How Fatal Medication Errors in the USA Changed Our Practice:
Safety Strategies for "Never Again"

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OhioHealth Continuing Education

- Dan Sheridan has no relevant financial disclosures with regard to this presentation

- Lorrie Burns has no relevant financial disclosures with regard to this presentation

OhioHealth Continuing Education

- OhioHealth Pharmacy Services is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education

- This presentation is approved for 1 hour (0.1 CEUS) for pharmacists and technicians

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Activity Objectives

1. Define high-alert medications
2. Identify high-alert medications associated with patient harm and death
3. Discuss various risk mitigation strategies to improve the safe use of high-alert medications
4. Relate medication safety strategies employed by OhioHealth for these medications

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High-Alert Medications

- What exactly does that mean?

"High-Alert Medications are those that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are more devastating to patients"

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High-Alert Medications

- What medications are we talking about?

?

ISMP High-Alert Medications

- Adrenergic agonists
- Adrenergic antagonists
- Anesthetic agents
- Antiarrhythmic agents
- Antithrombotic agents
- Cardioplegic Solutions
- Chemotherapy agents
- Hypertonic Dextrose
- Dialysis Solutions
- Epidural/intrathecal meds

- Inotropic agents
- Insulin
- Liposomal forms of drugs
- Sedating agents
- Opioids
- Neuromuscular blocking agents
- Parenteral nutrition products
- Hypertonic sodium chloride
- Sterile water for irrigation
- Sulfonylurea hypoglycemics

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ISMP High-Alert Medications
2018 Medication Safety Self-Assessment

- Anticoagulants
- Chemotherapy agents
- Concentrated Electrolytes
- Insulin
- Lipid-based medications
- Neuraxials/Epidurals
- Neuromuscular Blockers
- Opioids
- Sedating agents

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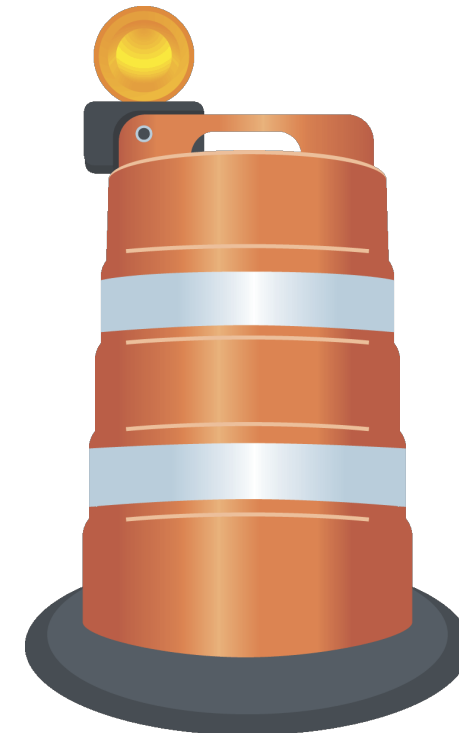
OhioHealth High Risk High Alert Medications Policy

- Anticoagulants
- Chemotherapy agents
- Insulin
- Neuromuscular Blockers
- Opioids
- Concentrated Electrolytes

POLICY and/or PROCEDURE

NUMBER: OH.POL.RX-910.022
EFFECTIVE: 5/17/2019

OhioHealth

TITLE: High Risk High Alert Medications
ISSUED: 9/19/2014
DEVELOPED BY: OhioHealth Medication Safety Committee
REVIEWED BY:
OhioHealth Pharmacy & Therapeutics Committee
Hospital Pharmacy & Therapeutics Committees
Hospital Medical Executive Committees
APPROVED BY: Quality Management Council

