Medication Safety Bootcamp

101: Introduction to Medication Safety Basics

Heather Dossett, PharmD, MHA, BCPS, CPHQ
Medication Safety and Pharmacy Education Pharmacist
Ascension – St. Vincent's Indianapolis
Heather.dossett@ascension.org

Jessalynn Henney, PharmD
Network Medication Safety Director
Community Health Network
jkhenney@ecommunity.com

Tuesday, September 22nd, 2020

Disclosure

The presenters have no conflicts of interest to disclose.

Midwest Medication Safety Symposium

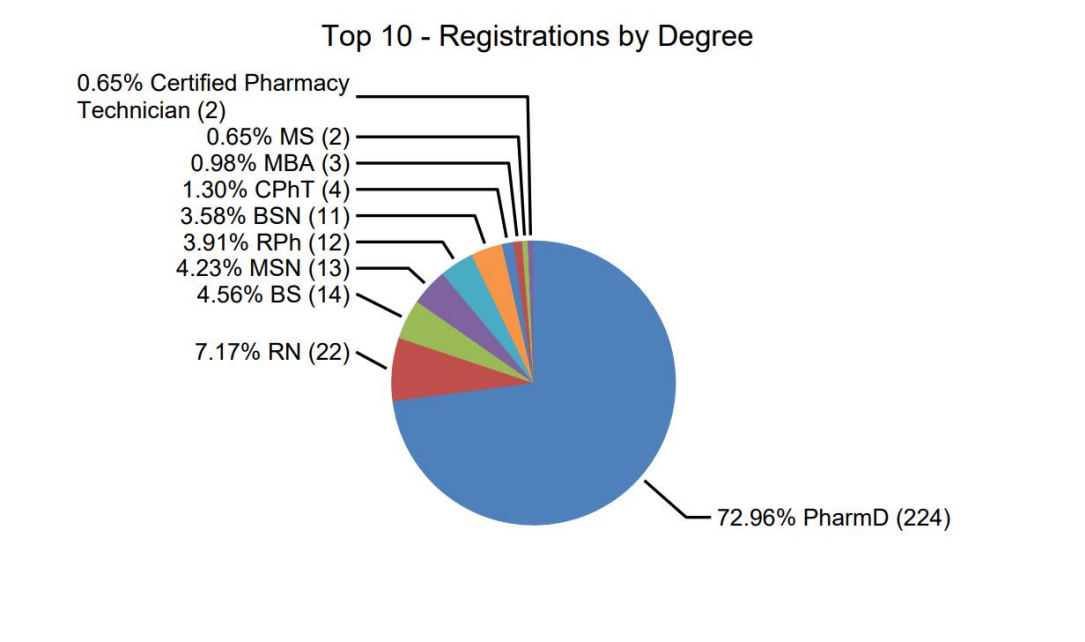
Housekeeping

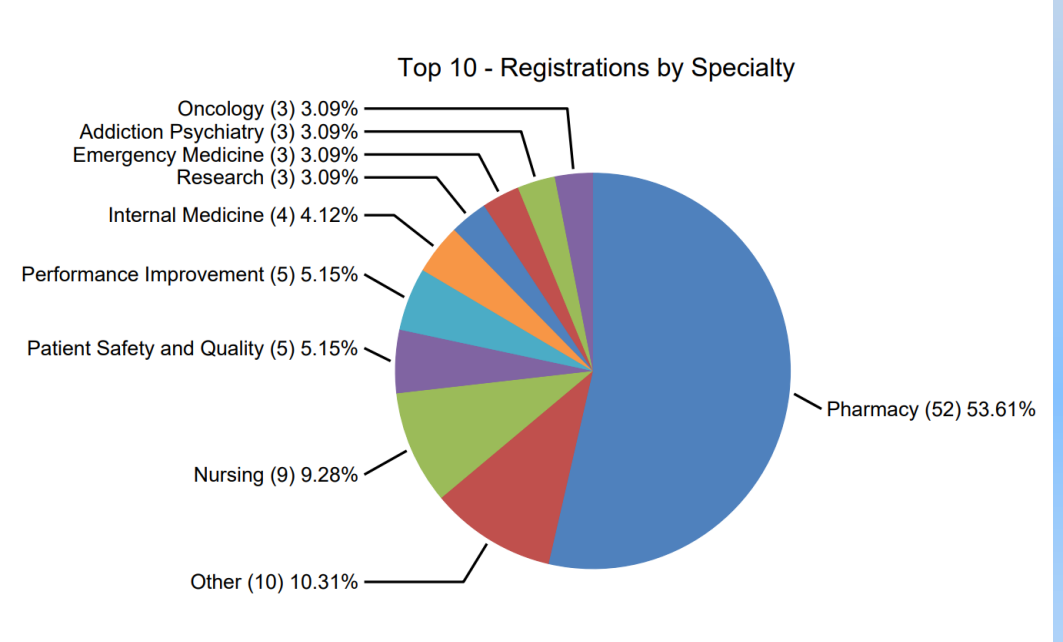
Questions?

- To ensure we are all on the same page…
  - We encourage questions throughout the presentation
  - Please utilize the ‘Chat’ tool to ask questions

Midwest Medication Safety Symposium

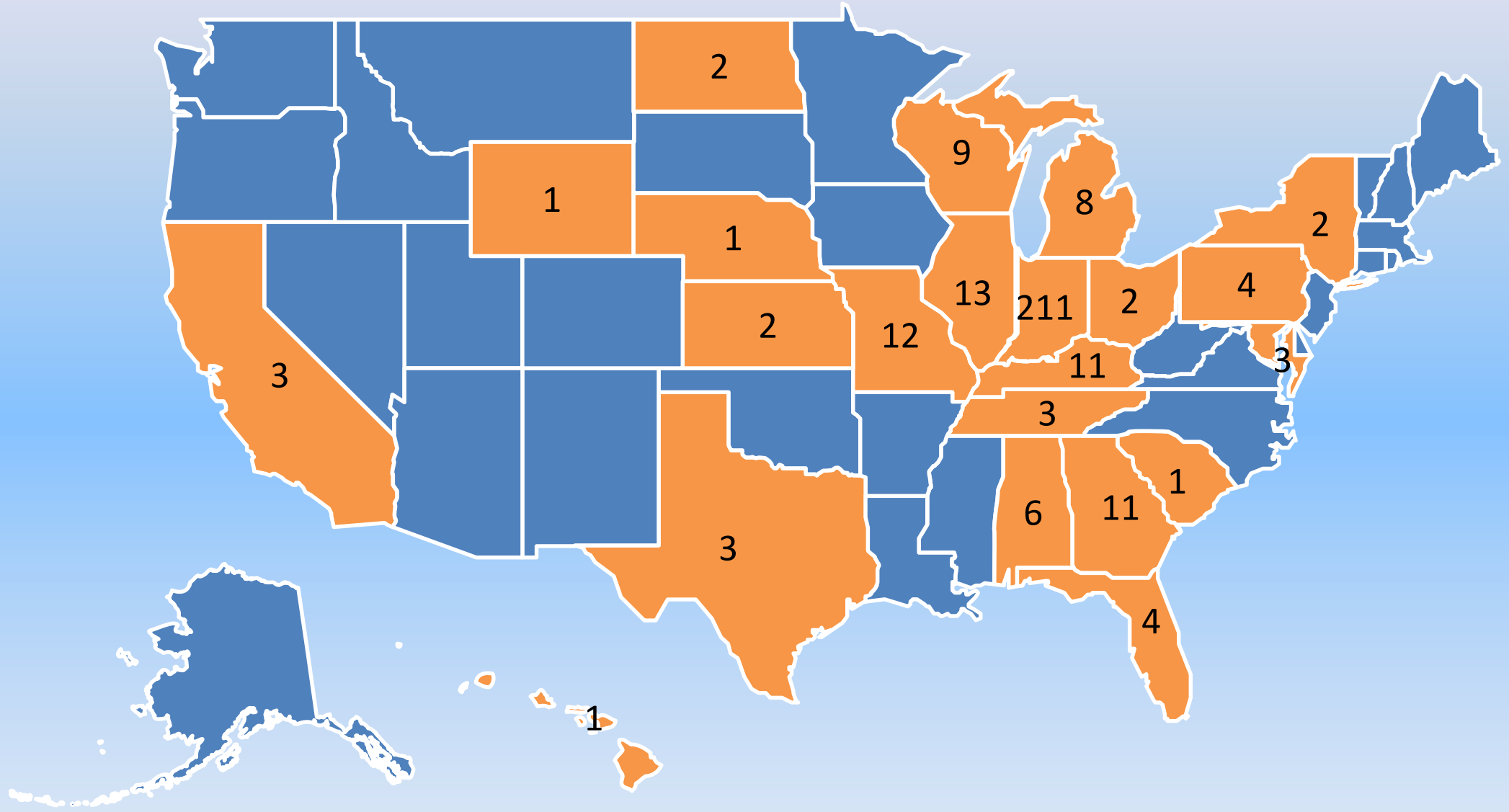
Who is with us tonight?





Midwest Medication Safety Symposium

Where is everyone from?



In the chat bar, please answer the following question:

What do you hope to gain/learn from this evening?

Midwest Medication Safety Symposium

Agenda

Time	
10 Minutes	• Introductions • Housekeeping • Pre-Assessment
55 Minutes	Didactics Part 1: • Overview: Importance and Roles • Definitions and Terminology • Detection/Reporting
	Break – 5 minutes
90 Minutes	Didactics Part 2: • Just Culture/Human Factors • Medication Use Process • Focus/Prevention (HAM, SALAD, Mitigation Strategies, Safety Behaviors) • Second Victim
20 Minutes	• Wrap-up/Housekeeping • Post-assessment • Q/A

Pre-Assessment

Midwest Medication Safety Symposium

Pre-Assessment Question #1

The pharmacy dispensed hydrALAZINE instead of the medication prescribed, which was hydrOXYzine. The patient was administered this medication, but thankfully no harm occurred. This event would be defined as:

a) Adverse Drug Reaction (ADR)

b) Medication Error

c) Near Miss

d) All of the above

Midwest Medication Safety Symposium

Pre-Assessment Question #2

Which of the following organizations are devoted entirely to preventing medication errors?

a) Food and Drug Administration (FDA)
b) Institute for Safe Medication Practices (ISMP)
c) American Academy of Pediatrics (AAP)
d) Walt Disney World (WDW)

Midwest Medication Safety Symposium

Pre-Assessment Question #3

Why is it important to report medication incidents both internally and externally?

A) Enhancement of medication use process within an organization

B) Captures the actual event and promotes a culture of safety

C) Improvement of package insert

D) None of the above

Midwest Medication Safety Symposium

Objectives

- Define the various terminology used within medication safety.
- Describe the medication use process.
- Discuss how various pharmacist roles, including those within national organizations, impact medication and patient safety.
- Recognize the importance of reporting medication incidents.
- Describe how to report medication incidents and adverse drug reactions during daily practice.

Acronyms

Common acronyms utilized throughout this session include:

- ACPE: Accreditation Council for Pharmacy Education
- ADC: Automated Dispensing Cabinet
- AHRQ: Agency for Healthcare Research and Quality
- ASHP: American Society of Health-System Pharmacists
- FDA: Food and Drug Administration
- ICPS: Indianapolis Coalition for Patient Safety
- ISMP: Institute for Safe Medication Practices
- NPSG: National Patient Safety Goal
- TJC: The Joint Commission
- USP: United State Pharmacopeia

Overview

History
Literature
Data

History[1-5]

Early 1990 to early 2000s: Evolution of the Medication Safety Officer (MSO) position

Hippocratic Oath
– First do no harm

1990: James Reason Swiss Cheese Model developed

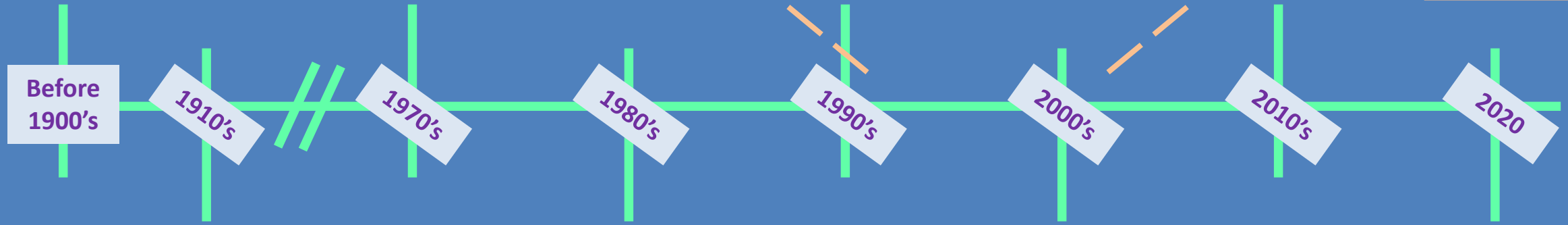
1995: ISMP's website went live

1999: To Err is Human publication

1991: Harvard Medical Practice Study

1998: High-alert medication list available by ISMP

Today: Incorporating at your facilities



1910's: Human factors/ ergonomics discipline starts (industry worker focus)

1919: American College of Surgeons "Minimum Standards" document

1975: ISMP officially begins with column in *Hospital Pharmacy*

1987: List of dangerous medical abbreviations published

2001: Tall Man lettering requested by ISMP to the FDA

2005: From ISMP's advocacy, TJC reveals new 2006 NPSG requiring medication labeling

2011: Medication safety listed by ACPE as a distinct section PharmD curriculum programs

2014: ISMP recommended to lower dose of dabigatran (4 years after approval)

Safety and Inherited Human Limitations are not new concepts…

Literature[6]

Medication errors resulting with death are difficult to capture

Literature estimates anywhere between 99,000 to 400,000 deaths a year

- Death certificates can only include ICD 10 codes as the reason the patient expired
- Medical error is not one of these items

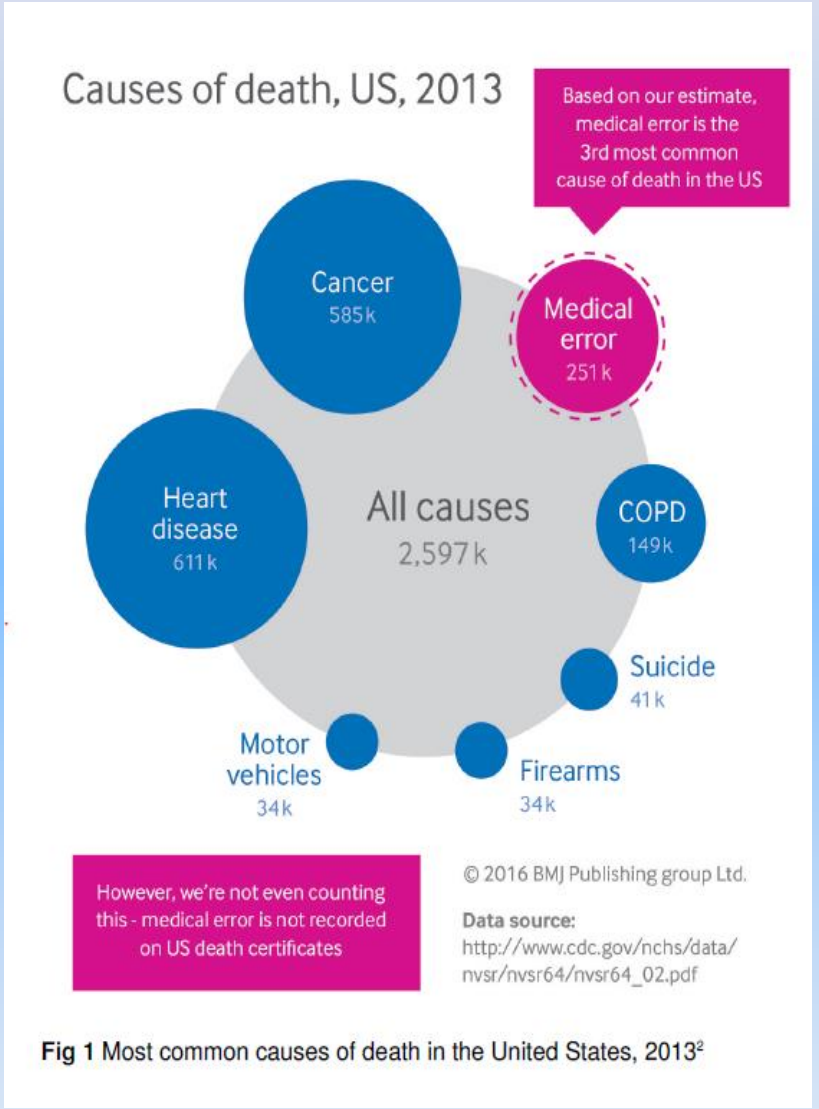


Fig 1 Most common causes of death in the United States, 2013[2]

Midwest Medication Safety Symposium

Impact of Medication Misadventures[7]

- Events occur within each step of the medication use process
- In 2006, Adverse Drug Events (ADEs) were noted...

