Just Culture: What It Is and What It Isn't (The RaDonda Vaught Case)

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Objectives

1. Identify system and human factors contributions to medication errors
2. Define the Just Culture three categories of behavior during a medication error
3. Compare the principles of Just Culture versus a recent healthcare error case and its consequences

Challenging times for healthcare

- As if the pandemic wasn't enough…
- Central Ohio local healthcare case
  - A different animal entirely
  - Conscious decisions made in dose selection
- Healthcare error consequences
  - We have a tendency to want to blame "someone"
  - We have hindsight bias – "how could they not have seen what would happen?"

When a mistake is made…..

- No jumping to conclusions!
- Careful review looking at system vulnerabilities
- Thoughtful evaluation of human error and the aspects of our tasks that can increase our human fallibility
- Then the event can be viewed through the lens of Just Culture

System Contributions to Med Errors

Systems Contributions to Med Errors

- Medication errors previously thought to be exclusively practitioner failure
- Initial thoughts of investigating events as system problems
- Lucian Leape et al, "Systems analysis of adverse drug events"
  - Systems failures: Lack of patient information, drug information were biggest causes, a total of 16 systems had potential vulnerabilities
- Institute of Medicine "*To Err is Human: Building a Better Health System*"
  - Building safety into systems is a more effective way to reduce errors than blaming individuals

Leape LL et al. Systems analysis of adverse drug events. *JAMA* 1995;274(1) 35-43.

To Err is Human: Building a Safer Health System National Academy Press, 1999.

ISMP 10 Key Elements of the Medication Use System. www.ismp.org

System Contributions to Med Errors

- Institute for Safe Medication Practices
  - Development of 10 Key Elements
    - Key elements that affect the medication-use process
    - Tool for breakdown of event to find system vulnerabilities

- Patient Information
- Drug Information
- Communication
- Labeling, packaging and nomenclature
- Drug storage, stock, standardization and distribution

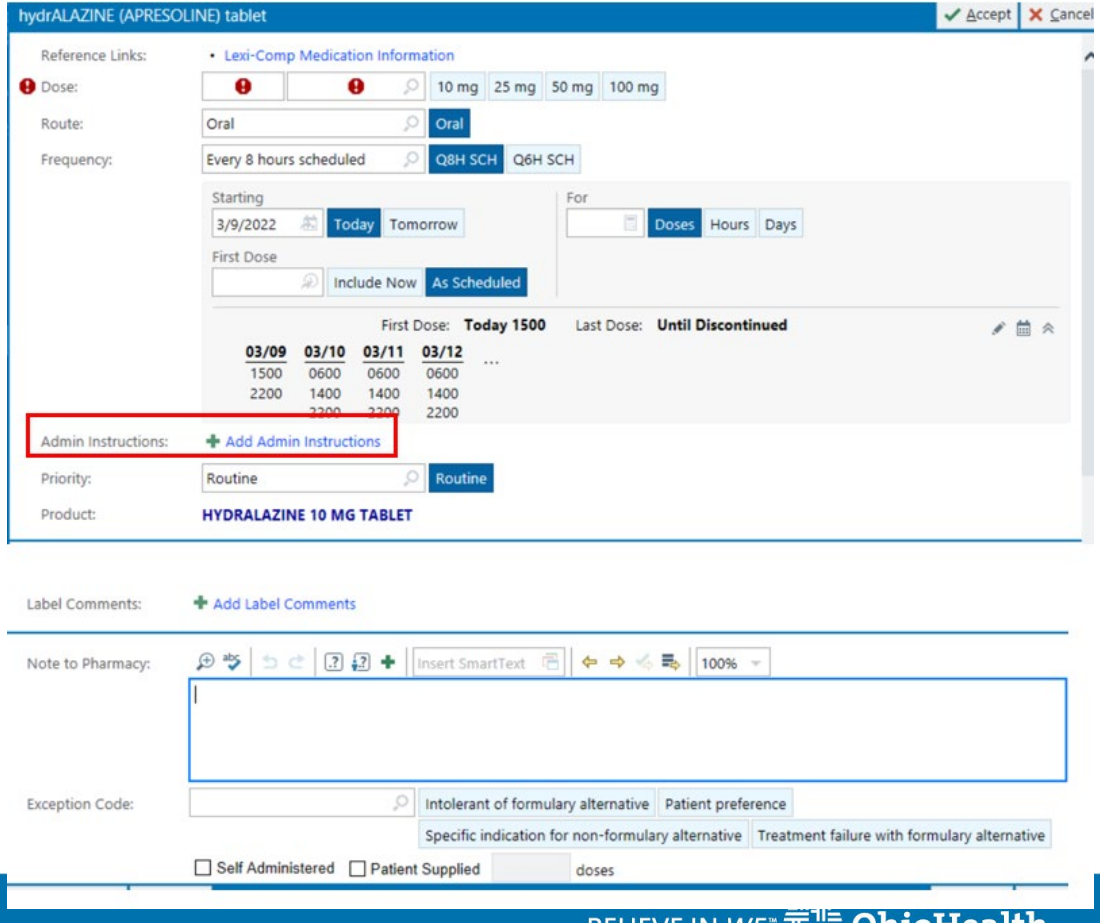
- Device acquisition, use and monitoring
- Environmental factors
- Staff competency and education
- Patient Education
- Quality and Risk Management Issues