DATE:
April 2019
April 2019
May 2019

OhioHealth High Risk High Alert Medications Policy

- Error Prevention Strategies are described

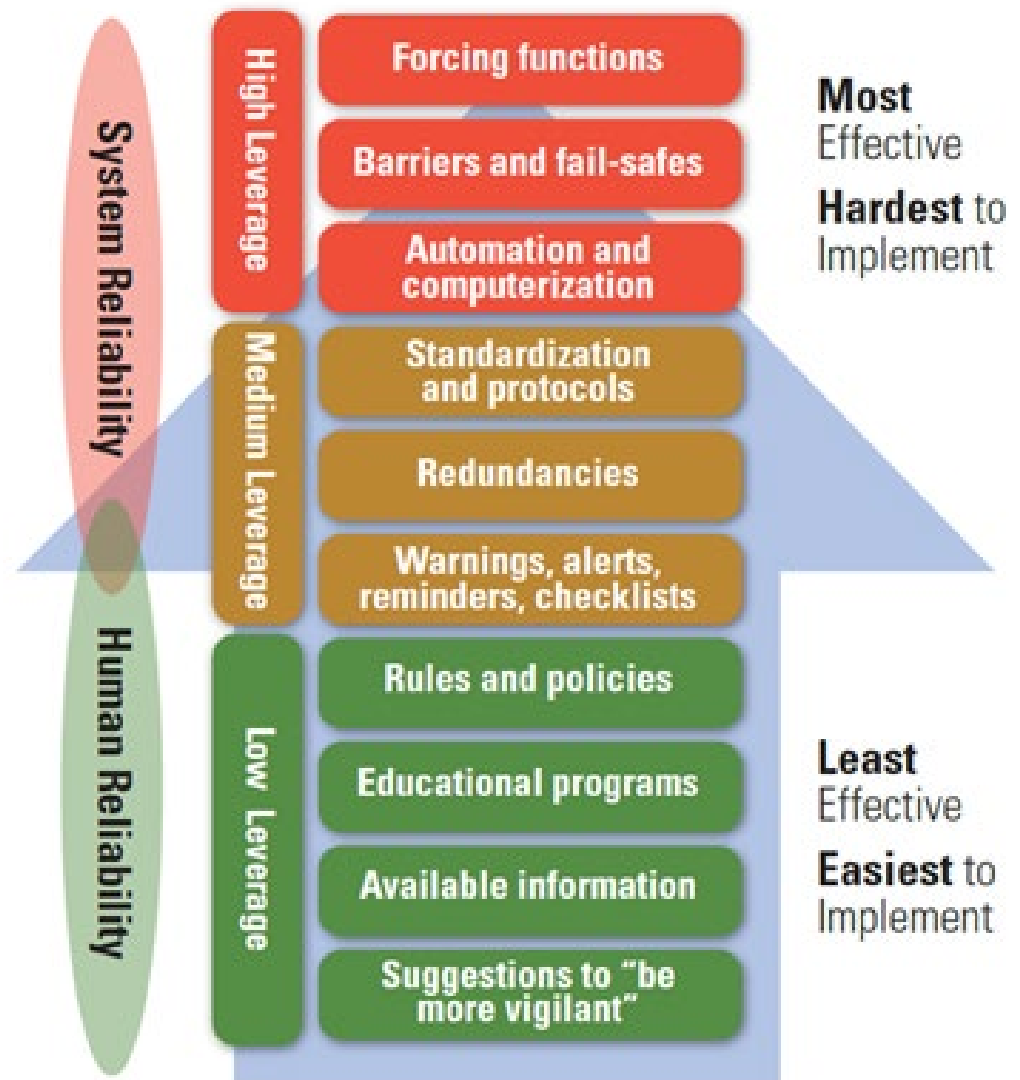| Generic & Proprietary Names | Stage of Medication-Use Process | | | | | Error Prevention Strategy |
	Prescribing	Transcribing	Preparation/Dispensing	Administration	Monitoring	
Chemotherapeutic Agents						
All Oral and Pareteral Chemotherapuetic Agents			X			Chemotherapeutic agents will only be dispensed from the Pharmacy Department.
		X				Steps are taken to round doses to match commercially available strengths/concentrations when calculating dose requirements, whenever possible.
			X			All chemotherapy (oral and parenteral) is dispensed with auxiliary labeling (e.g., "Chemotherapy") so that it is easily identified and understood as being cytotoxic.
			X			Chemotherapeutic agents stored in the Pharmacy Department will be segregated from other medications and/or feature distinctive labeling.
	X					Pharmacist independent double checks/dual verification are used for order entry of all Chemotherapeutic agents prescribed for cancerous conditions.
		X				When an order for a weight-based Chemotherapeutic agent is received and the patient has a reported weight greater than 110 kilograms, the reviewing pharmacist will verify the accuracy of the reported weight.

