An Overview of Approaches to Minimize the Risk of Medication Errors

By Tammy J. Butler, Pharm.D

Objectives for Pharmacists

1. Outline the classification of medication errors.
2. Discuss examples of the types of medication errors and examine related clinical cases.
3. Examine approaches to reduce the risk of medication errors.
4. Review medication error reporting such as internal and external reporting and discuss guidelines to follow when reporting medication errors.
5. Summarize available resources for pharmacists and healthcare professionals.
6. Discuss the impact of medication errors and evaluate the related costs.

Objectives for Pharmacy Technicians

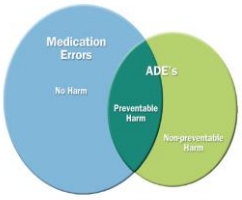
1. Outline the classification of medication errors.
2. Discuss examples of the types of medication errors and examine related clinical cases.
3. Examine approaches to reduce the risk of medication errors.
4. Review medication error reporting such as internal and external reporting and discuss guidelines to follow when reporting medication errors.
5. Summarize available resources for pharmacy technicians.
6. Discuss the impact of medication errors and evaluate the related costs.

What is a 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. Such events may be related to **professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.**"
- http://www.nccmerp.org/about-medication-errors. Accessed 5/30/2017.

What is a "**Medication Error**"?

Figure 1: Relationship between medication errors and ADEs



[1]Adapted from Figure 1 in Qual Saf Health Care 2004;13:306-314. doi: 10.1136/qshc.2004.010611

- National Coordinating Council for Medication Error Reporting and Prevention. Available at: www.nccmerp.org. Accessed 05/24/2017.

Culture of Safety

- "**People make errors**, which lead to accidents. Accidents lead to deaths. **The standard solution is to blame the people involved.** If we find out who made the errors and punish them, we solve the problem**, right**?
- **Wrong**. The **problem is seldom the fault of an individual; it is the fault of the system.** Change the people without changing the system and the problems will continue."

Don Norman
The Design of Everyday Things

NCCMERP
National Coordinating Council for Medication Error Reporting and Prevention

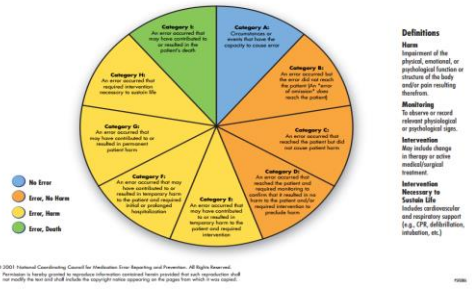
Classification of Medication Errors

ISMP Institute for Safe Medication Practices
A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices

- On July 16, 1996, the NCC MERP adopted a **Medication Error Index** that classifies an error according to the severity of the outcome.
- The Council realized the need for a standardized categorization of errors.
- It is hoped that the index will help health care practitioners and institutions to track medication errors in a consistent, systematic manner.
- The index considers **factors such as whether the error reached the patient and, if the patient was harmed, and to what degree**.
- The Council encourages the use of the index in all health care delivery settings and by researchers and vendors of medication error tracking software.
- The ISMP Medication Errors Reporting Program has implemented this index for use in its database.

Classification of Medication Errors

NCC MERP Index for Categorizing Medication Errors



Category	Description	Example
A	No error, capacity to cause error	NA
B	Error that did not reach the patient	NA
C	Error that reached patient but unlikely to cause harm (omissions considered to reach patient)	Multivitamin was not ordered on admission
D	Error that reached the patient and could have necessitated monitoring and/or intervention to preclude harm	Regular release metoprolol was ordered for patient instead of extended-release
E	Error that could have caused temporary harm	Blood pressure medication was inadvertently omitted from the orders
F	Error that could have caused temporary harm requiring initial or prolonged hospitalization	Anticoagulant, such as warfarin, was ordered daily when the patient takes it every other day
G	Error that could have resulted in permanent harm	Immunosuppressant medication was unintentionally ordered at one-fourth the dose
H	Error that could have necessitated intervention to sustain life	Anticonvulsant therapy was inadvertently omitted
I	Error that could have resulted in death	Beta-blocker was not reordered post-operatively

