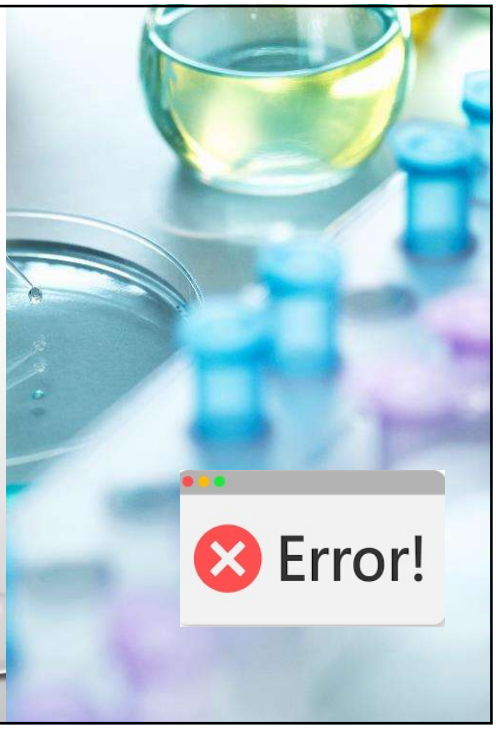
MITIGATION AND **PREVENTION** OF MEDICATION ERRORS IN PHARMACY PRACTICE 2024



1

RX

Learning Objectives

Upon completion of this program, the Pharmacist and Registered Pharmacy Technician shall be able to:

-Recognize statutory responsibilities that foster ongoing pharmacy regulatory compliance

-Describe quality improvement regulations for pharmacies licensed in Florida

-Recognize recurring medication errors

-Define elements of a proactive Continuous Quality Improvement process

-Discuss the use of Root Cause Analysis (RCA) to enhance quality pharmacy services and prevent errors

-Describe the implementation of an action plan to improve overall pharmacy practice quality and mitigate medication errors

-Demonstrate enactment of procedures that promote ongoing patient safety in pharmacy practice

2

DISCLOSURE

- I, NORMAN TOMAKA, DO NOT HAVE A VESTED INTEREST OR AN AFFILIATION WITH ANY CORPORATION OR ORGANIZATION OFFERING FINANCIAL SUPPORT OR GRANT MONIES FOR THIS SEMINAR.
- I DO NOT HAVE AN AFFILIATION WITH ANY ORGANIZATION WHOSE PHILOSOPHY COULD POTENTIALLY BIAS THIS PRESENTATION.
- I DO NOT PRESENT THE FOLLOWING AS LEGAL ADVICE OR REGULATORY MANAGEMENT CONSULTATION.

3

SPEAKER

Norman P. Tomaka

- Pharmacist, Consultant Pharmacist
- BS Pharmacy- Duquesne University
- MS Pharmacy- University of Florida
- Health Care Risk Manager
- **Affiliations**
  - American Pharmacists Association
  - Brevard County Pharmacy Association
  - Florida Pharmacy Association
  - Florida Society of Health-System Pharmacists
  - Palm Beach County Pharmacy Association
  - Treasure Coast Society of Health-System Pharmacists
  - American Society of Consultant Pharmacists

4

ACKNOWLEDGEMENT

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

www.ismp.org

AHRQ
Agency for Healthcare Research and Quality

www.ahrq.gov

PSA Patient Safety Authority

Patientsafety.pa.gov

5

MSOS Forum

Mission: advance and encourage excellence in medication safety.

Provide communication, leadership, direction, and education.

Opportunity for information sharing and collaboration.

6

ASSESSMENT QUESTIONS

IN FLORIDA, PHARMACISTS ARE REQUIRED TO DOCUMENT AND EVALUATE QUALITY RELATED EVENTS (**QRE.**) DESCRIBE A **QRE**

YOU HAVE JUST DOCUMENTED A **QRE**.
CAN THIS DOCUMENT BE USED AGAINST YOU?

RECURRENT QUALITY RELATED EVENTS OFTEN INVOLVE **HIGH-RISK** DRUG PRODUCTS.
HOW CAN YOU DECIDE THE POTENTIAL FOR HIGH RISK AND ERROR?

QRE IS OFTEN PREVENTABLE IF PROCESS MANAGEMENT IS REVIEWED AND AN ACTION PLAN ENACTED.
WHAT'S THE DIFFERENCE BETWEEN THE RCA AND FMEA?

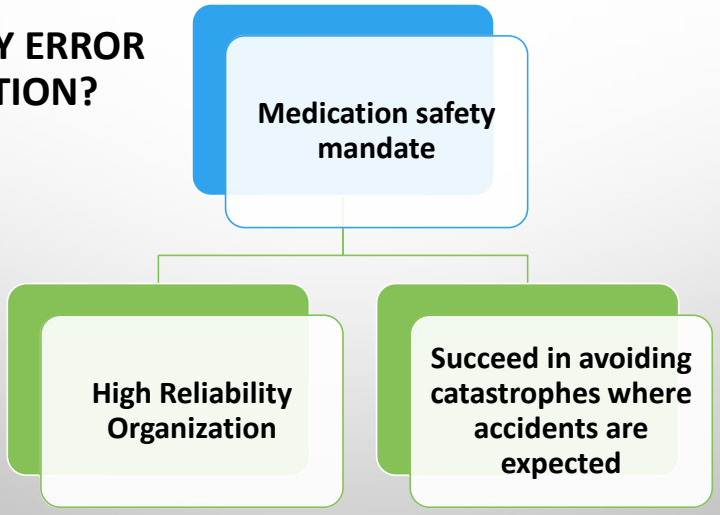
7

POLL

PROFESSIONAL PRACTICE? PRACTICE ENVIRONMENT?

8

WHY STUDY ERROR PREVENTION?



9

STATUTORY RESPONSIBILITY
FL PHARMACY QUALITY ASSURANCE

- CONDUCT AN ONGOING ANALYSIS OF QUALITY RELATED EVENTS (ERRORS)
- REVIEW EXTERNAL EVENTS
- REVIEW INTERNAL OCCURRENCES

- 64B16-27.300 STANDARDS OF PRACTICE
- CONTINUOUS QUALITY IMPROVEMENT PROCESS
- POLICY AND PROCEDURE FOR CQI COMMITTEE
  - DESCRIBE MEMBERS
  - COMPREHENSIVE PROCESS REVIEW
  - QUARTERLY DOCUMENTATION
  - MAINTAIN SUMMARIES FOR 48 MONTHS

10

64B16-26.103 CONTINUING EDUCATION LICENSE RENEWAL

Prior to renewal a licensee must complete, within the 24 month period prior to the expiration date of the license, a **two-hour continuing education course** approved in advance by the Board on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety.

https://www.flrules.org/gateway/ruleno.asp?id=64B16-27.300

11

FL Statutes: CQI

https://qualitysifu.com/achieving-excellence-through-continuous-quality-improvement/

Continuous **Q**uality **I**mprovement

Standards of Practice: system of standards and procedures to identify and evaluate quality-related events and improve patient care

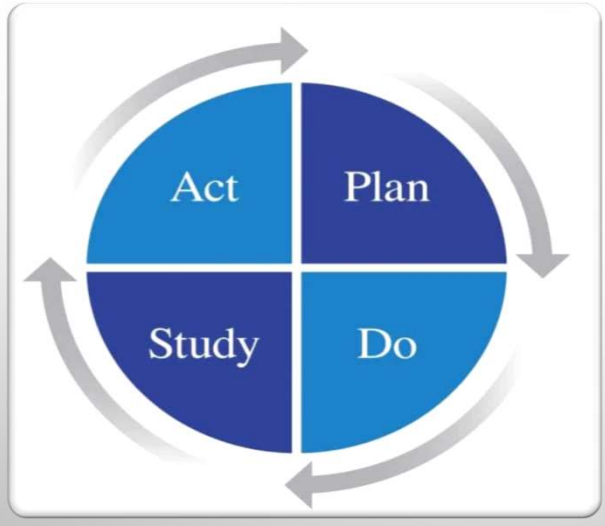
Pharmacy must accumulate data and actively study errors (**Q**uality **R**elated **E**vent)

Error vs Good Catch **QRE**

Focus on prevention through active process

https://www.flrules.org/gateway/ruleno.asp?id=64B16-27.300

12



PLAN-DO-STUDY-ACT

- SYSTEMATIC PROCESS
- PURPOSE: GAINING KNOWLEDGE
- LEADS TO CONTINUAL IMPROVEMENT OF A PROCESS OR SERVICE

The Deming Institute. https://deming.org/explore/pdsa/

13

QUALITY RELATED EVENT

QRE

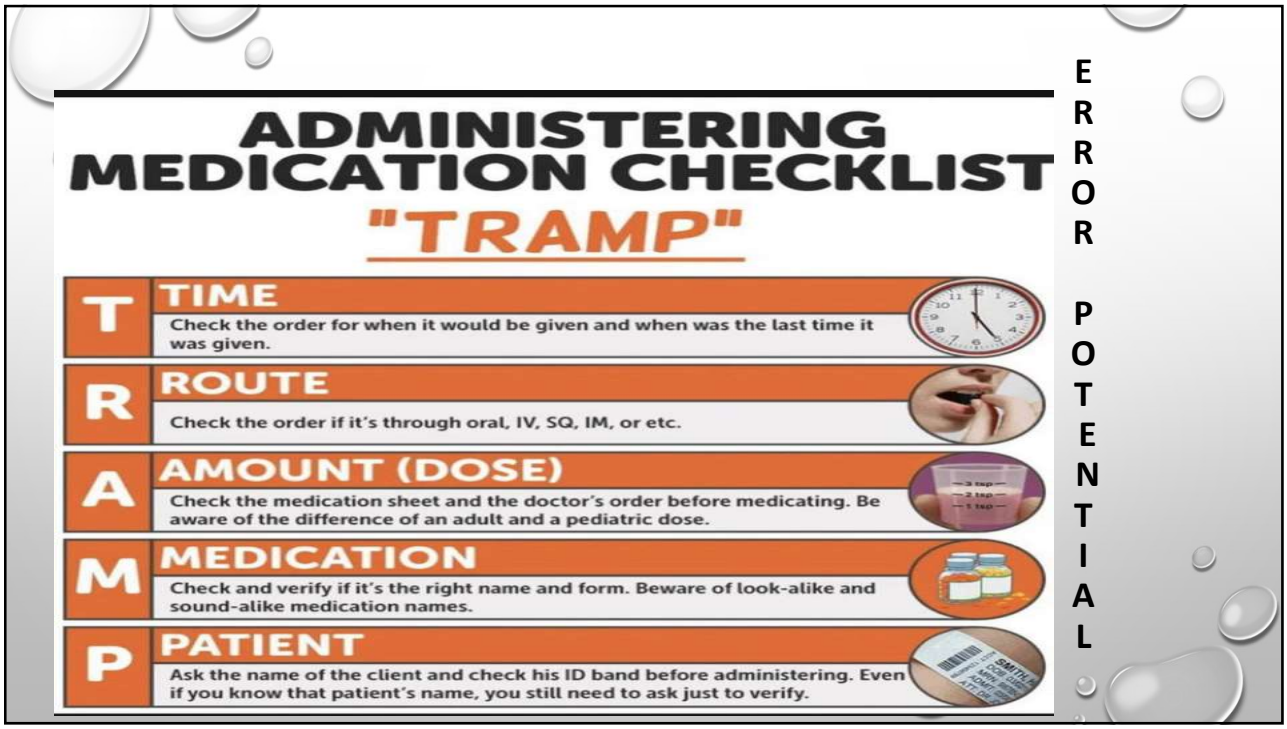
Internal Event
Near Miss
"Good Catch"

