MEDICATION ERRORS, YOUR PRACTICE AND THE LAW: A REVIEW FOR THE PHARMACIST

AVOIDING, DETECTING AND PREVENTING DISPENSING ERRORS

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Objectives

- State the definition of a medication-related error.
- List factors that contribute to medication errors.
- Identify the commonly reported errors
- List abbreviations and symbols that should no longer be used
- Explain the concept of root cause analysis as it relates to medication errors
- Explain the role of the board of pharmacy and legal consequences of medication errors
Program Overview

- Definition
- Types of medication errors
- Causes of medication errors
- Strategies to reduce medication errors
- Legal consequences of medication errors
- Case studies
“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.”
As many as 98,000 Americans estimated to die in hospitals annually from medical errors

More than 7,000 deaths per year from medication errors
Medication Errors Include…

- Administration
  - Timing
  - Omissions
  - Route

- Monitoring
  - Laboratory data
Factors That May Contribute To Medication Errors

- Unavailable drug information (such as lack of up-to-date warnings)
- Miscommunication of drug orders, which can involve poor handwriting, confusion between drugs with similar names, misuse of zeroes and decimal points, confusion of metric and other dosing units, and inappropriate abbreviations
- Lack of appropriate labeling when a drug is prepared and repackaged into smaller units
Factors That May Contribute To Medication Errors

- Environmental factors such as lighting, heat, noise, and interruptions that can distract health care professionals from their medical tasks
- Complex or poorly designed technology
- Poor procedures or techniques
- Job stress
Factors That May Contribute To Medication Errors

- Dose miscalculations
- Deficiencies related to knowledge of drug therapy
- General failure to act in accordance with education and training
- Incorrect diagnosis
- Patient misuse of medication due to lack of patient information or education
Why Do Medication Errors Occur?

- Environmental
  - Distractions
  - Stress
- Individual
  - Concentration
  - Health
  - Experience
- System
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"STRESS"

THE CONFUSION CREATED WHEN ONE’S MIND OVERRIDES THE BODY’S BASIC DESIRE TO CHOKE THE LIVING DAYLIGHTS OUT OF SOMEBODY WHO DESPERATELY NEEDS IT!
In the interest of public protection, the North Carolina BOP ruled that a pharmacist may not work more than a 12 hour day or fill more than 250 prescriptions in a shift. If this law is not followed and there is a pharmacist error, a claim of morbidity or mortality can be argued in the courts. This law was recently upheld in the courts using the argument of public protection.
A Study Of Medication Errors...

- Released from the State of Massachusetts..
- The Board of Registration in Pharmacy
- 46 of the 51 pharmacists involved in medication errors during this time period agreed to participate in the study. Thirty-four of these pharmacists provided valid data appropriate for statistical analysis.
Fisher's Exact Test found no statistically significant differences between the number of prescriptions filled on the day of the alleged incident versus a typical working day.
Handwritten prescriptions accounted for 45% of errors and 37% of errors were made on prescriptions phoned into the pharmacy.

The study indicated that 63% of the errors were made filling new prescriptions while 37% were made on refills.
In addition, the dispensing of incorrect drugs and/or incorrect strengths accounted for 88% of errors made.
The study revealed that pharmacists perceived the following as causative factors for medication errors:

- too many telephone calls (62%);
- overload/unusually busy day (59%);
- too many customers (53%);
- lack of concentration (41%);
- no one available to double check (41%);
- staff shortage (32%);
- similar drug names (29%);
- no time to counsel (29%);
- illegible prescription (26%);
- and misinterpreted prescription (24%).
Pharmacists reported that there were significantly fewer supportive personnel available on the day the medication error occurred.

Medication errors were more likely to occur when pharmacists reported being understaffed.

A closer examination of staffing and appropriate pharmacist to technician/intern ratios should be included in future studies.

Leaders of the pharmacy profession should encourage and support prospective research in this area to establish new standards for optimal patient care.
According to the FDA...

- Fatal medication errors
  - Improper dose
  - Senior citizens susceptible
Types of Medication Errors?

- System
  - Prescribing
  - Transcription
Types of Medication Errors?

- System
  - Dispensing
  - Administration
Medication Errors Include...

