Lessons Learned about Human Fallibility, System Design, and Justice in the Aftermath of a Fatal Medication Error

Presented by:
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and
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Tragedy in Tennessee

Two days after Christmas in 2017, Charlene Murphey, a patient at Vanderbilt University Medical Center, died after receiving an IV medication in error. The medication was administered by RaDonda Vaught, an experienced registered nurse who had retrieved the wrong drug and subsequently failed to detect and correct her mistake. Standard safety norms and technologies used to prevent and detect the original error before it could reach the patient were absent or incompletely deployed. The nurse, attempting to accomplish multiple tasks simultaneously, did not perform standard visual checks that could have surfaced the error.

In this tragic constellation of individual and system failures, patient Charlene Murphey lost her life. Her family lost a beloved mother and grandmother, and Ms. Murphey’s community lost a treasured friend and engaged citizen. Eight days later, Vanderbilt University Medical Center fired RaDonda Vaught, citing her failure to adhere to the Five Rights of Medication Administration. In July 2021, the Tennessee State Board of Nursing revoked RaDonda Vaught’s nursing license and on March 25, 2022, she was convicted on two criminal counts: criminally negligent homicide and gross neglect of an impaired adult. She will be sentenced on May 13th in Davidson County, TN and could serve up to 12 years in prison.
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A Good Root Cause Analysis

But are we willing to look into her theatre of consciousness? What risks did she see?

And what of others? How are they making choices? What risks do they see?

We can see RaDonda Vaught’s visible actions

We can see the behavior of RaDonda’s peers

• Sensory inputs?
• Memories?
• Sensemaking?
• Decision-making?
• Subroutines?

The Story: Roles & Responsibilities of the Help-All Nurse

<table>
<thead>
<tr>
<th>Background &amp; Activities of Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Neuro-ICU designates a nurse (Help-All Nurse) to assist other nurses in moving planned care forward for patients within the unit</td>
</tr>
<tr>
<td>RaDonda Vaught is the designated Help-All Nurse on 12-26-17</td>
</tr>
<tr>
<td>She is the preceptor of a new-graduate RN, orienting to the Neuro-ICU</td>
</tr>
<tr>
<td>The preceptor-preceptee dyad were preparing to go to the ED to perform a swallowing study immediately before RaDonda is tapped to provide care to Ms. Murphey</td>
</tr>
</tbody>
</table>
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The Story: Prescribing the Medication

<table>
<thead>
<tr>
<th>Background &amp; Activities of Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>The need for Ms. Murphey to have an anxiolytic was not anticipated, creating an urgency when discovered after her arrival in Radiology</td>
</tr>
<tr>
<td>A radiology team member alerted the primary nurse in the Neuro-ICU of Ms. Murphey’s need for anxiolysis</td>
</tr>
<tr>
<td>A provider’s order for an IV anxiolytic, midazolam, was secured</td>
</tr>
<tr>
<td>The order was entered electronically (accurately)</td>
</tr>
</tbody>
</table>

The Story: Adaptive Care Planning

<table>
<thead>
<tr>
<th>Background &amp; Activities of Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>The schedule was too busy for one of the Radiology RNs to administer the ordered anxiolytic</td>
</tr>
<tr>
<td>Ms. Murphey’s primary nurse could not go &amp; sought task-assistance from the Help-All nurse to prevent the case from being cancelled</td>
</tr>
<tr>
<td>The name of the ordered anxiolytic was communicated verbally between the primary nurse &amp; RaDonda as Versed</td>
</tr>
<tr>
<td>Neither the primary nurse nor RaDonda routinely administer Versed</td>
</tr>
<tr>
<td><strong>Patient monitoring</strong> was discussed by the primary nurse and the Radiology Tech with the primary nurse concluding monitoring was not indicated</td>
</tr>
<tr>
<td><strong>Patient monitoring</strong> was discussed by the primary nurse and RaDonda, with the same conclusion. RaDonda did not plan to provide monitoring to Ms. Murphey</td>
</tr>
</tbody>
</table>
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The Story: Pharmacy Review

- The timeliness of pharmacy review of provider orders was variable
  - EHR – ADC interface change in Nov. 2017
  - RaDonda recalls emails supporting use of OVERRIDE to assure timely care
  - Ms. Murphey received ~20 drugs via OVERRIDE
- RaDonda concludes pharmacy review of Ms. Murphey’s anxiolytic will not occur timely
- The ordered medication has been reviewed and is listed on the pt.’s ADC profile as *midazolam*
- RaDonda does not know *midazolam* is the generic name of *Versed*
- She elects to use the ADC’s override function
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## The Story: ADC Drug Procurement

**Background & Activities of Note**

- RaDonda’s preceptee is present at the time of drug selection. She is multi-tasking & recalls focus of conversation as the upcoming procedure in the ED.
- Types in V-E:
  - Vecuronium appears at the top of the list.
  - Selects it.
  - Interacts with **standard warnings** that were present for all drugs removed on OVERIDE.
  - Vecuronium, a paralytic, was not constrained nor differentiated from other vials in the ADC nor through programmed screen warnings.