Categories of Medication Error Classification with Examples

- **What is the most common medication error?**
- In a study by the FDA that evaluated reports of fatal **medication errors** from 1993 to 1998, the **most common error** involving **medications** as related to <u>administration of an improper dose of medicine</u>, accounting for 41% of fatal **medication errors**.

Examples of the Types of Medication Errors

Examples of the Types of Medication Errors:

- **<u>Top Drugs Associated with Medication Errors:</u>**
- 1. insulin
- 2. albuterol
- 3. morphine
- 4. potassium chloride
- 5. heparin
- 6. cefazolin
- 7. warfarin
- 8. furosemide
- 9. levofloxacin
- 10. vancomycin
- 11. metoprolol
- 12. enoxaparin
- 13. lorazepam
- 14. acetaminophen
- 15. ipratropium
- 16. hydrocodone/acetaminophen
- 17. oxycodone/acetaminophen
- 18. meperidine
- 19. levothyroxine
- 20. aspirin

(MEDMARX USP data report 2003-2006)

Ten most common lethal medication errors in hospitals:

- Concentrated **potassium chloride injections**
- **Insulin errors**
- Intravenous **calcium and magnesium**
  - EX: calcium chloride contains 13.6 mEq of Ca/gm; calcium gluconate contains 4.65 mEq/gm
- Inadvertent administration of **50% dextrose**
- **Known allergy**
- Miscalculated **digoxin dose in pediatrics**
- Confusing **vincristine and vinblastine**
  - EX: max dose of vincristine is 2 mg, while 6 mg/m2 for vinblastine
- **Concentrated sodium chloride injections**
  - EX: cases where 23.4% sodium chloride was employed to dilute antibiotics
- **Intravenous opioids**
  - EX: availability of a variety of concentrations
- **Aminophylline errors**
  - EX: 7.4 mg ordered for an infant, but 7.4 ml (185 mg) administered >> Outcome: Death

(Argo et al, 2000)

Examples of the Types of Medication Errors

Related Clinical Cases

- Wrong drug errors represent ~ **8% of medication errors in outpatient pharmacy**, and occur in ~ 0.13% of all dispensed prescriptions.
- A wrong drug error rate of 0.13% **for 3.7 billion prescriptions** (2006 U.S. number of outpatient prescriptions) would translate to 4.8 million wrong drug errors.

Facts to Keep in Mind

2008 MEDMARX data report, USP

Case Description

- A 71-year-old female accidentally received **thiothixene (*Navane*),** an antipsychotic, instead of her anti-hypertensive medication **amlodipine (*Norvasc*)** for 3 months.
- She sustained physical and psychological harm including ambulatory dysfunction, tremors, mood swings, and personality changes.
- Despite the many opportunities for intervention, multiple health care providers overlooked her symptoms.
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5016741/. Accessed on 6/1/2017.

Related Clinical Cases: Case # 1

Case Description:

- **Hydralazine/hydroxyzine** – a nurse attempting to order hydralazine through a hospital computer system mistakenly chose hydroxyzine.
- The patient received 10 doses of hydroxyzine and developed bowel obstruction and worsening congestive heart failure.
- Required transfer to a critical care unit for stabilization.
- **Selected Findings from MEDMARX USP data report 2003-2006**

Related Clinical Cases: Case # 2

Case Description:

- **Lamictal/lebetalol** – a refill for lebetalol 200 mg was mistakenly filled by a pharmacy technician with lamictal 200 mg.
- The pharmacist did not catch the error.
- Lamictal was stored in a separate shelve at this pharmacy where look alike/sound alike drugs are stored.
- The patient took the wrong drug for several weeks before being admitted for nausea/vomiting and elevated BP.
- **Selected Findings from MEDMARX USP data report 2003-2006**

