February 14, 2019 ▪ Volume 24 Issue 3

ISMP 25 YEARS ADVANCING MEDICATION SAFETY

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Another round of the blame game

A paralyzing criminal indictment that recklessly "overrides" Just Culture

ISMP was shocked and saddened to learn that, once again,[1-4] a frontline healthcare practitioner has found herself on the receiving end of a criminal indictment after making a medication error that led to the tragic death of a patient. RaDonda Vaught, a 35-year-old registered nurse, was indicted on charges of reckless homicide and abuse of an impaired adult, more than a year after inadvertently administering intravenous (IV) vecuronium instead of **VERSED** (midazolam) to a patient in radiology. Prior to a full body scan, IV Versed had been ordered as an anxiolytic due to the patient's claustrophobia. Unable to find Versed on the patient's profile in an automated dispensing cabinet (ADC), RaDonda enabled the override function, entered "VE" into a search field, and erroneously selected and removed vecuronium. She did not notice the selection error and administered vecuronium to the patient, believing it was Versed. The patient experienced an unwitnessed respiratory arrest and died.[5]

According to the Davidson County (Tennessee) District Attorney's Office, the nurse's decision to obtain the medication via ADC override was central to the criminal indictment.[6] While barred from discussing details of the case, the District Attorney's Office noted that safeguards at the ADC were "overridden" by the nurse, and that the Office felt the nurse's "actions justify the charge" based on the legal definition of "reckless."[6] RaDonda is out on bail and awaiting arraignment on February 20. If found guilty of the felony offenses, she faces 2 to 12 years in prison and a hefty fine. The felony charges could also lead to nursing license restriction or revocation, although no licensure action has been taken yet.

News of the nurse's criminal indictment has spurred considerable dialog in both the lay and healthcare media. While the death of any patient due to a medication error is a tragedy on countless levels, many safety experts, healthcare professionals, and consumers believe we have once again thrown a frontline practitioner under the bus for a mistake that could have happened in many other hospitals given the common, underlying system vulnerabilities that contributed to the error (see **Sidebar 1** on page 2). Those who enter the healthcare profession unwittingly put themselves at risk because they are fallible human beings destined to make mistakes. We as humans also have a natural tendency to drift away from strict procedural compliance as perceptions of risk fade while trying to do more in a demanding environment.[7] While we may not be in the ideal position to judge the quality of behavioral choices made by RaDonda while working within imperfect systems, we are deeply concerned about the latest round of criminal charges against a healthcare professional involved in a medication error. Based on what we do know, this is what we have to say:

① We support the nurse.

RaDonda has been described in the media as a well-liked, respected, and competent nurse who had no previous disciplinary actions against her nursing license. While we know nothing more about her than what has been shared in public reports and

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In Memoriam
Dr. John Senders

ISMP was deeply saddened to learn of the death earlier this week of John Senders, PhD. Dr. Senders was a professor emeritus at the University of Toronto and was a key figure in the patient safety movement, focusing on the reduction of medication errors. He coauthored an article that introduced the failure mode and effects analysis (FMEA) concept into medicine in 1994. He served for many years as an advisor to ISMP on human factors and was a cofounder of ISMP Canada, serving in the past as a board member.

Dr. Senders worked throughout his life to benefit others through an understanding of human error. Along with his wife, Ann Crichton-Harris, his journey began in 1980 by organizing an international "clambake" conference on human error in Columbia Falls, Maine (www.ismp.org/ext/164). Dr. Senders was pivotal in promoting the science behind human error. One of his fundamental contributions was noting the heterogeneity of human errors, teaching us that we cannot toss all errors into a neat, causal category labeled "human error." He was among the first to help us see that erroneous actions should be the starting point for an investigation, not an end point. Dr. Senders helped us understand that the causes of errors are multifactorial; there is no single, clearly identifiable cause. He also famously said, "The greatest error you can make is to believe that you won't make errors."

Most of all, Dr. Senders helped in ways that saved thousands of lives from medical errors and harm. We are keenly aware of the pivotal role he played in making ISMP what it is today—we would not be the same organization without him. To learn more about his life, visit: www.johnwsenders.net/.