To harm at least 1.5 million people each year	On average, each day hospital patients will experience at least one	Annual nation estimated cost was $3.5 billion (not including lost earnings and other indirect costs)	At least 25% of harmful ADEs are preventable

Although accurate data is difficult to obtain, various studies estimate each year preventable ADEs occur among

- Hospital patients = 380,000
- Patients within long-term care facilities = 800,000
- Medicare outpatients = 530,000

Midwest Medication Safety Symposium

Roles Focusing on Medication Safety

ISMP states

“Dedicated safety personnel are needed to ’establish safety-related goals, policies and practices, and to ensure that organizational standards on agency-wide issues are disseminated and understood by all employees’”

Medication Safety Officer/Patient Safety Officer[3,11,12]

ASHP definition:

- Authoritative expert in safe medication use

ISMP states:

- Provides vision and direction
- Conducts investigations, utilizes data, and identifies opportunities to improve the medication use system
- Lead implementation of error prevention strategies
- Medication safety centralized expert resource
- Serve an authoritative resource and champion by being a visible campaigner

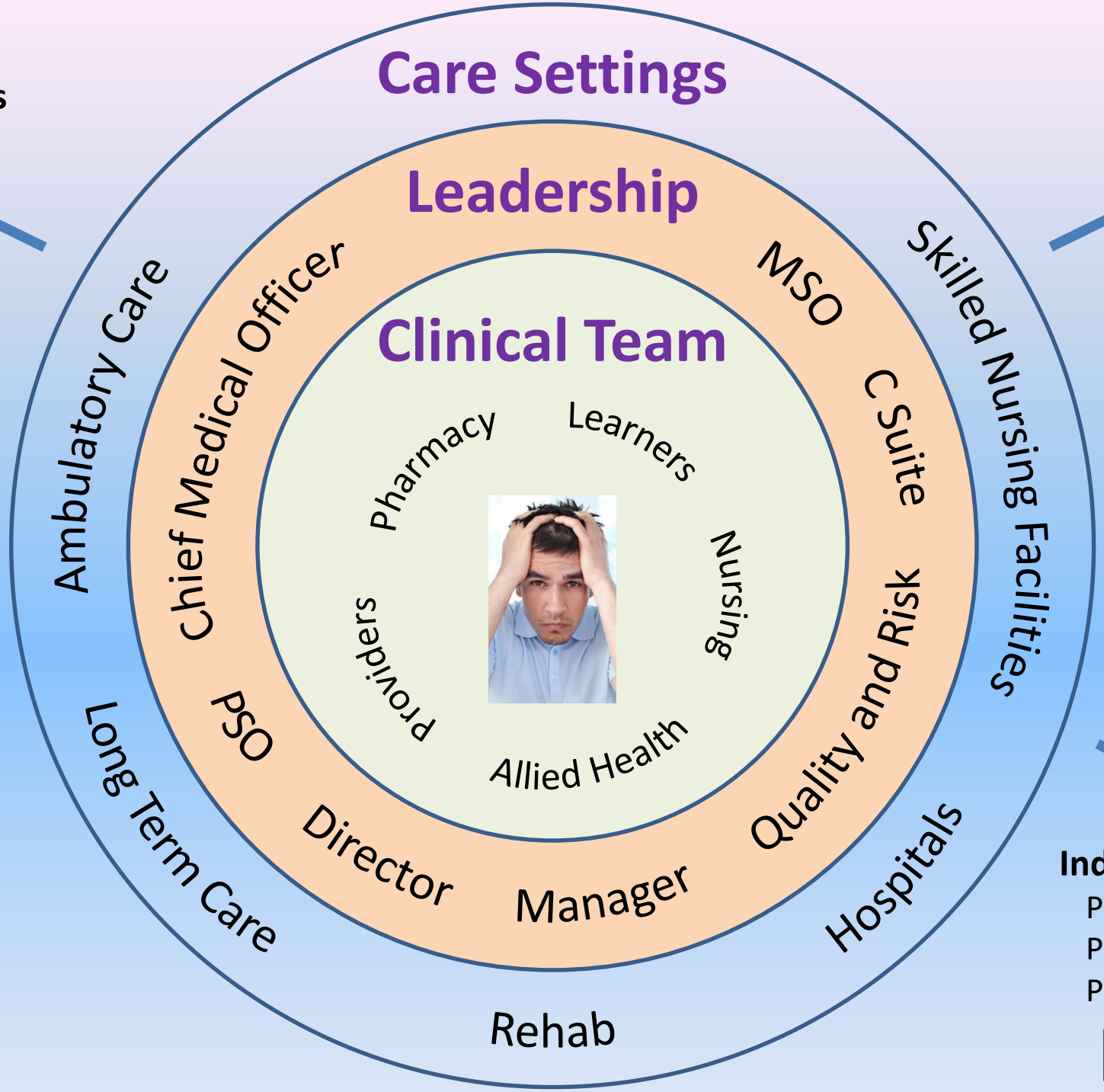
Other titles include:

- Medication Safety Pharmacist
- Medication Safety Coordinator
- Medication Safety Director

Midwest Medication Safety Symposium

Safety Organizations
- ICPS
- ISMP
- AHRQ

Regulatory
- FDA MedWatch
- Drug Approvals
- Joint Commission



Regardless of where we serve patients…

Center of all decisions
→ **PATIENT**

Included in all roles
→ **SAFETY**

Industry/Drug Companies
- Package inserts
- Post surveillance studies
- Pharmacovigilance

Midwest Medication Safety Symposium

Reference 13

Definitions and Terminology

Medication Error

Near Miss

Adverse Drug Reaction (ADR)

Adverse Drug Event (ADE)

Medication Error[14]

According to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP):

"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.“

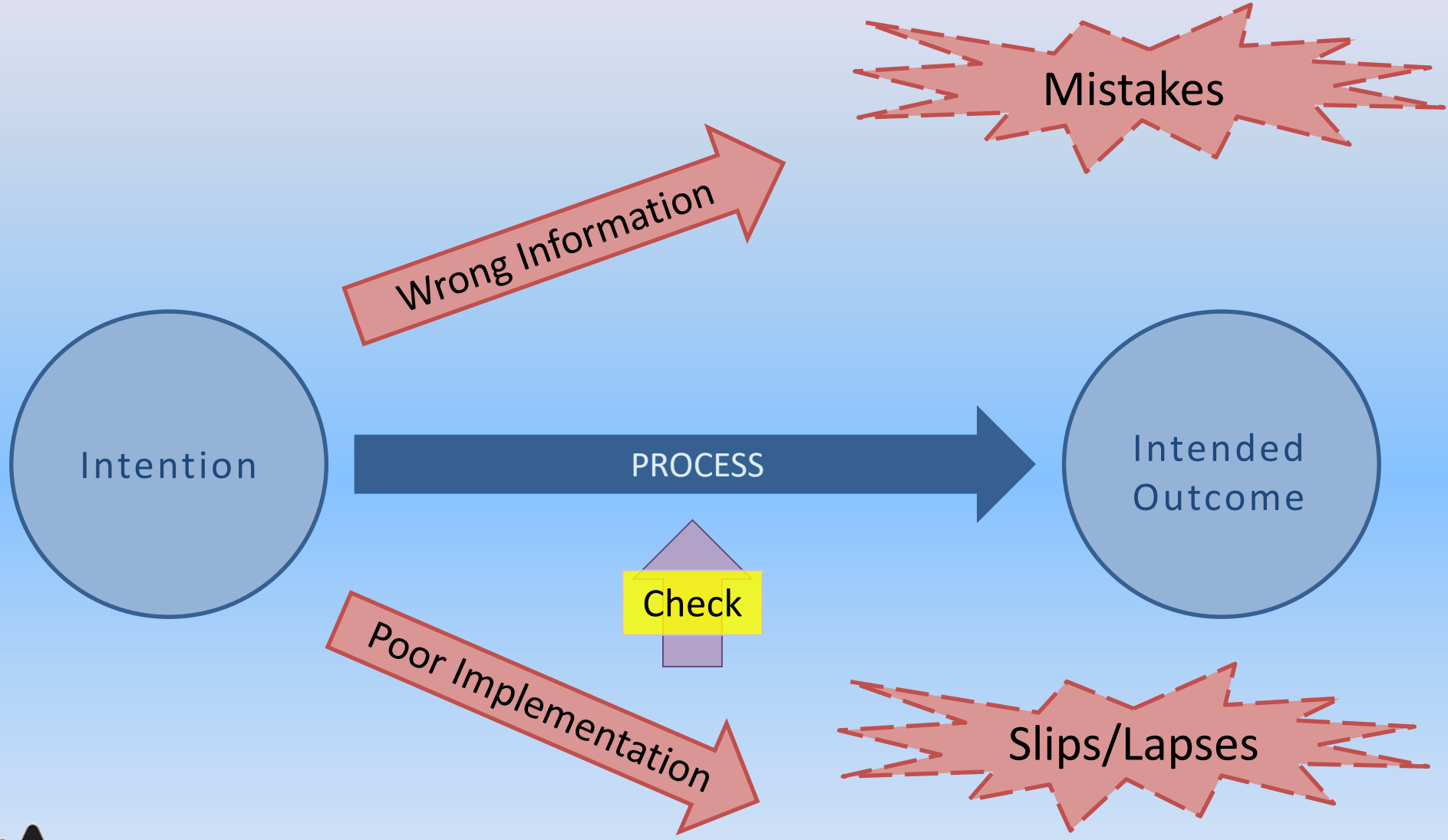
Midwest Medication Safety Symposium

Medication Error[15]

- AHRQ definition:
  - Error (of commission or omission) at any step along the pathway that begins when a clinician prescribers a medication and ends when the patient actually receives the medication

- Example:
  - An order is written for **Insulin NPH 6U BID** and is interpreted by the pharmacist and nurse as **Insulin NPH 60 Units BID**. Patient is administered several doses and suffers hypoglycemia before the error is discovered.

Errors[16]



Midwest Medication Safety Symposium

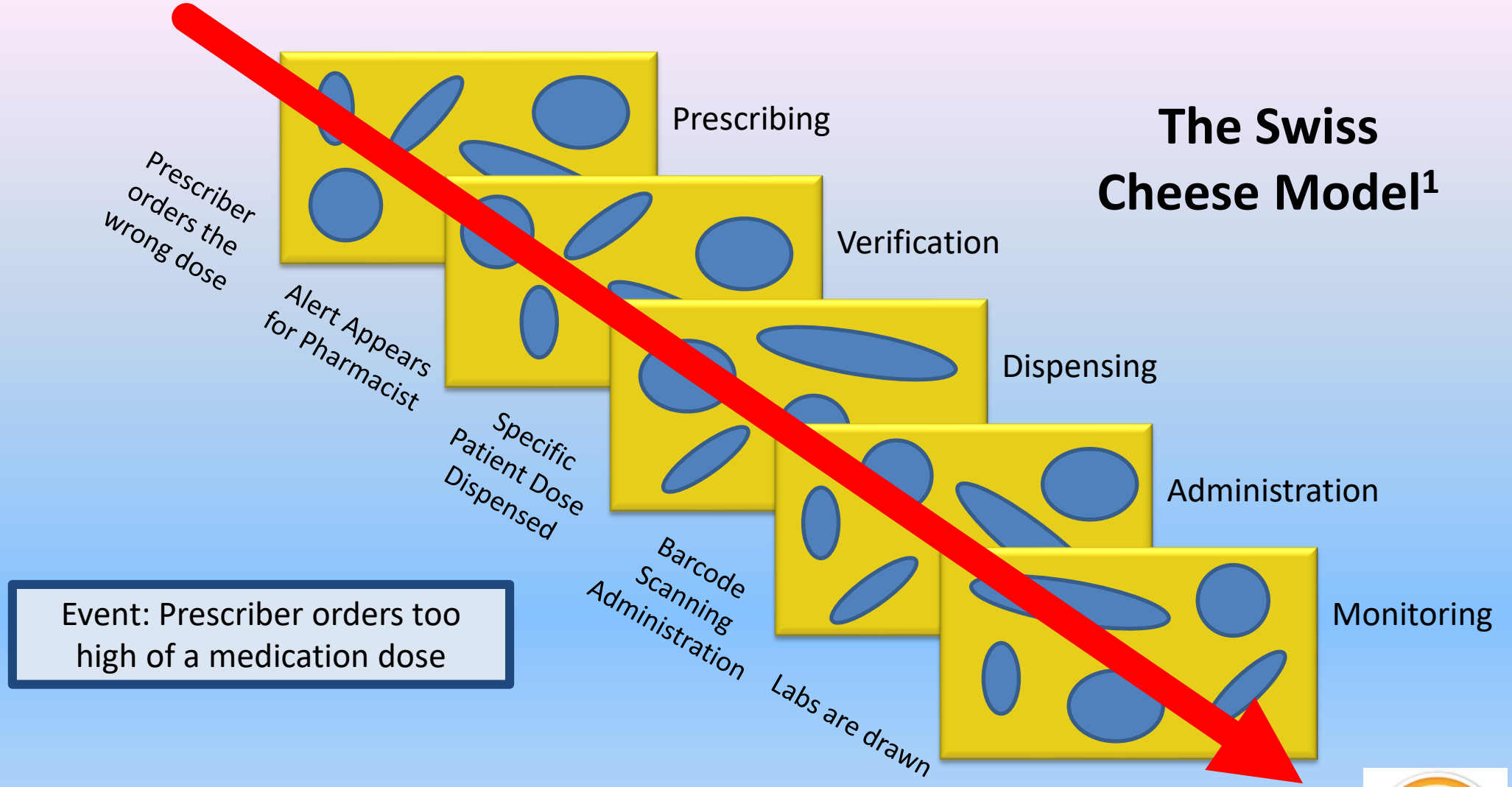
How do medication errors occur?[16]

- The medication use process is complex
  - Errors can occur at any step along the way, from prescribing to administering or taking the medicine.
- Common causes of medication errors include the following:

❖ Incorrect drug administration
❖ Incorrect diagnosis
❖ Dose miscalculations
❖ Drug and drug device related problems
❖ Prescribing errors
❖ Failed communication
❖ Poor drug distribution practices

Midwest Medication Safety Symposium

The Swiss Cheese Model[1]



