Medication Errors – An Opportunity to Improve
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Pharmacist Objectives
- Compare and contrast medication errors and adverse drug events (ADE)
- Describe methods and responsibilities for reporting errors
- Summarize Failure Mode Effects Analysis (FMEA) and Root Cause Analysis (RCA)
- Analyze pediatric and adult medication error examples
- Apply strategies for reducing medication risks

Technician Objectives
- Identify medication errors and adverse drug events (ADE)
- Recognize methods and responsibilities for reporting errors
- Define Failure Mode Effects Analysis (FMEA) and Root Cause Analysis (RCA)
- Summarize pediatric and adult medication error examples
- Describe strategies for reducing medication risks

Have you ever made an error
“...to err is human; to forgive, divine.”
-Alexander Pope, An Essay on Criticism
1688 - 1744

Disclosure
Laura Monroe-Duprey - I do not have (nor does any immediate family member have) a vested interest or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias my presentation.

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Medication Error

**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, 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 4/30/17)

Medication Errors vs. Adverse Drug Events

**Medication Errors**

- 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.

**Adverse Drug Events (ADE)**

- Any injury, large or small, caused by the use (including non-use) of a drug.

2 types of ADEs

1) Preventable ADEs - Caused as a result of an error
2) Non-preventable ADEs - Occur despite proper usage
   a) Also known as an Adverse Drug Reaction (ADR)


Causes of Medication Errors

**Cause:**

- Rarely the failure of a single element or person
- Combined effects

**Types of failures:**

- Latent failures in the system
- Active failures by people

**Solutions:**

- Recognize and correct latent failures
- Increase redundancy
- Establish systems to minimize risk of medication errors


Where Medication Errors Occur

Prescribing 39-49%
- Physician
- Physician extender
- Pharmacist

Transcribing 11-12%
- Physician
- Physician extender
- Pharmacist
- Nurse
- Non-healthcare professional

Dispensing 11-14%
- Pharmacist
- Pharmacy technician
- Pharmacy student

Administering 26-38%
- Nurse
- Respiratory therapist

Monitoring 8%
- Physician
- Physician extender
- Pharmacist
- Nurse
- Respiratory therapist

Medication Errors vs. Adverse Drug Events

Adverse Drug Event (ADE)

Definition:

An injury, large or small, caused by the use (including non-use) of a drug.

2 types of ADEs

1) Preventable ADEs - Caused as a result of an error
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Adverse Drug Reaction (ADR)

“any unexpected, unintended, undesired, or excessive response to a drug that...

- requires discontinuing the drug (therapeutic or diagnostic)
- requires changing the drug therapy
- requires modifying the dose (except for minor dosage adjustments)
- necessitates admission to a hospital
- prolongs stay in a healthcare facility
- necessitates supportive treatment
- significantly complicates diagnosis
- negatively affects prognosis or
- results in temporary or permanent harm, disability, or death.”

Includes allergic reactions and idiosyncratic reactions

Making errors is a significant problem in healthcare, and medication errors in particular can lead to adverse drug events (ADEs). These errors can be classified into categories such as medication errors, potential ADEs, preventable ADEs, and non-preventable ADEs (also known as ADEs). The incidence of medication errors and adverse drug events is significant:

- ~1 medication error per patient per day
- >1.5 million preventable ADEs each year in the US
- Estimated annual cost of preventable ADEs = $3.5 billion
- Underestimated due to variability of definitions used & methods used to identify


Factors placing pediatric patients at increased risk for medication errors include:

- Changing pharmacokinetic parameters at various ages and stages of development
- Need for calculation of individualized doses based on patient’s age, weight (mg/kg), body surface area (mg/m2), and clinical condition
- Lack of available dosage forms and concentrations appropriate for administration to neonates, infants, and children. Frequently, dosage formulations are extemporaneously compounded and lack stability, compatibility, or bioavailability data
- Need for precise dose measurement and appropriate drug delivery systems
- Lack of published information or Food and Drug Administration-approved labeling regarding dosing, pharmacokinetics, safety, efficacy, and clinical use of drugs in the pediatric population


Reporting
To Err is Human
The Quality of Health Care in America 1998 Project

- Medical errors are major risks to public health
- Medication errors alone, either in a hospital or elsewhere, was estimated to account for over 1,000 deaths annually
- Public insulation
- Liability insurance and culture contributions


Recommendations contained in this report suggest a four-tiered approach:

1. Establish a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
2. Identify and learn from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;
3. Raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups;
4. Create safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.