Patient Level
Incorrect
Dispensing
Administration

- INAPPROPRIATE DISPENSING
- MIS-ADMINISTRATION OF A PRESCRIBED MEDICATION

"Fla. Admin. Code Ann. R. 64B16-27.300" Fla. Admin. Code R. 64B16-27.300

14



15

QUALITY RELATED EVENT

VARIATION FROM PRESCRIBER'S MEDICATION ORDER

- INCORRECT DRUG
- INCORRECT DRUG STRENGTH
- INCORRECT DOSAGE FORM
- INCORRECT PATIENT
- INADEQUATE DRUG PACKAGE/LABEL

FAILURE TO IDENTIFY AND MANAGE

- OVER/UNDER-UTILIZATION
- THERAPEUTIC DUPLICATION
- DRUG-DISEASE CONTRAINDICATIONS
- DRUG-DRUG INTERACTIONS
- INCORRECT DRUG DOSAGE
- INCORRECT DURATION OF TREATMENT
- DRUG-ALLERGY INTERACTIONS
- CLINICAL ABUSE/MISUSE

"Fla. Admin. Code Ann. R. 64B16-27.300" Fla. Admin. Code R. 64B16-27.300

16

FL 64B16-27.300 **QRE**

VS

≠

FL 65G-7.006 MEDICATION ERROR

- TERMS AND CONDITIONS TO BE FOLLOWED BY A PHARMACIST WHEN ORDERING AND DISPENSING APPROVED MEDICINAL DRUG PRODUCTS
- STANDARDS OF PRACTICE - CONTINUOUS QUALITY IMPROVEMENT PROGRAM REQUIREMENT

FL Department of Health, Board of Pharmacy, Pharmacy Practice
https://www.flrules.org/gateway/ruleno.asp?id=64B16-27.300

- AUTHORIZATION FOR MEDICATION ADMINISTRATION AND INFORMED CONSENT
- SELF-ADMINISTRATION OF MEDICATION WITHOUT SUPERVISION
- MEDICATION ADMINISTRATION TRAINER REQUIREMENTS, MEDICATION ADMINISTRATION

FL Dept. of Children and Families
https://www.flrules.org/gateway/RuleNo.asp?ID=65G-7.006

17

CQI PROCESS PLAN-DO-STUDY-ACT

- **PDSA**: Plan-Do-Study-Act (Deming cycle[1])

  Four-step process for quality improvement[2]
- **Plan** objectives and desired outcomes
- **Do** phase allows for plan implementation
- **Study/Check** phase gather data
- **Act** phase: Outcome achieved?

ACTION PLAN

Quality Related Event (**QRE**) requires process analysis that may lead to change/improvement.

Unique for each **QRE**

1. https://deming.org/explore/pdsa/
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3963536/

18

PHARMACY CQI PROCESS
KEY ELEMENTS

- **ROOT CAUSE ANALYSIS (RCA)**
  - Why?
  - Reactive
- **FAILURE MODE EFFECTS ANALYSIS (FMEA)**
  - Risk mitigation
  - Proactive

ACTION PLAN

Quality Related Event (**QRE**) requires process analysis that may lead to changes

Unique for each **QRE**

Internal and External events

19

ASSESSMENT

IN FLORIDA, PHARMACISTS ARE REQUIRED TO DOCUMENT AND EVALUATE QUALITY RELATED EVENTS (**QRE**)

WHICH STATEMENT(S) BEST DESCRIBE A **QRE**?

A) TECHNICIAN REPORTS THAT LEVOFLOXACIN 500 MG TABLETS WERE MIXED IN THE PHARMACY STORAGE CAROUSEL WITH LEVETIRACETAM 500 MG TABLETS

B) NURSING ADMINISTRATION OF A MEDICATION TO THE WRONG CLIENT IN A LICENSED HEALTHCARE FACILITY

C) PATIENT RECEIVED A PRESCRIPTION CONTAINER WITH CLONAZEPAM (KLONOPIN®) 1 MG INSTEAD OF THE PRESCRIBED MEDICATION CLONIDINE 0.1 MG

D) PATIENT REPORTED INCIDENCE TO FL DEPARTMENT OF HEALTH THAT A **PHYSICIAN** REFUSED TO REFILL A ROUTINE MEDICATION

20

ASSESSMENT

IN FLORIDA, PHARMACISTS ARE REQUIRED TO DOCUMENT AND EVALUATE QUALITY RELATED EVENTS (**QRE**)

WHICH STATEMENT(S) BEST DESCRIBE A **QRE**?

A) TECHNICIAN REPORTS THAT LEVOFLOXACIN 500 MG TABLETS WERE MIXED IN THE PHARMACY STORAGE CAROUSEL WITH LEVETIRACETAM 500 MG TABLETS

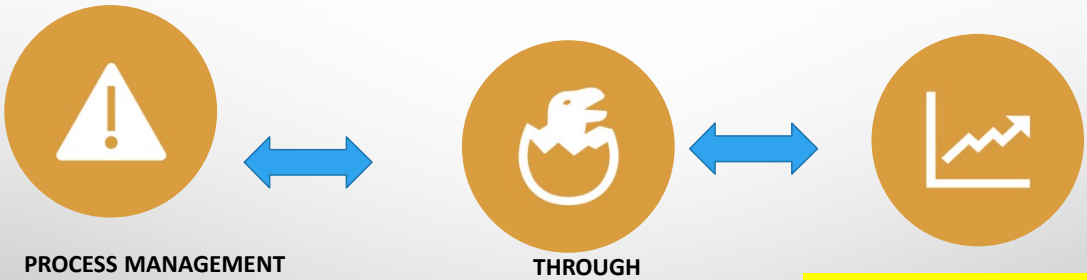
B) NURSING ADMINISTRATION OF A MEDICATION TO THE WRONG CLIENT IN A LICENSED HEALTHCARE FACILITY

C) PATIENT RECEIVED A PRESCRIPTION CONTAINER WITH CLONAZEPAM (KLONOPIN®) 1 MG INSTEAD OF THE PRESCRIBED MEDICATION CLONIDINE 0.1 MG

D) PATIENT REPORTED INCIDENCE TO FL DEPARTMENT OF HEALTH THAT A PHYSICIAN REFUSED TO REFILL A ROUTINE MEDICATION

21

Mitigating Medication Errors



PROCESS MANAGEMENT **THROUGH** **PHARMACY CONTINUOUS QUALITY IMPROVEMENT**

https://www.flrules.org/gateway/RuleNo.asp?ID=64B16-27.300

22

ISMP TOP 10 ACUTE CARE
RECURRENT MEDICATION ERRORS

1. **SELECTING INCORRECT DRUG IN THE DATA SYSTEM/EMR**
2. **INAPPROPRIATE ORAL METHOTREXATE DOSE**
3. **LOOK-ALIKE-SOUND-ALIKE DRUG LABELS**
4. **VERBAL COMMUNICATION ERRORS**
5. **SAFETY OVERRIDES AUTOMATED DISPENSING CABINETS**
6. **IV-PUSH MEDICATION ERRORS**
7. **INCORRECT ADMINISTRATION ROUTE**
8. **UNSAFE LABELING PREFILLED SYRINGES**
9. **INCORRECT DOSING OF CYTOTOXIC DRUGS**
10. **TRACE ELEMENTS IN PARENTERAL NUTRITION**

ISMP Medication Safety Alert! Acute Care. January 2020. Accessed 8/12/2023
https://www.ismp.org/acute-care/medication-safety-alert-january-16-2020

23

10 MOST COMMON
PRESCRIPTION ERRORS

1. UNCLEAR OR ILLEGIBLE PRESCRIPTIONS
2. INCORRECT DOSAGE OR QUANTITY OF MEDICATION
3. DRUGS THAT INTERACT
4. INCORRECT INSTRUCTIONS (SIG)
5. RATE OF USAGE
6. ERRORS IN DIAGNOSIS AND TREATMENT
7. INACCURATE DRUG NAME
8. INCORRECT PRESCRIPTION FORMAT
9. OMISSION OF PRESCRIPTION
10. PRESCRIPTION OF UNAUTHORIZED DRUGS

https://therapybrands.com/blog/the-10-most-common-prescription-errors/

24

RECOGNIZE RECURRING MEDICATION ERRORS

- High risk drugs/process
- Narrow therapeutic index
- Frequently administered drugs
- Sound alike look alike drugs

25

HIGH RISK DRUGS

NT0

HIGH RISK --> Frequent recurrent errors	https://home.ecri.org/blogs/ismp-resources/high-alert-medications-in-acute-care-settings
INJECTABLE DOSE FORM	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2935650/
ANTICOAGULANTS	https://zavaromd.com/services/Anticoagulant
EPINEPHrine	https://www.parpharm.com/products/sterile/adrenalin-injection
INSULIN	https://humulin.lilly.com/what-is-humulin
POTASSIUM Chloride	https://www.pfizerhospitalus.com/products/potassium-chloride-injection
503 B Compounded Syringes	https://www.medsafetyboard.com/patient-safety-issues-with-503b-labeling-and-packaging-making-the-case-for-outsourcers-to-follow-fda-guidance/

26

Slide 26

NT0 Anesthesia Syringes

Tomaka, Norman, 2024-05-29T17:47:48.158

HIGH RISK PROCESS

- Staffing deficits
- Training gaps
- Unfamiliar tasks
- Workload
- Patient/customer interaction

27

NARROW THERAPEUTIC INDEX (NTI)

- Drug related problems are more frequently associated with Narrow therapeutic index (nti) drugs
- ERRORS associated with increased morbidity, mortality and cost
- Small change in dosage could cause adverse effects
- *Study: high proportion of hospitalized patients (35%) RECEIVE NTI-drugs, markedly higher than ambulatory care

*Blix HS, Viktil KK, Moger TA, Reikvam A. *Drugs with narrow therapeutic index as indicators in the risk management of hospitalized patients*. Pharm Pract (Granada). 2010 Jan;8(1):50-5. doi: 10.4321/s1886-36552010000100006. Epub 2010 Mar 15. PMID: 25152793; PMCID: PMC4140577. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4140577/

28

FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters

Table 1. FDA-Approved List of Generic Drug Names with Tall Man (Mixed Case) Letters

Drug Name With Tall Man Letters	Confused With
acetaZOLAMIDE	acetoHEXAMIDE*
acetoHEXAMIDE*	acetaZOLAMIDE
buPROPion	busPIRone
busPIRone	buPROPion
CARBOplatin	CISplatin
chlorproMAZINE	chlorproPAMIDE
chlorproPAMIDE	chlorproMAZINE
CISplatin	CARBOplatin
clomiPHENE	clomiPRAMINE
clomiPRAMINE	clomiPHENE
cycloSERINE	cycloSPORINE
cycloSPORINE	cycloSERINE
DAUNOrubicin	DOXOrubicin
dimenhyDRINATE	diphenhydrAMINE
diphenhydrAMINE	dimenhyDRINATE
DOBUTamine	DOPamine
DOPamine	DOBUTamine
DOXOrubicin	DAUNOrubicin
gliclZIDE	glyBURIDE
glyBURIDE	gliclZIDE
hydrALAZINE	HYDROmorphone — hydrOXYzine
HYDROmorphone	hydrALAZINE — hydrOXYzine
hydrOXYzine	hydrALAZINE — HYDROmorphone
medroxyPROGESTERone	methylPREDNISolone — methylTESTOSTERone
methylPREDNISolone	medroxyPROGESTERone — methylTESTOSTERone
methylTESTOSTERone	methylPREDNISolone — medroxyPROGESTERone
migALAstat	migLUstat
migLUstat	migALAstat
mitoXANTRONE	Not specified
niCARdipine	NIFEdipine
NIFEdipine	niCARdipine
prednisoLONE	predniSONE
predniSONE	prednisoLONE
risperiDONE	rOPINIRole
rOPINIRole	risperiDONE
sulfADIAZINE	sulfISOXAZOLE*
sulfISOXAZOLE*	sulfADIAZINE
TOLAZamide	TOLBUTamide*
TOLBUTamide*	TOLAZamide
traMADol	traZODone
traZODone	traMADol
vinBLAStine	vinCRIStine
vinCRIStine	vinBLAStine

* These drugs have been discontinued and are not marketed in the United States.