Systems Analysis in Action

- LMA for Moduretic flipped to Aldactazide (also nonfo) rather than its components
- Ropinirole (Requip) 0.25mg defaulted to TID when most use is for RLS with frequency of qhs
- Order for octreotide IV given SQ by RN in error

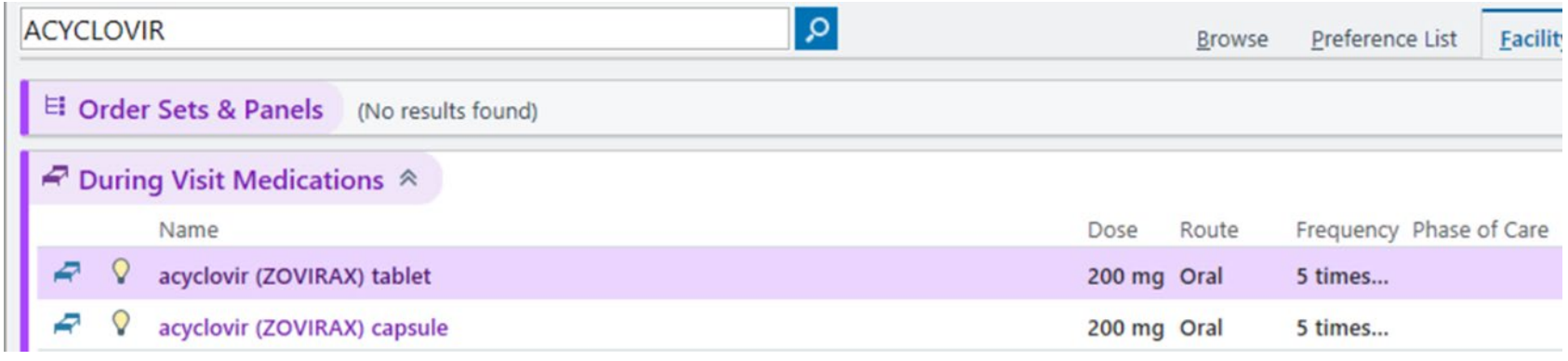
Systems Analysis in Action

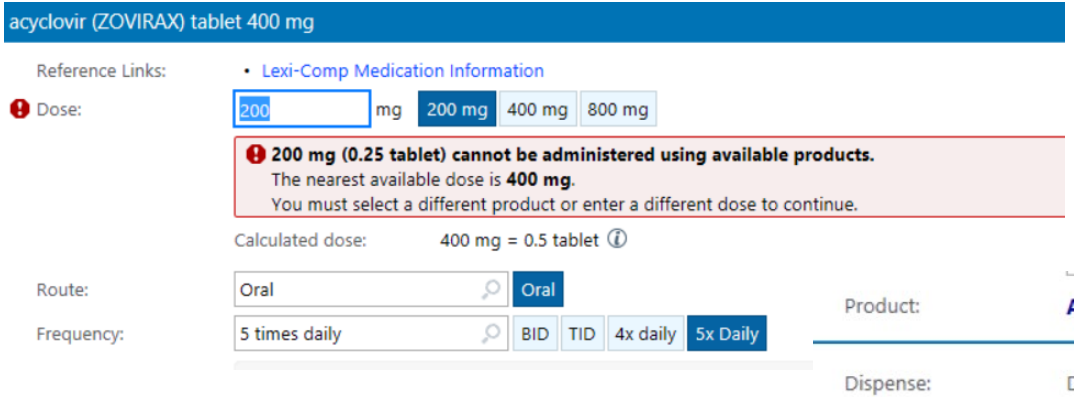
- ADC override review and considerations
- Review of new processes prior to implementation
  - Pulmonary hypertension medication concerns
- Modifications to Admin Instructions and Note to Pharmacy fields