Medication Error Reporting IOM Recommendation

- Recommendation 5.1: Nationwide mandatory reporting system for providers which allows for collection of standard information
- Recommendation 5.2: “Center of Patient Safety” to describe and disseminate information on voluntary reporting systems
- Recommendation 6.1: Legislation to protect peer review patient safety data
- Recommendation 8.2: Health care organizations should implement proven medication safety practices

Ten Year Journey
Medicare Modernization Act of 2003
- Mandated the Centers for Medicare and Medicaid Services to sponsor study by IOM

“To formulate a national agenda for reducing medication errors by developing estimates of the incidence of such errors and determining the efficacy of prevention strategies”

Health Care Organizations should implement active internal monitoring programs so that progress toward improved medication safety can be accurately demonstrated (2007)
Patient Rights to Their Medication Management

Be the source of control for all medication management decisions that affect them (that is, the right to self-determination).
Accept or reject medication therapy on the basis of their personal values.
Be adequately informed about their medication therapy and alternative treatments.
Ask questions to better understand their medication regimen.
Receive consultation about their medication regimen in all health settings and at all points along the medication-use process. Designate a surrogate to assist them with all aspects of their medication management.
Expect providers to tell them when a clinically significant error has occurred, what the effects of the event on their health (short- and long-term) will be, and what care they will receive to restore their health.
Ask their provider to report an adverse event and give them information about how they can report the event themselves.

Issues for Nurses, Physicians and Pharmacists

- Review the patient's medication list routinely and during care transitions.
- Review different treatment options.
- Review the name and purpose of the selected medication.
- Discuss when and how to take the medication.
- Discuss important and likely side effects and what to do about them.
- Discuss drug-drug, drug-food, and drug-disease interactions.
- Review the patient's or surrogate's role in achieving appropriate medication use.
- Review the role of medications in the overall context of the patient's health.

Where to report

Contact your health care provider right away so that they can advise you on the necessary actions to take. Also, urge the provider to report the problem to FDA's MedWatch hotline, at 800-FDA-1088. Your health care provider, however, is not required to report to FDA. Therefore, consumers can report problems directly. For more information, visit MedWatch.

Reporting Errors

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)
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)
What Not to Report to FDA MedWatch:

- Tobacco
  - Safety Reporting Portal: [https://www.safetyreporting.hhs.gov/fpsr/WorkflowLoginIO.aspx?metinstance=D432215BCD68831461E102E11540AD46662CAE5D](https://www.safetyreporting.hhs.gov/fpsr/WorkflowLoginIO.aspx?metinstance=D432215BCD68831461E102E11540AD46662CAE5D)

- Vaccines: Report vaccine events to the Vaccine Adverse Event Reporting System (VAERS) online at [https://vaers.hhs.gov/index](https://vaers.hhs.gov/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. [http://www.fda.gov/Drugs/ResourcesforYou/HealthcareProfessional/ResearchSafety/ucm073778.htm](http://www.fda.gov/Drugs/ResourcesforYou/HealthcareProfessional/ResearchSafety/ucm073778.htm)


- Reporting on Veterinary Medicine Products: [http://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm055305.htm](http://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm055305.htm)

- Reports FDA Does Not Handle (e.g. CPSC, FTC, State Health Department): [http://www.fda.gov/Safety/ReportaProblem/QuestionsandAnswersProblemReporting/default.htm](http://www.fda.gov/Safety/ReportaProblem/QuestionsandAnswersProblemReporting/default.htm)

- FDA reports process: [https://www.fda.gov/Safety/MedWatch/default.htm](https://www.fda.gov/Safety/MedWatch/default.htm) accessed 4.23.17


- The National Alert Network (NAN) publishes the alerts from the National Medication Errors Reporting Program. NAN encourages the sharing and reporting of medication errors, so that lessons learned can be used to increase the safety of the medication use system.