Event: Prescriber orders too high of a medication dose

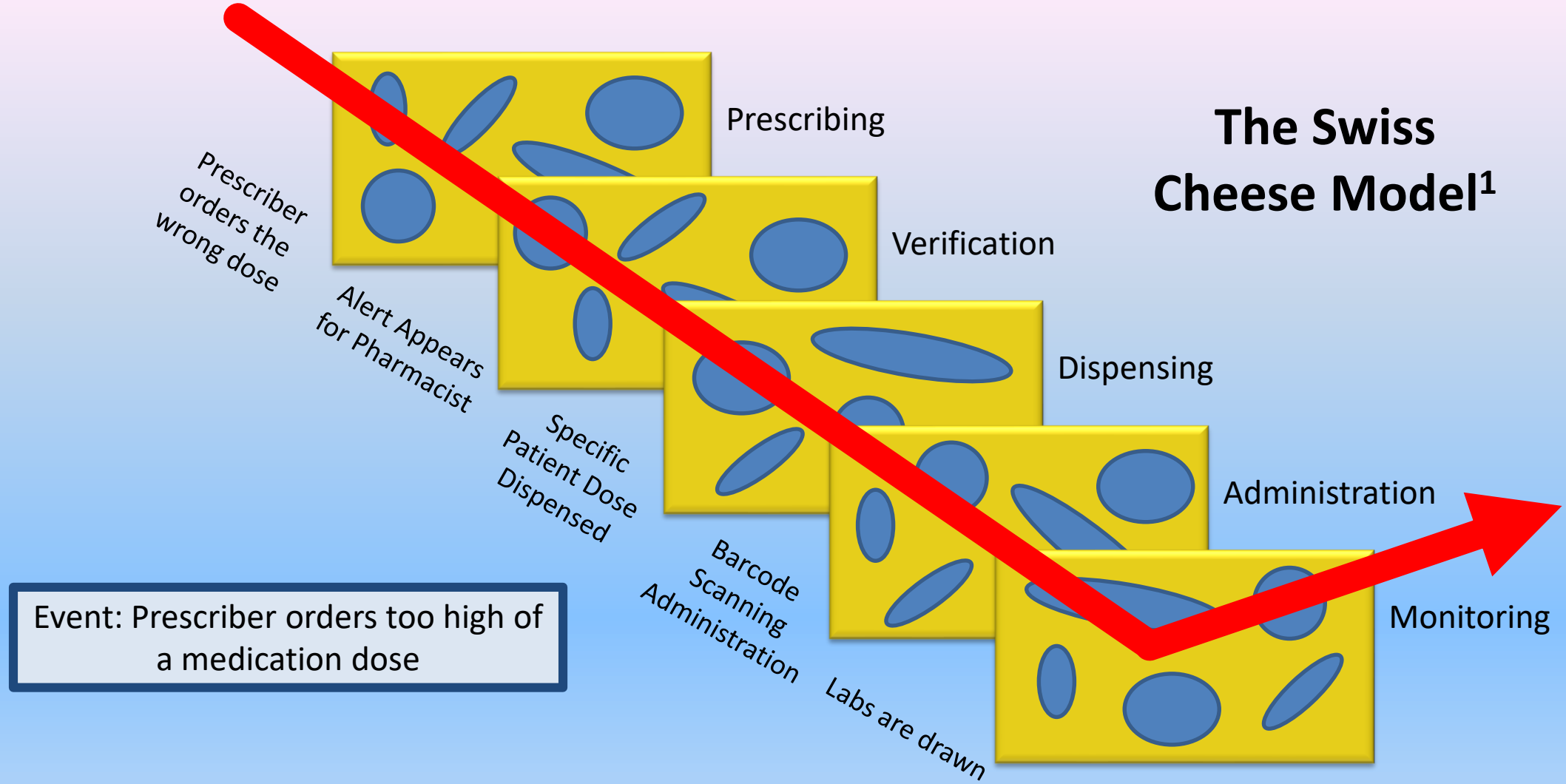
- There is no perfect system, and each barrier or safeguard (i.e. cheese slice) has unintended weaknesses (i.e. holes)
- Due to the process and people constantly changing, these weaknesses are dynamic and holes can "open" or "close" at random
- When by chance all holes align, the hazard reaches the patient and may cause harm

Midwest Medication Safety Symposium

Near Miss[17]

- An unplanned event that did not reach the patient, but has potential to do so
  - Process related
  - May also be called safety catches or success stories
- Example:
  - A nurse pulls succinylcholine to administer to the patient. When using bar-code medication administration (BCMA), realizes she should have pulled diltiazem. Nurse returns succinylcholine and retrieves diltiazem.

The Swiss Cheese Model[1]



Event: Prescriber orders too high of a medication dose

- Illustrates how a particular hazard must penetrate multiple barriers and safeguards in order to cause harm.
- Multiple barriers can help prevent an error from reaching the patient

Midwest Medication Safety Symposium

Adverse Drug Reaction (ADR)[17]

- Any response to a drug, which is noxious and unintended, that occurs at doses "normally used in man"
  - **Not preventable**
  - Inherit risk of the drug

- Example:
  - A patient is prescribed lisinopril, who has never taken it before, and develops angioedema
  - A patient is administered IV iron and develops an allergic reaction (hives, itching, difficult breathing)

Midwest Medication Safety Symposium

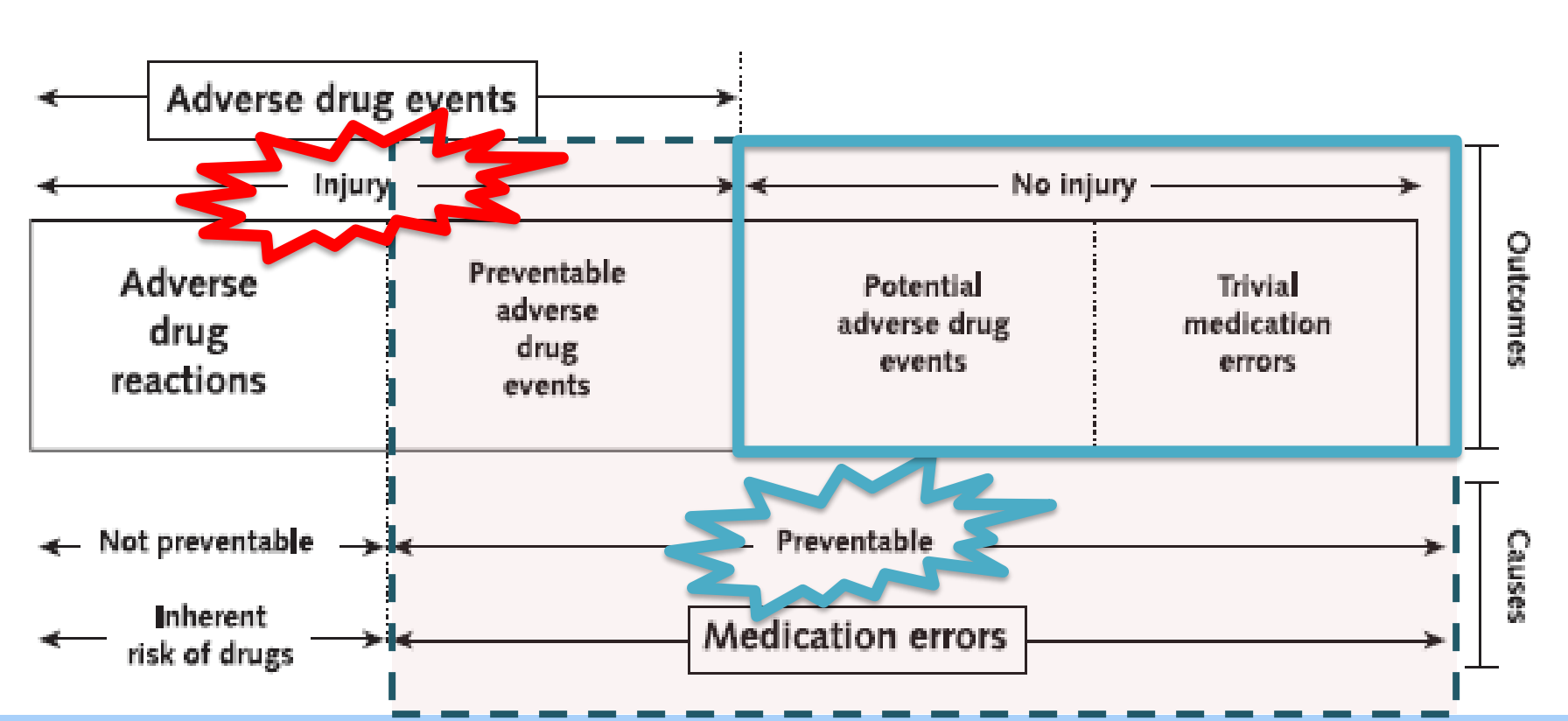
Adverse Drug Event (ADE)[17]

- Any injury resulting from medical intervention related to a drug
- Always reaches the patient regardless of how it occurred
- By definition, all ADEs are associated with patient harm, but not all ADEs are due to an error.
  - An ADR, therefore, is a subtype of an ADE
  - All ADRs are ADEs, but not vice versa

CONFUSED?

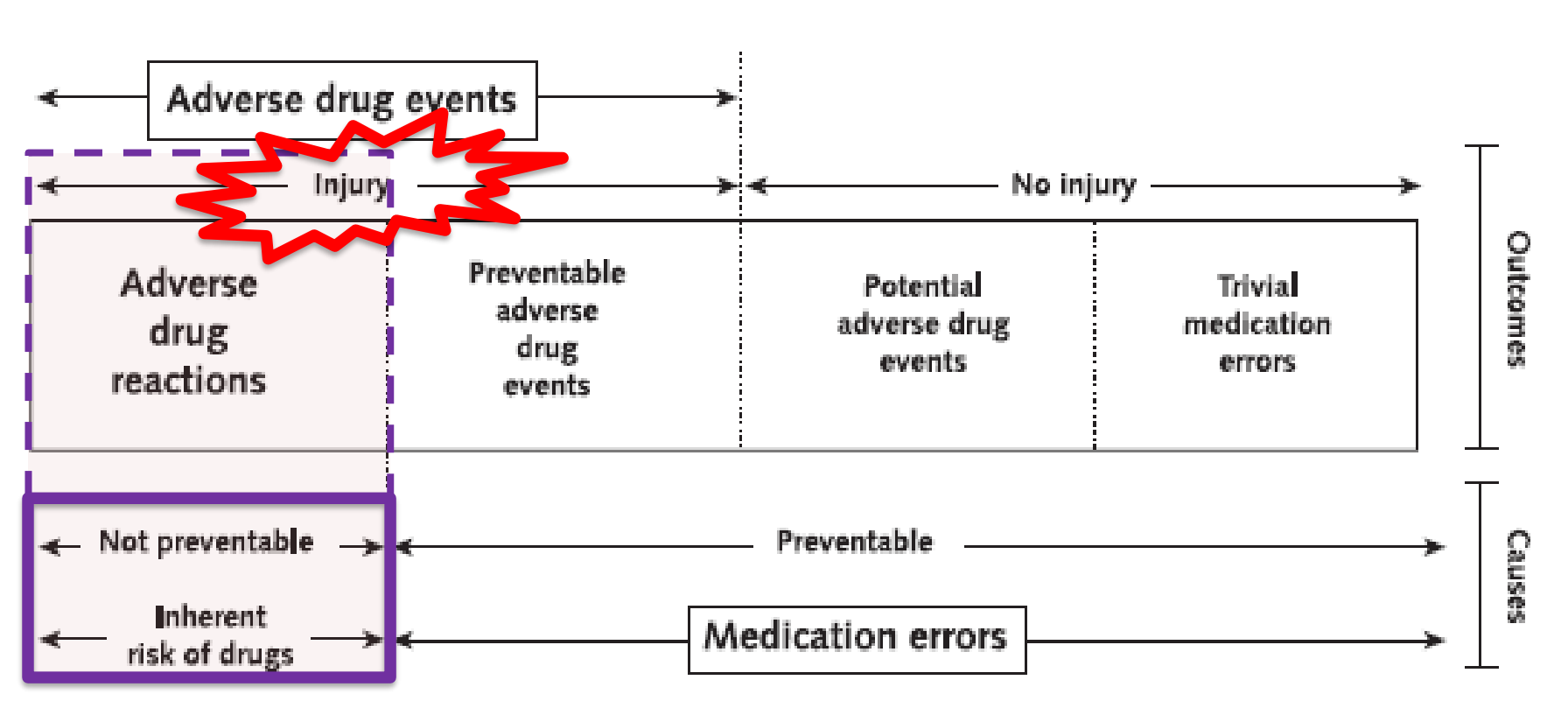
Midwest Medication Safety Symposium

Putting It All Together[18]



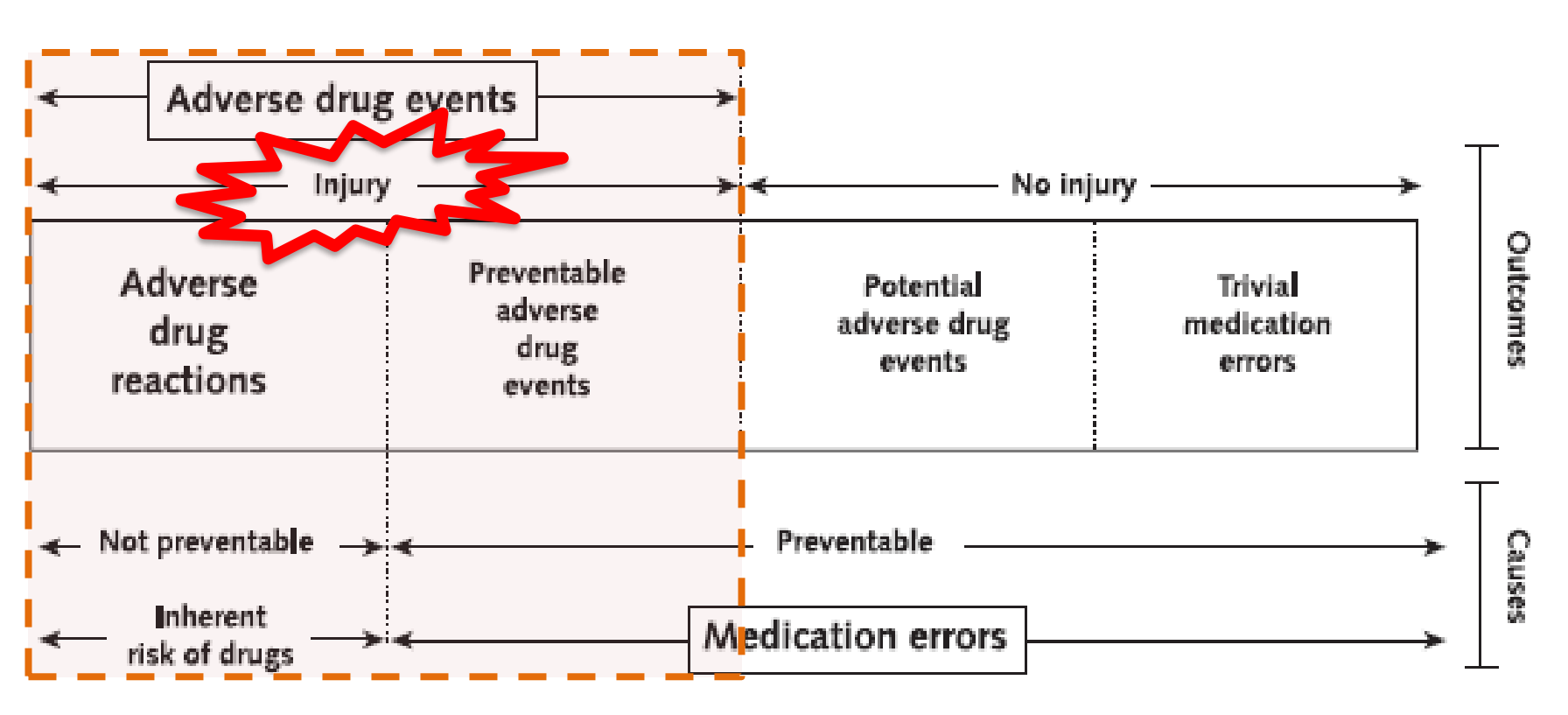
Medication Error: Any **PREVENTABLE** event, regardless of no injury or injury

Putting It All Together[18]



ADR: Any response to a drug, which is noxious and unintended, that occurs at doses "normally used in man"

Putting It All Together[18]



ADE: Any injury resulting medical intervention related to a drug

Lets Practice

Scenario #1

- The concentration for gentamicin in the NICU is 4 mg/1 mL. A NICU patient was ordered gentamicin 4 mg (1 mL).
- When this was prepared by the pharmacy technician, the amount (mg) on the syringe label was mistaken for the volume (mL) ordered. As a result, gentamicin 4 mL (16 mg) was prepared in the syringe instead of 4 mg (1 mL).
- After the pharmacist checked and verified the syringe, it was dispensed to the unit.
- The nurse, who had a larger patient workload than normal, barcode scanned the syringe upon administration. This did not produce an alert, since it scanned correctly (i.e. label correctly matched the order for this patient).
- Prior to starting the medication, the RN discovered the incorrect amount of drug was drawn up into the syringe. The incorrect dose was not given to the patient and the syringe was sent back to pharmacy to be remade.

Scenario #1

Classify this event as an ADR, ADE, Medication Error, and/or Near Miss (select all that apply).

How many slices of swiss cheese did this event successfully pass through?

Midwest Medication Safety Symposium

Scenario #1 Response

Midwest Medication Safety Symposium

Scenario #2

- A physician ordered amlodipine besylate 100 mg by mouth daily, instead of 10 mg the patient was taking at home, and was missed by the verification pharmacist reviewing the order.
- The computer system generated an alert for both the pharmacist and physician, but did not require a response before bypassing.
- The next day, the same pharmacist is working in the ICU when the patient is transferred due to a sharp decrease in blood pressure requiring vasopressors (these can only be given in the ICU).
- When the pharmacist completed a patient chart review, they discover the 10 fold overdose that was given on the floor. It was even noted the nurse appropriately acquired the 10 tablets to complete the ordered dose from the automated dispensing cabinet, scanned the patient's wristband and medication with no warnings, and assist the patient to take all 10 amlodipine 10 mg tablets.
- At this time, the pharmacist notices that they completed the pharmacy verification of this order leading to an overdose.
- After being transferred to the ICU, the patient was placed on a ventilator until her death two days later.