System Analysis in Action

- Acyclovir messiness with 800mg tablets



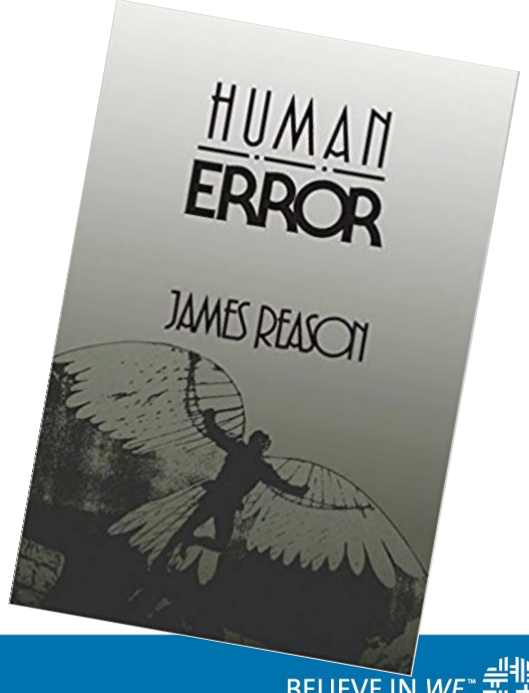


Human Factors Contributions to Med Errors

Human Factors Contribution to Med Errors

- So…humans make mistakes – because they are human!
- Dr. James Reason
  - Human contribution to errors, systems vulnerabilities and need to design defense barriers
  - "Swiss Cheese Model"

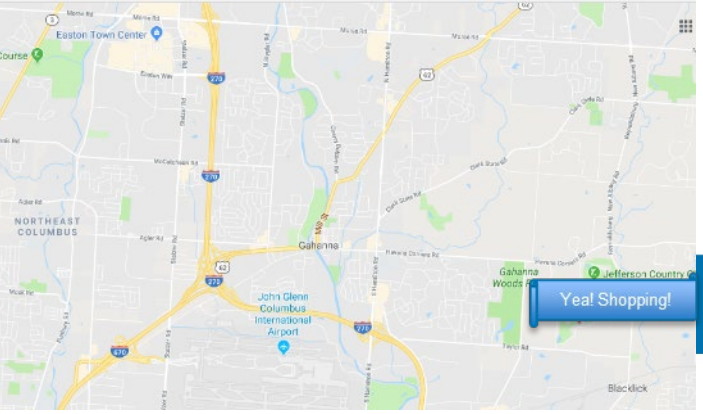
"Though we cannot change the human condition, we can change the conditions under which humans work"



Reason J. Understanding adverse events: human factors. *Qual Health Care* 1995;4:80-89.

Human Factors Contribution to Med Errors

- *Error is the failure of planned actions to achieve their desired goal"*
- **Execution failures**
  - Plan is adequate, but the associated actions are not!
    - Slips, lapses – occur while in "automatic" mode
      - Slips – errors due to attention failures
      - Lapses – failures of memory
      - Recognition, attention, memory or selection failures

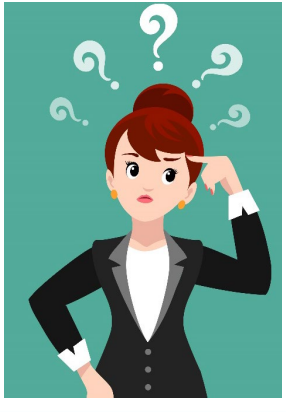


Milk in the cabinet
Pepper in the frig
Oops…..

Reason J. Understanding adverse events: human factors. *Qual Health Care* 1995;4:80-89.

Human Factors Contribution to Med Errors

- *"Error is the failure of planned actions to achieve their desired goal"*
- **Intention Failures**
  - Actions go as planned, but the plan is inadequate to achieve its intended outcome!



- Mistakes – upon detection of problem
  - Rule-based – some exposure to issue but:
    - » Misapply good rule, apply wrong rule
  - Knowledge-based – novel situation
    - » Slow, conscious reason, subject to confirmation bias, "pattern-matching"

Reason J. Understanding adverse events: human factors. *Qual Health Care* 1995;4:80-89.