- Prescribing errors
  - Drug
  - Dose
  - Dosage form
  - Route of administration
Wrong Directions: Methotrexate

- Wrong time ..Methotrexate for arthritis given weekly incorrectly dispensed DAILY..Whenever possible do not use “every Monday that may be read as “every morning”

- (Know your patient and disease state) Prescribers should write INDICATION on rx

- Improper labeling or unclear directions
Other Causes of Medication Errors...

- Lack of knowledge of the drug
- Lack of information about the patient
- Failure to follow accepted, well-established rules
- Slips and memory lapses
- Transcription errors
- Faulty drug identity checking
Workload

- Long work shifts without adequate breaks
- Inadequate staff
- Do we sacrifice accuracy for speed?
Work Environment

- Lighting
- Interruptions
- Distractions
- Noise
- Unnecessary people
- Clutter
Work Environment
Work Environment
Medication Errors Include...

- Transcription errors
  - Transmission
  - Data entry
Handwriting

- Prescriber/ pharmacist transcribing
- Never dispense guess work
- Look at the entire prescription/order

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Verbal Orders...

- In order to avoid confusion with spoken numbers, a dose such as 50 mg should be dictated as "fifty milligrams...five zero milligrams" to distinguish from "fifteen milligrams...one five milligrams."

- Instructions for use should be provided without abbreviations. For example, "1 tab tid" should be communicated as "Take/give one tablet three times daily."

- The entire verbal order should be repeated back to the prescriber, or the individual transmitting the order, using the principles outlined in these recommendations.

- All verbal orders should be reduced immediately to writing and signed by the individual receiving the order.
Communication Errors

- Faxes
- Other electronic means
- Security
- Telephone
Electronic Prescribing...

- To help prevent and reduce medication errors, many groups have made computer prescribing a top priority. Currently, only 5-9% of U.S. hospitals use such systems.

- Computerized physician order entry (CPOE) is widely held as an answer to preventing medication errors. Physician order entry and electronic prescribing will reduce illegible scribbles...allow prescriptions to get to pharmacies quicker...reduce errors with similar drug names.

- Facilities using CPOE have shown error reduction rates between 17-81%.
E-Prescribing (benefits)

- Saves time on renewal authorizations and new prescriptions
- Reduces the number of phone calls
- Eliminate transcribing errors
The Center for Information Technology Leadership estimates that the nationwide adoption of e-prescribing would prevent over 3 million adverse drug events annually.

- Preventing nearly 1.3 million provider visits, more than 190,000 hospitalizations, and more than 136,000 life-threatening adverse drug effects.
Studies suggest that national savings from universal adoption of e-prescribing could be as high as 27 billion dollars each year from adverse drug event prevention and better utilization of drugs (e.g., generic prescribing, adherence to formulary, prevention of therapeutic duplication).
Paying MDs More...

- Congress considers mandate for Medicare e-prescribing

- Bipartisan bill would boost payments for doctors who prescribe electronically but cut these reimbursements for physicians who don't.

Electronic, cure all?

- Not foolproof
- Lead to E-errors
- Unfamiliarity with software
  Minimum effective doses
  vs in stock
E-Prescribing: Things To Ensure

- Ensure patient freedom of choice
- Transmit data directly from prescriber to pharmacist
- Be secure (data encryption)
- Know the applicable laws in your state
- “SureScripts” as an example
Medication Errors Include...

- Labeling
- Drug selection
  - Who selects the drug?
- Storage
Technology...

- Systems available for scanning, RX Checking and Tracking...

Kirby Lester..identifies and records who fills Rx

- Every stage of the dispensing process is downloaded to a database

- www.kirbylester.com
The RxScan® Ultra Prescription Verifier will scan the NDC number bar code on the patient label or receipt and by using a complex algorithm to match it to the scanned NDC number bar code on the stock drug container from which the prescription is to be filled. Then the RxScan Ultra displays the correct product on-screen.