Scenario #2

Classify this event as an ADR, ADE, Medication Error, and/or Near Miss (select all that apply).

How many slices of swiss cheese did this event successfully pass through?

Midwest Medication Safety Symposium

Scenario #2 Response

Midwest Medication Safety Symposium

Medication Incidents/Reporting

Importance of Reporting

How are they detected? (Location)
Why should they be detected? (Importance)
What happens after detected? (Classification)

Importance of Reporting[6]

- **Goal is to learn and prevent future harm**

It is better to report than to not report at all

(even if all information is not available or if you believe another caregiver has completed the report)

- **Reports help to learn about the process and how to incorporate human factors**
  - Human Factors: Examines the relationship between human beings and how they interact with in a system
  - Goal: accommodate the system for all users

Midwest Medication Safety Symposium

Internal Incident Reporting

- Patient safety must the first aim in every setting in order to build safer systems, learning from errors and reducing the human and fiscal costs
- Reporting discloses medication errors, can trigger warnings, and encourages the diffusion of a culture of safe practice.
- Combining and comparing data from various locations encourages a culture of safe practices and increases the reliability of the system
- During orientation at any facility, you should be trained on how to report incidents and how those incidents are investigated and followed up upon.

Midwest Medication Safety Symposium

Reporting Process

Figure 1 Responding to an Event: Sample Process

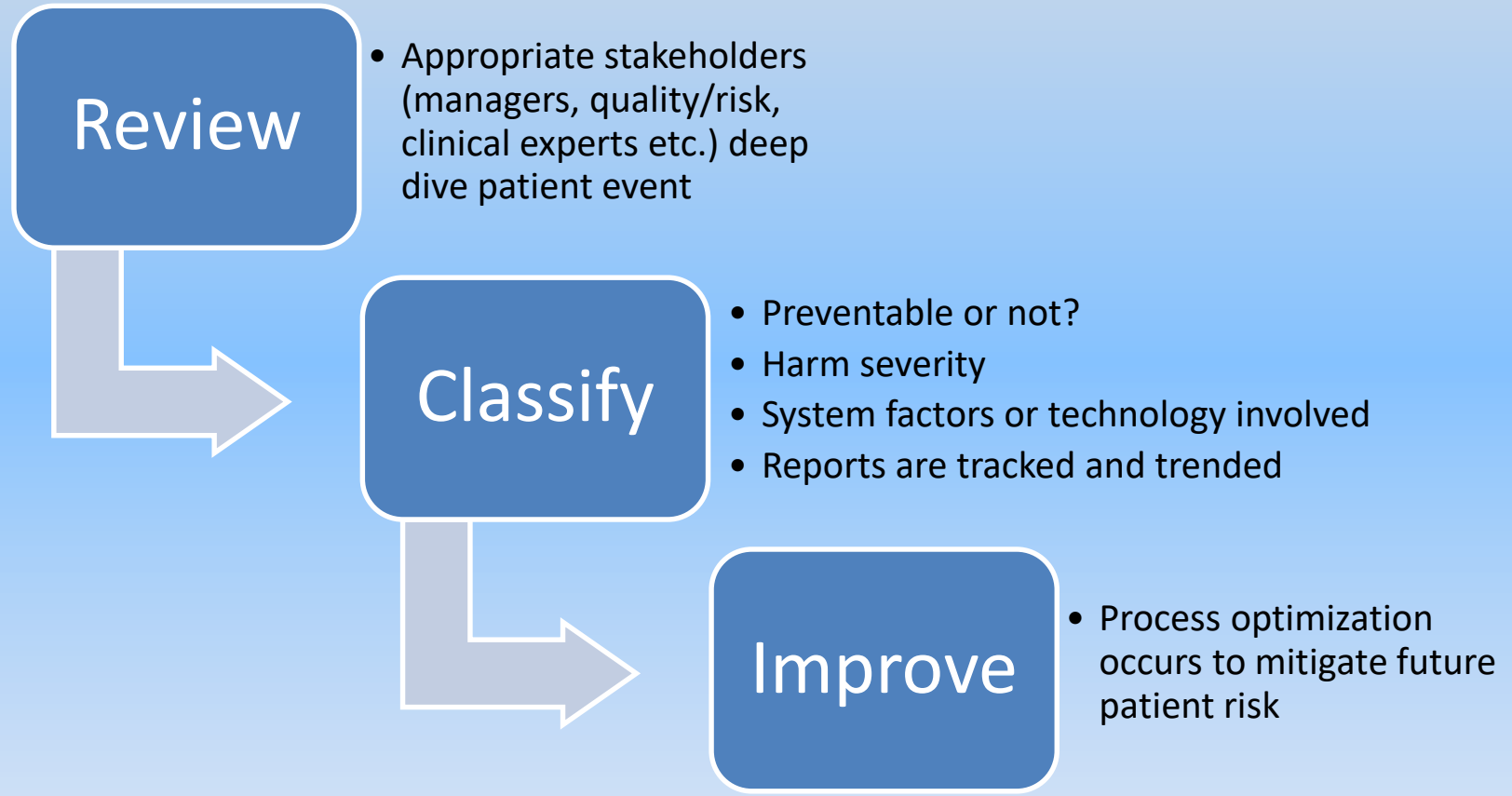
Adapted from: ECRI Institute PSO. Improving physician office event reporting [webinar]. 2017 Nov 16 [cited 2019 Jun 3]. https://www.ecri.org/components/PSOCore/Pages/PSOWebinar_111617_Improving_Physician_Office_Event_Reporting.aspx

Note: The above is a sample process. For smaller or stand-alone practices, some of the above roles may be combined.

Behind the Scenes: Overview

Perception information was not used to improve process

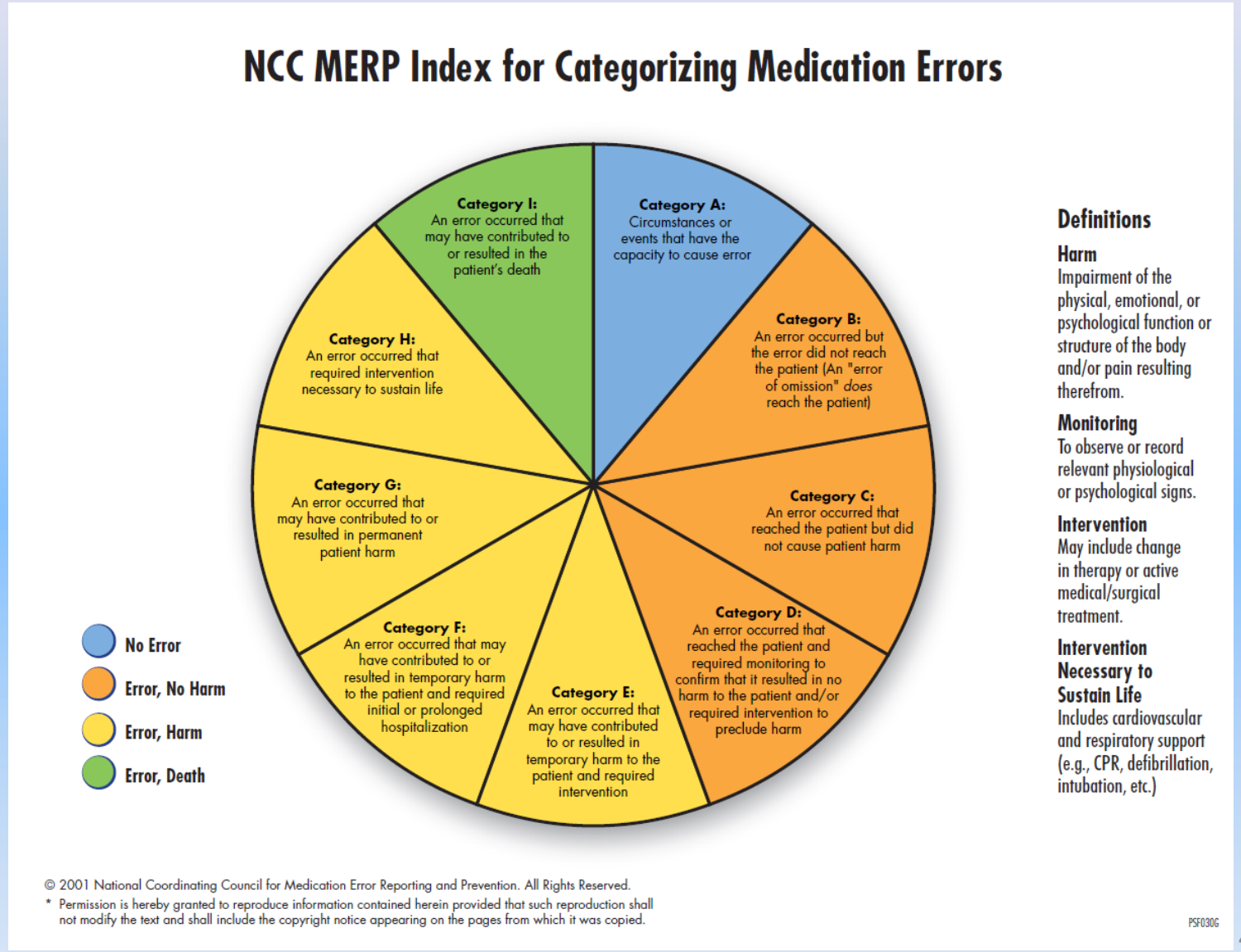
After report is submitted …



Midwest Medication Safety Symposium

How to classify medication errors

- Many different classification systems exist
- NCC MERP is the most common



NCC MERP[15]

How to classify medication errors

Category A:	• Circumstances or events that have the capacity to cause error

Midwest Medication Safety Symposium

NCC MERP[15]

How to classify medication errors

Category B:

- An error occurred but the error did not reach the patient (an "error of omission" does reach the patient)

Category C:

- An error occurred that reached the patient but did not cause patient harm

Category D:

- An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm

NCC MERP[15]

How to classify medication errors

Category E:	• An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
Category F:	• An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
Category G:	• An error occurred that may have contributed to or resulted in permanent patient harm
Category H:	• An error occurred that required intervention necessary to sustain life

NCC MERP[15]

How to classify medication errors

NCCMERP
National Coordinating Council for Medication Error Reporting and Prevention

Category I:	• An error occurred that may have contributed to or resulted in the patient's death

Midwest Medication Safety Symposium

NCC MERP[15]

External Reporting Locations

Voluntary	Required
IMSP MERP: • **A confidential program where healthcare professionals share medication errors occurring in the workplace** • **Program features experts that can analyze the causes and factors that lead to the particular error** **MEDMARX:** • **A commercial database that allow participating hospitals to report both medication errors and adverse drug reactions** • **The national data is used to track data through internal benchmarking and trend analysis** **Joint Commission Sentinel Event Policy:** • **The adverse event is added to the Joint Commission's Sentinel Event Database** • **A root cause analysis and action plan is created in coordination with Joint Commission staff**	Indiana Medical Error Reporting System: • A system that requires hospitals, ambulatory surgery centers, birthing centers, and abortion clinics to report serious adverse events in the facility • Serious adverse events are defined as adverse events that result in death or serious disability. Other serious adverse events include any surgical event featuring the wrong patient, wrong body part, or wrong procedure • Serious disability is defined as a significant loss of function* or unintended loss of a body part *Sensory, motor, physiologic, or intellectual impairment not present on admission or for which there is a high chance of permanent lifestyle change on discharge)

ISMP MERP[14]

- Internationally recognized program for healthcare professionals to share potential or actual medication errors that occurred at their workplace.
- Reporting an error or hazardous condition is simple and confidential.
- After you submit your confidential report, ISMP staff will follow up with you to ask additional questions to clarify what went wrong and to identify the causes and factors that contributed to the reported event.

REPORT A MEDICATION ERROR

Midwest Medication Safety Symposium

Food & Drug Administration (FDA)

- MedWatch:
  - Safety alert for human medical products
  - Alerts provide timely new safety information on human drugs, medical devices and other biologics, dietary supplements, and cosmetics
  - Alerts contain actionable information that may impact both treatment and diagnostic choices for healthcare professional and patient

Food & Drug Administration (FDA)

- MedWatch:
  - How to report:
    - MedWatch Online Voluntary Reporting Form
    - Vaccines: Vaccine Adverse Event Reporting System (VAERS)

Midwest Medication Safety Symposium

Food & Drug Administration (FDA)

FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems

Does not affect FDA-approved uses for malaria, lupus, and rheumatoid arthritis

July 1, 2020 Update: A summary of the FDA review of safety issues (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/OSE%20Review_Hydroxychloroquine-Cholorquine%20-%2019May2020_Redacted.pdf) with the use of hydroxychloroquine and chloroquine to treat hospitalized patients with COVID-19 is now available. This includes reports of serious heart rhythm problems and other safety issues, including blood and lymph system disorders, kidney injuries, and liver problems and failure.

June 15, 2020 Update: Based on ongoing analysis and emerging scientific data, FDA has revoked the emergency use authorization (EUA) to use hydroxychloroquine and chloroquine to treat COVID-19 in certain hospitalized patients when a clinical trial is unavailable or participation is not feasible. We made this determination based on recent results from a large, randomized clinical trial in hospitalized patients that found these medicines showed no benefit for decreasing the likelihood of death or speeding recovery. This outcome was consistent with other new data, including those showing the suggested dosing for these medicines are unlikely to kill or inhibit the virus that causes COVID-19. As a result, we determined that the legal criteria for the EUA are no longer met. Please refer to the Revocation of the EUA Letter (/media/138945/download)and FAQs on the Revocation of the EUA for Hydroxychloroquine Sulfate and Chloroquine Phosphate (/media/138946/download) for more information.

[4-24-2020] FDA Drug Safety Communication

What safety concern is FDA announcing?

The FDA is aware of reports of serious heart rhythm problems in patients with COVID-19 treated with hydroxychloroquine or chloroquine, often in combination with azithromycin and other QT prolonging medicines. We are also aware of increased use of these medicines through outpatient prescriptions. Therefore, we would like to remind health care professionals and patients of the known risks associated with both hydroxychloroquine and chloroquine. We will

authorized their temporary use during the COVID-19 pandemic for treatment of the virus in hospitalized patients when clinical trials are not available, or participation is not feasible, through an Emergency Use Authorization (EUA) (/media/136784/download). The medicines being used under the hydroxychloroquine/chloroquine EUA (/media/136534/download) are supplied from the Strategic National Stockpile, the national repository of critical medical supplies to be used during public health emergencies. This safety communication reminds physicians and the public of risk information set out in the hydroxychloroquine (/media/136537/download) and chloroquine healthcare provider fact sheets (/media/136535/download) that were required by the EUA.

Hydroxychloroquine and chloroquine can cause abnormal heart rhythms such as QT interval prolongation and a dangerously rapid heart rate called ventricular tachycardia. These risks may increase when these medicines are combined with other medicines known to prolong the QT interval, including the antibiotic azithromycin, which is also being used in some COVID-19 patients without FDA approval for this condition. Patients who also have other health issues such as heart and kidney disease are likely to be at increased risk of these heart problems when receiving these medicines.

What is FDA doing?

To decrease the risk of these heart problems that can be life-threatening, we are warning the public that hydroxychloroquine and chloroquine, either alone or combined with azithromycin, when used for COVID-19 should be limited to clinical trial settings or for treating certain hospitalized patients under the EUA. FDA will continue to investigate risks associated with the use of hydroxychloroquine and chloroquine for COVID-19, and we will communicate publicly when we have more information.

What are hydroxychloroquine and chloroquine and how can they help me?

Hydroxychloroquine and chloroquine are FDA-approved to treat or prevent malaria. Hydroxychloroquine is also FDA-approved to treat autoimmune conditions such as chronic discoid lupus erythematosus, systemic lupus erythematosus in adults, and rheumatoid arthritis.

The EUA was based upon limited evidence (/media/136784/download) that the medicines may provide benefit, and for this reason, we authorized their use only in hospitalized patients under careful heart monitoring.