ISMP An ECRI Affiliate

www.ismp.org | 2

ISMP Institute for Safe Medication Practices An ECRI Affiliate

SOUND ALIKE LOOK ALIKE DRUGS (SALAD)

ISMP Institute for Safe Medication Practices

ISMP List of *Confused* Drug Names

This list of confused drug names, which includes look-alike and sound-alike name pairs, consists of those name pairs that have been published in the ***ISMP Medication Safety Alert!® Acute Care***, the ***ISMP Medication Safety Alert!® Community/Ambulatory Care***, and the ***FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters***. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as: using both the brand and generic names on prescriptions and labels; including the purpose of the medication on prescriptions; configuring computer systems to require a minimum of the first five letters of a drug name during product searches to limit similar names from appearing together on the same screen; and changing the appearance of look-alike product names to draw attention to their differences. Both the US Food and Drug Administration (FDA)-approved and the ISMP-recommended tall man (mixed case) letters have been included in this list.

Updated through February 2023

Drug Name	Confused Drug Name
Abelcet	amphotericin B
Accupril	Aciphex
acetaminophen	acetaZOLAMIDE
acetaZOLAMIDE	acetaminophen
acetaZOLAMIDE	acetoHEXAMIDE
acetic acid for irrigation	glacial acetic acid
acetoHEXAMIDE	acetaZOLAMIDE
Aciphex	Accupril
Aciphex	Aricept
Activase	Cathflo Activase
Activase	TNKase
Actonel	Actos
Actos	Actonel
Adacel (Tdap)	Daptacel (DTaP)
Adderall	Adderall XR
Adderall	Inderal
Adderall XR	Adderall
ado-trastuzumab emtansine	trastuzumab
Advair	Advicor
Advicor	Advair
Advicor	Altocor
Afrin (oxymetazoline)	Afrin (saline)
Afrin (saline)	Afrin (oxymetazoline)

Drug Name	Confused Drug Name
ALfentanil*	SUFentanil*
Alkeran	Leukeran
Alkeran	Myleran
Allegra	Viagra
Allegra (fexofenadine)	Allegra Anti-Itch Cream (diphenhydrAMINE/allantoin)
Allegra Anti-Itch Cream (diphenhydrAMINE/allantoin)	Allegra (fexofenadine)
Alora	Aldara
ALPRAZolam	clonazePAM
ALPRAZolam	LORazepam
Altocor	Advicor
amantadine	amiodarone
Amaryl	Reminyl
Ambien*	ambrisentan*
Ambisome	amphotericin B
ambrisentan*	Ambien*
Amicar	Omacor
Amikin	Kineret
aMILoride	amLODIPine
amiodarone	amantadine
amLODIPine	aMILoride
Anaprox DS	Aleve

https://www.ismp.org/recommendations/confused-drug-names-list

29

Drug Names	Aware of Confusion? (%)	Add to List? (%)
pyRIDostigmine and PHYSostigmine	49	91
cycloPHOSphamide (confused with cycloSPORINE and cycloSERINE, already on FDA list)	50	83
droPERidol and droNABinol	37	82
linaGLIPtin and linaCLOtide	27	79
leNALIDomide and leFLUNomide	21	79
hydroxyUREA (confused with hydrOXYzine, already on FDA list)	43	77
dexAMETHasone and dexmedeTOMIDine	44	75
DESMOpressin and VASOpressin	44	71
NIZatidine and nitaZOXanide	21	68
methoTREXate (confused with metOLazone, methIMAzole, and methazolAMIDE, already on ISMP list)	31	63

TALLMAN LETTERS

2023 ISMP™

30

SOUND ALIKE LOOK ALIKE DRUGS

- **Estimated 25% of medication errors**
- **Drug pairs often implicated in error**
- **Name similarity (Sound and Text)**
- **Look alike packaging**

https://www.apsf.org/newsletter/june-2023/

31

ASSESSMENT

*RECURRENT QUALITY RELATED EVENTS OFTEN INVOLVE **HIGH-RISK** DRUG PRODUCTS*

WHICH STATEMENT(S) BEST DESCRIBE THE POTENTIAL FOR HIGH RISK AND ERROR?

ALL ARE HIGH RISK

A) A PATIENT PRESENTS A PRESCRIPTION FOR ***DIGOXIN 0.25 MG*** PO DAILY. THE PATIENT'S WEIGHT AND AGE LISTED ON THE RX ARE INCORRECT.

B) THE HOSPITAL PHARMACY RECEIVES AN ORDER FOR ***HEPARIN INFUSION*** ON A NEWLY ADMITTED PATIENT. THERE ARE NO "HOME" MEDICATIONS DOCUMENTED

C) PATIENT'S REPRESENTATIVE TELEPHONES THE PHARMACY ASKING FOR A REFILL FOR INSULIN. THERE ARE TWO RXS LISTED: ***HUMALOG®R*** AND ***NOVOLIN®70/30*** IN THE CHART.

D) YOU THE PHARMACIST RECEIVE AN RX FOR ***EXTEMPORANEOUS COMPOUNDED CREAM*** WITH DRUGS YOU ARE NOT FAMILIAR WITH.

32

MANAGING NEGATIVE QUALITY RELATED EVENTS

- LISTEN TO THE PATIENT OR PATIENT'S CAREGIVER
- ASSUME THAT AN ERROR HAS OCCURRED
- INVESTIGATE THE FACTS SURROUNDING THE EVENT
- SHOW GENUINE CONCERN FOR THE PATIENT
- APOLOGIZE FOR THE INCONVENIENCE BUT USE JUDGMENT ON ACCEPTING FULL RESPONSIBILITY
- DOCUMENT THE EVENT IMMEDIATELY
- NOTIFY SUPERVISOR/MANAGER/OWNER
- **IF ITS BROKEN, FIX IT & DOCUMENT THE REPAIR**

33

DOCUMENTING THE QRE

- DESCRIBE THE QRE
- DATE & TIME WHEN QRE OCCURRED
- DATE AND TIME QRE WAS REPORTED
- HOW THE QRE WAS DISCOVERED
- WAS TREATING PHYSICIAN OR OTHER PROVIDER NOTIFIED?
- PATIENT/CAREGIVER ATTITUDE
- PHYSICIAN/PRESCRIBER ATTITUDE
- IF DISPENSING ERROR OCCURRED, WAS THE CONTAINER RETRIEVED?
- HOW MUCH OF THE DRUG DID THE PATIENT USE/TAKE?
- WHO WERE THE STAFF/CAREGIVER(S) INVOLVED?
- WHAT IS THE STATUS OF THE PATIENT?

34

ASSESSMENT

YOU HAVE JUST DOCUMENTED A QRE.

YOU DESCRIBED THE EVENT, INCLUDING STAFFING LEVELS, WORKFLOW ANALYSIS AND DESCRIPTION OF THE TECHNOLOGICAL SUPPORT AT THE TIME OF THE EVENT

- WHO IS GOING TO HAVE ACCESS TO DOCUMENTS GENERATED THROUGH THE CQI PROGRAM?
- CAN THESE DOCUMENTS BE USED AGAINST YOU?

35

ASSESSMENT

YOU HAVE JUST DOCUMENTED A QRE.

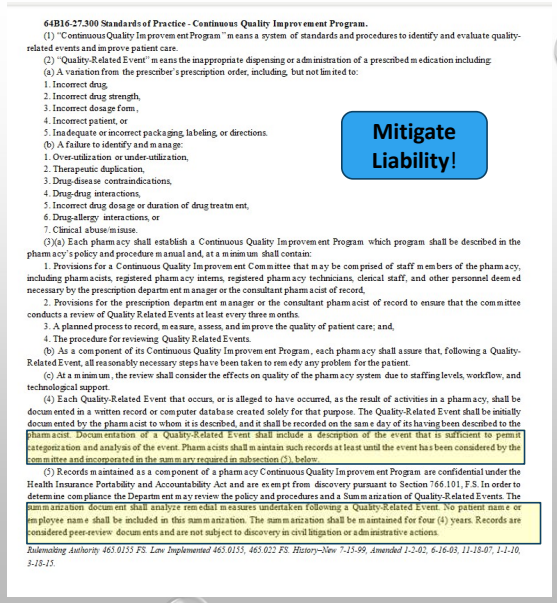
YOU DESCRIBED THE EVENT, INCLUDING STAFFING LEVELS, WORKFLOW ANALYSIS AND DESCRIPTION OF THE TECHNOLOGICAL SUPPORT AT THE TIME OF THE EVENT

- WHO IS GOING TO HAVE ACCESS TO DOCUMENTS GENERATED THROUGH THE CQI PROGRAM?
- CAN THESE DOCUMENTS BE USED AGAINST YOU?

36

QRE
DOCUMENTATION

- **OMIT** PATIENT NAME
- **OMIT** ALL PATIENT IDENTIFIERS
- **OMIT** NAMES OF PATIENT PROVIDERS
- **OMIT** NAMES OF PHARMACY PERSONNEL
- **OMIT** STATUS OF MALPRACTICE REPORT OR SETTLEMENT



64B16-27.300 Standards of Practice - Continuous Quality Improvement Program.

(1) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) "Quality-Related Event" means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug,
2. Incorrect drug strength,
3. Incorrect dosage form,
4. Incorrect patient, or
5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-utilization,
2. Therapeutic duplication,
3. Drug-disease contraindications,
4. Drug-drug interactions,
5. Incorrect drug dosage or duration of drug treatment,
6. Drug-allergy interactions, or
7. Clinical abuse/misuse.

(3)(a) Each pharmacy shall establish a Continuous Quality Improvement Program which program shall be described in the pharmacy's policy and procedure manual and, at a minimum shall contain:

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, registered pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager or the consultant pharmacist of record,

2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality Related Events at least every three months.