**People, Processes, Technology**

- RaDonda removes the *<wrong>* drug from the ADC bin.
- Upon retrieval, she notes powdered formulation; flips the vial and begins to read reconstitution directions on the back of the label.
- She does *not read the label* on front of vial.

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## The Story: Drug Administration

**Background & Activities of Note**

- RaDonda locates & identifies Ms. Murphey in the Radiology corridor.
- She attempts to locate an EHR terminal and barcode scanning equipment.
  - **Barcode scanning is not in place in the Radiology area**
  - **EHR access for documentation is not available**
- RaDonda does *not read the drug name* or appreciate the warnings on the vial label.
- She reconstitutes the medication & administers it IV via central venous catheter.
- The Radiology Tech is present while the medication is administered.
The Story: Drug Monitoring

<table>
<thead>
<tr>
<th>Background &amp; Activities of Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>RaDonda is not familiar with Radiology norms, flow or competing priorities within the Radiology Suite</td>
</tr>
<tr>
<td>Ms. Murphey is taken to a Holding Area by the Radiology Tech</td>
</tr>
<tr>
<td>Nurse Vaught and the preceptee proceed to the ED as planned</td>
</tr>
<tr>
<td>The Holding Area where the patient awaits PET scanning is equipped with a surveillance camera</td>
</tr>
<tr>
<td><strong>Post-administration drug monitoring does not occur</strong></td>
</tr>
<tr>
<td>Ms. Murphey is discovered unresponsive ~25 minutes later. She undergoes resuscitation but experiences brain damage such that supportive care is withdrawn the next day</td>
</tr>
</tbody>
</table>

People, Processes, Technology

Opportunities for Improvement

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ISMP National Medication Error Reporting Programs

- National Medication Errors Reporting Program
- National Vaccine Errors Reporting Program
- Consumer Errors Reporting Program

[Image of ISMP logo and website information]

[Image of ISMP Medication SafetyAlert]

[Image of ISMP National Medication Error Reporting Programs]

[Image of ISMP Acute Care Medication Safety Alert]

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With neuromuscular blockers, many hospitals have been paralyzed by mistakes

— ISMP has observed many of the same system vulnerabilities in other hospitals, and they are frequently at the root of a variety of medication errors reported to the ISMP National Medication Errors Reporting Program (ISMP MERP)

— Make no mistake—this type of error could happen in your hospital, and it is crucial to take steps to reduce the risk of a similarly tragic event
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Recommendations for providers
(upstream interventions)

— Retire discontinued brand names
  • The brand name Versed (midazolam) was discontinued in 2003
  • Related errors have happened when “Versed” was typed on cabinet override

— ADC order entry on override – use 5-letter characters when typing drug names
  • Recent error report: RO – Rocephin – rocuronium

How a Few Letters Can Spell Trouble
Many hospital medication cabinets can be searched by inputting only a few letters. Since 2017, there have been at least eight reports of hospital staff accidentally withdrawing and then administering or nearly administering the wrong drug for this reason. Because hospitals are not required to report most drug mis-ups, this is likely a small sampling of a much larger total.

<table>
<thead>
<tr>
<th>Letters typed</th>
<th>Intended drug (effect)</th>
<th>Withheld drug (effect)</th>
<th>Year of error report</th>
</tr>
</thead>
<tbody>
<tr>
<td>V-E</td>
<td>Versed (sedative)</td>
<td>vecuronium (paralytic)</td>
<td>2017</td>
</tr>
<tr>
<td>V or V-*</td>
<td>Versed (sedative)</td>
<td>vecuronium (paralytic)</td>
<td>2019</td>
</tr>
<tr>
<td>R-E-T</td>
<td>ketamine (ain he anesthesia)</td>
<td>ketorolac (pain reliever)</td>
<td>2019</td>
</tr>
<tr>
<td>R-O</td>
<td>rocuronium (paralytic)</td>
<td>romazicon (reverses sedatives, overdoses)</td>
<td>2019</td>
</tr>
<tr>
<td>R or R-G*</td>
<td>rocuronium (paralytic)</td>
<td>romazicon (reverses sedatives, overdoses)</td>
<td>2021</td>
</tr>
<tr>
<td>R-O</td>
<td>rocuronium (paralytic)</td>
<td>rocephin (antibiotic)</td>
<td>2021</td>
</tr>
<tr>
<td>P-I-T</td>
<td>Pitocin (induces labor)</td>
<td>pitrespin (treats diabetes insipidus)</td>
<td>2021</td>
</tr>
<tr>
<td>V-E-R</td>
<td>Versed (sedative)</td>
<td>verapamil (treats high blood pressure, chest pain)</td>
<td>2022</td>
</tr>
</tbody>
</table>

