Medication Errors
The Big Picture

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Objectives

1. Medicine-related sources of adverse clinical events
2. Background on Medication Error Prevention
3. Examples of Medication Errors

Medicine-related adverse clinical events
Pharmacovigilance

- "...science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems..." (World Health Organization)
- Pharmacovigilance programs – monitor events that may be related to previously known or unknown ADRs, product quality and medication errors

Background

FDA Perspective on Medication Error
Medication Error

“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” (NCCMERP.org)

Exposing the Problem

- The December 1999 Institute of Medicine (IOM) report “To Err is Human”, found that 48,000 to 98,000 people die yearly due to medical errors. 7,000 of which are related to Medication Errors

- The July 2006 IOM report, found that on average a hospital patient is subject to at least one medication error per day – Major Naming, Labeling and Packaging Problems

Medication Use System

Procurement
Prescribing
Dispensing
Administration
Monitoring
FDA focuses on errors related to:

Premarket and Postmarket review of:
- Product naming
- Labeling
- Packaging

*CDER: ~ > 10 years
*CBER: ~ 8 years
*CVM: 2 years, an evolving process

What's in a name?...

- Accurate interpretation of a product's name is essential to ensure that the correct product is procured, prescribed, prepared, dispensed, and administered to the patient.
- Healthcare practitioners rely on a product's name as a critical identifier of the appropriate therapy in a market of thousands of products.
- Sound-alike/Look-alike drug (SALAD) names or misleading names can lead to misprescribing or misinterpreting the name, dispensing and/or administering the wrong product, or dispensing it incorrectly.

What's in a label?...

- The label and labeling of a drug product are the primary means by which practitioners and caregivers/patients interact with the pharmaceutical product.
- The carton labeling and container label communicate critical information including proprietary and established name, strength, form, container quantity, expiration, and so on.
Conceptual Framework

Any or all characteristics of a drug product can increase or decrease risk, and MUST be considered in risk assessment:
- Established name, brand name, Suffix, etc
- Dose, strength(s), dose form, packaging
- Route, frequency, instructions
- Storage requirements
- Indications, patient population
- Likely care environment
- Etc.

Overall Safety Recommendations

- Acceptability of name
  - Promotional (avoid names that are overly fanciful, overstate product efficacy, minimize risk, broaden product indication, or make unsubstantiated superiority claims)
  - Safety (avoid error-prone names)

- Areas of safety concern with label, labeling, packaging, and product design

Common Sources of Error:
Carton labeling and Container labels

- Inadequate differentiation between different drugs or strengths
- Confusing statements
- Missing/excessive information
- Distracting images
- Small font size/ illegible information
- Error-prone abbreviations or symbols
- Expression of strength, established name, dosage form
Common Sources of Error: Proprietary Names

- Look-alike/sound-alike names
- Failure to recognize active ingredient (e.g., Umbrella branding)
- Modifier omission or oversight
- Dangerous abbreviations and medical abbreviations

Medication Error Examples

Human drugs are used to illustrate error prone areas. However, the same error prone areas also exists for animal drugs.

- Label Design
- Packaging Design
- Look-alike/Sound-alike names
- Umbrella branding
- Advertising

Can you “label-away” all adverse events and/or medication errors?

No
Placement and Prominence on Label

Example: Established name

Fabdrug
(Tobedecided)

Fabdrug
<Tobedecided>

Fabdrug
(Tobedecided)
Graphics/Logos/Symbols

Similar Packaging and Similar Trade Dress

Similar Packaging and Similar Trade Dress
Expression of Strength
Percent/ratio expression of concentration

Silverbullet
(Littlebitoffish 1.5% and Somewhat 2%)

Umbrella branding

- When the same root name is used for products that do NOT share any active ingredients with the base brand
- Types of errors
  - Use of wrong product
  - Administration of unnecessary active ingredient
  - Wrong indication
  - Wrong patient population