- NCCMERP: National Coordinating Council for Medication Error Reporting and Prevention

- The mission NCCMERP is to maximize the safe use of medications and to increase awareness of medication errors through open communication, increased reporting and promotion of medication error prevention strategies.

- Reporting Errors:
  - Recognize methods and responsibilities for reporting errors
  - MedMarx
  - [https://www.fda.gov/Safety/MedWatch/default.htm](https://www.fda.gov/Safety/MedWatch/default.htm)
  - [https://vaers.hhs.gov/index](https://vaers.hhs.gov/index)
  - Co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is a post-marketing surveillance program, collecting information about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the United States.

- Reporting Errors:
  - Why do we report errors?
  - What do the number of errors reported at our facility mean?
  - What are the challenges with voluntary reporting?
**Reporting Errors**

Best Designs
- Simple, intuitive
- Requirement for front line staff—only information easily known
- Non-punitive
- Ability to be anonymous

**Medication Error Examples**

**Categorizing Medication Errors – NCC MERP**

**Medication Error Assessment**

Harm
- Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
- To observe or record relevant physiological or psychological signs.

Intervention
- May include change in therapy or active medical/surgical treatment
- Intervention Necessary to Sustain Life
- Includes cardiovascular and respiratory support (e.g., CPAP, defibrillation, intubation, etc.)

*An error of omission does reach the patient*

**Algorithm**

**RCA**
RCA

Root Cause Analysis
• The “When’s”
• The “Why’s”

What is a Root Cause?
• A root cause is a factor that caused the original variance
• Ideal state - permanently eliminate through process improvement
• Root cause analysis uses tools, techniques and other approaches with goal of cause finding
• Can there be multiple root causes?

What is a FMEA?
Process used to prospectively identify and prioritize failures in the system

Failure
• When a system or part of a system performs in a way that is not intended or desirable.

Mode
• The way or manner in which something, such as a failure, can happen. Failure mode is the manner in which something can fail.

Effects
• The results or consequences of a failure mode.

Analysis
• The detailed examination of the elements or structure of a process.

How to Conduct an FMEA

1. Identify causes of the failure mode
2. Assess the severity, probability, likelihood of detection for each failure mode
3. Determine each step that can fail (failure modes)
4. Evaluate possible and potential consequence that each failure mode can have
5. Implement actions to reduce the occurrence of the highest ranked failure modes
6. Maintain the redesigned process

Failure Mode Effects Analysis (FMEA)
FMEA Review of Each Step of the Process

<table>
<thead>
<tr>
<th>Step in Process</th>
<th>Failure Modes</th>
<th>Proximate Causes</th>
<th>Effects</th>
<th>Severity</th>
<th>Probability</th>
<th>Likelihood of Detection</th>
<th>Risk Priority Number</th>
<th>Actions to Reduce Failure Mode</th>
</tr>
</thead>
</table>

Rate the following on a scale of 1-10
- Severity - 10 = most severe effect
- Probability - 10 = very likely to occur
- Detection – 10 = very unlikely to detect

Risk Priority Number = Severity x Probability x Detection

FMEA Scoring System

<table>
<thead>
<tr>
<th>Severity</th>
<th>Probability</th>
<th>Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>No effect (1)</td>
<td>Remote (1): no known occurrence; or happens &lt; 10 % of the time</td>
<td></td>
</tr>
<tr>
<td>Slight annoyance (2): may affect the system</td>
<td>Low (3): possible, but no known data; or happens 10 - 30 % of the time</td>
<td></td>
</tr>
<tr>
<td>Moderate system problem (3): may affect the patient</td>
<td>Moderate (5): documented but less frequent; or happens 40 - 60 % of the time</td>
<td></td>
</tr>
<tr>
<td>Minor system problem (5): may affect the patient</td>
<td>High (7): documented and frequent; or happens 70-80% of the time</td>
<td></td>
</tr>
<tr>
<td>Major system problem (6): permanent lessening of body function, surgical intervention required, disfigurement</td>
<td>Very high (10): documented, almost certain; or happens &gt;90% of the time</td>
<td></td>
</tr>
</tbody>
</table>