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Error Prevention Strategies

- Design method to improve safety of medication systems as well as interface healthcare professionals

- More positive impact on safety if change to system, weaker impact if depending on human memory or vigilance

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ISMP Error Reduction Strategies

- High-level strategies are most effective; they "design out" hazards – but difficult to implement!

- Medium-level strategies – easier to implement, reduce errors and harm but will need updating and reinforcement from time to time

- Low-level strategies – easier and quicker to implement BUT are the least likely to reduce errors and harm

System Reliability

Human Reliability

High Leverage
- Forcing functions
- Barriers and fail-safes
- Automation and computerization

Medium Leverage
- Standardization and protocols
- Redundancies
- Warnings, alerts, reminders, checklists

Low Leverage
- Rules and policies
- Educational programs
- Available information
- Suggestions to "be more vigilant"

Most Effective
Hardest to Implement

Least Effective
Easiest to Implement

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Institute for Safe Medication Practices. ISMP Medication Safety Safety Alert! Education is "predicably disappointing" and should never be relied upon alone to improve safety. June 4, 2020.

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ISMP Error Reduction Strategies

- Fail Safes/Constraints
  - Prevent malfunction
  - Limit access to make it more difficult to err
- Forcing Functions
  - Prevent something from happening
- Automation and Computerization
  - Reduce reliance on memory

- Standardization
  - Uniform model for care
- Redundancies
  - Duplicate steps or checks
- Warnings, Reminders and Checklists
  - Important info readily available
- Rules and Policies
  - Provide guidance and structure
- Education and Information
  - Important – but need to be used with other strategies!

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Jasmine Gant (Madison, WI, 2006)

- 16 year old Jasmine Gant in labor, in a darkened room.
- RN mistakenly gave bupivacaine IV instead of via epidural
- Jasmine suffered cardiac arrest, died.
- 8 lb baby boy survived.

https://www.twincities.com/2006/12/16/nurse-avoids-felony-charge-in-teens-death/

Epidural-Penicillin look alike bags

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Jasmine Gant (Madison, WI) - Contributing factors

- BCMA system didn't work well for IV bags.

- RN had worked a double shift the day before, slept at hospital.

- Penicillin and epidural in similar bags on counter.

Jasmine Gant's mother prepares to read statement in court as nurse Julie Thao looks on. Photo used with permission of Wisconsin State Journal and Lee Enterprises.

https://www.twincities.com/2006/12/16/nurse-avoids-felony-charge-in-teens-death/

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Lessons learned from Jasmine

- Make epidural bags look different from IV bags.
- Different pumps for epidurals.
- Have fat emulsion available in areas where local anesthetics are given epidurally.
- Ensure that BCMA systems can scan IV bags.
- Provide adequate nurse staffing.
- Encourage staff to report safety concerns.

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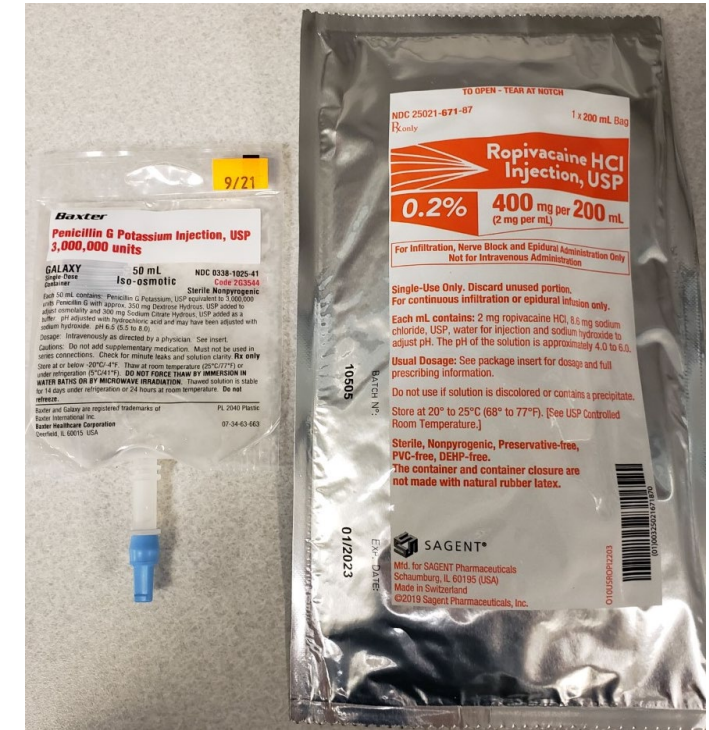
Blake Seamonson (2011, Deerfield, WI)

- 2 years old, visited great-grandmother in ECF.