The RxScan® 3800 Barcode Scanner hooks up to your pharmacy system through it's keyboard connection. It complements your keyboard by allowing you to scan Rx number bar codes on labels and manufactures containers and automatically inserts the proper information into your application. It eliminates keypunching errors!!!
Medication Error Prevention

- Pharmacist Awareness Education
  - Continuing Education
  - Safe Practice web sites
  - Lists and tables
Drug Name Confusion

- Result in injury or death
- Look alike or sound alike
- Errors are often underreported
Drugs With Similar Names

- Accupril
- Accutane
- Aldara
- Altace
- Alupent
- Ambien
- Atarax
- Benylin
- Bumex
- Betoptic
- Aciphex
- Accupril
- Alora
- Artane
- Atrovent
- Amen
- Ativan
- Ventolin
- Permax
- Betagan
- Calan
- Celexa
- Celebrex
- Cerebyx
- Cefzil
- Chlorpromazine
- Chlorpropamide
- Cozaar
- Covera
- Cyclobenzaprine
- Cytoxan
- Colace
- Cefol
- Zocor
- Provera
- Cyproheptadine
- Cytotec
Omacor (omega 3 acid ethyl esters being mistakenly dispensed as Amicar (aminocaproic acid).

Omacor is indicated for hypertriglyceridemia and Amicar is indicated to enhance hemostasis in patients with fibrinolysis.

Name Change Announcement

The name
OMACOR®
omega-3-acid ethyl esters

will be
LOVAZA™
omega-3-acid ethyl esters

Reliant Pharmaceuticals, Inc. is taking this step at the request of the US Food and Drug Administration (FDA) and in response to a limited number of reports of prescribing and dispensing errors due to similarity in name between the company’s OMACOR® (omega-3-acid ethyl esters) capsules and Xanodyne Pharmaceuticals’ Amicar® (aminocaproic acid). The name change is intended to minimize the potential for such errors in the future.

1. Data on file, Reliant Pharmaceuticals, Inc.
2. Amicar is a registered trademark of Xanodyne Pharmaceuticals, Inc.

Please see brief summary of full prescribing information on the adjacent page.

VISIT OUR WEB SITE AT www.OMACORrx.com
For your customers, be sure it says

LAMICTAL®
(LAMOTRIGINE)

Available in easy-to-follow Starter Kits to help reduce the chance for medication errors.

For your customers, be sure it says

LAMICTAL®
(LAMOTRIGINE)

Medication errors have occurred between LAMICTAL and other medications, most commonly Lamisil®,* lamivudine, Ludiomil®,* labetalol, and Lomotil®.* No one is more aware of the importance of correctly dispensing prescriptions than pharmacists, and no one is in a better position to help ensure that all patients receive the treatment they need.

IMPORTANT NOTE: Medication errors have occurred between LAMICTAL and other medications, most commonly Lamisil®,* lamivudine, Ludiomil®,* labetalol, and Lomotil®.* Patients who do not receive LAMICTAL would be inadequately treated and could experience serious consequences. Conversely, patients erroneously receiving LAMICTAL, especially high initial doses, would be unnecessarily subjected to a risk of serious side effects.

If you become aware of a prescription dispensing error involving these products, please contact GlaxoSmithKline at 1-800-334-4153; the USP Medication Errors Reporting Program at 1-800-233-7767; or the US Food and Drug Administration's MedWatch program by phone at 1-800-FDA-1088. You may also contact MedWatch by fax at 1-800-FDA-0178, via the Internet at www.fda.gov/medwatch, or by mail: MedWatch, 5600 Fishers Lane, Rockville, MD 20857-9787.*

* Lamisil (terbinafine HCl tablets) and Ludiomil (maprotiline HCl) are registered trademarks of Novartis Pharmaceuticals Corporation. Lomotil (diphenoxylate HCl, atropine sulfate) is a registered trademark of G.D. Searle & Co.
Look-Alike/Sound-Alike Drug Names and Other Product-Related Issues

- **Zyrtec (cetirizine) and Zyprexa (olanzapine)** Mix-ups between the antihistamine, Zyrtec (cetirizine), and Zyprexa (olanzapine), an antipsychotic.
- Both drugs are available in 5 mg and 10 mg tablet strengths.
The doctor wrote "ZYPREXA."
Help make sure that’s what this patient gets.
Dispensing errors have been reported involving TOPROL-XL®, TOPAMAX®, and TEGRETOL®/TEGRETOL®-XR