Making errors….let me count the ways

- Taxonomy of “individual failure modes” – deficiencies in:
  - Competency
  - Consciousness
  - Communication
  - Critical Thinking
  - Compliance
- 20 subcategories!

High Reliability Healthcare: The Science of Safety and Operational Excellence. Health Performance Improvement: *Scorch Workshop 2015.*

Mitigating Human Error in Action

- Reducing memory burden – anaphylaxis or severe allergic reaction

Hypersensitivity Reaction Panel (Epinephrine, Diphenhydramine, Methylprednisolone)

☐ EPINEPHrine 1:1,000 (ADRENALIN) injection
0.3 mg, Intramuscular, As needed, anaphylaxis, May repeat every 3 minutes x 2 doses for a total of 1 mg, for 3 doses, - Administer in the anterolateral aspect of the middle third of the thigh (Avoid administration into the buttock)

☐ diphenHYDRAMINE (BENADRYL) injection
25 mg, Intravenous, As needed, other, For pruritus or urticaria, for 2 doses, May repeat x 1 dose in 30 minutes for persistent pruritus or urticaria

☐ methylprednisoLONE sodium succinate (Solu-MEDROL)
125 mg, Intravenous, Once as needed, For signs and symptoms of anaphylaxis, Do NOT give before, or in place of, Epinephrine

- How do I give that epi?

Epinephrine ANAPHYLAXIS kit

IM administration ONLY

0.3mg IM to anterolateral thigh

Contents:
Epinephrine 1mg/ml ampule
Filter needle
23G x 1 safety needle
Alcohol swab

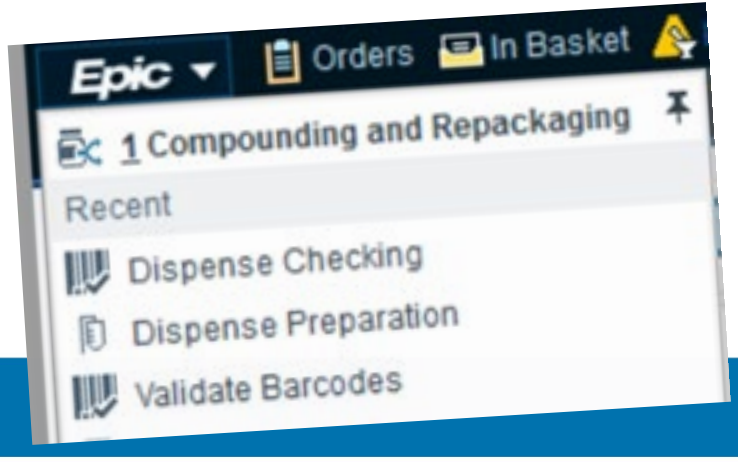
Mitigating Human Error in Action

- High Alert Medications – layer strategies for safety
  - Constraints – limit availability of the product
  - Appearance/warning of display if in ADC
  - Appearance/warning on product

Neuromuscular Blocking Agents

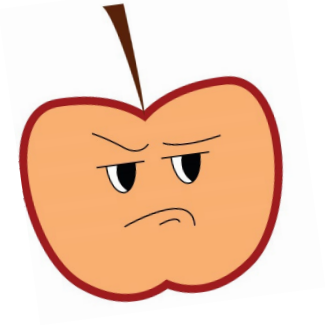
Mitigating Human Error in Action

- A thoughtful layer of technology can help…

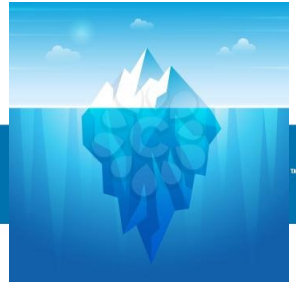


Just Culture

Just Culture



- ***Where we have been***
  - Punitive Culture
    - Blaming the practitioner solely, "Bad Apple"
    - No considerations of system/human contributions to event
    - Threat of disciplinary action will keep folks from making errors
- ***What we learned***
  - Punitive Culture
    - Fear of retribution, embarrassment, termination drove error reporting underground
    - Practitioners were afraid to report their errors or those of colleagues



Just Culture and its critical link to patient safety (Part II). *ISMP Nurse Advise-ERR* 2013;11(8):1-4.

Just Culture

- ***Where we have been***
  - Blame-Free Culture
    - Awareness of prevalence of errors increased
    - Acknowledged human fallibility and system vulnerabilities considered during error review
- ***What we learned***
  - Blame-Free Culture
    - Practitioners will make mistakes – not much benefit from blaming or punishing them…*BUT*
    - This approach fails to confront individuals who willfully make ***unsafe behavioral choices***

Just Culture and its critical link to patient safety (Part II). *ISMP Nurse Advise-ERR* 2013;11(8):1-4.