Tips and Tricks for Reporting

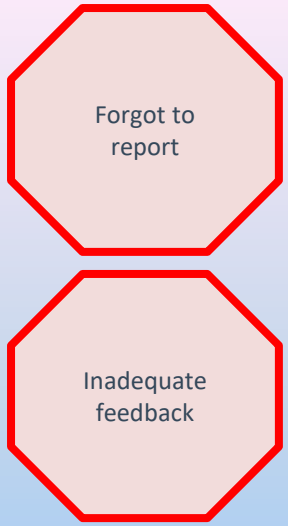
- Reporting blame free helps to identify trends and potential misses, which helps to optimize processes and create a safer environment for patients
- To prevent blame
  - Tell the story using **fact**
  - Make the story as **objective** as possible

Example: If the nurse just did her job, then this would not have happened

Example: This physician does not care about their patients

Midwest Medication Safety Symposium

Tips and Tricks for Reporting



- Incorporating reporting into daily workflow
- If unsure, ask those reviewing reports for specific examples on the type of information valuable to include in the report
- Connect the dots by providing examples of how reports have brought improvements
  - **Leaders/MSO/Quality and Risk:** Provide specific examples to caregivers on how changes, such as new developed processes or additional FTEs/resources, were inspired due to reporting
  - **Direct caregivers:** Ask your leader (Pharmacy Director, MSO, Quality/Risk, etc.) for examples of process improvements

Midwest Medication Safety Symposium

Lets Practice

Scenario #1

- The concentration for gentamicin in the NICU is 4 mg/1 mL. A NICU patient was ordered gentamicin 4 mg (1 mL).
- When this was prepared by the pharmacy technician, the amount (mg) on the syringe label was mistaken for the volume (mL) ordered. As a result, gentamicin 4 mL (16 mg) was prepared in the syringe instead of 4 mg (1 mL).
- After the pharmacist checked and verified the syringe, it was dispensed to the unit.
- The nurse, who had a larger patient workload than normal, barcode scanned the syringe upon administration. This did not produce an alert, since it scanned correctly (i.e. label correctly matched the order for this patient).
- Prior to starting the medication, the RN discovered the incorrect amount of drug was drawn up into the syringe. The incorrect dose was not given to the patient and the syringe was sent back to pharmacy to be remade.

Scenario #1

Would the NCC MERP classification system apply in this situation? If yes, please classify as Category A – Category I.

Who would need to be informed (consider both internal and external)?

Midwest Medication Safety Symposium

Scenario #2

- A physician ordered amlodipine besylate 100 mg by mouth daily, instead of 10 mg the patient was taking at home, and was missed by the verification pharmacist reviewing the order.
- The computer system generated an alert for both the pharmacist and physician, but did not require a response before bypassing.
- The next day, the same pharmacist is working in the ICU when the patient is transferred due to a sharp decrease in blood pressure requiring vasopressors (these can only be given in the ICU).
- When the pharmacist completed a patient chart review, they discover the 10 fold overdose that was given on the floor. It was even noted the nurse appropriately acquired the 10 tablets to complete the ordered dose from the automated dispensing cabinet, scanned the patient's wristband and medication with no warnings, and assist the patient to take all 10 amlodipine 10 mg tablets.
- At this time, the pharmacist notices that they completed the pharmacy verification of this order leading to an overdose.
- After being transferred to the ICU, the patient was placed on a ventilator until her death two days later.

Scenario #2

Would the NCC MERP classification system apply in this situation? If yes, please classify as Category A – Category I.

Who would need to be informed (consider both internal and external)?

Midwest Medication Safety Symposium

5 Minute Break

Just Culture

https://www.youtube.com/watch?v=zeldVu-3DpM

Annie's Story: How A System's Approach Can Change Safety Culture

MedStar Health

Just Culture[11]

Error Management Techniques

Punitive
(Blame and Train)

Believed <u>perfect</u> human performance to be achieved through education

Counter productive to reporting, learning, and safety advancement

- Punitive
- Event outcomes focused
- Addressed only those
- Reckless behavior not addressed with no adverse outcomes
- “Perfect performance” to avoid errors

No Accountability
Blame-free Environment

Believed latent failures will always be present in the system

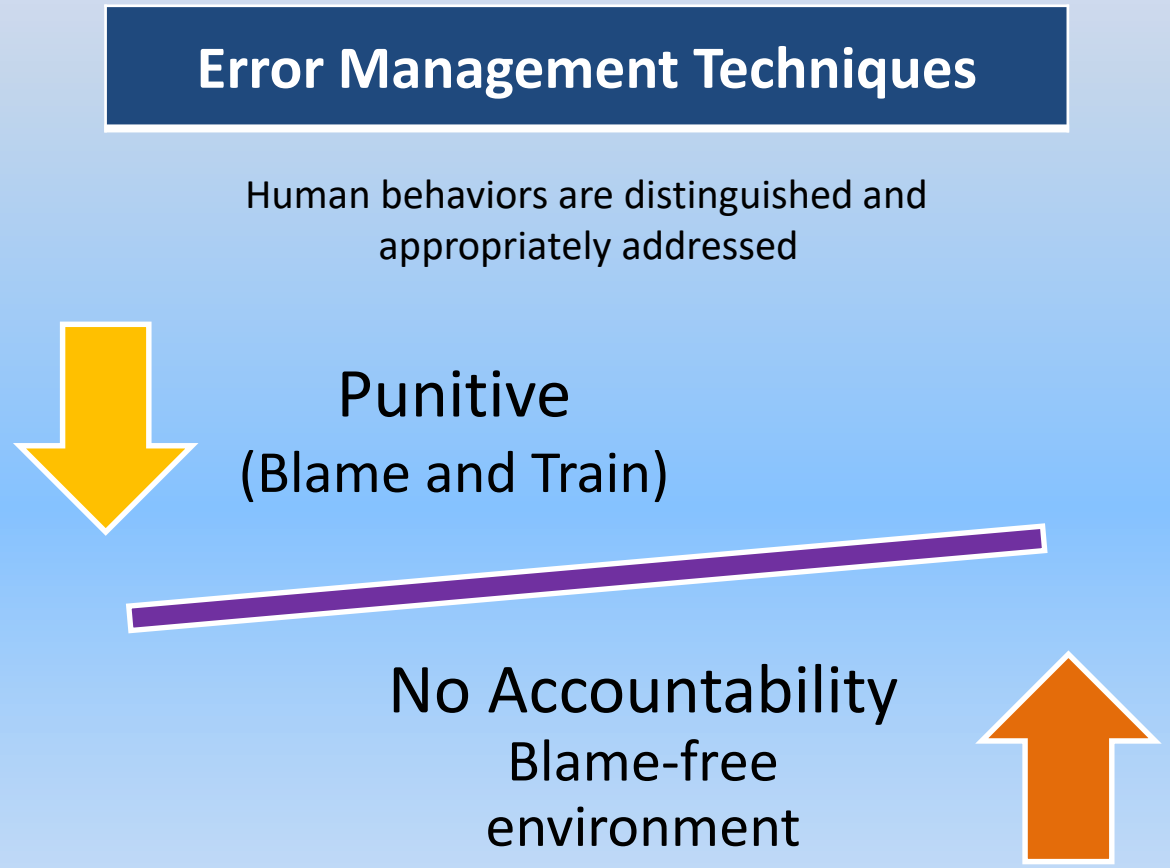
Confusion with how to manage reckless behavior, disregarding safety procedures, and actions with malicious

- Blame-free; Non-punitive
- Human fallibility recognized as a patient safety risk
- Focused on the system/processes
- Solutions directed to systems’ latent failures

Midwest Medication Safety Symposium

Just Culture[11]

- Model asking WHAT, not who, is responsible
- Embraces and supports those who are caught in faulty processes
- Recognizes both latent failures and active failures contribute to errors
- Incorporates accountability
  - Understands punishment for most active failures (unsafe acts or honest mistakes to which we are all vulnerable) is counter-productive to reporting, learning, and the advancement of safety



Just Culture[11, 45]

What will be observed in a "Just Culture" environment?

- Staff, patients, and caretakers are treated fairly, with empathy and consideration when they have been involved in a patient safety incident or have raised a safety issue
- Reported events
  - Free of blame and reprimanding
  - Used as an learning opportunity
- Questioning attitude is promoted
- Resistance to complacency or status quo
- Commitment to excellence
- Fosters both personal accountability and corporate self-regulation
  - Focuses on identifying and addressing issues that lead to unsafe behaviors and errors by changing processes, while not tolerating reckless behavior

Human Error

Inadvertent action: slip, lapse, mistake

CONSOLE

Support person involved with error;
Alter system to prevent from occurring again

At-Risk Behavior

Consciously choosing an action without realizing the level of risk of an unintended outcome

COACH

Counsel and explain why the behavior is risky; Focus process improvements on preventing people from partaking in this behavior

Reckless Behavior

Choosing an action with knowledge and conscious disregard of the risk of harm

PUNISH

Disciplinary action

Human Factors[11]

- Examines the relationship/interaction between people and systems
- Goal: accommodate the system for all users
  - Meaning the same task can be accomplished by both

calm, rested, experienced

stressed, fatigued, rushing, inexperienced

- Make it easier to complete the task the correct way
- Design the system to fit people instead of having the person fit the system

https://www.youtube.com/watch?v=VJ0UtU58d9M&feature=youtu.be

Midwest Medication Safety Symposium

Let’s compare situations

89 Year-old patient receiving multivitamins

↓

Nurse skips barcode medication administration scanning

↓

Patient receives vitamin D instead

↓

Nurse realizes and administers multivitamins with dinner

89 Year-old patient receiving insulin

↓

Nurse skips barcode medication administration scanning

↓

Patient receives incorrect type and dose of insulin

↓

Patient experiences severe hypoglycemia

↓

Patient does not recover and dies

Midwest Medication Safety Symposium

Medication Use Process

Medication Use Process[39]

Prescribing
- Ordering the use of a specific medication, dose, route, and frequency for a specific patient

Transcribing
- Manual conversion of voice, written, typed, or other forms of communication from a practitioner to a functional drug order or prescription

Storage
- Housing medications, which are not labeled for specific patients, in medication rooms, refrigerators, storage cabinets, automated dispensing cabinets, IV rooms, or pharmacy storage areas prior to medication dispensing and administration

Dispensing/ Preparation
- Preparation, packaging, labeling record keeping, and issuing of a medication in a suitable container with appropriate labeling to an intermediary or the patient, who is responsible for administration of the medication

Administering
- Direct application, instillation, insertion, injection, ingestion, or inhalation of a medication to the body of a patient

Monitoring
- Collection and evaluation of patient data to monitor care

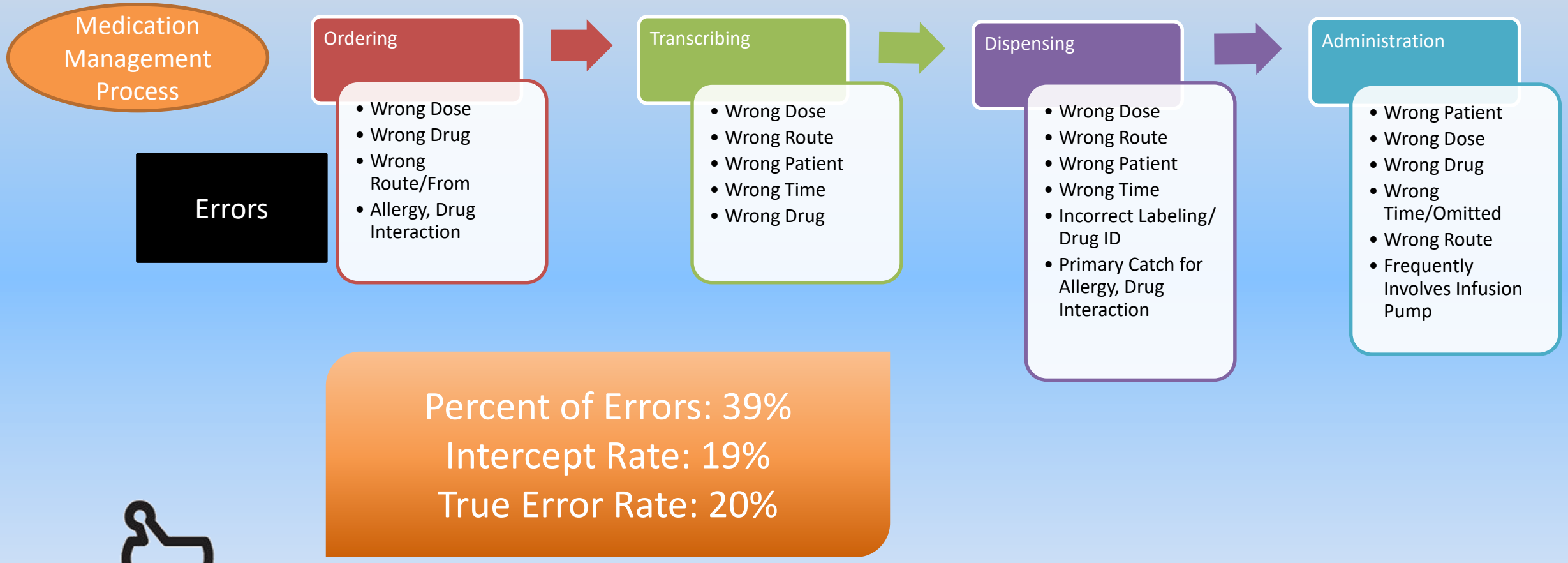
Who are the participants?

- Physicians
- Nurses
- Pharmacists
- Respiratory Therapists
- Patients
- The casual observers who can alert the care providers about opportunities for errors

EVERYONE

Midwest Medication Safety Symposium

Errors in the Medication Use Process[40]



Percent of Errors: 39%
Intercept Rate: 19%
True Error Rate: 20%

Midwest Medication Safety Symposium

Prescribing Errors[15]

- Is a collaborative effort
- There is an increasing body of knowledge
  - New therapeutic entities
  - Drug interactions
  - Allergies
  - Food-drug interactions
- Safety strategies to prevent ADEs while prescribing:
  - Avoid unnecessary medications by adhering to conservative prescribing principles
  - Computerized provider order entry, especially when paired with clinical decision support systems
  - Medication reconciliation at times of transitions in care

Transcribing Errors[15]

- Anecdotally, transcription errors should be decreasing as the use of computerized provider order entry (CPOE) increases
- A safety strategy to prevent ADEs while transcribing:
  - CPOE to eliminate handwriting errors
  - Eliminate use of unapproved abbreviations
  - Reduce verbal orders

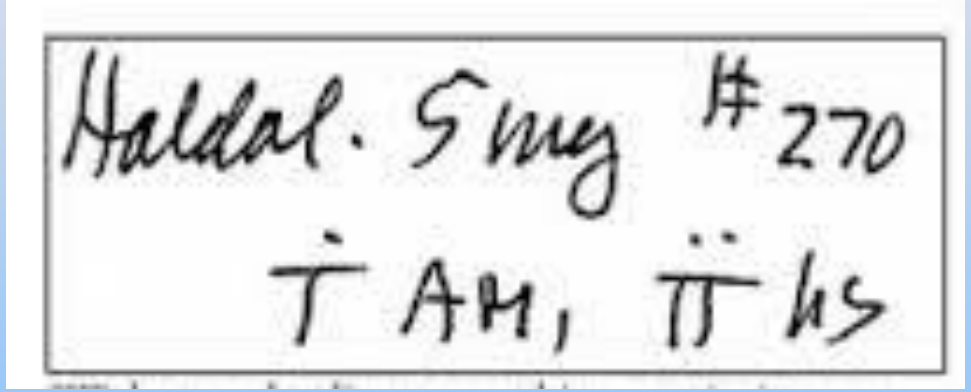
Transcribing Errors

What is this prescription?

1. Avandia 4mg po qd
2. Coumadin 4mg po qd
3. Avandia 0.4mg po qid
4. Coumadin 4mg po QPM
5. Coumadin 0.4mg qd

Midwest Medication Safety Symposium

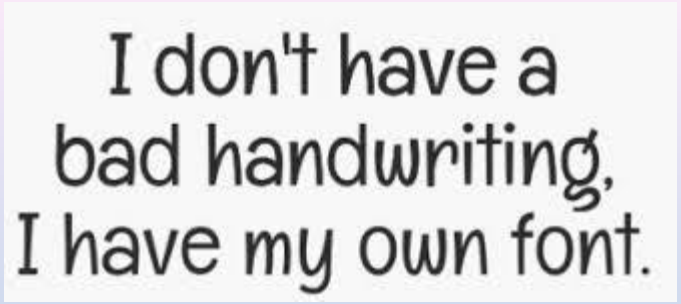
Transcribing Errors



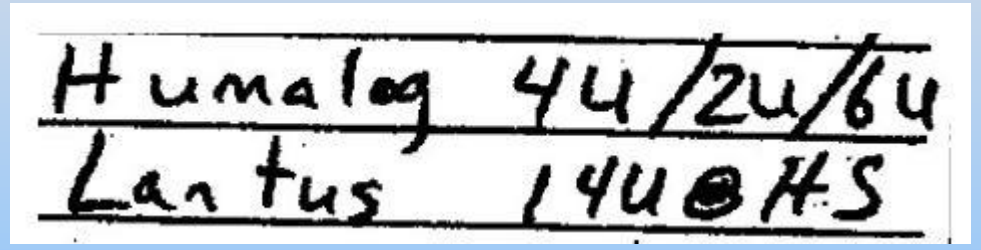
What is this prescription?