- Used patches later found on floor, bedrails, and in trash cans at ECF

- Tonka truck, fentanyl patch on floor.

- 2 days later, Blake was found in respiratory arrest, part of patch in throat.

ISMP Medication Safety Alert, Dec 13, 2012

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Lessons learned from Blake

- Always counsel on disposal of fentanyl patches.
- Deactivation pouches, or fold and flush.

Ruth Ann Collins (2014)

"60-year-old woman with a history of brain cancer, died a slow and painful death after accidentally taking the equivalent of 3 cycles of oral lomustine therapy at one time (450 mg), believing the pharmacy had dispensed just a single dose (150 mg)."

"ISMP has previously published at least five similar errors with lomustine in which more than 1 dose was dispensed and taken, either all at once or daily instead of every 6 weeks."

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Ruth Ann Collins (2014)

Ruth Ann Collins
Lomustine caps 40mg
Mfg: Nextsource Biot
Take one capsule with 100Mg and 10Mg for a
Total Of 150 Mg Once Per Month As Directed.
3 Refills   Qty: 3   Pkg: 1 of 3
(Lomustine)

Prepared from picture of bottle in Institute for Safe Medication
Practices. ISMP Medication Safety Alert! With oral
chemotherapy we simply must do better!   July 17th, 2014

- Mail order pharmacy
- No counseling
- Past therapy had included multiple strengths in one bottle.
- 3 bottles, with 3 capsules each of 10 mg, 40mg, 100 mg

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Lessons learned from Ruth Ann

- Patient counseling is critical for high alert medications.

- Periodic oral chemotherapy should be filled for one dose at a time.

- Prescription instructions should be crystal clear.

- Implications for OhioHealth oncology pharmacists, med red techs.

Emily Jerry (Cleveland, OH, 2006, age 2)

Emily Jerry. (Image used with permission of Emily Jerry Foundation)

- 23.4% sodium chloride in chemotherapy bag instead of 0.9%
- Death from hypernatremia.

https://www.ismp.org/resources/ohio-government-plays-whack-mole-pharmacist

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Emily Jerry – contributing factors

- No scanning technology in IV room
- Computer system was down longer than expected
- Pharmacy was short-staffed
- IV checking area was undersized and piled with products
- Weekend chemotherapy
- Poorly trained technician
- RN called asking for the chemotherapy early
- RPh called in for third straight 16 hour "double shift"

https://www.ismp.org/resources/ohio-government-plays-whack-mole-pharmacist

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Emily Jerry changed the face of pharmacy

Emily's Law (Jan 7, 2009)

Pharmacy technicians must:
- Be at least 18 years old
- HS diploma or GED
- Pass a competency exam approved by Ohio Board of Pharmacy
- Criminal background check shows no felonies.

Emily Jerry. (Image used with permission of Emily Jerry Foundation)

https://www.jonesday.com/en/insights/2009/09/emilys-law-ohio-pharmacy-technicians-and-their-employers-face-new-state-regulations

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Emily Jerry changed the face of pharmacy

Every state except Hawaii and Wisconsin now have some oversight of pharmacy techs.