Related Clinical Cases: Case # 3

Case Description:

- **Fentanyl/sufentanil** – a nurse provided a verbal order to pharmacy for fentanyl for an endoscopy procedure.
- The pharmacist heard sufentanil instead, which was dispensed.
- The patient received the sufentanil at the fentanyl dose and required CPR.
- The error was discovered later when the written orders were reviewed in the pharmacy.
- **Selected Findings from MEDMARX USP data report 2003-2006**

Related Clinical Cases: Case # 4

Brilinta vs. Brintellix Name Confusion:

- July 2015: FDA issued a Drug Safety Communication: As of June 2015, the FDA received 50 medication error reports describing brand name confusion with Brintellix (vortioxetine) and Brilinta (ticagrelor). In most cases, Brintellix was mistaken as Brilinta.
  - Some of the contributing factors to the name confusion included the following: Both brand names begin with the same three letters.
  - Both brand names are presented when selecting medications in a computerized physician order entry (CPOE) system.
  - The pharmacist was not familiar with the new medication Brintellix and dispensed Brilinta.

Related Clinical Cases: Case # 5 cont.

Brilinta vs. Brintellix Name Confusion

- Since the July 2015 DSC, the FDA received 5 additional cases describing brand name confusion involving Brilinta and Brintellix
- Recommended a proprietary name change for Brintellix
- **FDA Action Taken: May 2016 name change to Trintellix**

Related Clinical Cases: Case # 5 cont.

Related Clinical Cases: Case # 5 cont.

FDA Drug Safety Communication: FDA approves brand name change for antidepressant drug Brintellix (vortioxetine) to avoid confusion with antiplatelet drug Brilinta (ticagrelor)

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This is an update to the FDA Drug Safety Communication: FDA warns about prescribing and dispensing errors resulting from brand name confusion with antidepressant Brintellix (vortioxetine) and antiplatelet Brilinta (ticagrelor) issued on **July 30, 2015**.

Safety Announcement

[05-02-2016] The U.S. Food and Administration (FDA) has approved a brand name change for the antidepressant Brintellix (vortioxetine) to decrease the risk of prescribing and dispensing errors resulting from name confusion with the blood-thinning medicine Brilinta (ticagrelor). The new brand name of the drug will be Trintellix, and it is expected to be available starting in June 2016. No other changes will be made to the label or packaging, and the medicine is exactly the same.

Because of the lag time associated with manufacturing bottles with the new brand name, health care professionals and patients may continue to see bottles labeled with the brand name Brintellix during the transition period.

- **Fatal 1000-fold error in iv zinc TPN order** received with zinc ordered as 300 mcg/100ml
- Pharmacist converted this dose to mcg/kg correctly, **but entered the final dose in mg (i.e. 330 mg/100ml instead of 330 mcg/100ml)** from a pull down menu.
- A 2nd pharmacist checked the work but also didn't notice **mg instead of mcg**.
- The technician prepared the dose, having to replenish the compounder syringe containing the **zinc a total of 11 times during the automated preparation** (requiring dozens of zinc vials)
- Final TPN bag dispensed to the NICU.
- A 2nd oncoming technician discovered the error (via a discussion with the preparing technician) and alerted a pharmacist, but by the time the infusion was stopped an antidote (calcium EDTA) was administered, **the infant died from cardiac failure due to zinc intoxication**.