3. A planned process to record, measure, assess, and improve the quality of patient care; and,

4. The procedure for reviewing Quality Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

(4) Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the pharmacist. Documentation of a Quality-Related Event shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacists shall maintain such records at least until the event has been considered by the committee and incorporated in the summary required in subsection (5), below.

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the Health Insurance Portability and Accountability Act and are exempt from discovery pursuant to Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for four (4) years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

Rulemaking Authority 465.0155 FS. Law Implemented 465.0155, 465.022 FS. History–New 7-15-99, Amended 1-2-02, 6-16-03, 11-18-07, 1-1-10, 3-18-15.

Mitigate Liability!

37

QRE DATA

QRE SHOULD BE CONSIDERED CONFIDENTIAL

- DATE/TIME
- LOCATION
- REPORTING STAFF MEMBER
- TYPE OF QRE
  - INCORRECT DRUG
  - DRUG STRENGTH
  - DOSAGE FORM
  - INCORRECT PATIENT
  - OVER/UNDER UTILIZATION
  - INTERACTION
  - THERAPEUTIC DUPLICATION
  - ALLERGY

38

QRE DATA

QRE SHOULD BE CONSIDERED CONFIDENTIAL

- LEVEL OF WORKLOAD
- TURNAROUND TIME
- FREQUENCY OF INTERRUPTIONS
- CONSULTATION REQUESTS
- ENVIRONMENT
  - LIGHTING, NOISE, DISTRACTIONS
- INTERPRETATION
  - TRANSCRIPTION ERROR
  - LOOK ALIKE-SOUND ALIKE DRUGS
- OTHER ENVIRONMENTAL FACTORS INVOLVED
  - EMR SYSTEM (SOFTWARE), FAX MACHINE, VOICE MAIL, COUNTING MACHINES, IV HOOD

39

WHAT IS A POSITIVE QUALITY RELATED EVENT? DOES A PHARMACIST CREATE ONE?

- **REASON** - TAMPA PHARMACIST UNDER COLLABORATIVE PRACTICE AGREEMENT RECEIVES A PRESCRIPTION REFILL REQUEST FOR A CHOLESTEROL LOWERING DRUG
- **ACTION** – PHARMACIST PERFORMS CHOLESTEROL ANALYSIS AND FINDS THE PATIENT NOT RESPONDING TO CURRENT THERAPY
  - PHARMACIST CONTACTS PHYSICIAN/PROVIDER
- **RESOLUTION** – PHYSICIAN CHANGES MEDICATION
- **OUTCOME** – PATIENT'S CHOLESTEROL LEVELS DROP

40

QRE

Near Miss/Good Catch:
A mistake in prescribing, dispensing, or planned medication administration that is detected and corrected through intervention (by another healthcare provider or patient)

Occurs before the patient receives medication

Adverse Drug *Reaction* (ADR):
Unwanted or *harmful side effect* experienced following the administration of a drug or combination of drugs

Suspected to be related to the drug at normal doses

Adverse Drug *Event* (ADE):
Harm experienced by a patient as a result of exposure to a medication

-Agency for Healthcare Research and Quality (AHRQ) and Patient Safety Network (PSNet™) https://ahrq/psnet.gov
-National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP™) https://www.nccmerp.org/

41

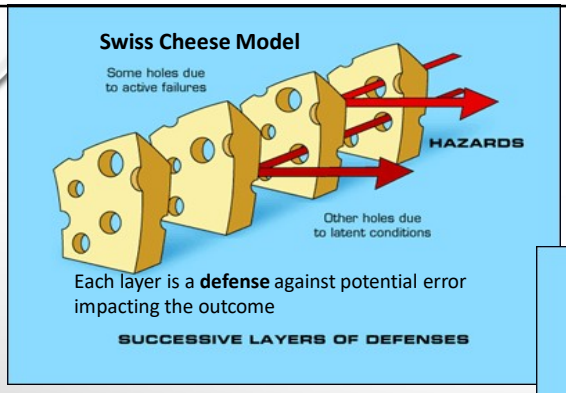
MEDICATION RELATED **ERROR**

HUMAN ERROR

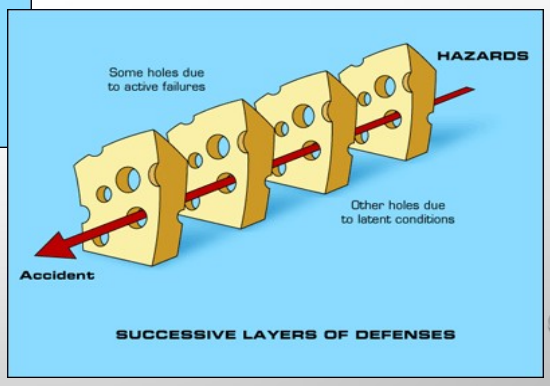
"WE CANNOT CHANGE THE HUMAN CONDITION, BUT WE CAN CHANGE THE CONDITIONS UNDER WHICH HUMANS WORK."

JAMES REASON, *PH.D. (PROFESSOR OF PSYCHOLOGY)*
UNIVERSITY OF MANCHESTER, UK

42



For a catastrophic error to occur, the holes need to align for each step in the process allowing all defenses to be defeated



Reason's "Swiss Cheese Model" of system failure

Every step in a process has the potential for failure, to varying degrees

http://patientsafetyed.duhs.duke.edu/module_a/module_overview.html

43

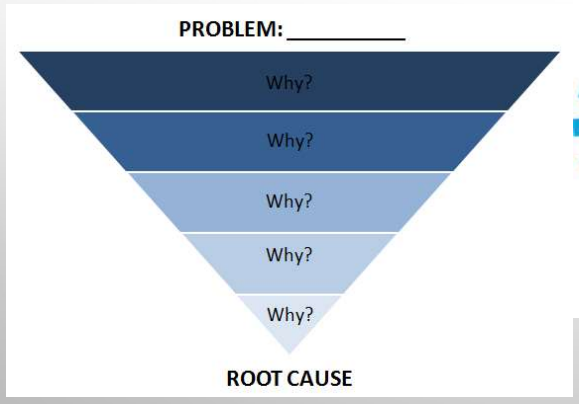
ERROR MITIGATION TOOLS

- Communicate
  - CQI meetings
  - In-services
- Plan for error
- Report
  - Document Event
  - Internal QRE

44

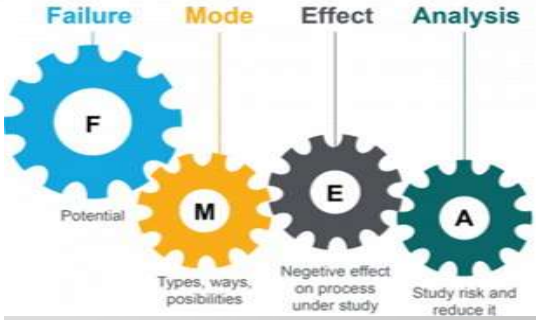
PROBLEM-SOLVING TOOLS

ROOT CAUSE ANALYSIS



https://ox-journey.com/2016/09/the-5-whys-getting-to-root-of-matter.html

FMEA



https://news.gminternational.com/risk-analysis-fmea-failure-mode-effect-analysis

45

RCA: Root Cause Analysis *Reactive*

erroralert

Root causes: A roadmap to action

INSTITUTE FOR SAFE MEDICATION PRACTICES

Errors are almost never caused by the failure of a single element in the system. More often, multiple underlying system failures lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Multiple system failures

Partial patient identifies. This story begins with a handwritten order for carbamazepine 400 mg twice daily for an adult patient with a history of seizures. After receiving the order, a pharmacist retrieved the patient profile by typing the last name only and subsequently entered the medication into the profile of a 4-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

Computer system weaknesses. During order entry, the pharmacist did not recognize that the dose of carbamazepine represented an overdose based on the child's weight. In fact, he failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. As a rule, patients' diagnoses and comorbid conditions were not listed on the pharmacy profiles, so the pharmacist was unable to match the prescribed medication to the child's medical condition. Likewise, the pharmacy computer did not require entry of a weight for pediatric patients. Nevertheless, even if a weight had been entered, there were no functional dose alerts in the system.

Adult dose/dosage form for a child. The next morning, a nurse gave the child the first erroneous 400-mg dose of carbamazepine. She failed to recognize that the dose was too high for a child. She also never questioned why the pharmacy had sent oral tablets for a 4-year-old child considering that the drug is available in chewable tablets and as a liquid suspension.

Unverified patient history. The nurse who administered the first dose assumed that the child was receiving the medication because he had a history of seizures. But the nurse did not verify this assumption by checking the patient's medical record. In fact, the child did not have a history of seizures.

Language barrier. The child's parents were present when one of the erroneous doses was administered to their child. The nurse attempted to tell the parents that the medication was used to control seizures. However, the parents (and child) had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At that point, one of the nurses suspected a problem with the carbamazepine dose and contacted the physician, who stated that the medication had never been prescribed for the patient. At the time of discovery, the child's carbamazepine level was 18 mcg/mL (levels greater than 12 in pediatric patients are supratherapeutic).[1]

Analyzing the error

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root-cause analysis will uncover the latent failures and produce an action plan to avoid future errors.

The Institute for Safe Medication Practices (ISMP), through a generous grant from the National Association of Boards of Pharmacy (NABP) Foundation, has developed the *Root Cause Analysis (RCA) Workbook for Community/Ambulatory Pharmacy*. The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of sentinel events. The goal is to create an action plan framework that includes risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for sentinel events is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, APhA, and American Society of Health-System Pharmacists, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-service pharmacy, or other ambulatory pharmacy practice settings that need to investigate a sentinel event. For more information and to access the workbook, go to www.ismp.org/tools/rca/.

Reference

1. http://pediatrics.aappublications.org/content/113/2/406.abstract

Institute for Safe Medication Practices, Horsham, PA

Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program (MERP) at www.ismp.org/MERP or ismp.org, or 800-FAIL-SAFE (800-324-5723) to activate an alert that reaches manufacturers, the medical community, and FDA. Your information may also be published anonymously to alert your professional colleagues.

70 PharmacyToday • MAY 2014

www.pharmacytoday.org

A thorough **root-cause analysis** will uncover the latent **failures** and produce an **action plan** to **avoid future errors.**

https://pharmacist.com/Publications/Pharmacy-Today/Archives

46

RCA: WHAT IS A ROOT CAUSE ANALYSIS?