1. Haldol 5mg
2. Haldol 0.5mg
3. Haldol 5 mcg
4. Haldol 0.5mcg

Midwest Medication Safety Symposium

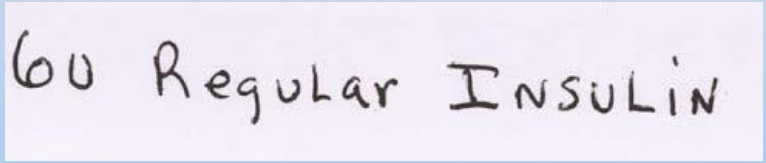


Transcribing Errors



What is this prescription?

1. Humalog 44 units/ 2 units/ 6 units
2. Humalog 44 units/ 24 units/ 64 units
3. Humalog 4 units/2 units/ 6units
4. Humalog 40 units/ 20 units/6 units

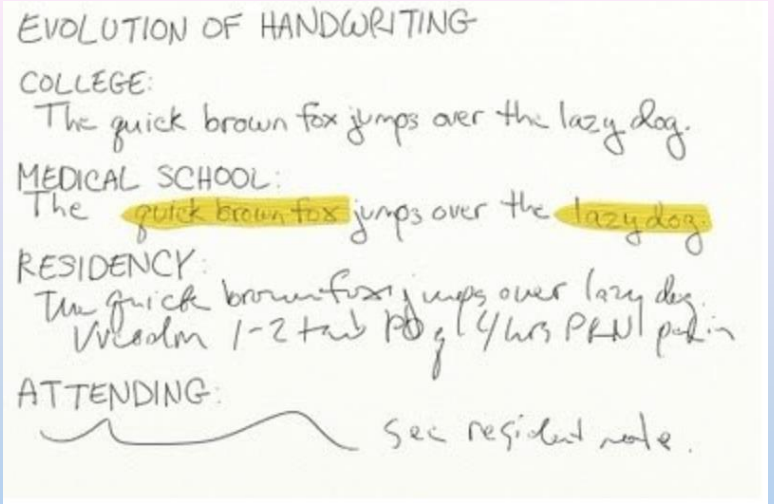


What is this prescription?

1. 6 units regular insulin
2. 60 units regular insulin

Midwest Medication Safety Symposium

Transcribing Errors



What is this prescription?

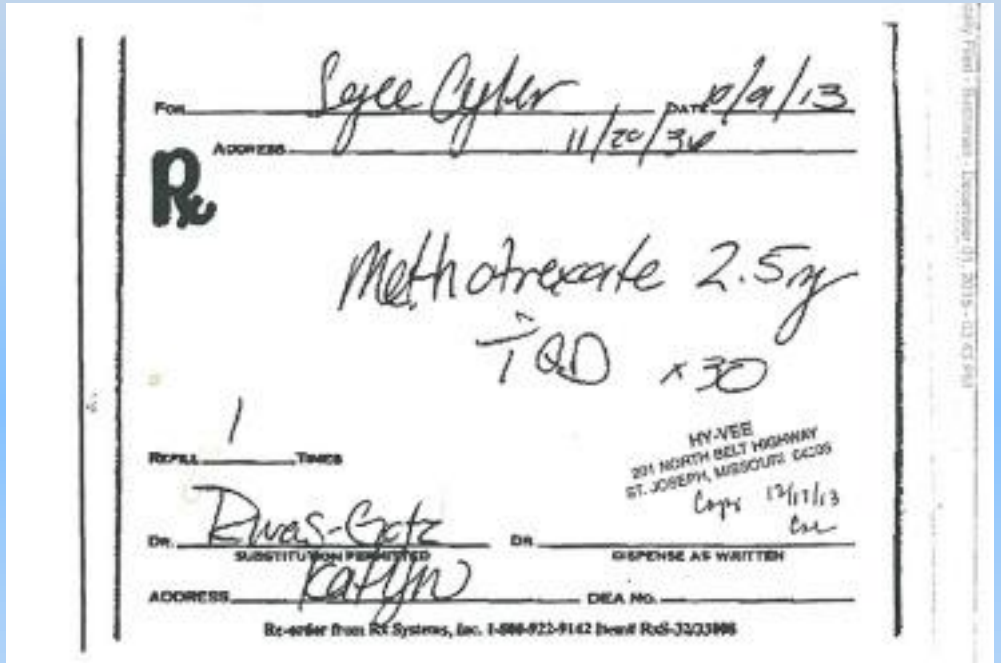
1. Sildenafil 125 mg po qam
2. Sildenafil 125mg po qprn
3. Sildenafil 125 qhs
4. Sildenafil 25 mg po qam
5. Sildenafil 25 mg po qprn
6. Sildenafil 25 mg po qhs

What is this prescription?

1. Flomax 0.4mg po qid
2. Flomax 0.4mg po qd
3. Flomax 0.4mcg po qid
4. Flomax 0.4mcg po qd

Midwest Medication Safety Symposium

A Tragic Event



Midwest Medication Safety Symposium

Dispensing Errors[15, 39, 41]

- Include any inconsistencies or deviations from the prescription or order, such as dispensing the incorrect drug, dose, dosage form, wrong quantity, or inappropriate, incorrect, or inadequate labeling.
- Confusing or inadequate directions for use, incorrect or inappropriate preparation, packaging, or storage of medication prior to dispensing are considered to be errors.
- Errors occur at a rate of 4 per day in a pharmacy filling 250 prescriptions daily, which amounts to an estimated 51.5 million errors out of 3 billion prescriptions filled annually nationwide.
- Safety strategies to prevent ADEs while dispensing:
  - Clinical pharmacists to oversee medication dispensing process
  - Use of "tall man" lettering and other strategies to minimize confusion between look-alike, sound-alike medications
  - Be careful with zeros and abbreviations
  - Provide thorough patient counseling

Look alike Sound alike Drugs

Exparel, Propofol and Cleviprex are all medications with white milky solutions that pose dangerous risks with inadvertent injections

- Bupivacaine liposome is the generic drug name for Exparel™
- Clevidipine is the generic drug name for Cleviprex™

Midwest Medication Safety Symposium

Administration Errors[15]

- Multifaceted:
  - Nurses are primarily involved in administering medications
  - Physicians, certified medication technicians, and patients and family members also administer
- Safety strategies to prevent ADEs while administering medications:
  - Adherence to the "Five Rights" of medication safety (administering the Right Medication, in the Right Dose, at the Right Time, by the Right Route, to the Right Patient)
  - Barcode medication administration to ensure medications are given to the correct patient
  - Minimize interruptions to allow nurses to administer medications safely
  - Smart infusion pumps for intravenous infusions
  - Patient education and revised medication labels to improve patient comprehension of administration instructions

This alert is based on information from the National Medication Errors Reporting Program (MERP) operated by the Institute for Safe Medication Practices (ISMP).

September 9, 2020

Dangerous wrong-route errors with tranexamic acid

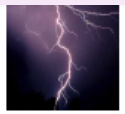
We recently learned about three cases of accidental spinal injection of tranexamic acid instead of a local anesthetic intended for regional (spinal) anesthesia. Container mix-ups were involved in each case. In one case, a patient scheduled for knee surgery received tranexamic acid instead of bupivacaine. The anesthesiologist immediately realized the error, but by then, the patient began to experience seizures. The patient later recovered. In a second case, a patient undergoing hip replacement surgery received tranexamic acid instead of a local anesthetic for spinal anesthesia. The patient survived but also experienced seizures and had extreme pain due to arachnoiditis. In a third case, a patient scheduled for bilateral knee replacement also inadvertently received tranexamic acid instead of bupivacaine for spinal anesthesia. The patient experienced seizures, which necessitated placing her into an induced coma for several days.

Figure 1. While label colors and vial sizes are different, the caps on ropivacaine, bupivacaine, and tranexamic acid vials may have the same blue color and could lead staff to select a vial based on cap color, without reading the label, especially if the vials are stored upright with only the caps showing.

We previously reviewed errors with tranexamic acid in our May 23, 2019, *ISMP Medication Safety Alert!* (www.ismp.org/node/8705). We noted that in the US, bupivacaine, ropivacaine, and tranexamic acid are packaged in vials that may have the same blue color cap (**Figure 1**). While label colors and vial sizes may be different, when the vials are stored upright near each other, only the blue caps may be visible, making it more difficult to differentiate one drug from the other. To make matters worse, these drugs are often found in areas where barcode scanning may not have been implemented or is not routinely utilized (e.g., peri-operative areas, labor and delivery, emergency department). So, mix-ups are less likely to be detected. Unfortunately, the literature has additional reports of serious medication errors due to mix-ups between tranexamic acid and bupivacaine or ropivacaine during regional anesthesia. Syringe labeling issues may also contribute to such errors.

Tranexamic acid is an antifibrinolytic that prevents the breakdown of fibrin, thus promoting clotting. It is approved for short-term use (2-8 days) in patients with hemophilia to reduce the risk of hemorrhage during and following tooth extraction; however, it is also used off-label in a variety of hemorrhagic conditions to control bleeding, including postpartum hemorrhage. Although tranexamic acid is not indicated for joint surgeries, it is often used intravenously (IV) or topically during these procedures to

continued on page 2 — NAN>



This alert is based on information from the National Medication Errors Reporting Program (MERP) operated by the Institute for Safe Medication Practices (ISMP).

September 9, 2020

Dangerous wrong-route errors with tranexamic acid continued from page 1

decrease blood loss. Tranexamic acid is also available as an oral tablet for the treatment of cyclic heavy menstrual bleeding in women.

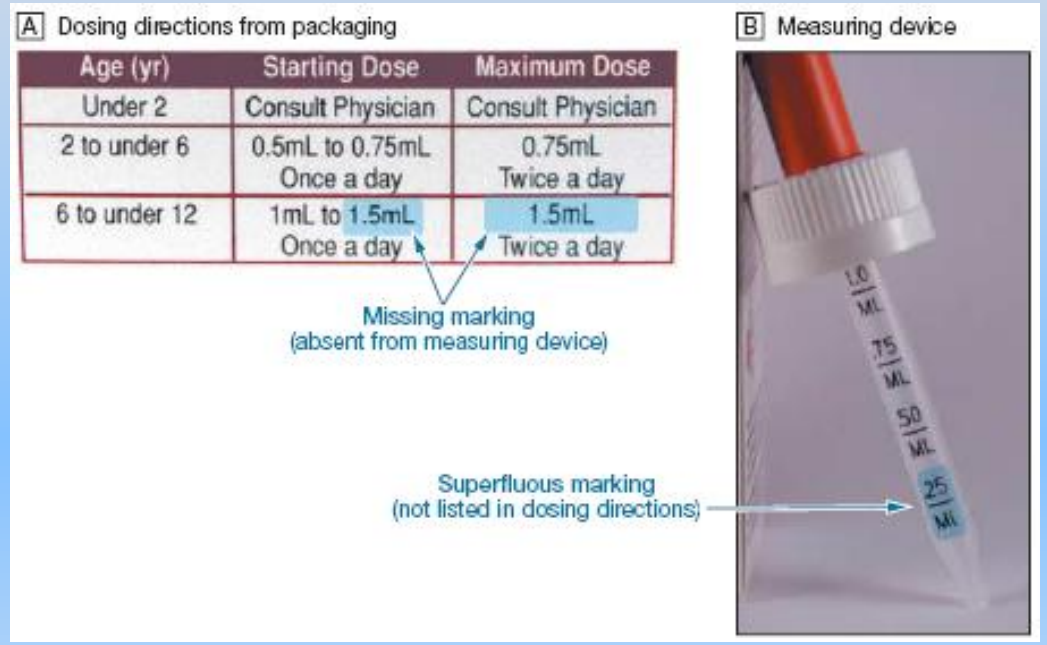
When given via the spinal route in error, tranexamic acid is a potent neurotoxin that is harmful to patients, with a mortality rate of about 50%. Survivors often experience seizures, permanent neurological injury, ventricular fibrillation, and paraplegia (Palanisamy A, Kinsella SM. Spinal tranexamic acid–a new killer in town. *Anaesthesia*. 2019;74[7]:831-3; www.ismp.org/ext/263).

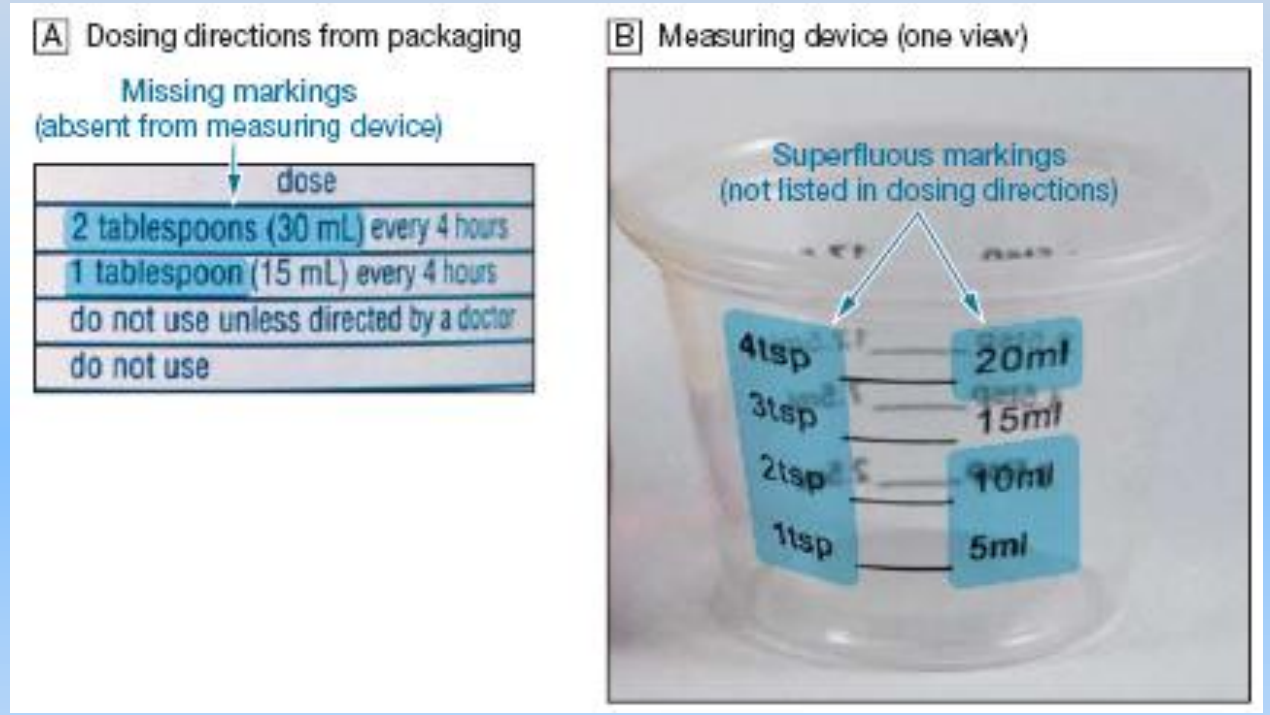
Prevention measures

- Separate or sequester tranexamic acid in storage locations and avoid storing local anesthetics and tranexamic acid near one another.
- To prevent reliance on identifying the drug by viewing only the vial caps, never store injectable drug vials in an upright position, especially when stored in a bin or drawer below eye level. Store them in a way that always makes their labels visible.
- Minimize look-alike vials (caps) by purchasing these products from different manufacturers.
- Consider purchasing labels that state, "**Contains Tranexamic Acid**" to place over the vial caps.
- Utilize barcode scanning prior to dispensing as well as when accessing the drug in surgical and obstetrical areas.
- Consider NRFit syringes and connectors for local anesthetics used for regional anesthesia administered via the neuraxial route. NRFit connectors are incompatible with Luer connectors, thus preventing misconnections with drugs intended for IV use, such as tranexamic acid (see ISMP's July 16, 2020, article on NRFit, www.ismp.org/node/18860).
- Consider the use of pharmacy-prepared or commercially available premixed containers of tranexamic acid, which would be less likely to be confused with local anesthetic vials. Pharmacy preparation and labeling of syringes or infusions would help alleviate these errors. A premixed container of IV tranexamic acid in a sodium chloride solution for injection, 1 g/100 mL (10 mg/mL), is commercially available. While the only approved indication for tranexamic acid is to reduce or prevent hemorrhage for patients with hemophilia undergoing tooth extraction, this product could be used off-label to treat other forms of bleeding. However, vials of tranexamic acid may still be needed since loading doses may be required prior to infusion (or a smart infusion pump loading dose feature could be used that automatically switches to a continuous infusion once the loading dose has been delivered). Also note: local anesthetics may be available at some locations in premixed containers or prepared by pharmacy for use in regional anesthesia.