Please be aware that these products

- Have similar names and dosage strengths
- Are often stocked in close proximity on pharmacy shelves

Help minimize medication errors.
Choose Carefully…
Choose Carefully…
Not All Capsules Are Meant To Be Swallowed

- Foradil (aerolizer)
- Spiriva (handihaler)

**Actonel & Fosamax**

- **Actonel** now available in 75mg tablets for monthly dosing (must be taken on 2 consecutive days)

- **Fosamax D**; now in 2 strengths of Vit D 5600 IU / week as compared to 2800 IU/ week
One patient died because 20 units of insulin was abbreviated as "20 U," but the "U" was mistaken for a "zero." As a result, a dose of 200 units of insulin was accidentally injected..

http://www.ismp.org/
Zeros and decimal points

U – Units: Mistaken as a zero or a four (4) resulting in overdose. Also mistaken for "cc" (cubic centimeters) when poorly written.

µg - Microgram: Mistaken for "mg" (milligrams) resulting in an overdose.

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Common Failures</th>
<th>Common Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>U</td>
<td>Units</td>
<td>Mistaken as a zero or a four resulting in overdose. Also mistaken for cc when poorly written</td>
</tr>
<tr>
<td>Ug</td>
<td>Micrograms</td>
<td>Mistaken for mg resulting in an overdose</td>
</tr>
<tr>
<td>Q.D.</td>
<td>Latin abbreviation for every day</td>
<td>The period after the Q has been mistaken for an ‘I’ and the drug has been given QID rather than daily</td>
</tr>
<tr>
<td>Q.O.D</td>
<td>Latin abbreviation for every other day</td>
<td>Misinterpreted as QD or QID. If the O is poorly written, it looks like a period or I</td>
</tr>
<tr>
<td>SC or SQ</td>
<td>Subcutaneous</td>
<td>Mistaken as SL (sublingual) when poorly written</td>
</tr>
<tr>
<td>TIW</td>
<td>Three times a week</td>
<td>Misinterpreted as three times a day or twice a week</td>
</tr>
<tr>
<td>D/C</td>
<td>Discharge also discontinue</td>
<td>Patient’s medications have been prematurely discontinued when D/C (intended to mean discharge) was misinterpreted as discontinue, because it was followed by a list of drugs</td>
</tr>
<tr>
<td>HS</td>
<td>Half strength</td>
<td>Misinterpreted as the Latin abbreviation QHS</td>
</tr>
<tr>
<td>Cc</td>
<td>Cubic centimeters</td>
<td>Mistaken as U when poorly written</td>
</tr>
<tr>
<td>AU, AS, AD</td>
<td>Latin abbreviation for both ears; left ear; right ear</td>
<td>Misinterpreted as the Latin abbreviation of OU (both eyes), OS (left eye) OD (right eye)</td>
</tr>
<tr>
<td>IU</td>
<td>International unit</td>
<td>Mistaken as IV or 10 (ten)</td>
</tr>
<tr>
<td>MS, MSO4, MgSO4</td>
<td>Confused for one another</td>
<td>Can mean morphine sulfate or magnesium sulfate</td>
</tr>
</tbody>
</table>
Recommendation

- Specify the medication’s indication on prescriptions and ensure that patients know its purpose.

- Encourage patients never to leave the pharmacy without verifying with the pharmacist that the prescription matches what their doctor told them.

- Counseling patients when presenting new prescriptions.
Verify if patients have any allergies and/or reactions to medications

Inquire of patients if they have any current medical conditions, particularly diabetes, kidney disease, liver disease, cardiovascular disease, and psychiatric disease

Ask patients about medications they are currently taking, including any nonprescription products, vitamins and minerals, and herbals

Try to standardize use of height and weight measurements, preferably using metric units
Strategies To Reduce Medication Errors

- Make sure drug information databases are up to date.
- Compile a list of high-alert medications, i.e., medications that require extra precautions when administered, prescribed, dispensed, or refilled.
- Compile a list of similar drug names and circulate it among pharmacy staff, and do not store these drugs near each other.
- Ensure patients are aware of the indication for which a drug is prescribed.
Medication Error Prevention

- Continuous Quality Improvement
  - Focus on system, not individual
  - Incorporate automation
  - Efficient work flow
Medication Errors Nationwide: Tracking

MedMarx  https://www.medmarx.com/

- Developed by United States Pharmacopeia (USP) Center for Advancement of Patient Safety (CAPS)
- hospitals across the country share similarities in errors
Voluntary Reporting of Errors

- Establishing a non-punitive reporting program:
  - initial goal of non-punitive policy is to increase the number of reports so that administrators have more data about system problems and are able to fix them.”
  - increase in the number of errors reported.
  - reduction in medication errors.