Umbrella Branding

<table>
<thead>
<tr>
<th>Active ingredients (in each tablet)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>clemastine, 1 mg</td>
<td>antihistamine</td>
</tr>
<tr>
<td>loratadine, 10 mg</td>
<td>antihistamine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Active ingredients (in each caplet)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>acetaminophen, 500 mg</td>
<td>pain relief</td>
</tr>
<tr>
<td>pseudoephedrine, 30 mg</td>
<td>nasal decongestion</td>
</tr>
</tbody>
</table>
Umbrella Branding
Zyrtec (Cetirizine)

Zyrtec Itchy Eye (Ketotifen fumarate)

Packaging Design
- Illegible markings on dosing cups and oral syringes
- Improper calibrations
- Can't achieve the dose*

* Illegible markings on dosing cups and oral syringes
* Improper calibrations
* Can't achieve the dose*
Dose calculation

With the aid of 1 of several dosing tables in the package insert (intended for prescribers), you can work out an equation to get the correct dose.

Specifically, the following equation for the milligram equivalent of the 3/4-tsp dose:

\[ 5 \text{ ml (volume of a teaspoon)} \times 0.75 \times 12 \text{ mg per milliliter Tamiflu suspension} = 45 \text{ mg on the syringe} \]
Kapidex vs. Casodex and Kadian

- Name confusion between Kapidex (dexlansoprazole) and the products Casodex (bicalutamide tablets) and Kadian (morphine sulfate extended-release capsules).

- Verbal orders for Kapidex 60 mg were misinterpreted as Casodex 50 mg.

- Written prescriptions were received for Kapidex but Kadian was dispensed in error.
**Error Prone Abbreviations**

- **Examples:**
  - **At the vet clinic:**
    Baytril “SID” prescribed → transcribed and labeled wrong as “QID”
  - **At the pharmacy:**
    A pet prescription written as “SID” → “QID” or “BID”
    - µg or mcg → mg
    - Using trailing zero (5.0 mg → 50 mg)
    - Not using a leading zero (.5 mg → 5 mg)

- FDA education campaign (http://www.fda.gov/bbs/topics/NEWS/2006/NEW01390.html)

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**CVM Outreach**

- FDA Veterinary
  - All activities Related to Animal Health Care and Public Welfare
  - FDA's mission to protect and promote human and animal health through the regulation and oversight of the manufacture, distribution, and use of veterinary drugs and biologicals
  - Ensuring the safety, efficacy, and quality of veterinary products
  - Supporting the development and review of new veterinary products
  - Conducting outreach and education to veterinary professionals, consumers, and other stakeholders
  - Promoting the responsible use of veterinary products

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Over the last decade, the FDA has received and analyzed many documented cases of medication errors in people.

- Identified medication error reports which point to similar problems in veterinary clinical practice.
Added VedDRA medication error coding terminologies in PV Works to capture and analyze postmarket medication error reports for signals and risk assessments.

- Trade name reviews (name recommendations)
- Medication error review of container Label, carton and insert Labeling, and packaging design (label/labeling recommendations)

- Outreach/Educate the industry and healthcare professional about Medication Error Prevention
- Encourage / Report Medication Errors regardless of patient outcome

The Big Picture:
- Drug names, labels and packaging are major contributors to medication error
- Risk for error is determined by both drug product characteristics and the care system processes where drugs are used
- Use lessons learned from the human drug arena to prevent similar medication errors for animals, a proactive approach
- The predictable nature of errors provides opportunity for better name and product design which enhances safe use of drug products
Thanks!

References

- NCCMERP, National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org)
- ISMP, Institute for Safe Medication Practices (www.ismp.org), 200 Lakeside Drive; Suite 200 Horsham, PA 19044-2321

References

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- A Microgram of Prevention is Worth a Milligram of Cure: Preventing Medication Errors in Animals; Linda Kim-Jung, PharmD, FDA/CVM/OSC/DS http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm214772.htm
- All creatures great and small: Properly medicate them all; Linda Kim-Jung, PharmD, FDA/CVM/OSC/DS http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm221945.htm