The National Alert Network **(NAN)** is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP), distributes NAN alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCC MERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication-use system.

Administration Errors





Midwest Medication Safety Symposium

Lets Practice

Scenario #1

- The concentration for gentamicin in the NICU is 4 mg/1 mL. A NICU patient was ordered gentamicin 4 mg (1 mL).
- When this was prepared by the pharmacy technician, the amount (mg) on the syringe label was mistaken for the volume (mL) ordered. As a result, gentamicin 4 mL (16 mg) was prepared in the syringe instead of 4 mg (1 mL).
- After the pharmacist checked and verified the syringe, it was dispensed to the unit.
- The nurse, who had a larger patient workload than normal, barcode scanned the syringe upon administration. This did not produce an alert, since it scanned correctly (i.e. label correctly matched the order for this patient).
- Prior to starting the medication, the RN discovered the incorrect amount of drug was drawn up into the syringe. The incorrect dose was not given to the patient and the syringe was sent back to pharmacy to be remade.

Scenario #1

In which step of the Medication Use Process did this event occur?

Midwest Medication Safety Symposium

Scenario #2

- A physician ordered amlodipine besylate 100 mg by mouth daily, instead of 10 mg the patient was taking at home, and was missed by the verification pharmacist reviewing the order.
- The computer system generated an alert for both the pharmacist and physician, but did not require a response before bypassing.
- The next day, the same pharmacist is working in the ICU when the patient is transferred due to a sharp decrease in blood pressure requiring vasopressors (these can only be given in the ICU).
- When the pharmacist completed a patient chart review, they discover the 10 fold overdose that was given on the floor. It was even noted the nurse appropriately acquired the 10 tablets to complete the ordered dose from the automated dispensing cabinet, scanned the patient's wristband and medication with no warnings, and assist the patient to take all 10 amlodipine 10 mg tablets.
- At this time, the pharmacist notices that they completed the pharmacy verification of this order leading to an overdose.
- After being transferred to the ICU, the patient was placed on a ventilator until her death two days later.

Scenario #2

In which step of the Medication Use Process did this event occur?

Midwest Medication Safety Symposium

The Tool Box!

What is in your tool box?

Prevention/Focus

HAMs[19-21]

High-alert medications (HAMs)

- Bear a heightened risk of causing significant patient harm when they are used in error
- Mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients
- ISMP has three lists based on setting:
  - Acute Care, Long Term Care (LTC), and Community/Ambulatory

Remember to ask about your facility's HAM list!

Acute Care	Long-Term Care	Community/Ambulatory
Antithrombotic Agents (including anticoagulants, direct thrombin inhibitors thrombolytics, etc.)	Anticoagulants, parenteral and oral	Antiretroviral agents
Chemotherapeutic Agents, parenteral and oral	Chemotherapeutic agents, parenteral and oral (excluding hormonal agents)	Chemotherapeutic agents, parenteral and oral (excluding hormonal agents)
Insulin, subcutaneous and IV	Insulin, all formulations and strengths	Insulin, all formulations
Narcotics/opioids – IV, transdermal, oral	Opioids- parenteral, transdermal, and oral	Opioids- all formulations
Oxytocin, IV	Digoxin, parenteral and oral	metFORMIN
Potassium chloride for injection concentrate	Concentrated morphine solution, oral	Warfarin

Midwest Medication Safety Symposium

Drug Name	Confused Drug Name
aMILoride	amLODIPine
Apidra	Spiriva
Benadryl	Benazepril
CARBOplatin	CISplatin
Diprivan	Diflucan
HumuLIN R U-100	HumuLIN R U-500
HydrOXYzine	HydrALAZINE
LamiVUDine	LamoTRIgine
Metadate ER	Metadate CD
Paxil	Plavix
Prozac	PriLOSEC
Restoril	RisperDAL

SALAD[22]

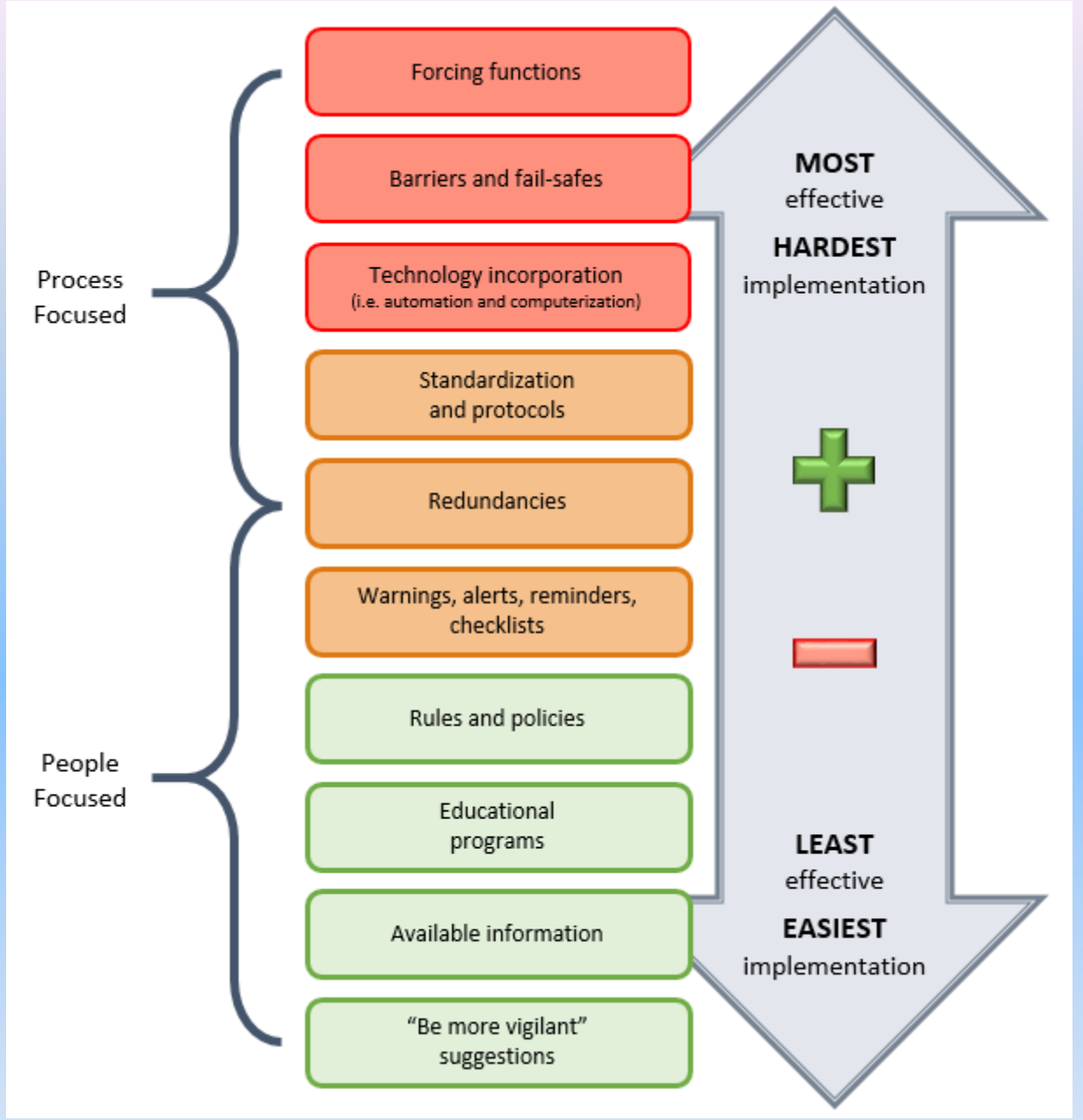
Look Alike-Sound Alike (LASA) Drugs

- Medications with drug names that look similar in print or sound similar to other drugs when their names are spoken
  - Sound Alike-Look Alike Drugs (SALAD)
- Can be easily confused and carry a significant risk of being exchanged for one another
- TALLman lettering (i.e. capitalization of certain letters within a medication name) is a mitigation strategy
  - Helps to highlight certain sections of the drug name and draw attention to the dissimilarities in similar medication names to allow them to become more distinguishable and to help prevent medication variances affiliated with name confusion or mix-ups
  - Endorsed by the ISMP, TJC, and the FDA

Strategies to decrease risk of errors[32]

- Using both the brand and generic names on prescriptions and labels
- Including the purpose/indication of the medication on prescriptions
- Configuring computer selection screens to prevent look-alike names from appearing consecutively
- Changing the appearance of look-alike product names to draw attention to their dissimilarities
- Storing medication in different locations

Midwest Medication Safety Symposium


Forcing functions
Barriers and fail-safes
Technology incorporation
(i.e. automation and computerization)
Standardization
and protocols
Redundancies
Warnings, alerts, reminders,
checklists
Rules and policies
Educational
programs
Available information
"Be more vigilant"
suggestions
Process
Focused
People
Focused
MOST
effective
HARDEST
implementation
LEAST
effective
EASIEST
implementation

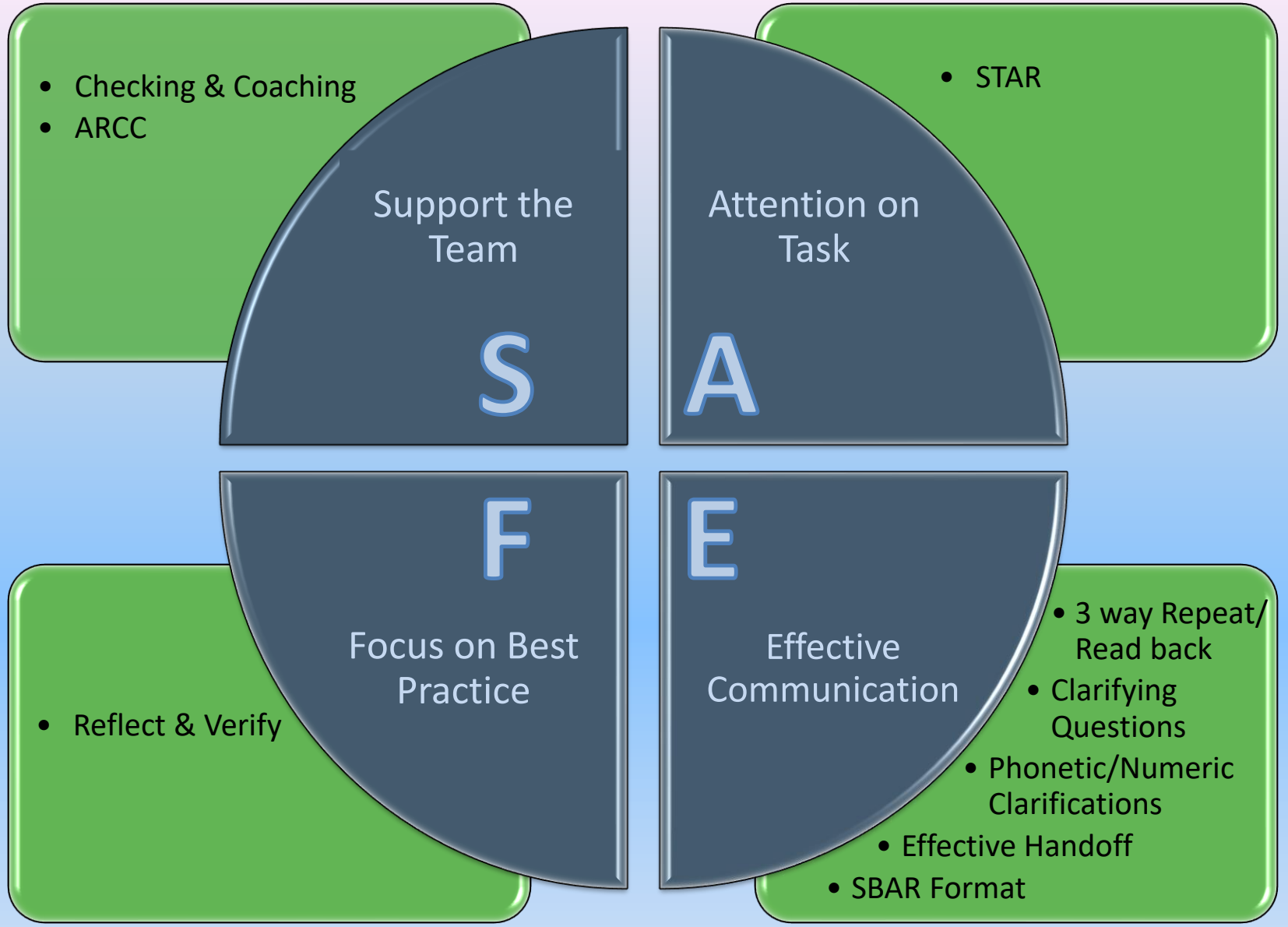
Safety Behaviors

With everyone contributing to safety, what are some tools that can be used to accomplish this?

The Most Important Universal Skill for High Reliability

SPEAK UP!

Additional Universal Skills to have in your tool box include…



UNIVERSAL SKILL

Attention on Task
by using…

STAR

Prevent Errors by Thinking Before Acting

Stop	Pause for *1 to 2 seconds* to focus your attention on the task at hand
Think	Consider the action you're about to take
Act	Concentrate and carry out the task
Review	Check to make sure that the task was done right and that you got the right result

STOP is the most important step. It gives your brain a chance to catch up with what your hands are getting ready to do.

E
Effective Communication

UNIVERSAL SKILL

Effective Communication

Phonetic & Numeric Clarifications

- Use numeric clarifications for numbers that sound alike. Example: "15, that's one-five" or "50, that's five-zero"
- Use phonetic clarification for letters that sound alike—the letter followed by a work that starts with that letter.

  Example: "A as in apple" or "B as in boy"

Ask one or two clarifying questions…

…In all high risk situations

…When information is incomplete or unclear

Effective Handoff Communication

- Actively & purposefully involve patients & families as able
  - **Bedside Shift Report supports this goal**
- Tips for Safe Handoffs
  - Face-to-face communication is best
  - Handoff should be as close as possible to the time of transfer
  - Minimize outside interruptions
  - Use repeat backs & clarifying questions
  - Checklists can be helpful for an effective handoff

Asking clarifying questions can reduce the risk of making an error by 2½ times!

Lets Practice

Scenario #1

- The concentration for gentamicin in the NICU is 4 mg/1 mL. A NICU patient was ordered gentamicin 4 mg (1 mL).
- When this was prepared by the pharmacy technician, the amount (mg) on the syringe label was mistaken for the volume (mL) ordered. As a result, gentamicin 4 mL (16 mg) was prepared in the syringe instead of 4 mg (1 mL).
- After the pharmacist checked and verified the syringe, it was dispensed to the unit.
- The nurse, who had a larger patient workload than normal, barcode scanned the syringe upon administration. This did not produce an alert, since it scanned correctly (i.e. label correctly matched the order for this patient).
- Prior to starting the medication, the RN discovered the incorrect amount of drug was drawn up into the syringe. The incorrect dose was not given to the patient and the syringe was sent back to pharmacy to be remade.

Scenario #1

What prevention strategies would you employ to prevent this incident from occurring again?

Midwest Medication Safety Symposium

Scenario #2

- A physician ordered amlodipine besylate 100 mg by mouth daily, instead of 10 mg the patient was taking at home, and was missed by the verification pharmacist reviewing the order.
- The computer system generated an alert for both the pharmacist and physician, but did not require a response before bypassing.
- The next day, the same pharmacist is working in the ICU when the patient is transferred due to a sharp decrease in blood pressure requiring vasopressors (these can only be given in the ICU).
- When the pharmacist completed a patient chart review, they discover the 10 fold overdose that was given on the floor. It was even noted the nurse appropriately acquired the 10 tablets to complete the ordered dose from the automated dispensing cabinet, scanned the patient's wristband and medication with no warnings, and assist the patient to take all 10 amlodipine 10 mg tablets.
- At this time, the pharmacist notices that they completed the pharmacy verification of this order leading to an overdose.
- After being transferred to the ICU, the patient was placed on a ventilator until her death two days later.

Scenario #2

What prevention strategies would you employ to prevent this incident from occurring again?