PURPOSE

IDENTIFY SYSTEM VULNERABILITIES AND THE CRITICAL UNDERLYING REASONS FOR **QRE**

- OCCURRENCE
- ADVERSE EVENTS
- NEAR MISSES

GOAL

REDUCE/PREVENT HARM TO PATIENTS

https://www.courtemanche-assocs.com/root-cause-analysis/

47

Conducting a Root Cause Analysis

1. Form a team (stakeholders)
2. Determine the events/Identify breaches of duty
3. Diagram the event
4. Identify the root cause
5. Develop action plan
6. Establish measurable items

48

RCA TEAM

- MULTI-DISCIPLINARY
- INQUISITIVE NATURE
- KNOWLEDGEABLE
- DETAIL-ORIENTED
- OBJECTIVE
- STRONG LISTENING SKILLS
- CULTIVATES COOPERATION
- DIVERSE PERSPECTIVE
- PRODUCTIVE
- LOYALTY TO THE ORGANIZATION
- EFFECTIVE COMMUNICATION

https://www.hubgets.com/blog/teamwork-matters-business-success/

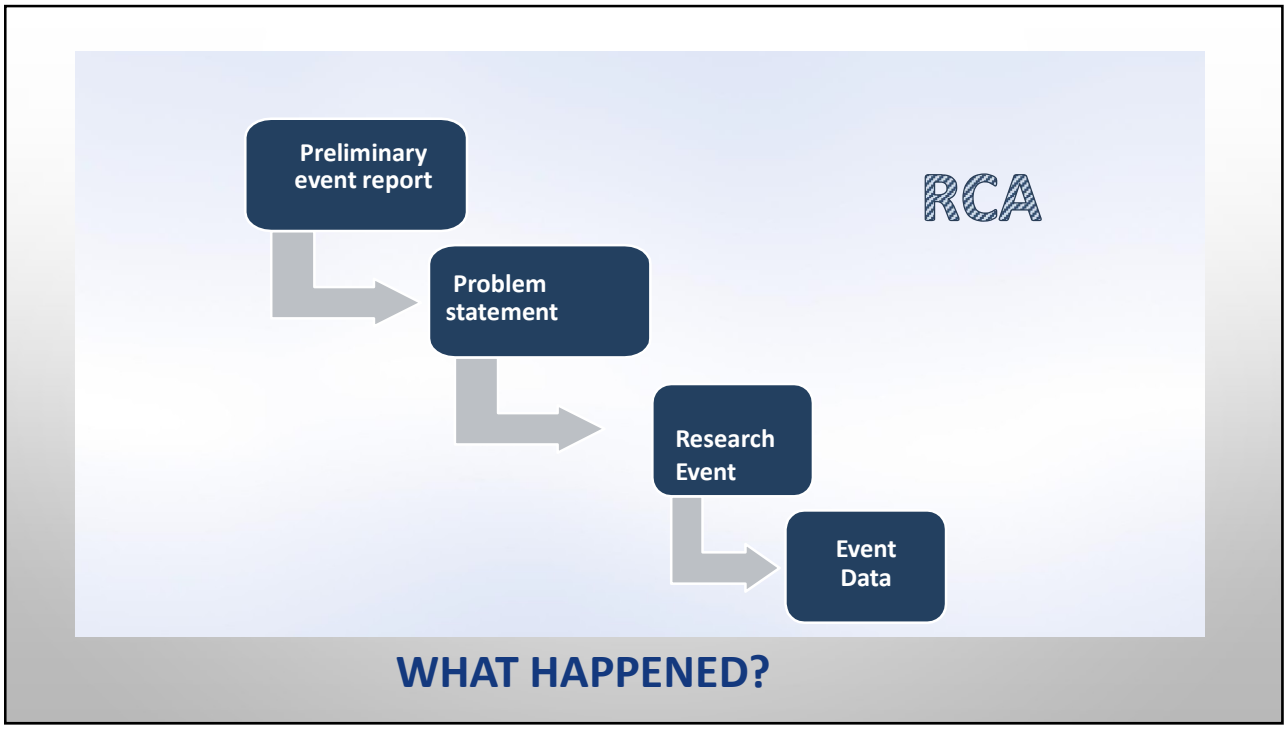
49

RCA MEETING

- BEGIN THE MEETING BY INTRODUCING NEW COLLEAGUES OR TEAM MEMBERS BE UNFAMILIAR WITH EACH OTHER
- REMIND THE TEAM OF THE IMPORTANCE OF USING APPROPRIATE VERBIAGE (E.G., “IT APPEARS”, “POTENTIALLY”, “FROM MY REVIEW”)
- ENCOURAGE COMMENTS AND QUESTIONS TO BE DIRECTED TO THE ENTIRE TEAM
- ESTABLISH GOALS FOR THE MEETING (E.G., IDENTIFY ROOT, CLEAR UP DISCREPANCIES, IMPROVE COMMUNICATION)
- CREATE AN ACTION PLAN

Cohen MR, ed. Medication errors. 2nd ed. Washington, DC: American Pharmaceutical Association; 2007.
https://psnet.ahrq.gov/issue/medication-errors-2nd-ed

50



51

"5 WHYS"

↓

ACTION PLAN

- **WHY 5 "WHYS"?**
  - FOSTERS THE DEEP DIVE FOR ANSWERS
  - ESSENTIAL FOR EFFECTIVE RCA
- ***WHY* DID EVENT HAPPEN?**
  - *WHERE* DID IT HAPPEN?
  - *WHEN* DID IT HAPPEN?
  - *WHAT* CHANGES IN PROCESS WILL PREVENT REOCCURRENCE?

52

PLAN-DO-CHECK-ACT

Reactive

RCA → WHY → **ACTION**

53

PROACTIVE

https://www.linkedin.com/pulse/fmea-effective-approach-risk-management-shreya-dasgupta

54

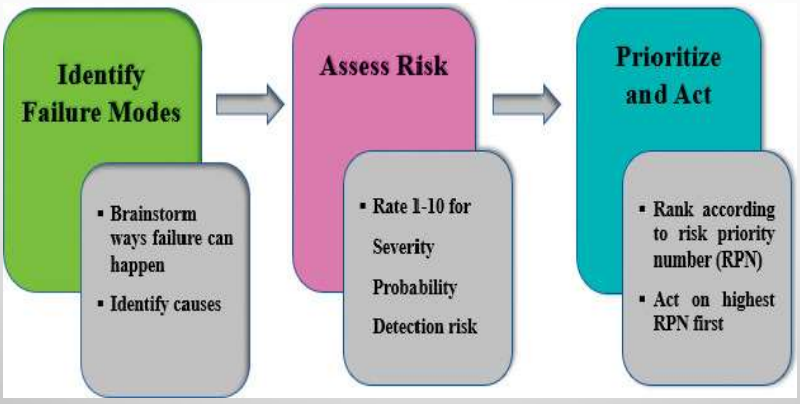
FAILURE MODE EFFECTS ANALYSIS

- **FMEA**
- Purpose: identify system failures of high-risk processes before they occur
- Proactive
- Team-based
- Structured

https://doi.org/10.1186%2Fs12889-021-11369-5

55

FMEA



Serious complex processes priority!

https://pubmed.ncbi.nlm.nih.gov/37260856/

56

FMEA Action Plan

Medication Errors Prevention

ACTION PLAN LEADS TO SOLUTIONS

FMEA requires process analysis that may lead to changes

Unique for each risk

Often initiated by documented "Good Catch"

57

ASSESSMENT

***QRE** IS OFTEN PREVENTABLE IF THE PROCESS MANAGEMENT IS REVIEWED AND AN ACTION PLAN FOR CHANGE IS ENACTED*

WHICH STATEMENT(S) ARE ACCURATE IN PREVENTING A **QRE**?

A) AFTER A QRE, THE MANAGER SHOULD EVALUATE AND DESIGNATE THE **ROOT CAUSE**

B) ONLY PHARMACISTS ON THE **RCA** TEAM SHOULD FORMULATE AN ACTION PLAN

C) EACH MEMBER OF THE PHARMACY TEAM INVOLVED IN ERROR-PRONE PROCESSES SHOULD BE INVITED TO PARTICIPATE IN **FMEA**

D) ***LESS*** COMPLEX ERROR-PRONE PROCESSES SHOULD BE THE FIRST **FMEA** THE PHARMACY CONDUCTS

58

ASSESSMENT

QRE ARE OFTEN PREVENTABLE IF THE PROCESS MANAGEMENT IS REVIEWED AND AN ACTION PLAN FOR CHANGE IS ENACTED.

WHICH STATEMENT(S) ARE ACCURATE IN PREVENTING A QRE?

A) AFTER A QRE, THE MANAGER SHOULD EVALUATE AND DESIGNATE THE ROOT CAUSE

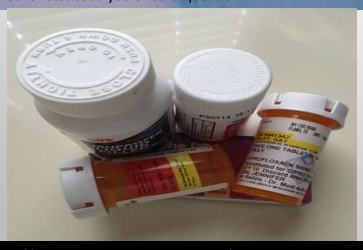
B) THE RCA TEAM SHOULD ONLY BE THE PHARMACISTS WHEN FORMULATING AN ACTION PLAN.

C) EACH MEMBER OF THE PHARMACY TEAM INVOLVED IN ERROR-PRONE PROCESSES SHOULD BE INVITED TO PARTICIPATE IN FMEA.

D) LESS COMPLEX ERROR-PRONE PROCESSES SHOULD BE THE FIRST FMEA THE PHARMACY CONDUCTS

59

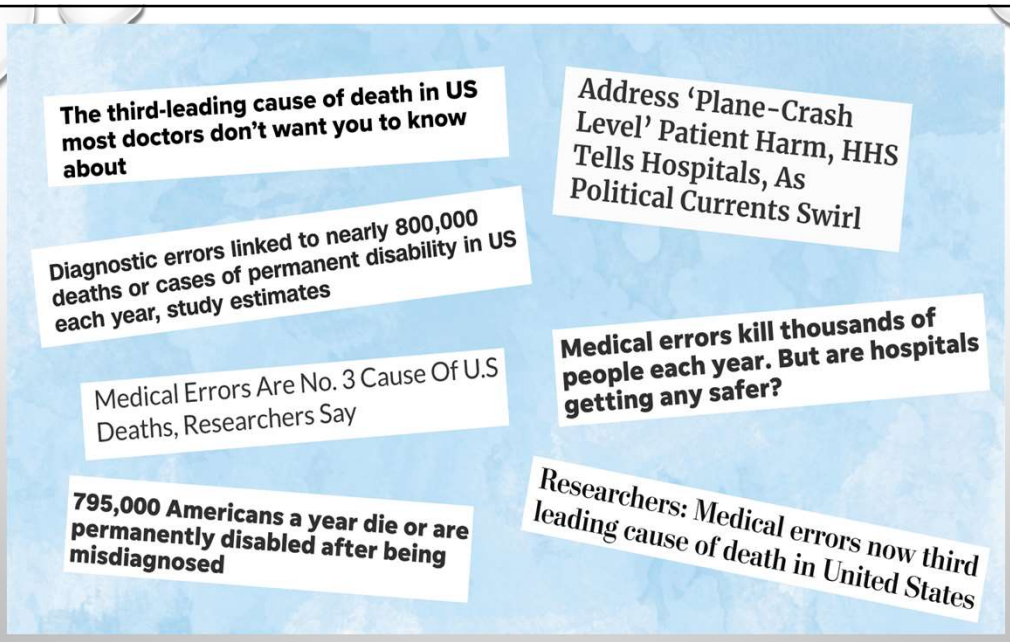
https://healthjournalism.org/blog/2023/07/medical-errors-are-the-third-leading-cause-of-death-and-other-statistics-you-should-question



https://www.netnutritionist.com/medication-heal-or-harm/

Jaime-Swint-Q-A-Prescription-Medication

60



https://healthjournalism.org/blog/2023/07/medical-errors-are-the-third-leading-cause-of-death-and-other-statistics-you-should-question/

61

CASE STUDY
EXTERNAL
QUALITY RELATED EVENT

- Concentrated potassium chloride was administered IV push to a patient during a cardiac arrest (code)
- **Potassium chloride vials were only stocked in the pharmacy, not on patient care units**
- Restricted access is the effective safeguard to prevent IV administration of concentrated potassium chloride

62

CONCENTRATED INJECTION

https://www.pfizerhospitalus.com/products/potassium-chloride-injection

The event happened when a clinical pharmacist called the central pharmacy to *ask staff to bring a vial of concentrated potassium chloride* to a code he was attending

Through a series of *miscommunications* and incorrect *assumptions*, the drug was administered undiluted to the patient.