*Unlikely is whether the hospital staff typed one or two letters. Source: Institute for Safe Medication Practices error reports
Lydia Zutaw and Brett Helman, KHN [linked]
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Recommendations for providers

(upstream)

- Store neuromuscular blockers safely
  - Eliminate storage of neuromuscular blockers where not routinely needed.

- Limiting neuromuscular blockers in ADCs can also help reduce mix-ups with other drugs due to similar appearance

- Outside ICU, ED and perioperative settings, provide in sealed box, clear plastic zip bags, or rapid sequence intubation (RSI) kit.

- Enable an ADC block load feature where available, to prevent users from inappropriately stocking the cabinet. If vials must be stored, keep them in locked-lidded pockets, never open matrix.
Recommendations for providers

(upstream)

Plan for sedation

- In procedural areas, including radiology, establish a standard process for patients who require sedation prior to procedures that starts with an oral anxiolytic (e.g., LORazepam) as the medication of choice

- Include patient monitoring requirements during and after drug administration that avoid handoffs. Who is responsible? What is needed?

- Patients who receive sedation for procedures (e.g., IV midazolam) require some level of monitoring, regardless of the indication

- Hospital procedures should specify required monitoring, including use of pulse oximetry and other means of evaluating the adequacy of ventilation, along with criteria for when monitoring can be stopped

- Monitoring requirements should be approved by the anesthesia department to standardize the care of patients who receive IV sedation and provide oversight
Recommendations for providers

(upstream)

- Affix warnings
  - Place auxiliary labels on all storage locations and/or ADC pockets/drawers/lids that contain neuromuscular blockers that clearly warn that respiratory paralysis will occur, and ventilation is required (e.g., "WARNING: CAUSES RESPIRATORY ARREST—PATIENT MUST BE VENTILATED")
  - Warnings should be visible when ADC pockets/drawers/lids are open
  - Consider shrink wrap sleeves for vials, although these can make different neuromuscular blockers look similar

- Build interactive ADC warnings
  - Display an interactive warning (e.g., "Patient must be intubated to receive this medication"). The warning should require user to enter or select the purpose of the medication removal ("other" should not be a choice) and verify that the patient is (or will be) manually or mechanically ventilated. In most ADC systems, this type of warning is configurable by medication, and in some systems, by cabinet

Recommendations for providers

(upstream)

- Clarify override policies
  - Safety risks exist when removing and administering medications via override before pharmacy verifies the order
  - Review the hospital’s ADC override policy to confirm its permitted use is limited to emergency or urgent situations when a patient would be significantly compromised by the delay (or if a licensed independent practitioner controls the medication use process)
  - Manage the override list. Be sure the policy clearly communicates the hospital’s overall expectation of very limited overrides for defined urgent and emergent situations (e.g., antidotes, rescue agents, reversal agents, lifesaving medications, comfort care medications for acute pain and intractable vomiting)

- Educate staff
  - Allow simultaneous searching by brand and generic names. Teach practitioners how to toggle between brand and generic or display both on-screen
  - Teach practitioners to access and remove medications in profile mode whenever possible, as it directs them to a patient-specific medication profile and limits their access to medications that were verified by a pharmacist
  - Teach practitioners how to toggle between brand and generic name search functions
Recommendations for providers

(upstream)

– ISMP Targeted Medication Safety Best Practices
  • New Best Practice #18 consists of interventions designed to expand the use of barcode verification prior to medication and vaccine administration beyond inpatient care areas
  • However, lower levels of full implementation reported in radiology (31%), catheterization (23%), procedure rooms (16%), and operating rooms (7%)

Recommendations for providers

(downstream)

– Implement barcode scanning verification in all areas
  • Prior to administration, verify each medication via barcode medication administration (BCMA) to ensure accuracy
  • Get ready for the future - RFID