Midwest Medication Safety Symposium

Second Victims

Who is a Second Victim?

- “healthcare providers who are involved in an unanticipated adverse patient event, medical error and/or a patient related injury and become victimized in the sense that the provider is traumatized by the event.”
- This can occur to any healthcare provider, in any organization, for example, hospitals, EMS, LTC, home health & hospice, pharmacies, medical offices and physicians, ASCs, etc.

https://www.youtube.com/watch?v=YeSvCEpg6ew

Second Victims

Frequently, Second Victims…

- Feel personally responsible for the unexpected patient outcomes
- Feel as though they have failed the patient
- Second-guess their clinical skills
- Second-guess their knowledge base

Midwest Medication Safety Symposium

Second Victims- What can you do to help?

DO	DON'T
• Find a quiet place. • Ask open-ended question and help the person to process how the event has impacted him or her. • Listen and offer support to the person, regardless of whether you endorse his or her actions or believe the story. • Paraphrase what you're hearing. For example: "It sounds like you're pretty angry with the situation. Is that right?" • Make empathetic statements, such as "That must be overwhelming for you." • Ask the individual to identify resources in his or her life that are positive, such as running or cooking. • Help the person plan the next day or week, and incorporate positive activities into his or her schedule. • Direct the person to resources, such as an employee assistance program	• Ask questions about the event or try to investigate whether he or she was at fault. You are there for the person. • Try to "fix" anything. You are just there to listen. • Tell the person how you feel about the event. • Use statements that belittle the person's feelings, such as "I know how you feel," "The same thing happened to me" or "It's a routine complication; get over it." • Tell the caregiver what to do, how to feel or how not to feel. • Shut the person down. If they are crying, don't hug them or give them tissues just to make them stop. • Share any information about the encounter unless there is an overwhelming reason, such as fear they may hurt themselves.

https://www.youtube.com/watch?v=55jwN4OOF4s

Post-Assessment Question #1

The pharmacy dispensed hydrALAZINE instead of the medication prescribed, which was hydrOXYzine. The patient was administered this medication, but thankfully no harm occurred. This event would be defined as:

a) Adverse Drug Reaction (ADR)

b) Medication Error

c) Near Miss

d) All of the above

Midwest Medication Safety Symposium

Post-Assessment Question #2

Which of the following organizations are devoted entirely to preventing medication errors?

a) Food and Drug Administration (FDA)
b) Institute for Safe Medication Practices (ISMP)
c) American Academy of Pediatrics (AAP)
d) Walt Disney World (WDW)

Midwest Medication Safety Symposium

Post-Assessment Question #3

Why is it important to report medication incidents both internally and externally?

A) Enhancement of medication use process within an organization

B) Captures the actual event and promotes a culture of safety

C) Improvement of package insert

D) None of the above

Midwest Medication Safety Symposium

Q/A Session

Medication Safety Bootcamp

101: Introduction to Medication Safety Basics

Heather Dossett, PharmD, MHA, BCPS, CPHQ
Medication Safety and Pharmacy Education Pharmacist
Ascension – St. Vincent's Indianapolis
Heather.dossett@ascension.org

Jessalynn Henney, PharmD
Network Medication Safety Director
Community Health Network
jkhenney@ecommunity.com

Tuesday, September 22nd, 2020

References

1. Horn JR , Hansten PD . Sources of Error in Drug Interactions: The Swiss Cheese Model. *Pharmacy Times*. New Drugs of 2003; 53-54: 2008.
2. ISMP. Historical Timeline. Available at: https://forms.ismp.org/about/timeline.aspx Accessed on August 20th, 2019.
3. The Growing Role of the Patient Safety Officer: Implications for Risk Managers. Chicago, IL: American Society for Healthcare Risk Management of the American Hospital Association; 2004.
4. Benchmark Research & Safety. What is Human Factors and Ergonomics?. Available at: http://benchmarkrs.com/main/human-factors/what.aspx. Accessed on August 20th, 2019.
5. American College of Surgeons. Most Hospitals Fail to Meet Minimum Standards of College Hospital Standardization Program. Available at: http://timeline.facs.org/1913.html. Accessed on August 20th, 2019.
6. Makary M and Daniel M. Medical Error - The Third Leading Cause of Death in the US. *BMJ* 2016;353:i2139. doi: 10.1136/bmj.i2139
7. Institute of Medicine. Committee on Identifying and Preventing Medication Errors. Preventing Medication Errors, Washington, DC: The National Academies Press 2006.
8. Cina J, Gandhi T, Churchill W, et al. How many hospital pharmacy medication dispensing errors go undetected? *Joint Commission Journal on Quality and Patient Safety* . 2006;32(2): 73-79.
9. Campbell PJ, Patel M, Martin JR, et al. Systematic review and meta-analysis of community pharmacy error rates in the USA: 1993-2015. *BMJ Open Quality* . 2018: 1-7. doi: 10.1136/bmjoq-2017-000193.
10. Sarkar U, López A, Maselli JH, Gonzales R. Adverse drug events in U.S. adult ambulatory medical care. Health Serv Res. 2011;46:1517-1533.
11. Saine D and Larson C. (2013). Medication Safety Officer's Handbook. Bethesda, MD. American Society of Health-System Pharmacists.
12. The Case for Medication Safety Officers (MSO). Horsham, PA: Institute for Safe Medication Practices; 2018.
13. W. Levinston. (2017, August 5). Too Much Health Care Can Actually Hurt You. [Blog post]. Retrieved from https://www.huffingtonpost.ca/wendy-levinson/overdiagnosis_b_9849506.html

References

14. NCCMERP. About Medication Errors. Available at: http://www.nccmerp.org/about-medication-errors. Accessed on August 20th, 2019.
15. Patient Safety Network. Patient Safety Primer: Medication Errors and Adverse Drug Events. Available at: https://psnet.ahrq.gov/primers/primer/23. Accessed on August 20th, 2019.
16. McDowell S, Ferner H, Ferner R. The Pathophysiology of Medication Errors: How and Where They Arise. Br J Clin Pharmacol. 2009; 67(6): 605-613.
17. National Safety Council. Near Miss Reporting Systems. Available at https://www.nsc.org/Portals/0/Documents/WorkplaceTrainingDocuments/ Near-Miss-Reporting-Systems.pdf. Accessed on August 17th, 2018.
18. Otero MJ, Schmitt E. Clarifying terminology for adverse drug events. Ann Intern Med. 2005 Jan 4; 142(1): 77.
19. Institute for Safe Medication Practices. High Alert Medications in Acute Care Settings. Available at: https://www.ismp.org/recommendations/high-alert-medications-acute-list. Accessed on August 20th, 2019.
20. Institute for Safe Medication Practices. High Alert Medications in Acute Care Settings. Available at: https://www.ismp.org/recommendations/high-alert-medications-long-term-care-list. Accessed on August 20th, 2019.
21. Institute for Safe Medication Practices. High Alert Medications in Acute Care Settings. Available at: https://www.ismp.org/recommendations/high-alert-medications-community-ambulatory-list. Accessed on August 20th, 2019.
22. Institute for Safe Medication Practices. List of Confused Drug Names. Available at: https://www.ismp.org/recommendations/confused-drug-names-list. Accessed on August 20th, 2019..
23. Aronson JK. Medication errors: definitions and classification. *BJCP.* 2009; 67(6): 599-604.
24. World Health Organization. Reporting and Learning Systems for Medication Errors: The Role of Pharmacovigilance Centres. 2014. Available at http://apps.who.int/medicinedocs/documents/s21625en/s21625en.pdf. Accessed August 20th, 2019.
25. Mosby's Medical Dictionary. 9th edition. St. Louis, MO: Mosby Elsevier, 2013. Print.

Midwest Medication Safety Symposium

References

26. Patient Safety Network. Patient Safety Primer: Reporting Patient Safety Events. Available at: https://psnet.ahrq.gov/primers/primer/13/voluntary- patient-safety-event-reporting-incident-reporting. Accessed on August 20th, 2019.

27. Wolf ZR and Hughes RG. Error Reporting and Disclosure. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville, MD: Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 35. Available from: https://www.ncbi.nih.gov/books/NBK2652/

28. Griffin FA, Resar RK. *IHI Global Trigger Tool for Measuring Adverse Events (Second Edition)*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2009.

29. MedMarx International Reporting. Available at: https://www.medmarx.com/. Accessed on August 20th, 2019.

30. The Joint Commission. Sentinel Events Data – General Information. Available at: https://www.jointcommission.org/sentinel_event.aspx. Accessed on August 20th, 2019.

31. FDA U.S. Food & Drug Administration. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at: https://www.fda.gov/Safety/MedWatch/default.htm. Accessed on August 18th, 2018.

32. The Joint Commission. 2019 National Patient Safety Goals. Available at: www.jointcommission.org/standards_information/npsgs.aspx. Accessed on August 20th, 2019.

33. The Joint Commission. Hospital: 2019 National Patient Safety Goals. Available at: https://www.jointcommission.org/hap_2019_npsgs/. Accessed on August 20th, 2019.

34. The Joint Commission. Ambulatory Health Care: 2019 National Patient Safety Goals. Available at: http://www.jointcommission.org/ ahc_2019_npsgs/. Accessed on August 20th, 2019

35. The Joint Commission. Sentinel Event Alert 61: Managing the risks of direct oral anticoagulants. Available at: https://www.jointcommission.org/ sentinel_event_alert_61_managing_the_risks_of_direct_oral_anticoagulants/ Accessed August 20th, 2019.

36. Evans SM, Berry JG, Smith BJ, et al. Attitudes and barriers to incident reporting: a collaborative hospital study. Qual Saf Health Care. 2006;15:39-43.

37. Health Quality Onatrio. Patient Safety Learning Systems: A Systematic Review and Qualitative Synthesis. Ont Health Technol Assess Ser [Internet]. 2017 Mar; 17(3): 1-23. Available at: http://www.hqontario.ca/Evidence-to-Improve-Care/Journal-Ontario-Health-Technology-Assessment-Series. Accessed August 20th, 2019.

Midwest Medication Safety Symposium

References

38. Gross J. 5 Whys Folklore: The Truth Behind a Monumental Mystery. Available at: http://thekaizone.com/2014/08/5-whys-folklore-the-truth-behind-a-monumental-mystery/. Accessed on August 20th, 2019.

39. Patient Safety Network. Patient Safety Primer: Medication Errors and Adverse Drug Events. Available at: https://psnet.ahrq.gov/primers/primer/23. Accessed on August 20th, 2019.

40. Leape et al. System Analysis of Adverse Drug Events. ADE Prevention Study Group. JAMA. 1995; July; 274(1): 35-43.

41. Nair RP, Kappil D, Wod TM. 10 Strategies for Minimizing Dispensing Errors. Pharmacy Times. Available at: https://www.pharmacytimes.com/ publications/issue/2010/january2010/p2pdispensingerrors-0110. Accessed on August 20th, 2019

42. Yin HS, Wolf MS, Dreyer BP, Sanders LM, Parker RM. Evaluation of Consistency in Dosing Directions and Measuring Devices for Pediatric Nonprescription Liquid Medications. *JAMA*. 2010;304(23):2595-2602.

43. Wolf MS, Davis TC, Shrank, et al. To err is human. Patient misinterpretations of prescription drug label instructions. Patient Educ Couns. 2007; 67:293-300.

44. International Medication Safety Network. IMSN Global Targeted Medication Safety Best Practices. Available at: https://www.intmedsafe.net/imsn-global-targeted-medication-safety-best-practices/ Accessed on August 20th, 2019.

45. Patient Safety Network. Culture of Safety. Available at: https://psnet.ahrq.gov/primers/primer/5/culture-of-safety. Accessed on August 20th, 2019.

46. World Health Organization. To Err is Human. Available at: http://www.who.int/patientsafety/education/curriculum/course2_handout.pdf. Accessed on August 20th, 2019.

47. McCusker, L. X., Gough, P. B., Bias, R. G. (1981) Word recognition inside out and outside in. Journal of Experimental Psychology: Human Perception and Performance, 7(3), 538-551

Supplemental Packet

- NCC MERP
- TJC Document – RCA questions
- External reporting:
  - ISMP: Steps to enter report and ISMP Newsletter example
  - FDA MedWatch: Steps to enter and FAERS database
- Mitigation Strategies
- Safety Behaviors
- NPSG
- Med Safety References

Midwest Medication Safety Symposium

Medication Safety Organizations and Resources

Core Medication Safety Resources

Organization	Website	Resources Provided
Agency for Healthcare Research and Quality (AHRQ)	www.ahrq.gov	• Patient Safety Network • Understand Just Culture Toolkit • Guide to Patient and Family Engagement in Hospital Quality and Safety • Medications at Transitions and Clinical Handoff (MATCH) Toolkit
American Society of Health-System Pharmacists (ASHP)	www.ashp.org	• Policy positions, statements, guidelines • Therapeutic position statements and guidelines • Professional Certificate Programs (Medication Safety) • Medication Safety Section Advisory Group (SAG)
Medication Safety Officers Society	www.medsafetyofficer.org	• Open forum for information sharing and collaboration (founded by ISMP)
Institute for Healthcare Improvement (IHI)	www.ihi.org	• IHI Open School • Global Trigger Tool for Measuring Adverse Events • Success Stories • Toolkits
Institute for Safe Medication Practices (ISMP)	www.ismp.org	• Medication Safety Self- assessments (HAMs, ADCs, etc.) • Targeted Medication Safety Best practices • Guidelines (Optimizing Safe Implementation and Use of Smart Infusion Pumps, Safe Electronic Communication of Medication Information) • Confused Drug Names • Do Not Crush Medication List
World Health Organization (WHO)	www.who.int	• Global Patient Safety Challenge: *Mediation Without Harm* • Educational materials for medication safety • Education and training materials
Safe Medication	www.safemedication.com	• Helps patients keep track of their medication in one place • Medication tips and tools (What you need to know about blood thinners, preventing the flu, tips to reduce prescription drug costs)

Additional Medication Safety Resources

Organization	Website	Resources Provided
American Academy of Pediatrics	www.aap.org	• The AAP Parenting Website (healthychildren.org) • Pediatric Care Online (online library and tool set for current clinical information) • Pediatric Patient Education
Centers for Disease Control (CDC)	www.cdc.gov	• Put your medicines up and away and out of sight • Treating for Two: Medicine and Pregnancy • One and Only • PROTECT Initiative: Advancing Children's Medication Safety • Medication Safety Program
Coalitions: • Massachusetts Coalition for the Presentation of Medical Errors • Pennsylvania Patient Safety Authority • SLAMS • ICPS	http://macoalition.org/ http://patientsafety.pa.gov/ http://indypatientsafety.org/	• Coalition initiatives • Medication Event Sharing
Joint Commission (TJC)	www.jointcommission.org www.jointcommission.org/standards_information/spsg.aspx	• National Patient Safety Goals • Medication Management Standards • Sentinel Event Information
Michigan Pediatric Safety Collaboration	http://mipedscompounds.org/	• Initiative to Standardize the Compounding of Oral Liquids in Pediatrics
National Coordinating Council for Medication Error Reporting and Prevention	www.nccmerp.org	• Taxonomy of Medication Errors • Adverse Drug Event Algorithm • Index of Categorizing Medication Errors • Index for Categorizing Medication Errors Algorithm

Additional Medication Safety Resources

Organization	Website	Resources Provided
National Quality Forum	www.qualityforum.org	• Develops consensus standards • Establishes working groups to foster quality improvement
The Leapfrog Group	www.leapfroggroup.org	• Leapfrog Hospital Safety Grade: assigns letter grades to hospitals based on their record of patients safety to help consumers protect themselves and their families from errors, injuries, accidents and infections
Pediatric Pharmacy Advocacy Group	www.ppag.org	• PPAG University • The Journal of Pediatric Pharmacology and Therapeutics (JPPT) • Therapeutic position statements • KidsMeds (online resource for parents and families on medicine and medication use)
U.S. Food & Drug Administration (FDA)	www.fda.gov www.fda.gov/cder/drugsafety.htm	• Publishes Drug Safety Communications • Database of approved Risk Evaluation and Mitigation Strategies (REMS) • Drug shortage and Recall Information
United States Pharmacopeia	www.usp.org	• Medicines we can trust campaign • Antimicrobial Resistance • Promoting the Quality of Medicines (PQM) Program • USP <795> Nonsterile Preparation, USP <797> Sterile Preparations, USP <800> Handling of Hazardous Drugs, UPS <825> Handling of Radiopharmaceutical Preparations
VA National Center for Patient Safety	www.patientsafety.va.gov	• Root Cause Analysis Tool