63

CONCENTRATED POTASSIUM CHLORIDE

70-year-old intensive care unit (ICU) patient in isolation with a contagious infectious disease (not COVID) experienced a cardiac arrest

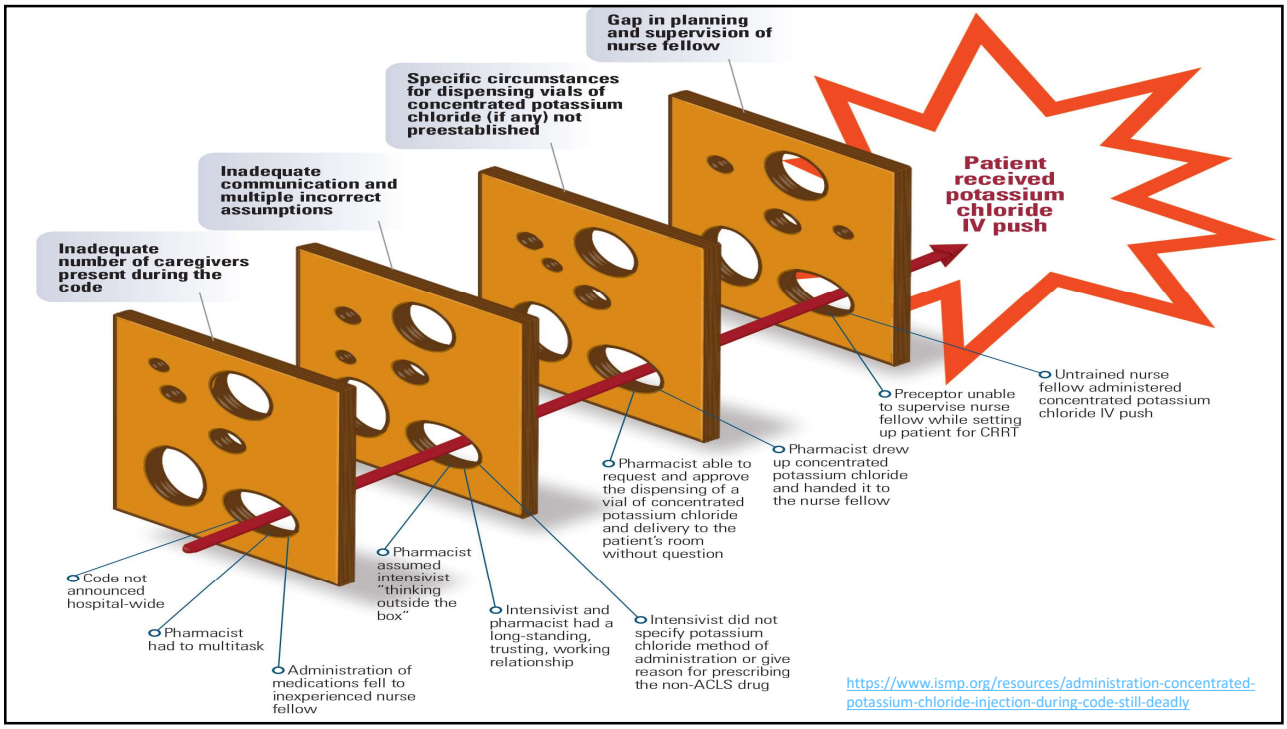
To prevent staff exposure to the infectious disease, the code was not announced hospital-wide but only in the ICU

Small code team—an experienced ICU intensivist, an experienced ICU pharmacist, and a nurse fellow and his preceptor (an experienced ICU nurse)

ICU intensivist verbally requested "potassium chloride 20 mEq IV." The pharmacist, preparing the requested medications, *assumed* the intensivist did not want to administer an infusion, (1 hour administration time)

Agency for Healthcare Research and Quality. https://psnet.ahrq.gov/issue/administration-concentrated-potassium-chloride-injection-during-code-still-deadly

64



65

RCA

ROOT CAUSE 1:

AN INADEQUATE NUMBER OF CAREGIVERS WERE PRESENT DURING THE CODE BECAUSE THE CODE WAS NOT ANNOUNCED HOSPITAL-WIDE DUE TO INFECTION CONTROL CONCERNS

ROOT CAUSE 2:

A LACK OF COMMUNICATION AMONG THE CODE TEAM LED TO THE IV PUSH ADMINISTRATION OF THE CONCENTRATED POTASSIUM CHLORIDE

ROOT CAUSE 3:

PHARMACY **DID NOT ESTABLISH CRITERIA** FOR DISPENSING CONCENTRATED POTASSIUM TO A PATIENT CARE UNIT

Administration of Concentrated Potassium Chloride for Injection During a Code: Still Deadly! | Institute For Safe Medication Practices (ismp.org)
https://www.ismp.org/nursing/medication-safety-alert-july-2021

66

RCA

ROOT CAUSE 4:

GAP IN TRAINING AND SUPERVISION
LED THE NURSE-FELLOW TO PRACTICE BEYOND SCOPE

ROOT CAUSE 5:

LACK OF STANDARDIZATION:
OVERHEAD ANNOUNCEMENT FOR ALL CODES TO ASSURE EXPERTS ATTEND

Committee to develop an Action Plan

Administration of Concentrated Potassium Chloride for Injection During a Code: Still Deadly! | Institute For Safe Medication Practices (ismp.org)
https://www.ismp.org/nursing/medication-safety-alert-july-2021

67

RCA
Action Plan

POTASSIUM CHLORIDE SAFEGUARDS

- DISPENSE VIALS PER ESTABLISHED CRITERIA
- IMPLEMENT A PLAN FOR DILUTE PRE-MIX POTASSIUM CHLORIDE SOLUTIONS ACCESSIBLE IN A CODE
- DO NOT TAKE INJECTABLE POTASSIUM CHLORIDE SAFETY FOR GRANTED, EVEN AFTER YEARS OF NO REPORTED EVENTS
- CLEARLY DESCRIBE SPECIFIC CIRCUMSTANCES WHEN CONCENTRATED POTASSIUM CHLORIDE VIALS MAY BE DISPENSED FROM THE PHARMACY
- ESTABLISH SAFEGUARDS FOR SPECIAL CIRCUMSTANCES TO AVOID ERRORS

68

FMEA

PROACTIVE

Risk determination: Same Active questions as in RCA but before an occurrence

Assemble team

Analyze the process

Intensivist-MD, Pharmacist, ICU-Nurse, Nursing assistant, ICU-manager

Brainstorm to identify and predict potential failures

Identify the priority: safe access to high-risk drugs

Implement changes: Action Plan

69

FMEA

PROACTIVE

- **HIGH RISK IDENTIFIED**: DRUG ACCESS FOR EMERGENCIES
- **IDENTIFY** POTENTIAL LAPSE THAT COULD CAUSE AN EVENT
  - STAFFING DURING AN UNPLANNED EVENT (CODE)
  - POINT OF CARE: LEVEL OF TRAINING ADDRESSED
  - COMMUNICATION STRATEGY DURING A CODE
  - DRUG PRODUCT ACCESS DEFINED
  - CONSIDER ALTERNATIVES WITH LESS RISK

Serious complex processes priority!

70

FMEA Action Plan: Education
Reducing Medication Errors: Injectable Drugs

1.Pharmacy should dispense ready-to-administer or ready-to-use injectable products in labeled syringes as prescribed for individual patients

2.Commercially available, prefilled syringes of medications that are already labeled should be used when possible

3.Commercially available labels for syringes should be provided and should be routinely restocked in all drug-preparation areas (e.g., ICU, radiology, nuclear medicine).

4.Nurses should be offered the opportunity to assess several label formats and to select one standard format that best meets their needs. Tape is not suitable for labeling syringes

71

FMEA Education
Reducing Medication Errors: Injectable Drugs

5. Guidelines should be established for placing the labels on the syringes. Specific directions should be included on how to avoid obstructing the view of gradations on the syringe barrel, contents and functionality

6. Pre-mixed IV Solutions or Syringes preferred in certain clinical areas. (ICU)

7. Staff should not assume that they know what is contained in an unlabeled syringe. All unlabeled syringes should be discarded immediately as a hazardous condition. LABELED Pre-mixed IV or Syringe preferred

8. The staff should reinforce and monitor compliance and should institute a policy mandating that all syringes containing injectable medications be properly labeled.

9. Concentrated high-risk drugs should be restricted but accessible in a premixed labeled dilution, E.g. Infusion bag or syringe.

72

STANDARD OF CARE IN PHARMACY

- CORRECT PATIENT
- ALLERGIES EVALUATED
- CORRECT DRUG
- CORRECT DOSE
- CORRECT ROUTE
- CORRECT TIME

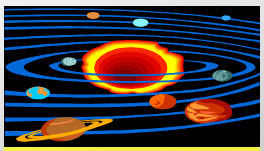
- DRUG FOOD ANALYSIS
- MOST APPROPRIATE DRUG FOR DIAGNOSIS
  - SOLVES PROBLEM
  - NO ADVERSE EVENT
  - ACCESSIBLE

73

WHAT DO OTHER HEALTH CARE PROVIDERS RECOGNIZE AS THE OUTCOME MEASURE RELATED TO PHARMACY?

MEASURE NEGLIGENCE THROUGH PATIENT CARE OUTCOMES

ERROR FREE PERFORMANCE



System-wide view

74

UNDERSTANDING ERRORS

ERROR

FAILURE OF A PLANNED SEQUENCE OF MENTAL OR PHYSICAL ACTIVITIES TO ACHIEVE ITS INTENDED <u>OUTCOME</u>

OR

MISTAKE

(QRE*) THAT REACHES A PATIENT

**Quality related event*

75

SLIPS, LAPSES, MISTAKES, VIOLATIONS

- *SLIPS* →ERRORS OF *COMMISSION* WITHOUT INTENT
- *LAPSES* → ERRORS OF *OMISSION* WITHOUT INTENT
- *MISTAKES* →ERRORS OF <u>BOTH</u> TYPES WITHOUT MALICIOUS INTENT
- VIOLATIONS→ ERRORS WITH INTENT

76

ALL HUMAN ERRORS ARE NOT EQUAL!