– Avoid unjustifiable overrides
  • Neuromuscular blockers may be needed via override for emergency intubation. Nevertheless, if neuromuscular blockers are on a list of overridable medications, each override should be situation dependent and justifiable, and not only based alone on its availability on a list of overridable medications

– Require a witness upon removal of certain medications on override
  • Provide an automated prompt and for documenting an independent double check with another practitioner at the ADC when removing facility-defined medication via override.
  • “Witness on dispense” by cabinet and by drug is an available prompt with some ADC systems that also allows documentation of the verification process
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Recommendations for providers

(downstream)

- **Distraction-free ADC drug removal.** Avoid distractions and talking at the ADC while searching for and removing medications.

- **Monitor overrides.** Monitor overrides daily to verify appropriateness, transcription of orders, and documentation of administration. Review aggregate override usage reports monthly, trending by medication, user, and location, to assess appropriateness, determine how well the hospital is managing overrides, and address barriers to the pharmacists’ review of medication orders prior to drug removal.

For cabinet vendors

- Assist hospitals with increasing the number of drug name letter characters when searching.
  - While efficiency is important, and spelling errors are a concern, safety may be jeopardized by allowing fewer than 5 letters of a drug name to populate the search results. It is recommended that vendors review potential software changes to allow a configurable option for the required number of letters to narrow the choices, ideally to one drug of drug category. Vendors have been helpful.

- Alert users to generic/brand name searches.
  - Some newer ADC systems allow both brand and generic drug names to be displayed and searched. Earlier versions may allow only one or the other. Vendors should enable simultaneous searching by both brand and generic drug name. If brand and generic search capabilities are separate, the ADC screen should clearly display to the user which type of search is currently being conducted (generic or brand) and make it easy to toggle between the two functionalities. Allow display of both generic and brand simultaneously.

- Retire discontinued brand names.
  - In consultation with customers, drug information vendors (Medispan, FirstDatabank, Multum, etc.) should retire discontinued brand names sooner than they now do (the brand name Versed was discontinued in 2003).
The “five rights”

1. Right time
2. Right patient
3. Right drug
4. Right dose
5. Right route

The fallacy of the five rights as an individual responsibility

— The focus is on individual performance where responsibility for accurate drug administration lies with multiple individuals and reliable systems to support safe medication use.

— The five rights are goals for safe medication practices but do not themselves provide procedural guidance on how to achieve them.

— Many errors, including lethal errors, have occurred in situations where practitioners firmly believed they had verified the “five rights.”

— Without adequate systems in place to help practitioners achieve the goals of the “five rights,” errors are likely.

— The “five rights” do not consider the significant contribution of human factors to errors
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ISMP articles & statements

- Criminalization of Human Error and a Guilty Verdict: A Travesty of Justice that Threatens Patient Safety (www.ismp.org/node/30912)
- Paralyzed by Mistakes – Reassess the Safety of Neuromuscular Blockers in Your Facility (www.ismp.org/node/247)
- Safety Enhancements Every Hospital Must Consider in Wake of Another Tragic Neuromuscular Blocker Event (www.ismp.org/node/1326)
- When did Human Error Become a Crime? (www.ismp.org/node/30896)
- The Five Rights: A Destination Without a Map (www.ismp.org/node/909)
- ECRI and ISMP Public Statement | Medication Errors are Complex; Criminal Charges Will Not Improve Care (www.ismp.org/node/31129)

ISMP Recommendations

- Guidelines for the Safety Use of Automated Dispensing Cabinets (www.ismp.org/node/1372)
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An Engineering Look at Preventing Wrong Drug Administered

The General Safeguards for Preventing Wrong Drug by Nurse Selection Error, Retrieval Error, or Pharmacy Stocking Error