(source: Emily Jerry Foundation)

2021 NATIONAL PHARMACY TECHNICIAN INITIATIVE AND SCORECARDS

= A
= B
= C
= D
= F
= 0

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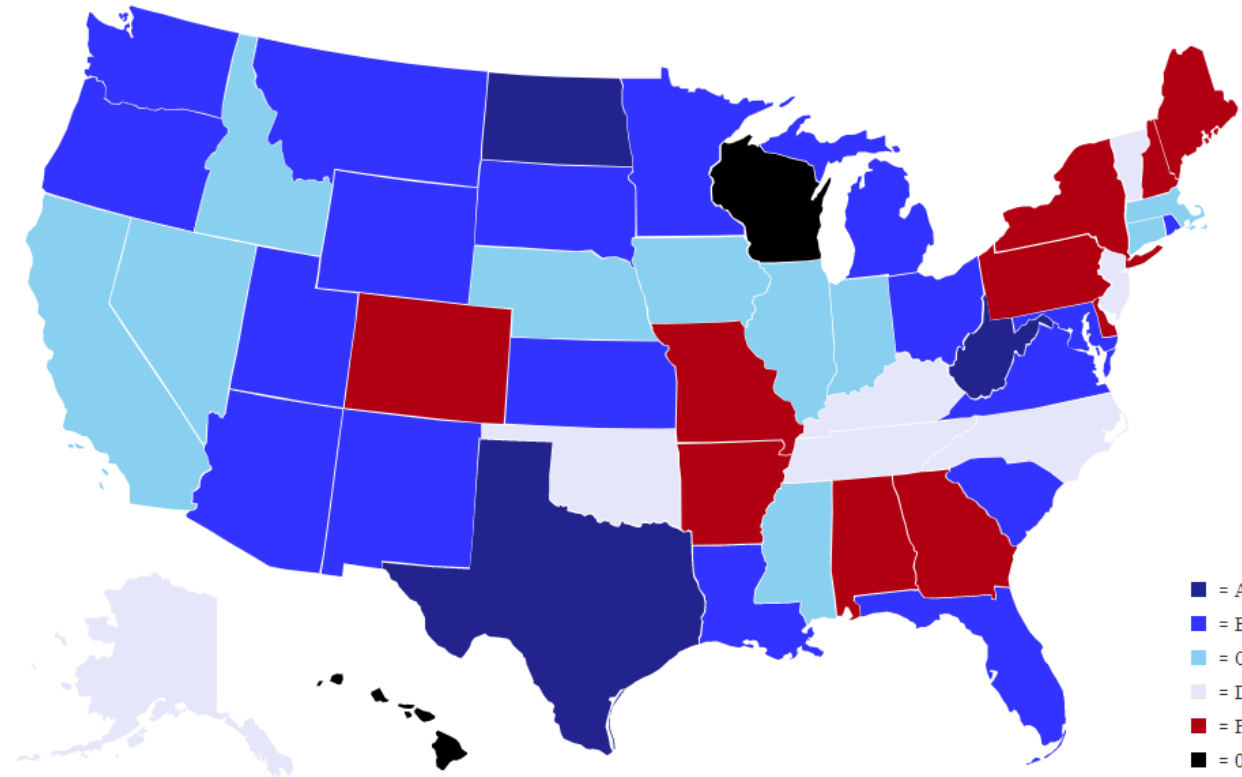
Emily Jerry changed the face of pharmacy

2021 NATIONAL PHARMACY TECHNICIAN
INITIATIVE AND SCORECARDS

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Betsy Lehman, age 39, Boston, 1994

- Investigational protocol misunderstood.
- She received 6,520 mg of cyclophosphamide daily instead of 1,630 mg.
- Fatal error
- Boston Globe reporter – had been writing about her healthcare journey and treatment for breast cancer

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Betsy Lehman, age 39, Boston, 1994

Experimental breast cancer protocol: "Cyclophosphamide 4 grams/m^2 over 4 days"

Does it mean:
4 grams/m^2 daily x 4 days? No
Or
1 grams/m^2 daily x 4 days?

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Betsy's Impact on Patient Safety

- Raised awareness of medication errors.

- Sped adoption of preprinted order forms for chemotherapy, and later electronic prescribing.

- Spurred growth of oncology safety processes.

OhioHealth oncology orders

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Charlene Murphy (Age 75, Nashville, 2017)

Vanderbilt University Medical Center

- Experienced RN called to radiology to sedate a PET scan patient with Versed

- While talking to a preceptee, typed "Ve" into ADC.
  - Vecuronium came up. RN removed it on override and gave it.