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the media, we can say unequivocally that ISMP supports the nurse as a second victim of a fatal error. It has been well established that healthcare providers who are involved in a harmful (or potentially harmful) error also become victimized and traumatized by the event, suffering deep and long-lasting emotions characteristic of post-traumatic stress disorder (PTSD), including sadness, depression, shame, guilt, self-doubt, disbelief, fear, and an increased risk of self-harm.[8,9] Second victims are often puzzled when common practices they have used in the past—such as obtaining a medication from an ADC via override—fail to keep a patient safe and result in an error. Fatal errors are known to haunt second victims throughout their lives, and ISMP believes we have a moral imperative to change the culture of blame, retribution, abandonment, and isolation of second victims to a culture of healing, forgiveness, support, learning, and restoration.

ISMP is not alone in supporting the nurse, as evidenced on various social media platforms[10] and a GoFundMe campaign set up to help defray the legal costs associated with a defense for RaDonda (www.gofundme.com/radonda-vaught). More than $50,000 was raised within the first 4 days of setting up the GoFundMe campaign, and the outpouring of emotional support, particularly from nurses, has been phenomenal. We personally thank all who show support of this nurse, as it is critical to her psychosocial and physical recovery.

② We do NOT believe criminal charges are justified.

While our legal system allows for the criminalization of human error even in the absence of any intent to cause harm (see **Sidebar 2** on page 3), ISMP does **NOT** believe criminal charges are justified in this case. In fact, we find it shameful that a nurse who is already suffering and paying the price for her error is now facing a criminal indictment and possible trial, loss of her nursing license and livelihood, and time in prison. The retrieval of the medication from the ADC via override should **NOT** be sufficient grounds for the nurse's criminal indictment, as the District Attorney's Office suggests, nor should any other "safeguards that were overridden" unless RaDonda was well aware that she was taking a substantial and unjustifiable risk.

The override feature is available in basically every hospital that utilizes ADCs and is a function used every day to obtain specific medications when a delay in treatment could impact patient care. Most often, these are emergent or urgent medications. However, the override feature may also be necessary for other medications and solutions in facilities that do not provide 24-hour pharmacy services. In many hospitals, both midazolam and vecuronium (or another neuromuscular blocker) are available via override for urgent or emergent use when needed. The hospital where RaDonda worked allowed nurses to remove certain medications via override, and it is highly likely that, prior to this event, midazolam and vecuronium had been removed from an ADC via override in this hospital. Also, it is unlikely that nurses, including RaDonda, perceived a significant or unjustifiable risk with obtaining medications via override. In fact, removing certain medications from an ADC via override is an accepted risk in healthcare and one that many practitioners take to provide care to their patients.

Any practitioner who did not consciously disregard what they knew in that moment to be a substantial and unjustifiable risk should not be disciplined, let alone charged with reckless homicide and abuse of an impaired adult. Whether the nurse made an error in judgement when deciding to obtain the medication via override is not the issue; the real issue in this case is that there were no effective systems in place to prevent or detect the accidental selection, removal, and administration of a neuromuscular blocker that had been obtained via override.

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Sidebar 1 System vulnerabilities that contributed to the error

For a complete account of the many system vulnerabilities that contributed to a nurse accidentally administering IV vecuronium instead of Versed (midazolam) to a patient, please see our January 17, 2019 newsletter article, *Safety enhancements every hospital must consider in wake of another tragic neuromuscular blocker event*.[5] Below is a short summary of some of the many system vulnerabilities present on the day of the event that contributed to the error.