From USP reprinted with permission from US Pharmacist, May 2004
Voluntary Reporting of Errors

- Http://www.ismp.org/pages/communications.asp
- https://www.accessdata.fda.gov/scripts/medwatch/medwatch_online.cfm

- **USP medication error reporting (MER) program**
  1-800-233-7767 U.S. Food and drug administration's

- **MedWatch reporting program**
  1-800-FDA-1088
Hey Doc, I think you made a mistake....
Handling Medication Errors

- Explain the error to the patient without any excuses. Counsel the patient on potential side effects of the error.

- Correct the mistake and if possible retrieve the incorrect prescription.
Handling Medication Errors

- Don’t be afraid to offer a sincere apology. Apologizing for inconvenience, or even for harm, is different from admitting liability. Thank them for their patience and understanding, or for noticing an error, if that was the case.

- Document the occurrence and your actions.

(reprinted with permission from Pharmacists Letter, June 2001)
Handling Medication Errors

- Act quickly and professionally
- Recognize that your first objective is to minimize any potential ill effects for the patient
- Take all comments and questions that hint of a question seriously
- Give the patient your immediate attention
- Move to a private area if possible
- Acknowledge the concern that an error may have been made
- Tell the patient that you will check into it thoroughly
Handling Medication Errors

Hey Doc, I’m gonna sue your ….

Types of action
Civil
BOP Complaint
Criminal
Legal Consequences

- Civil
  - Professional negligence, malpractice
    - Usually misfilling of a Rx
  - Demonstrate harm was done
  - Mechanical vs Intellectual errors
    - States have been inconsistent
- OBRA 90
Boards of Pharmacy
And Medication Errors

- Generally involves a complaint Initiated by patient or family member.

- BOP turn over to Attorney General for investigation and further action if needed.

- Pharmacist may or may not see the complaint depending on the state.
Boards of Pharmacy
And Medication Errors

The BOP Outcome

1. No action
2. Reprimand / Fines
3. License Suspension
4. License Revocation
Complaint Investigations

BOP and/or Attorney General gather information:

- In person interview with pharmacist.
- Mail a detailed questionnaire to out of state licensee.
- In person interview with the person making the complaint.
Complaint Investigations - results

- Close case
- Close case with reprimand
- Move forward with administrative action
Legal Consequences

- Criminal
  - Criminal Intent
  - Unlawful act
  - Controlled Substance violations
Case Discussions
Near Fatal Overdose

- Dennis Quaid Recounts Twins' Drug Ordeal
- Should have received Hep-Lock
- Were given Heparin

Question For The Audience: What was a contributory factor in this medication error?
Look-Alike Packaging
A Case Of Fatal Overdose

One person's error killed Elisha Crews Bryant, hospital officials said:

“a miscalculation by a nurse that overdosed the pregnant 18-year-old with a drug meant to slow her labor.”

(Tampa Bay Times, June 2006)
Patient received 16 gms Mag. Sulfate.

Patient should have received 4 gms.

How many ML @ 25 gm/50 ml should she have received?
Medical Errors Kill Kids Too

- Surgeon wrote for .5 milligrams of morphine
- Unit clerk filled out a form for 5 milligrams
- Pharmacists provided order
- Pediatric nurse administered the fatal dose
Question For The Audience:

How could this have been prevented?
$25.8 Million Verdict
In Walgreens Wrongful Death Suit

- Patient was dispensed coumadin, 10 times the prescribed dose.
- Prescription was filled by a 19 year old technician
Questions For The Audience:

How could this have been prevented?

What recent change in Florida, with respect to pharmacy, was influenced by this case, and will be implemented January 1, 2009?
QUESTIONS / COMMENTS?