- Difficult to monitor patient in scanner

- Patient suffered respiratory arrest and died
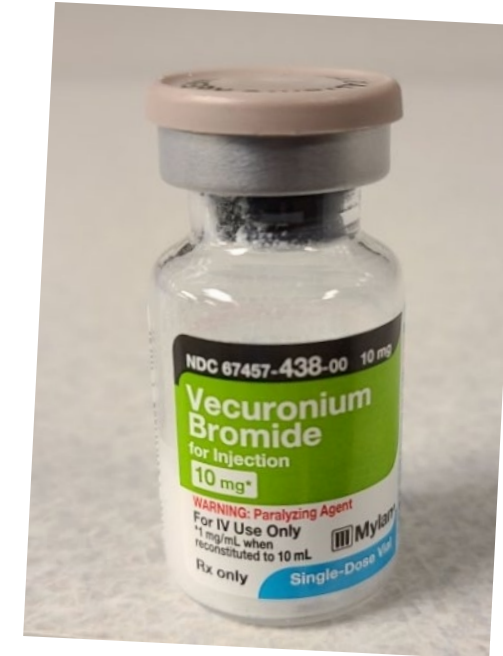
Lessons learned from Charlene

- Evaluate and restrict what can be removed on override

- ISMP recommends requiring 5 letters to be typed into ADC.

- Remove paralyzing drugs from units where not needed, or place in intubation kits.

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Loretta MacPherson (Bend, Oregon) 2014

- Pharmacy had scanning software in the clean room, but only used it for "high risk drugs".

- Fosphenytoin IVPB correctly ordered for an ED patient, but pharmacy employee mistakenly used rocuronium.

- Pharmacy didn't scan because fosphenytoin "not high risk"

- ED RN started infusion, then the fire alarm went off and all doors closed.

- Patient suffered cardiac arrest, brain death.

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Loretta's Impact on OhioHealth

- OhioHealth also planned to implement IV room scanning only for high-risk drugs, but this case changed our mind
- We keep paralyzing drugs in special storage containers

Speaking of paralyzing drugs…..

- It is unethical to extubate a medically paralyzed patient.
- Patients must have return of muscle function prior to compassionate extubation.
- The time it takes for muscle function to return depends on the NMBA and dose as well as renal and hepatic function.
- Wait at least 3 half-lives and confirm a TOF with 4 twitches.

LIKEWISE

- Patients need to be adequately sedated PRIOR to the administration of a paralyzing agent

Oral Methotrexate deaths

- "Since early 1996, harmful or fatal errors with daily oral methotrexate for nononcologic use have been reported to ISMP and published in more than 60 of our ISMP Medication Safety Alert! Newsletters."

- Example: Patient misunderstood instructions for methotrexate "every Monday" as "every morning". Patient suffered aplastic anemia and died.

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How these cases have changed our practice

- Methotrexate frequency defaults to once a week
- "***" forces pharmacists to acknowledge information sheet upon order verification.

Magnesium fatalities in L&D

- 52 cases of accidental overdoses of magnesium in L&D, some fatal.

- Example: RN added 40 grams of magnesium to one of two bags of LR, and then ran "LR" at 300 mL/hr. Patient died.

- Example: RN accidentally restarted magnesium instead of oxytocin after delivery. Patient in persistent vegetative state.

https://www.ismp.org/resources/preventing-magnesium-toxicity-obstetrics

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Magnesium in L&D: OhioHealth response