Related Clinical Cases: Case # 6 Cont. September, 2007

ISMP Vaccine Errors Reporting Program:

- Estimate (based upon spontaneous reports) that errors occur **in 27-35%** of vaccinations
- July newsletter provides summary of 4 yr of vaccination errors based on **> 1700 reports/mostly in outpatient settings**

Most frequent error types:

- Wrong vaccine – 23%
- Wrong age for vaccination – 20%
- Wrong vaccine dose – 12%
- Extra vaccine dose – 9%
- Wrong vaccine interval – 7%

ISMP Vaccine Errors Reporting Program (ISMP July, 2016)

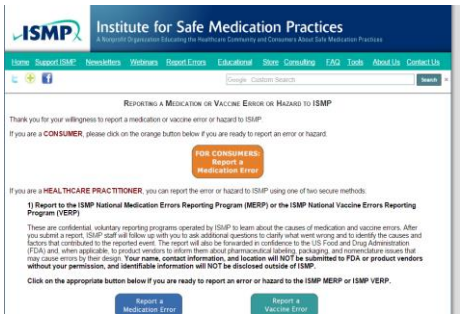
Reporting Medication Errors

Report Medication Errors

- ISMP Medication Errors Reporting Program (MERP): https://www.ismp.org/errorReporting/reportErrortoISMP.aspx
  1-800-233-7767
- U.S. Food and Drug Administration's MedWatch Reporting Program: https://www.fda.gov/Safety/MedWatch
  1-800-FDA-1088

Medication Error Reporting

Medication Error Reporting



Medication Error Reporting

What to Report to FDA MedWatch:

Use the MedWatch form to report adverse events that you observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))
- Medical devices (including in vitro diagnostic products)
- Combination products
- Special nutritional products (infant formulas, and medical foods)
- Cosmetics
- Foods/beverages (including reports of serious allergic reactions)

Guidelines to Follow When Reporting Medication Errors

What Not to Report to FDA MedWatch:

- Tobacco: Tobacco product problems should be reported to the Safety Reporting Portal.
- Vaccines: Report vaccine events to the Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov/esub/index
- Investigational (study) drugs: Report investigational (study) drug adverse events as required in the study protocol and send to the address and contact person listed in the study protocol.
- Mandatory reporting by regulated industry:
  - Drugs and Biologics
  - Applicable Regulations
  - Devices
- Reporting on Dietary Supplements
- Reporting on Veterinary Medicine Products
- Reports FDA Does Not Handle (e.g. CPSC, FTC, State Health Departments) and Where to Send Them

Guidelines to Follow When Reporting Medication Errors

Approaches to Reduce the Risk of Medication Errors

- **Drug labeling:**
  - Consumers tend to overlook important label information on OTC drugs
  - The FDA proposed a new format in 2000 to improve prescription drug labeling for physicians, also known as the package insert.
- **Error tracking and public education:**
  - In December 2003, the USP released an analysis of medication errors captured in 2002 by its anonymous national reporting database, MedMARX.
  - Of the errors reported to MedMARX, slightly more than one-third reached the patient and involved a geriatric patient.
  - Many of these medication errors were found to be harmful.
  - The FDA receives and reviews about 300 medication error reports each month and classifies them to determine the cause and type of error.
  - Depending on the findings, the FDA can change the way it labels, names, or packages a drug product.
  - In addition, once a problem is discovered, the FDA educates the public on an ongoing basis to prevent repeat errors.
- https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143553.htm

Approaches to Reduce the Risk of Medication Errors

- **Drug name confusion**
  - Minimize confusion between drug names that look or sound alike
- ***A Regulatory Approach***
  - Bar code label rule
  - July 2002, the FDA decided to propose a new rule requiring bar codes on certain drug and biological product labels.
  - FDA mandated drug name change 2004 when the cholesterol-lowering medicine Altocor was being confused with the cholesterol-lowering medicine Advicor. (Now Altocor is called Altoprev, and the agency hasn't received reports of errors since the name change).
- **After drugs are approved**
  - the FDA tracks reports of errors due to drug name confusion and spreads the word to health professionals, along with recommendations for avoiding future problems.
- https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143553.htm

Approaches to Reduce the Risk of Medication Errors

Common Hospital Strategies:

- Hospitals and other health care organizations work to **reduce medication errors by using technology, improving processes, zeroing in on errors that cause harm, and building a culture of safety.**

Here are a couple of examples:

- **Pharmacy intervention:**
  - To ensure that patients continued taking their regularly prescribed medicines when they entered the hospital.
  - **"Med Rec"**
- **Computerized Physician Order Entry (CPOE):**
- Studies have shown that CPOE is effective in reducing medication errors.
- https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143553.htm

Approaches to Reduce the Risk of Medication Errors

Improving Transition of Care: Opportunities for Community Pharmacists (February 2017, Vol 5, No 2 - *Inside Pharmacy)*:

- **Transition of care** is the transfer of the care of a patient from one setting to another.
- In the United States, approximately 20% of 30-day hospital readmissions occur because of uncoordinated transition of care.
- **Billions of dollars** are spent unnecessarily because patients are not receiving proper, coordinated, and consistent care when they are discharged from the hospital into their communities.
- In fact, Medicare reports show that more than **$17 billion are spent annually** on preventable readmissions; a large percentage of patients are readmitted because of **improper medication use after discharge**.

Approaches to Reduce the Risk of Medication Errors

Improving Transition of Care: Opportunities for Community Pharmacists *(cont.)*

- A systematic review showed that up to **2% of medication discrepancies are life-threatening and lead to death.**
- **Medication discrepancies** often occur when patients lack understanding of discharge medication plans, have inadequate literacy to understand the discharge instructions, become nonadherent to a medication regimen, and/or experience adverse drug events.
- **Expanding community pharmacists' involvement in post discharge transition of care and improving communication will benefit patients**, healthcare providers, and the healthcare system by decreasing hospital readmissions, medication-related adverse events, and financial burdens.
- (February 2017, Vol 5, No 2 - *Inside Pharmacy)*

Approaches to Reduce the Risk of Medication Errors

Barriers:

- Despite having community pharmacists readily accessible, many **roadblocks** discourage care transition services in community pharmacies.
- A study published in 2015 assessed community pharmacists' readiness to participate in care transition.
- The **primary barrier was the lack of time to offer** transition of care services in the community.
- The **inadequate staffing of pharmacists** and technicians prohibits the incorporation of other services, and prohibits pharmacists from providing efficient and/or sufficient care to patients.

Improving Transition of Care: Opportunities for Community Pharmacists (cont.)

Barriers (cont.):

- Other obstacles include **poor communication between the physicians and pharmacists**, and **lack of access to the patient's hospitalization data.**
- Lack of physician and patient acceptance and lack of reimbursements are also reasons why community pharmacists are hesitant to be more involved in transition of care.
- By failing to take a larger role and actively get **involved in transition of care**, pharmacists may leave patients unaware of the services that community pharmacists are capable of providing.
- Once pharmacies are able to **get reimbursed for their services,** it is likely that more community pharmacies will obtain sufficient resources, including time, and be willing to offer these services.

Improving Transition of Care: Opportunities for Community Pharmacists (cont.)

What Consumers/Patients Can Do?

- ***Recommendations by the FDA:***
  - Know **what kind of errors occur**.
  - Find out what **drug you're taking** and what it's for.
  - Find out how to take the drug and make sure you understand the directions.
  - **Keep a list of all medications**, including OTC drugs, as well as dietary supplements, medicinal herbs, and other substances you take for health reasons, and report it to your health care providers.
  - If in doubt**, ask, ask, ask**. Be on the lookout for clues of a problem, such as if your pills look different than normal or if you notice a different drug name or different directions than what you thought.
- https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143553.htm

Approaches to Reduce the Risk of Medication Errors

Available Resources

Who Tracks Medication Errors?