FMEA Pediatric Hospital Example

- Hundreds of patient specific oral medication doses are dispensed from the pharmacy each day.
- Potential for numerous errors:
FMEA Ex. Top Risk Priority Numbers (RPN)

- Bulk bottle and individual syringes lined up for checking RPN: 75
- Pharmacist verifies final product RPN: 75
- Labels are separated by drug and storage condition RPN: 63
- Bulk bottle selected and set out on counter with corresponding labels RPN: 63

FMEA Ex. Summary of Actions

- Implement bag system to group doses with bulk bottle for each medication
- Provide appropriate staffing for effective process
- Add technician position to help with the 10 pm list
- Address space constraints
  - Create an additional list at 10 pm to reduce the volume of the 5 pm list
  - Add a blank label with black division line in between each medication and strength that prints on list
- Provide training with computerized inventory system & expectation to remove bulk bottle when new bottle opened
  - Place label from inventory system on bottle when removed from system

FMEA Ex. Summary of Actions Cont.

- Separate bins containing look alike/sound alike medications and utilize tall man lettering on bin labels
- Pull 1 bulk bottle at a time to fill 1 strip of labels
- Place refrigerate sticker on bottles requiring refrigeration
- Provide training to ensure storage requirements are known
- Create separate area for pharmacists to check syringes
- Reduce environmental factors & workflow interruptions

Strategies to Reduce Error Risk

Fail-safes and Constraints

- Most powerful and effective strategy
- Involve system changes in product design or how individuals interact

Example
- Preventing scanning on administration unless the pharmacist verification sticker has been placed on the label
Forcing Functions

Use
• Creation of a “hard stop” to ensure important information is provided before proceeding

Example
• Hospital Formulary

Forcing Functions - Examples

• Requiring an acknowledgement of high dose

Automation and Computerization

Pros
• Limit reliance on memory
• Lessen potential for human error

Example
• Computerized physician order entry software that includes clinical decision support

Automation and Computerization - Examples

• IV room processing and tracking software
• Inventory tracking software
• Databases that provide warning related to allergies, drug interactions, or doses outside the recommended range

Standardization

Pros
• Reduces complexity and variation of a process

Use
• Uniform model to adhere to when performing tasks

Cons
• Less effective than previous strategies when used alone
• Relies on human vigilance to ensure the process is followed
Standardization - Examples

- Order sets
- Medication administration

Redundancies

**Pro**
- Reduces the likelihood both individuals will make the same error

**Use**
- Incorporate duplicate steps or an additional individual in the process

**Con**
- Potential failure if the redundancy is omitted or ignored

Redundancies - Examples

- Chemotherapy verification
- Filling of patient specific doses
- Double check of high alert medications
- Patient counseling

Reminders and Checklists

**Use**
- Highlight important information

**Example**
- Look-alike, sound-alike lists & alerts built into order entry system

- Auxiliary stickers to distinguish dose, route, storage
Rules and Policies

**Pro**
- Guide staff toward an intended positive outcome

**Cons**
- Potential to add unnecessary complexity
- May be met with resistance especially when implemented in response to an error
- Use relies on memory

**Use**
- Combine with other strategies that target the system

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Education

**Pro**
- Increases awareness to topic

**Use**
- In combination with other strategies

**Example:**
Medication Errors – An Opportunity to Improve
Louise Simone, CSPhA, BCPS, Phoenix, AZ

**Con**
- Effect relies on the individual’s ability to remember the information presented

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Automated Response

- A response done over and over again as part of a routine
- A repetitive learned behavior during the course of a person’s experience
- A reaction to a specific input

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Limitations on Human Performance

- Multi-tasking
- Dependence on heuristics when under time limits or stress conditions
- Environmental
- Fatigue - high or low volume
- Normalization of deviance
- Distractions
Best Practice #11

When compounding sterile preparations, perform an independent verification to ensure the proper ingredients (medications and diluents) are added, including confirmation of the proper amount (volume) of each ingredient prior to its addition to the final container.

Errors

Human Tendency

Other Resources

- ISMP quarterly reports
- ASHP online
- CDC: https://www.cdc.gov/medicationsafety/library.html
- FDA: https://www.fda.gov/Drugs/DrugSafety/default.htm
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