- Premixed bags of magnesium
- Only carry magnesium as 20 grams in 500 mL
- No other 500 mL bags in L&D
- Alaris Guardrails with 'Bolus from the bag" feature.
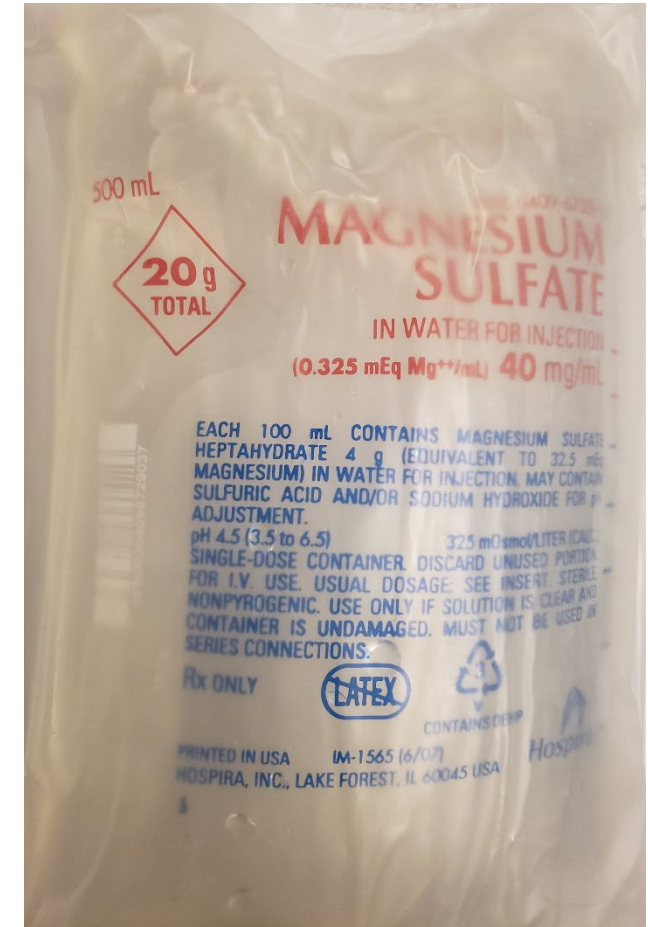
Naked Decimal Point errors (2000 and 2001)

- Babies in NYC and DC given morphine 5 mg when order for ".5 mg" interpreted as 5 mg.

- Both went into respiratory arrest and died

- Lesson: Always place a zero before the decimal point.

https://www.ismp.org/resources/please-dont-sleep-through-wake-call

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Lessons from Decimal Point Errors

- The Joint Commission enacted standards for unapproved abbreviations and included the use of a leading 0 when a dose less than 1 was indicated
  - *Not .5mg but 0.5mg to highlight the actual dose*
- Transcribing of poorly written orders occurred less and less as computerized prescriber order entry (CPOE) was developed and refined

Leslie Avenell, age 82, UK

- Discharged from hospital to care home with handwritten order for "8u" of regular insulin with meals.

- RN read order as "84 units", gave it.

- Patient collapsed 24 hours later and died.

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Lessons from "u" errors

- As with the danger of decimal point errors, the risk of misinterpreting "u" for "0" or "4" was identified

- This was also included in the Joint Commission's standards around decimal points and unapproved abbreviations

- "U" should ***NEVER*** be used as an abbreviation for "units" – the word must be written out

- Transcribing of poorly written orders occurred less and less as computerized prescriber order entry (CPOE) was developed and refined

OhioHealth Prohibited Abbreviations

H. The following unapproved abbreviations should NOT be used when placing medication orders:

The Joint Commission Official 'Do Not Use' List[†]

Do Not Use	Potential Problem	Use Instead
U, u (unit)	Mistaken for "0" (zero), the number "4" (four), or "cc"	Write "unit"
IU (International Unit)	Mistaken for IV (intravenous) or the number 10 (ten)	Write "International Unit"
Q.D., QD, q.d., qd (daily)	Mistaken for each other	Write "daily"
Q.O.D., QOD, q.o.d., qod (every other day)	Period after the Q mistaken for "I" and the "O" mistaken for "I"	Write "every other day"
Trailing zero (X.O mg)*	Decimal point is missed	Write X mg *A "trailing zero" may be used only where required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report size of lesions, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.
Lack of leading zero (.X mg)	Decimal point is missed	Write 0.X mg
MS, MSO4, MgSO, MgSO4	Can mean morphine sulfate or magnesium sulfate; can be confused for one another	Write "morphine sulfate" Write "magnesium sulfate"

Final thoughts…

- Many medications that we verify and dispense every day are in the high-risk category

- We must never lose our awareness of the risk of **harm** that occurs with errors in the use of high-alert medications

- Strategies to reduce this risk have been developed, both nationwide and here at OhioHealth to improve the safety of our processes

- Got an idea about how to further keep our patients safe? Please share with your local management and med safety teams!

Questions? Ideas?

- Thanks for your continued dedication to safety during a challenging time!