SLIPS ARE OBSERVABLE
REACHED FOR WRONG DRUG BECAUSE OF LABELING

LAPSES ARE NOT OBSERVABLE
COULDN'T REMEMBER WHICH DRUG TO PICK

Mistakes
Actions that proceed *as planned* but fail to achieve its intended outcome because the action was incorrect

Slips
Lapses
Mistakes

77

https://www.pharmacypracticenews.com/aimages/2023/PPN0523_008a_10040_600.jpg

78

EFFECTIVE MEDICATION ERROR RISK MANAGEMENT

HUMAN ERROR PREVENTION

PROACTIVE ACTIONS MANAGED THROUGH:

- PROCESS AND PROCEDURE CHANGES
- EDUCATION
- DESIGN
- ENVIRONMENT

AVOID behavioral choices that increases risk where risk is not recognized, or is mistakenly believed to be justified

79

HUMAN ERROR

- **HUMAN ERROR**
  - WHAT TO DO
  - HOW TO MEASURE IT
  - ERROR RATE
  - NEVER THE "ROOT CAUSE"
- TOOLS
  - PREDICTION OF FAILURE (FMEA)
  - ROOT CAUSE ANALYSIS (REACTIVE)
- TRENDING AND TRACKING
  - OUTCOMES METRICS
  - KEY PERFORMANCE INDICATORS
  - OVERALL EQUIPMENT EFFECTIVENESS
  - SYSTEMATIC PROCESS

80

HUMAN ERROR

HUMAN FACTORS ENGINEERING

- FOCUSES ON HOW SYSTEMS WORK IN ACTUAL PRACTICE WITH FALLIBLE HUMAN BEINGS IN CONTROL
- HUMANS ATTEMPT TO DESIGN SYSTEMS THAT OPTIMIZE SAFETY AND MINIMIZE THE RISK OF ERROR IN COMPLEX ENVIRONMENTS

https://psnet.ahrq.gov/primer/human-factors-engineering#Applications-of-Human-Factors-Engineering-to-Improving-Safety

81

HUMAN ERROR

HUMAN FACTORS ENGINEERING

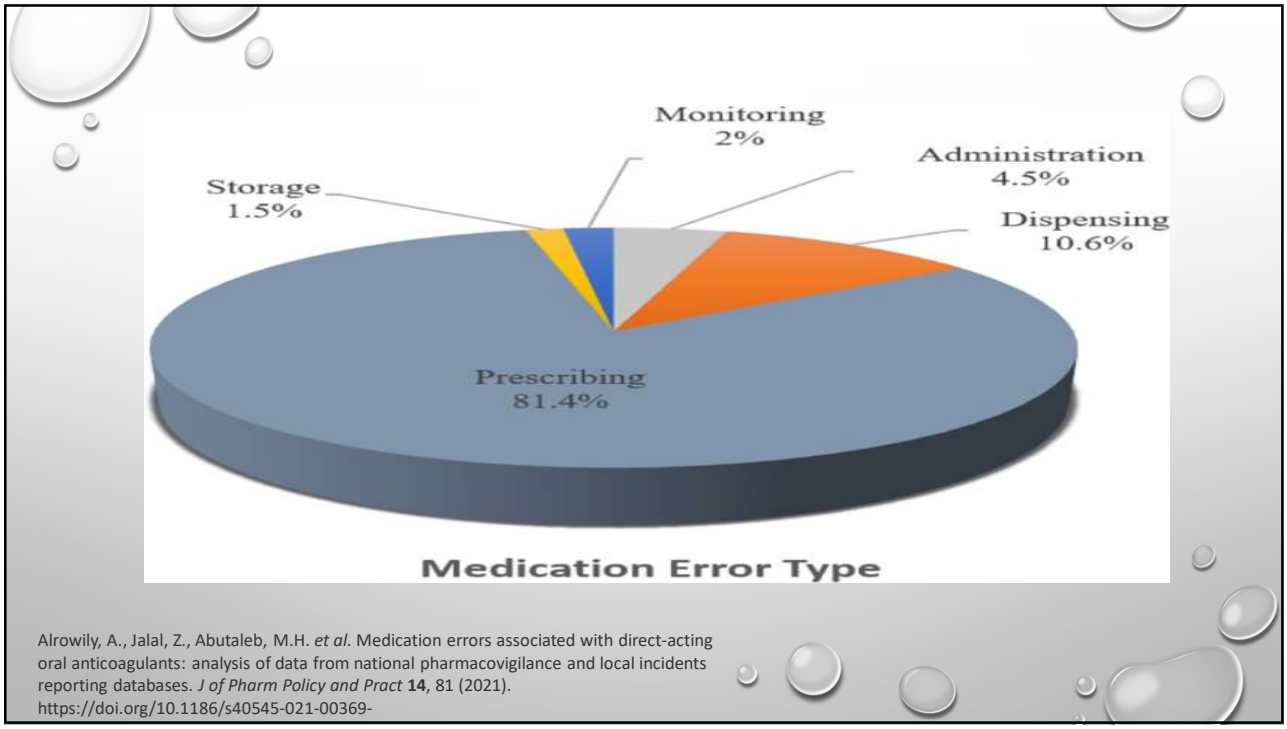
- *USABILITY TESTING:* TEST NEW SYSTEMS AND EQUIPMENT UNDER REAL-WORLD CONDITION
- *FORCING FUNCTIONS:* DESIGN THAT PREVENTS AN UNINTENDED ACTIONS FROM BEING PERFORMED
- ALLOWS DESIGN ONLY IF ANOTHER "PROTECTIVE" ACTION IS PERFORMED FIRST

https://psnet.ahrq.gov/primer/human-factors-engineering#Applications-of-Human-Factors-Engineering-to-Improving-Safety

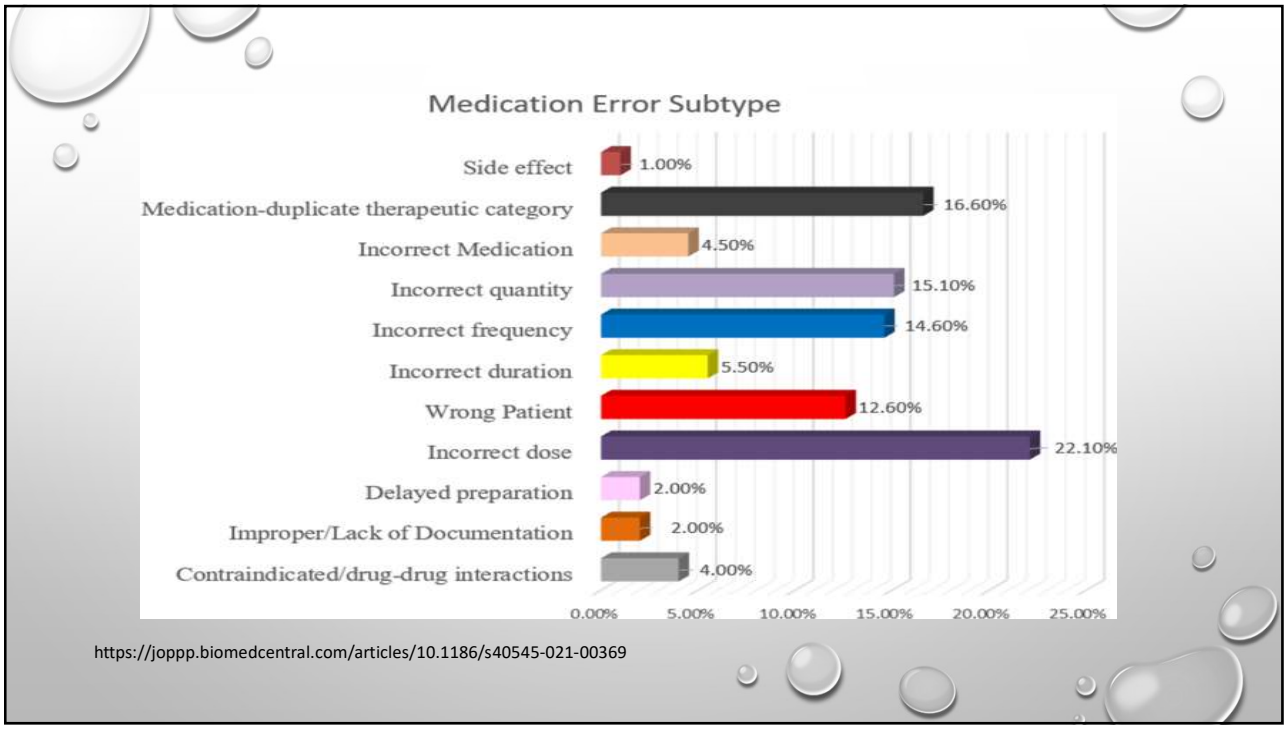
82


5
R
The right patient
The right drug
The right dose
The right route of administration
The right time
MEDICATION SAFETY
5 RIGHTS
https://www.swisslog-healthcare.com/en-sg/company/blog/5-rights-of-medication

83


Monitoring
2%
Administration
4.5%
Storage
1.5%
Dispensing
10.6%
Prescribing
81.4%
Medication Error Type
Alrowily, A., Jalal, Z., Abutaleb, M.H. *et al.* Medication errors associated with direct-acting oral anticoagulants: analysis of data from national pharmacovigilance and local incidents reporting databases. *J of Pharm Policy and Pract* **14**, 81 (2021). https://doi.org/10.1186/s40545-021-00369-

84



https://joppp.biomedcentral.com/articles/10.1186/s40545-021-00369

85

86

Often prescribed

https://www.psqh.com/analysis/look-alike-drug-name-errors/

Courtesy of ISMP

87

MEDICATION DISPENSING ERROR

PRESCRIPTION ORDER TRANSMITTED FOR

HYDROXYZINE HCL 10 MG, #24

DIRECTIONS: ONE (1) TABLET EVERY 4 TO 6 HOURS AS NEEDED FOR ITCH. NO REFILL

PRESCRIPTION DISPENSED AND LABELED

HYDRALAZINE HCL 50 MG #24

LOOK ALIKE SOUND ALIKE

- SECOND OCCURRENCE IN THREE MONTHS FOR THIS LOOK-ALIKE DRUG NAME PAIR
- WHY?
- *ROOT CAUSE ANALYSIS* COMPLETED
  - AFTER THE PREVIOUS ERROR: PHARMACY ADDED SHELF LABEL ON EACH PRODUCT LOCATION

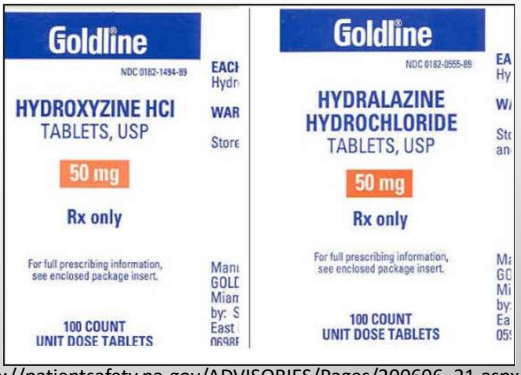
88

Slips
Lapses
Mistakes

DISPENSING ERROR

DISPENSED THE WRONG DRUG BUT BELIEVED 2 DIFFERENT DRUGS WERE THE <u>SAME</u> MEDICATION

- **LACK OF KNOWLEDGE**
- **LACK OF SAFEGUARDS**
- **ASSESSED INCORRECTLY**
- **DISPENSING ERROR**

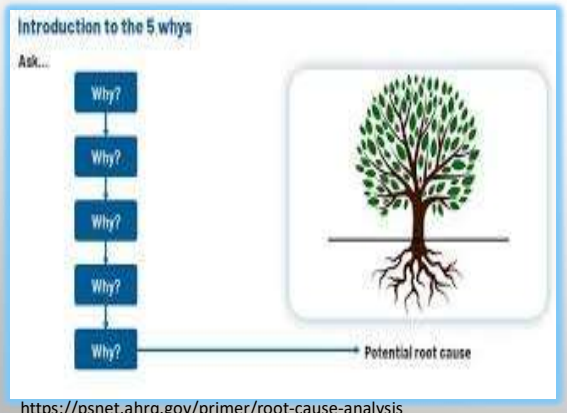


http://patientsafety.pa.gov/ADVISORIES/Pages/200606_21.aspx

89

ROOT CAUSE FAILURE!

