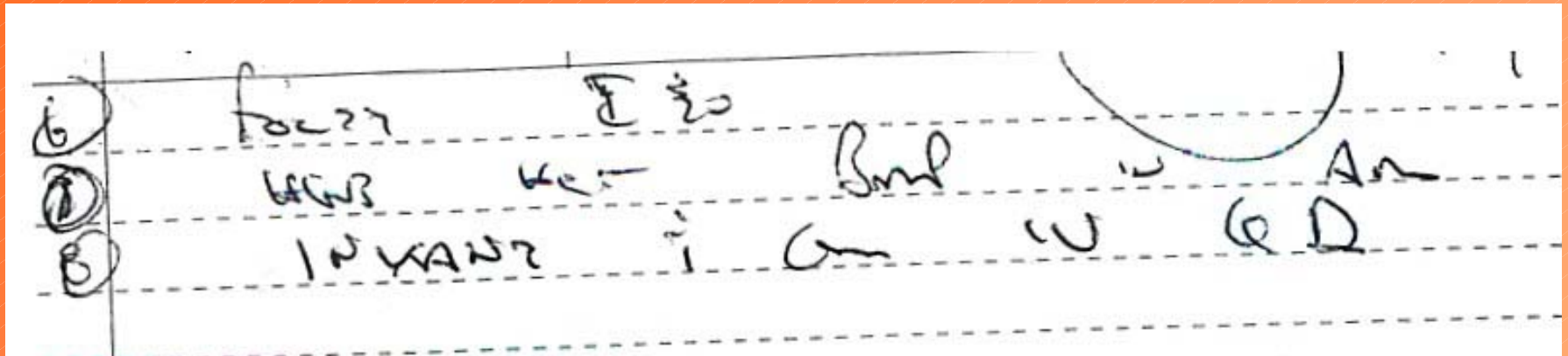
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**“Oh please! I promise I won’t
mess it up like last time.”**

Establish Nonpunitive Environment

- “Drive out fear” by reducing emphasis on punishment
- ADEs are always opportunities to learn about the system
- Punishment (e.g., sanctions, embarrassment, remedial education) drives errors underground where no one can learn from them, leaving system unchanged

Dangerous Abbreviations



Poor Handwriting

(9) Amery 12 mg po qd ✓

(10) Digoxin 0.125 mg po qd ✓

Confusing Symbols

Translating you go to

Confusion between Medication and Test

PHARMACY COPY PHYSICIAN'S ORDERS

Luvox 1mg/kg SC BID → Luvox Dose 74mg
 Antixa in Am (5 hours p.m. Dose)
 PO D1 Volk / Seren / E. S. Clackin

5/19/02	Antixa 5-6 hr after PM dose Luvox
	Drug sent reph STT.
	Antixa 100mg

5/19/02 1545

Confirmation Bias due to New Product

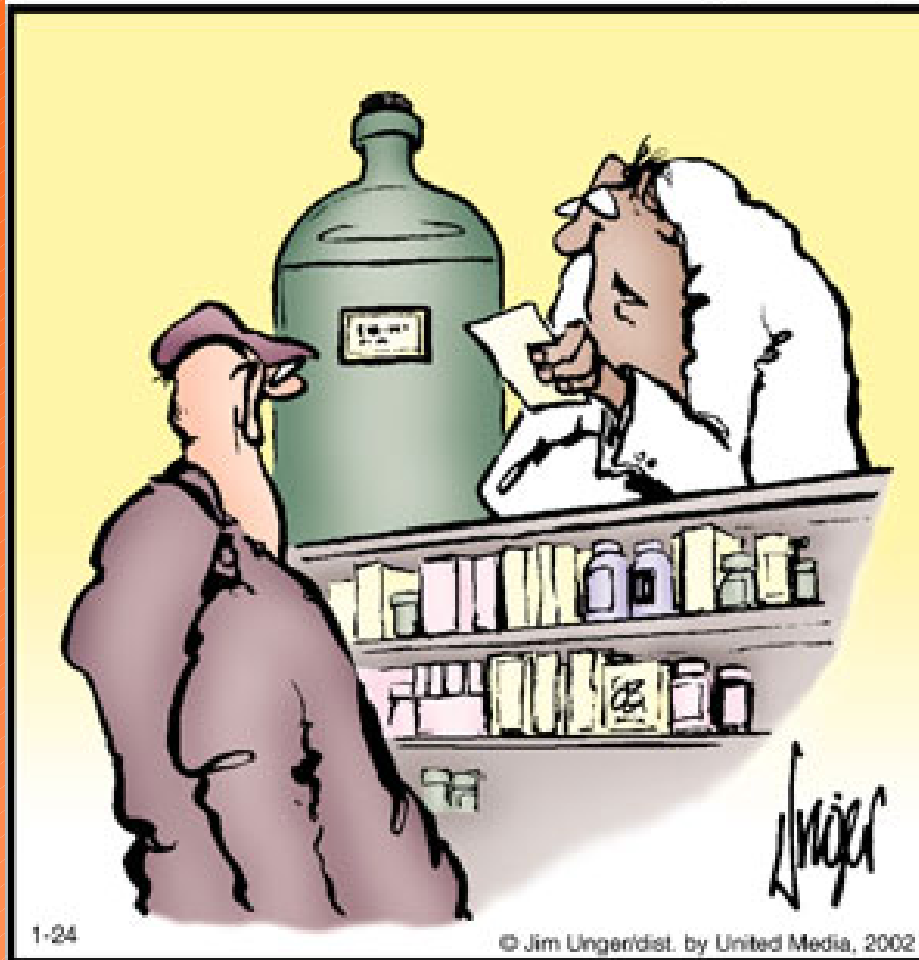
Electronics 10% [#] 100
Sales = 7 pages

Who would imagine?

② Zyntra 10.1 90% 9d

HERMAN[®]

by Jim Unger



1-24

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**“That’s what it says: ‘one tablespoonful,
300 times a day’.”**

Primary Principles in Error Reduction

- Reduce or eliminate the possibility of errors
- Make errors visible
- Minimize the consequence of errors
- Report and analyze internal errors
- Report errors externally

Reduce or Eliminate the Possibility of Errors

- Failure Mode and Effects Analysis (FMEA) of new medications and devices
 - review new medications for error potential
 - review new devices and equipment for error prone use
- Identify hazardous conditions
- System redesign/Decrease complexity/CPOE
- Standardize/Formulary control/Monitor use
- Involve all team members (including patients)

Make Errors Visible

- Pharmacy IT systems/CPOE
- Computer alerts
- Warnings/reminders
- Double check systems
- Triggers (markers)
- Clinical Pharmacists (high risk patients)
- Bar coding

System of Independent Checks (redundancies)

- Independent Double Check
 - Identify $> 90\%$ of errors
 - Focus on “high alert” medications (e.g., opiates, IV anticoagulants, chemotherapy , insulin)
- Self Check
 - Identify $> 80\%$ of errors

Minimize the Consequence of Errors

- Decrease amount of stock available
- Triggers (markers)
- Pharmacist rounds
- Available antidotes

Report and Share Errors

- Report and share internal errors
 - identify individual “responsible” for the project
 - culture change with team approach
 - share reports/high risk patients/new protocols
- Report errors externally
 - report to USP-ISMP MERP (www.ismp.org or www.usp.org) or FDA MedWatch

Collaborative Effort

- All parties have a role in reducing medication errors
- Important to provide input and share information
- New guidances by FDA for labeling, packaging and nomenclature may help standardize error reporting and reduce errors.