Just Culture

Where we are going…

- A "Just" Culture
  - Neither wholly punitive nor wholly blame free
  - Individuals are held accountable for the behavioral choices under their control
  - Leadership is held accountable for ensuring that the design of system processes give individuals the best opportunity to perform well
  - Concept recognizes three categories of human behavior
    - Human Error
    - At-Risk Behavior
    - Reckless Behavior

Just Culture and its critical link to patient safety (Part II). *ISMP Nurse Advise-ERR* 2013;11(8):1-4.

Human Error

- To recap….
  - **Execution failures** – slips, lapses, selection failures
  - **Intention failures** – rule-based, knowledge-based

High Reliability Healthcare: The Science of Safety and Operational Excellence. Health Performance Improvement: *Scorch Workshop 2015.*

Just Culture Response to Human Error

- Recognize that humans do have limits
  - Fatigue, stress, distractions…
- The proper response is to console and coach the individual who made the mistake
- Seek out opportunities to improve the design of the system!!

The differences between human error, at-risk behavior and reckless behavior are key to a Just Culture. *ISMP Acute Care Bulletin* 2020;25(12):1-5.

At-Risk Behavior

- We believe the risk is worth taking, or don't see the risk
- We convince ourselves we are operating in a safe place, a "justifiable" risk
  - Speeding…..

BUT

- Humans tend to **drift** (normalized deviance…)
  - We convince ourselves that we are safe because we have performed the task several times or nothing bad has ever happened when we skipped a step

The differences between human error, at-risk behavior and reckless behavior are key to a Just Culture. *ISMP Acute Care Bulletin* 2020;25(12):1-5.

Just Culture Response to At-Risk Behavior

- We have to set up systems, and performance expectations that discourage “drifting”
- Individuals should be coached around their awareness of risk
- Seek out opportunities to remove barriers that prevent compliance with rules and procedures

The differences between human error, at-risk behavior and reckless behavior are key to a Just Culture. *ISMP Acute Care Bulletin* 2020;25(12):1-5.

Reckless Behavior

- A choice to consciously disregard a substantial and unjustifiable risk.
- Individual may not have intended for harm to occur but they know they are operating in an unsafe place.

The differences between human error, at-risk behavior and reckless behavior are key to a Just Culture. *ISMP Acute Care Bulletin* 2020;25(12):1-5.

Just Culture Response to Reckless Behavior

- There comes a point where “wiggle room” in regard to guidelines crosses a line and becomes “reckless”
  - Example: Driving 75 MPH vs. driving 100 MPH
- We as a society clearly believe that the risk outweighs the rewards
- Response is to punish the act regardless if there was harm involved

The differences between human error, at-risk behavior and reckless behavior are key to a Just Culture. *ISMP Acute Care Bulletin* 2020;25(12):1-5.

Applying Just Culture to Medication Errors

- A quick history lesson – the Ohio State Board of Pharmacy takes a stance…..
- How it works at OhioHealth…
  - When medication errors are investigated, we construct a timeline to identify the “breakdowns” that led to the error.
  - Each “breakdown” identified will be examined to identify:
    - System Design Failures
    - Behavior Choices Involved (i.e., Human Error, At-Risk, Reckless)

Now…..

- Let's review the recent case in light of what we now know about systems failures, human error and the principles of Just Culture

The RaDonda Vaught Case: A Violation of Just Culture

Regarding the Event…

- Review sequence of events in the medication error
- Discuss legal proceedings of the case
- Review ISMP bulletins about neuromuscular blockers (NMB) and the case
- Understand the impact of the case on healthcare

Medication Event Timeline

Indication for Versed

- Patient admitted to the neurology intensive care unit (NCU) after confirming an IPH on MRI
- Patient is transferred to the step-down unit
- Patient is transported to radiology for a PET scan
- Patient requests medication to ease anxiety due to claustrophobia
- Physician enters an order for Versed (midazolam) 1 mg IV once

Institute for Safe Medication Practices (ISMP). Safety Enhancements Every Hospital Must Consider in Wake of Another Tragic Neuromuscular Blocker Event. 17 Jan 2019 Available from: https://www.ismp.org/resources/safety-enhancements-every-hospital-must-consider-wake-another-tragic-neuromuscular