TEAM DID <u>NOT</u> PERFORM THE **<u>5 WHYS</u>**



https://psnet.ahrq.gov/primer/root-cause-analysis

PHARMACY TECHNICIAN OBSERVATION:

- SHELF CONFIGURATION 4 X 3' SECTIONS INSTEAD OF 12' ACROSS. LINE OF VISION IMPAIRED!
- BOTH PRODUCTS SAME MANUFACTURER
  - SAME COLOR LABEL
  - SAME FONT
  - TALLMAN LETTERING ALONE INEFFECTIVE

90

UPDATED ACTION PLAN

- CONFIGURE PHARMACY SHELVES ACROSS DEPARTMENT TO 12' DIMENSIONS
- ADD "SHELF-TALKER" WITH ALERT: "LOOK ALIKE PRODUCTS"
- PROVIDE STAFF EDUCATION ON TALLMAN LETTERING
- FEEDBACK TO MANUFACTURER REGARDING STRENGTH NOTATION ON LABEL

HydrALAzine vs HydrOXYzine

https://www.pharmacypracticenews.com/PrintArticle/70253

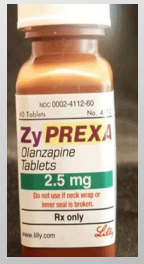
91

SUMMARY: DESIGN FOR SAFETY

Design patient care processes to **prevent error**

- **Automate** when appropriate – include use of forcing functions
  Implement TALLman LeTTERing for "look-alikes"
- **Standardize** – reduce reliance on memory
- **Reduce** the number of steps and handoffs (*workflow)*
- Add **redundancy** (double checks) for high risk processes
  (E.g. *every warfarin order dispensed is rechecked*)

http://patientsafetyed.duhs.duke.edu/module_e/basic_safety.html



92

REFERENCES

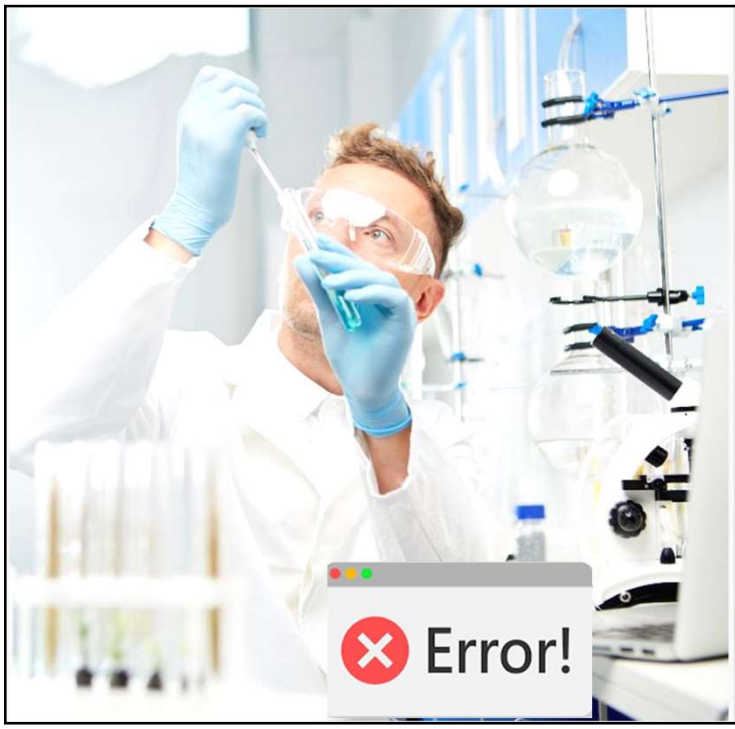
- FL Statutes, Current through Reg. 49, No. 153; August 8, 2023. "Fla. Admin. Code Ann. R. 64B16-27.300" Fla. Admin. Code R. 64B16-27.300. https://www.flrules.org/gateway/ruleno.asp?id=64B16-27.300 Accessed 5/18/24
- O'Donnell B, Gupta V. *Continuous Quality Improvement*. [Updated 2023 Apr 3]. In: StatPearls. Treasure Island (FL): StatPearls Publishing; 2023 Jan. https://www.ncbi.nlm.nih.gov/books/NBK559239/. Accessed 5/29/24
- Patient Safety 101: Human Factors Engineering Applications to Improving Safety. Agency for Health Research and Quality 9/7/2019. https://psnet.ahrq.gov/primer/human-factors-engineering Accessed 5/29/24
- Nicolay CR, Purkayastha S, Greenhalgh A, Benn J, Chaturvedi S, Phillips N, Darzi A. *Systematic review of the application of quality improvement methodologies from the manufacturing industry to surgical healthcare*. Br J Surg. 2012 Mar;99(3):324-35. doi: 10.1002/bjs.7803. Epub 2011 Nov 18. PMID: 22101509. https://pubmed.ncbi.nlm.nih.gov/22101509/ Accessed 5/4/24
- Josie King Foundation Patient Safety Program. Johns Hopkins Hospital, Baltimore, MD https://josieking.org/programs/josie-king-patient-safety-program/ Accessed 5/11/24
- Emily Jerry Foundation, 23220 Chagrin Blvd., Suite 476, Beachwood, OH 44122 https://emilyjerryfoundation.org/ Accessed 5/11/24
- Patient Safety Action Network (PSAN). Mothers Against Medical Error, Helen Haskel, BA.,MA www.patientsafetyaction.org
- Isaac Yip. "Quality SIFU: Achieving Excellence Through Continuous Quality Improvement." © 2022 QUALITYSIFU https://qualitysifu.com/achieving-excellence-through-continuous-quality-improvement/ Accessed 5/11/24
- Julia Kahraman. *5 Rights of Medication- How to achieve the 5R rule using unit doses.* © Swisslog Healthcare 2023 https://www.swisslog-healthcare.com/en-sg/company/blog/5-rights-of-medication Accessed 5/18/24
- *Therapy Brands Ten Most Common Prescription Errors.* © 2024 Therapy Brands. https://therapybrands.com/blog/the-10-most-common-prescription-errors/ Accessed 5/28/24

93

REFERENCES

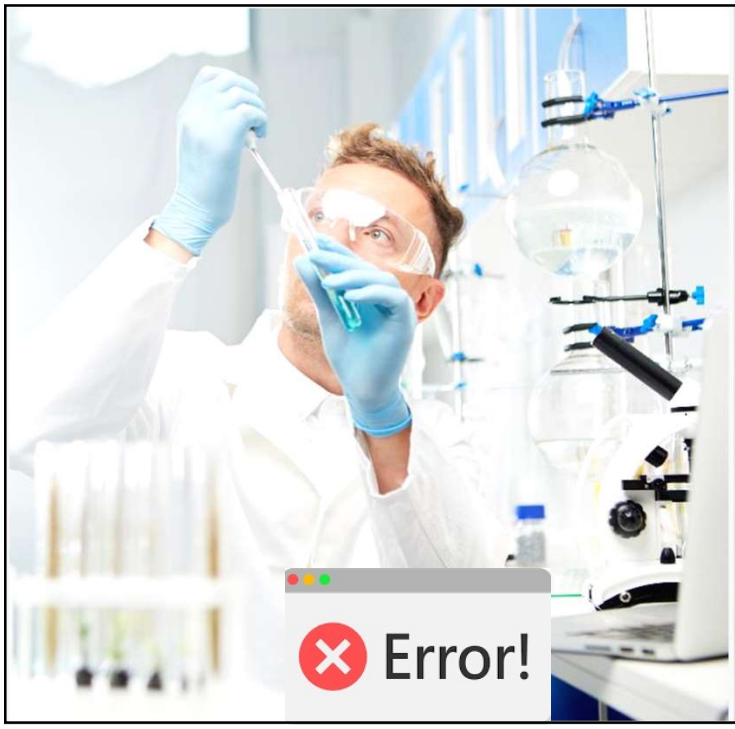
- Mamat R, Awang SA, Mohd Ariffin SA, Zakaria Z, Che Zam MH, Ab Rahman AF. *Knowledge and Attitude toward Medication Error among Pharmacists*. Hosp Pharm. 2021 Dec;56(6):765-771. doi: 10.1177/0018578720965414. Epub 2020 Oct 17. PMID: 34732936; PMCID: PMC8559048. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8559048/ Accessed 5/12/24
- The Deming Institute. PDSA Process. The W. Edwards Deming Institute® P.O. Box 309, Ketchum ID 83340. Tel: (206) 395-3084
- https://deming.org/explore/pdsa/ Accessed 5/11/24
  Horsham, PA; Institute for Safe Medication Practices: 2024. https://psnet.ahrq.gov/issue/ismps-list-high-alert-medications-acute-care-settings Accessed 5/8/24, 5/12/24.
- Tricia A. Meyer, PharmD, MS, FASHP; Russell K. McAllister, MD, FASA *Medication Errors Related to Look-Alike, Sound-Alike Drugs—How Big is the Problem and What Progress is Being Made?* https://www.apsf.org/article/medication-errors-related-to-look-alike-sound-alike-drugs-how-big-is-the-problem-and-what-progress-is-being-made Accessed 5/8/24
- Patricia Cook, BS. Pharm, RPh, HACP-CMS. *Root Cause Analysis – Does it Really Work?* August 2023 Newsletter. Accessed 5/8/24. Courtemanche & Associates Consulting Partners, Charlotte, NC. https://www.courtemanche-assocs.com/root-cause-analysis/
- Alice Calin. *Why Teamwork Matters to Business Success.* Published 8/1/2018. Hudgets.com Blog. Accessed 4/30/24 https://www.hubgets.com/blog/teamwork-matters-business-success/
- Anjalee JAL, Rutter V, Samaranayake NR. Application of failure mode and effects analysis (FMEA) to improve medication safety in the dispensing process - a study at a teaching hospital, Sri Lanka. BMC Public Health. 2021 Jul 20;21(1):1430. doi: 10.1186/s12889-021-11369-5. PMID: 34284737; PMCID: PMC8293514. https://doi.org/10.1186%2Fs12889-021-11369-5 Accessed 4/30/24.
- El-Awady SMM. Overview of Failure Mode and Effects Analysis (FMEA): A Patient Safety Tool. Glob J Qual Saf Healthc. 2023 Feb 23;6(1):24-26. doi: 10.36401/JQSH-23-X2.. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10229026/ Accessed 5/29/24
- Alrowily, A., Jalal, Z., Abutaleb, M.H. *et al.* Medication errors associated with direct-acting oral anticoagulants: analysis of data from national pharmacovigilance and local incidents reporting databases. *J of Pharm Policy and Pract* **14**, 81 (2021). Accessed 5/11/24. https://joppp.biomedcentral.com/articles/10.1186/s40545-021-00369-w

94



QUESTIONS?

95



NORMAN TOMAKA

FLRX9@AOL.COM

96