- **The Food and Drug Administration**
- Accepts reports from consumers and health professionals about products regulated by the FDA, including drugs and medical devices, through MedWatch, the FDA's safety information and adverse event reporting program.
(800) 332-1088
www.fda.gov/medwatch.htm
- **Institute for Safe Medication Practices**
- Accepts reports from consumers and health professionals related to medication. Publishes Safe Medicine, a consumer newsletter on medication errors.
1800 Byberry Road, Suite 810 Huntingdon Valley, PA 19006-3520
(215) 947-7797
www.ismp.org
- http://www.ismp.org/tools/default.aspx
- **U.S. Pharmacopeia**
- The Medication Errors Reporting (MER) Program, in cooperation with the Institute for Safe Medication Practices, is a voluntary national medication error reporting program.
12601 Twinbrook Parkway
Rockville, MD 20852 (800) 23-ERROR (233-7767)
www.usp.org
- **MedMARX**
- USP's anonymous medication error reporting program used by hospitals. These data are not submitted to the FDA.
www.medmarx.com

Available Resources for Pharmacists and Healthcare Professionals

Resource	Website
Guidances for Industry	
• Safety Considerations for Product Design to Minimize Medication Errors – April 2016	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM331810.pdf
• Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors (*Draft*) – April 2013	http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf
• Best Practices in Developing Proprietary Names for Drugs (*Draft*) – May 2014	http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm398997.pdf
• Applying Human Factors and Usability Engineering to Medical Devices – February 2016	http://www.fda.gov/downloads/MedicalDevices/.../UCM259760.pdf
Regulations	
• 21 CFR 200s, 300s and 600s	http://www.ecfr.gov/cgi-bin/textidx?tpl=/ecfrbrowse/Title21/21tab_02.tpl

For More Information

- Agency for **Healthcare Research and Quality**
  Brochures: "20 Tips to Help Prevent Medical Errors" and "20 Tips to Help Prevent Medical Errors in Children"
  (800) 358-9295
- Food and Drug Administration
  Think it Through: A Guide to Managing the Benefits and Risks of Medicines
  (888) 878-3256
- http://www.ismp.org/tools/default.aspx
- https://www.fda.gov/drugs/resourcesforyou

Additional Resources for Pharmacy Technicians

Impact and Related Costs of Medication Errors

Economic Impact (United States)

- Economic impacts have been inadequately studied.
- Medication errors harm an estimated 1.5 million people every year, **costing at least $3.5 billion annually**.
- It is estimated that ADEs affect approximately **2 million** hospital stays annually and prolong the length of stay by 1.7–4.6 days .
- In 2006, at least **1.5 million** preventable ADEs occurred totaling more than **$7 billion**.
- Preventable medication errors impact more than **7 million patients and cost almost $21 billion** annually across all care settings .
- Spending in the United States for prescription drugs in 2010 was **$259.1 billion** and is expected to double over the next decade .
- Total expenditures on the Medicare Part D program alone in 2012 were **$66.9 billion and are projected to reach $165.1 billion** by 2022.

- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5016741/

Impact and Related Costs of Medication Errors

- **Errors** occurred at multiple care levels, including **prescribing, initial pharmacy dispensation, hospitalization, and subsequent outpatient follow-up**.
- Adverse drug events (ADEs) account for more than **3.5 million physician office visits and 1 million emergency department visits** each year.
- It is believed that **preventable medication errors impact** more than **7 million patients** and cost almost **$21 billion** annually across all care settings.
- About 30% of hospitalized patients have at least one discrepancy on discharge medication reconciliation.
- **Medication errors and ADEs are an underreported burden** that adversely affects patients, providers, and the economy.

Summary

Questions

1. Argo AL, et al. The ten most common lethal medication errors in hospital patients. Hospital Pharmacy 2000; 35:470-4.
2. MEDMARX USP data report 2003-2006.
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6. http://www.insidepatientcare.com/issues/2017/february-2017-vol-5-no-2/455-improving-transition-of-care-opportunities-for-community-pharmacists. Accessed 6/5/2017.

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