Nursing Communication

- Radiology nurse refuses to administer Versed
- Radiology tech calls primary nurse to administer
- Primary nurse is covering another nurse's patients
- Primary nurse sends the help-all nurse to administer
- Help-all nurse is on her way to the ED to conduct a swallow test
- Help-all nurse agrees to stop by radiology to administer

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The Automatic Dispensing Cabinet (ADC)

- Help-all nurse enters “VE” into the NCU ADC
- No medications populate in the search results
- Help-all nurse initiates override setting and enters “VE” again
- Help-all nurse selects the first medication that results
- A red box warning appears that the “medication should be associated with a STAT order” and ADC opens
- Help-all nurse removes a vial of vecuronium bromide 10 mg/mL believing it was Versed

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Transportation to the Patient

- Help-all nurse notices medication is a powder and reads the reconstitution instructions on the back of the label
- Help-all nurse places vecuronium vial in a bag with two 10 mL NS flushes, alcohol pads, a blunt tip needle, and labels the bag

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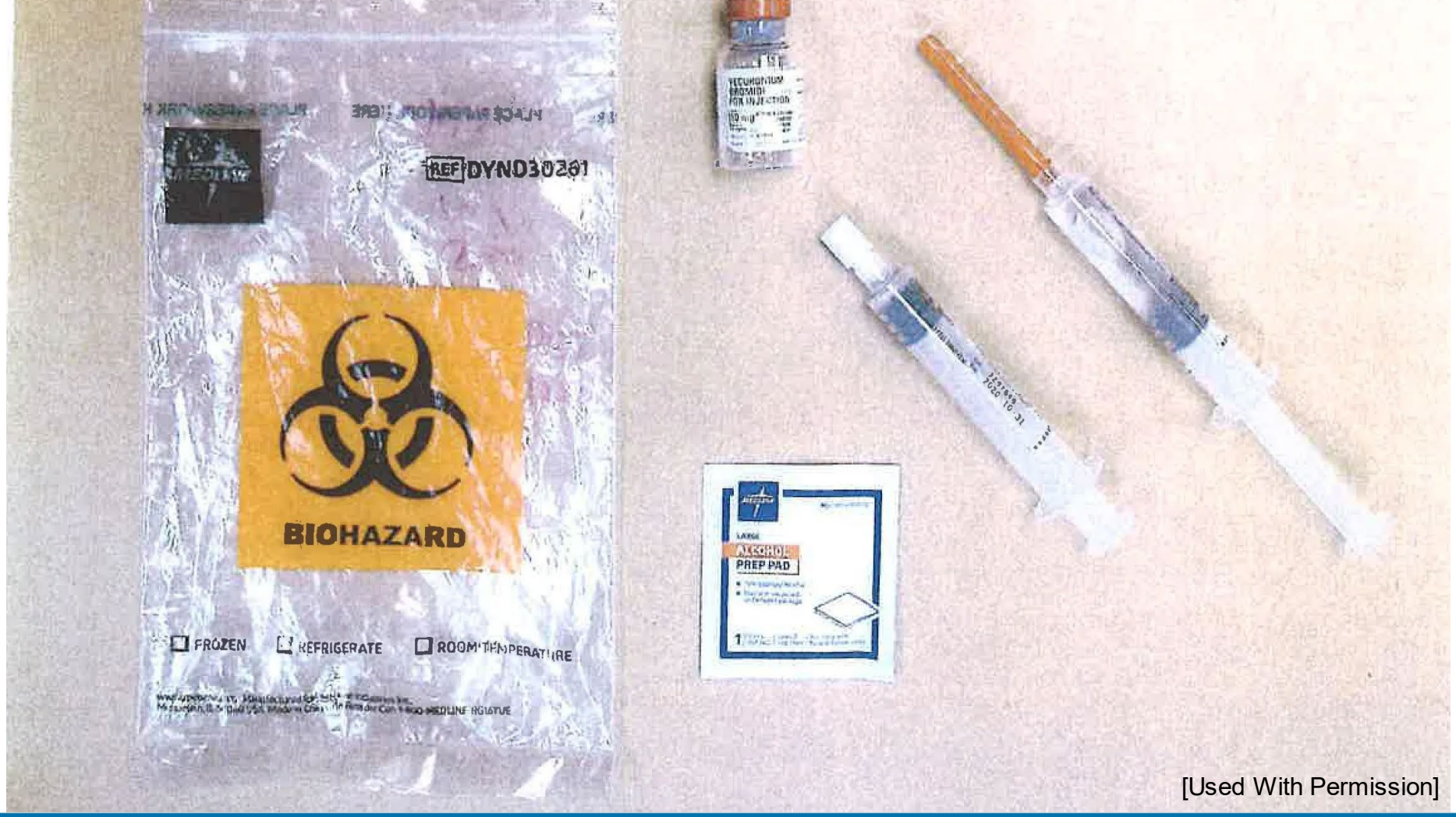