Selection, retrieval, or stocking error, plus errors at every step

<table>
<thead>
<tr>
<th>Error</th>
<th>Selection, Retrieval, or Stocking Error</th>
<th>Visually Confirm or ADC</th>
<th>Visually Confirm at Bedside</th>
<th>Barcode Scan at Bedside</th>
<th>Risk/Dose</th>
<th>Interval</th>
<th>Mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection, retrieval, or stocking error, plus at-risk behavior</td>
<td>.001</td>
<td>.001</td>
<td>.0001</td>
<td>1 x 10^-13</td>
<td>1 in 107 doses</td>
<td>Mitigation</td>
<td></td>
</tr>
<tr>
<td>Errors at each step, plus one at-risk behavior</td>
<td>.001</td>
<td>.001</td>
<td>.0001</td>
<td>1 x 10^-10</td>
<td>1 in 10^6 doses</td>
<td>Mitigation</td>
<td></td>
</tr>
<tr>
<td>Errors at each step, plus two at-risk behaviors</td>
<td>.001</td>
<td>.001</td>
<td>.0001</td>
<td>1 x 10^-7</td>
<td>1 in 10^5 doses</td>
<td>Mitigation</td>
<td></td>
</tr>
<tr>
<td>Selection, retrieval, or stocking error, plus three at-risk behaviors</td>
<td>.001</td>
<td>.001</td>
<td>.0001</td>
<td>1 x 10^-4</td>
<td>1 in 10^4 doses</td>
<td>Mitigation</td>
<td></td>
</tr>
<tr>
<td>Selection, retrieval, or stocking error, plus three at-risk behaviors</td>
<td>.001</td>
<td>.001</td>
<td>.0001</td>
<td>1 x 10^-3</td>
<td>1 in 10^3 doses</td>
<td>No Mitigation</td>
<td></td>
</tr>
</tbody>
</table>

Humans modeled at .001, Barcoding at .0001

The Charlene Murphey Event
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A Just Culture at Work?
An Analysis of the Firing, License Revocation, and Criminal Conviction of RaDonda Vaught

The Criminal Law’s General Approach

<table>
<thead>
<tr>
<th>Negligence</th>
<th>Reckless</th>
<th>Knowledge</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Should have been aware, but was unaware of a substantial and unjustifiable risk of harm</td>
<td>Conscious disregard of a substantial and unjustifiable risk of harm</td>
<td>Knowingly causing harm (sometimes justified)</td>
<td>A purpose to cause harm (never justified)</td>
</tr>
<tr>
<td>Sanction</td>
<td>Sanction</td>
<td>Sanction</td>
<td>Sanction</td>
</tr>
</tbody>
</table>

Wait for harm to occur
Judge independent of harm, but strong severity bias in penalty
Don’t learn, just judge
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The People of Tennessee

• Negligence
  • when the person ought to be aware of a substantial and unjustifiable risk
  • With no harm, not a crime
  • When death results, 1-6 years in prison

• Reckless
  • consciously disregards a substantial and unjustifiable risk
  • With no harm, less than 1 year in jail
  • When death results, 2-12 years in prison

• What say the People of Tennessee?
  • Don’t be reckless
  • And don’t kill another person by mistake

Our Model

Human Error
Unintended conduct: where the actor should have done other than what they did
Accept

At-Risk Behavior
A choice where risk is not recognized, or is mistakenly believed to be justified
Coach

Reckless
Consciously disregarding of a substantial and unjustifiable risk of harm
Sanction

Knowledge
Knowingly causing harm (sometimes justified)
Sanction

Purpose
A purpose to cause harm (never justified)
Sanction

React to all independent of the actual outcome (rejecting the severity bias)
Learn from them all
A Fundamental Disconnect

Patient safety specialists use human error, and if sophisticated, at-risk behavior to describe what the human resource leaders and legal systems see as negligence.

Negligence
- Should have been aware, but was unaware, of a substantial and unjustifiable risk of harm.
- Sanction

Human Error
- Unintended conduct: where the actor should have done other than what they did.
- Accept

At-Risk Behavior
- A choice where risk is not recognized, or is mistakenly believed to be justified.
- Coach

“Blaming individuals creates a culture of fear and defensiveness that diminishes both learning and the capacity to constantly improve systems.”

“when incompetence or sub-standard performance is revealed after careful collection of facts, and/or there is reckless or willful violation of policies or negligent behavior, corrective or disciplinary action may be appropriate.”

From one hospital’s Just Culture policy.
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What You Can Do as Leaders

1. Redesign the system to reduce the rate of harm
   For both patients and providers, the best thing that can be done is to prevent the harm in the first place.

2. Conduct and share a complete root cause analysis
   By conducting a meaningful investigation, we can develop understanding and empathy for another person’s experience and in doing so, we can focus on the real work of safety improvement, rather than on our generally punitive, self-righteous response of “I’d never do that. I’m a good employee.”

3. Revise your disciplinary policies
   An organization can and should make the unilateral commitment to employees that they will not face disciplinary action, in response to an event, for any conduct falling short of reckless behavior. This prohibition should cover both human error and at-risk behavior*, regardless of the severity of the outcome.

4. Get professional boards, regulators, and the press on board
   If the goal of professional boards, and state and federal regulators is to keep the public safe, they too should adopt the tenets of Just Culture.

Questions?