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Medication Administration

- Help-all nurse finds the patient and verifies her identity
- Help-all nurse reconstitutes the medication with 10 mL of NS flush
- Help-all nurse draws medication back into flush syringe
- Help-all nurse does not see red warning on the vial that says “Warning: Paralyzing Agent”
- Help-all nurse administers IV vecuronium and flushes line
- Help-all nurse leaves the room and continues to the ED

Institute for Safe Medication Practices (ISMP). Safety Enhancements Every Hospital Must Consider in Wake of Another Tragic Neuromuscular Blocker Event. 17 Jan 2019 Available from: https://www.ismp.org/resources/safety-enhancements-every-hospital-must-consider-wake-another-tragic-neuromuscular

Patient Completes MRI

- The hospital's drug administration policy did not specify the manner and frequency of monitoring patients during and after Versed administration
- The patient's eyes close and the radiology tech assumes the patient trying to relax
- The camera is not sharp enough to recognize the patient's chest is not rising and falling

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Patient is Unresponsive

- 25-30 minutes later a transporter notices the patient is unresponsive
- Code blue is called, patient intubated, and ROSC achieved
- Help-all nurse responds to the code blue
- Patient is transferred to the NCU

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The Error is Realized

- Help-all nurse explains that she gave the patient IV Versed
- The bag with the empty vial and syringes is shown to the primary nurse
- Primary nurse notices the error
- Error is reported to the patient's physicians and family
- Patient presenting with myoclonic jerks
- The next day, neurological sequelae worsens and patient dies

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ISMP-Identified Safety Measures

Packaging

- Warning verbiage and placement
- Look-alike drugs
- Drug shortages

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Policies and Procedures

- Warning verbiage and placement
- Look-alike drugs
- Drug shortages

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Storage

- Limit access and locations of NMB
- Provide NMB in sealed box or RSI kit
- Keep NMB in locked-lid ADC pockets
- Visible auxiliary labels on ADC pockets
- Limit number of NMB available in ADC

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ADC Removal

- Distraction-free
- Increase number of letters required while searching
- Allow simultaneous searching of brand and generic names
- Remove medications via patient profile
- Require entry of purpose for drug removal from ADC
- Witness override of medication removal
- Barcode scanning verification

Institute for Safe Medication Practices (ISMP). Safety Enhancements Every Hospital Must Consider in Wake of Another Tragic Neuromuscular Blocker Event. 17 Jan 2019 Available from: https://www.ismp.org/resources/safety-enhancements-every-hospital-must-consider-wake-another-tragic-neuromuscular

Administration

- Avoid reconstitution via flush syringes
- Include monitoring parameters with IV sedatives

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Legal Proceedings

2019 TN Board of Nursing Action

- Reversal of a 2018 decision to take no licensing action
- Charged with 3 violations:
  1. Unprofessional conduct
  2. Abandoning a patient requiring nursing care
  3. Failure to maintain record of interventions
- Nursing license revoked indefinitely
- Fined $3,000
- Required to pay $60,000 in prosecution costs

Institute for Safe Medication Practices (ISMP). TN Board of Nursing's Unjust Decision to Revoke Nurse's License: Travesty on Top of Tragedy!. 12 Aug 2021 Available from: https://www.ismp.org/resources/tn-board-nursings-unjust-decision-revoke-nurses-license-travesty-top-tragedy

2022 Trial

- Charged with reckless homicide
- Convicted on 2 counts
  1. Criminally negligent homicide
  2. Gross neglect of an impaired adult
- Faced 1-2 years in prison for negligent homicide
- Faced 3-6 years in prison for felony neglect
- Sentenced to 3 years probation

Institute for Safe Medication Practices (ISMP). Criminalization of Human Error and a Guilty Verdict: A Travesty of Justice that Threatens Patient Safety. 7 Apr 2022 Available from: https://www.ismp.org/resources/criminalization-human-error-and-guilty-verdict-travesty-justice-threatens-patient-safety

Trial Shortcomings

Lack of Evidence of System Failures

- Defense did not fully educate jury on system failures
- Blame placed on the nurse for not following “five rights”

- Blunt end vs sharp end

“She disregarded all of her training and stuck that needle into Charlene Murphey’s neck and killed her.”

Institute for Safe Medication Practices (ISMP). Criminalization of Human Error and a Guilty Verdict: A Travesty of Justice that Threatens Patient Safety. 7 Apr 2022 Available from: https://www.ismp.org/resources/criminalization-human-error-and-guilty-verdict-travesty-justice-threatens-patient-safety

Incrimination of Truthful Reporting

- Jury used RaDonda's transparency against her
- Psychological pain and self-blame not acknowledged
- Managing the Risks of Organizational accidents result

"Charlene Murphey was a disposable person to RaDonda Vaught, who didn't care about her."

Institute for Safe Medication Practices (ISMP). Criminalization of Human Error and a Guilty Verdict: A Travesty of Justice that Threatens Patient Safety. 7 Apr 2022 Available from: https://www.ismp.org/resources/criminalization-human-error-and-guilty-verdict-travesty-justice-threatens-patient-safety
Reason JT. Managing the Risks of Organizational Accidents. Aldershot, Hants, England: Ashgate, 1997.

Weaknesses of the Defense

- Defense only called one witness
  - Nurse educator who worked with RaDonda
- More witnesses could have been called
  - Human factors expert
  - Medication safety officer
  - Just culture expert

Institute for Safe Medication Practices (ISMP). Criminalization of Human Error and a Guilty Verdict: A Travesty of Justice that Threatens Patient Safety. 7 Apr 2022 Available from: https://www.ismp.org/resources/criminalization-human-error-and-guilty-verdict-travesty-justice-threatens-patient-safety

Misleading of the Jury

- Recklessness is a “conscious, substantial and unjustifiable risk”
- Prosecution did not differentiate at-risk and reckless choices
- Compared RaDonda’s actions to “driving drunk”
- Prosecution mockingly said that it was “ridiculous” to think that drug shortages could be related to medication errors

Institute for Safe Medication Practices (ISMP). Criminalization of Human Error and a Guilty Verdict: A Travesty of Justice that Threatens Patient Safety. 7 Apr 2022 Available from: https://www.ismp.org/resources/criminalization-human-error-and-guilty-verdict-travesty-justice-threatens-patient-safety

Lack of System Error Prevention

- Per ISMP reports, NMB warnings were not consistently effective
- In 2016, ISMP released:
  1. Feature article about errors with neuromuscular blocking agents (NMB)
  2. Targeted Medication Safety Best Practices for Hospitals regarding NMB
  3. Features included keeping NMB in lidded boxes, placing auxillary labels on bins, and barcode scanning of NMB

Institute for Safe Medication Practices (ISMP). Paralyzed by Mistakes - Reassess the Safety of Neuromuscular Blockers in Your Facility. 16 Jun 2016 Available from: https://www.ismp.org/resources/paralyzed-mistakes-reassess-safety-neuromuscular-blockers-your-facility

Effects on Healthcare

- Inhibit error reporting
- Undermine a culture of safety
- Exacerbate healthcare personnel shortages
- Perpetuate the myth of perfect performance
- Impede system improvements
- Public remains uneducated about the causes of medical errors

OhioHealth Stance

- Disagree with the verdict
- Recognize human error
- Just Culture
- Process improvement
- Liability coverage

Just Culture: What It Is and What It Isn't (The Radonda Vaught Case)

- Thoughts, questions, observations?

3 Ways to Claim CE via CloudCME

#1

Via CloudCME App

Download the CloudCME app for iPhone or Android

Open the app, use organization code "OhioHealth"

Click "Login or Create Account" - Login with OH OPID/password

Go to Claim Credit

Enter Event ID – **15312**

Check the attestation and insert your digital signature

Please complete the Evaluation for the activity

#2

Via Text Message

First time only: Text your email address to 614-412-1138 to pair your mobile number.

Text the event code **15312** to 614-412-1138

#3

Via CloudCME on Computer

Website: https://ohiohealth.cloud-cme.com/default.aspx

Go to My CME → Claim Credit → Enter Event ID **15312** → Hours attended 1.0 --> check box and complete signature

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

UAN: 0647-0000-22-004-L05-P/T

Credits: 1hour (0.1 CEUs)

*Attendance must be recorded within 24 hours of event start time

Thanks for your dedication to patient safety!

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