Sedation in Radiology

- No standard radiology protocol for patients who require sedation prior to a scan due to claustrophobia

ADC System Design

- ADC that populates a drug name search after just two letters of a medication name have been entered
- ADC that does not allow simultaneous searching by brand and generic names

ADC Implementation

- No special precautions in place to verify removal and intended use of a neuromuscular blocker via override
- No auxiliary warnings on neuromuscular blocker vials and ADC storage areas
- No interactive warning that requires selection/verification of a neuromuscular blocker's purpose and alerts practitioners about the need to ventilate the patient
- No requirement for a witness upon removal of a designated IV push high-alert medication obtained via override
- Unclear expectations regarding limited use of overrides for emergent or urgent situations

Medication Labeling

- Ineffective warning (i.e., **Warning–Paralyzing Agent**) on the ferrule of the neuromuscular blocker vial, which has been overlooked with other errors

Patient Monitoring

- Unclear/absent protocol for monitoring patients who receive IV doses of midazolam as an anxiolytic

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Even some professional associations[11] and licensing boards[12] have taken exception to the criminal prosecution of human error, citing that, if warranted, the licensing boards can adequately protect patients from reckless or incompetent actions of a healthcare practitioner by limiting or revoking licenses. (No action has been taken by the Tennessee Board of Nursing on the license of RaDonda.) Safety experts and many licensing boards agree that the criminal system need only be invoked in rare cases when harm is purposeful or knowingly caused without a justifiable benefit.

Incidentally, it appears that the patient's family does not agree with the criminal indictment of RaDonda. Despite the family's great sorrow, the patient's son has said that his mother would forgive RaDonda and feel sorrow for her, lamenting that the mistake had ruined the lives of two people and their families.[13] She would have been upset knowing that RaDonda may spend time in prison.

③ We do NOT believe criminal action will result in improved safety.

ISMP, along with many other safety experts, are again at odds with the criminal justice system regarding the proper course of action to take when a fatal medication error occurs. We advocate for a more fair and just path for individuals involved in adverse events, arguing that punishment does not serve the public interest simply because human error occurred, "safeguards were overridden," and the patient was harmed. Criminal prosecution has worrisome implications for safety. It can inhibit error reporting, contribute to a culture of blame, undermine the creation of a culture of safety, accelerate the exodus of practitioners from clinical practice, exacerbate the shortage of healthcare providers, perpetuate the myth that perfect performance is achievable, and impede system improvements.[11] For example, if an error happens when retrieving a medication via override, why would it ever be reported if the practitioner could be charged with a crime and it can easily be hidden? In an era when we need more transparency, cover-ups will reign due to fear. Even if errors are reported, effective event investigation and learning cannot occur in a culture of fear or blame. Criminal prosecution of practitioners who have made errors is also demoralizing and reduces morale on the frontline.[10]

In fact, in the wake of this recent criminal indictment, we have heard that some nurses are even more terrified of making an inevitable human error that could tragically harm a patient AND lead to their arrest. This event and the criminal charges that stem from it may conversely inhibit nurses from *appropriately* retrieving an urgently needed medication from an ADC via override, possibly leading to treatment delay and patient harm. It may also prompt organizations to inappropriately forbid any ADC overrides, inevitably leading to unauthorized stashes of medications. The detrimental effects of criminal prosecution on reporting, learning, culture, and safety strategies far outweigh its negligible impact on improving individual performance.

④ We urge leaders to be accountable for safe system design.

Clearly, the error that led to the criminal indictment of RaDonda could happen in almost any hospital that uses ADCs given the need for override functionality. As such, recommendations for safely removing medications, including neuromuscular blockers, from ADCs via override were recently published in our January 17, 2019 newsletter.[5] Also, we just released an updated edition of the ISMP ***Guidelines for the Safe Use of Automated Dispensing Cabinets*** (see **Sidebar 3** in the right column). In addition, as early as 2005 and as recently as 2016,[14] ISMP has published articles about the ongoing problem of inadvertently administering a neuromuscular blocker to an unventilated patient, which includes recommendations for preventing these types of errors. Thus, potentially catastrophic safety issues with ADC overrides and neuromuscular blockers are largely foreseeable and preventable.

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Sidebar 2 When did human error become a crime?

Many criminal laws and federal/state regulations make simple human error a crime. If you trace the long history of criminal law in the US, the birth of "criminal" human error (now called public welfare offenses) began during our industrial revolution.[7] Before then, both an *evil hand* and an *evil mind* (intent to harm) were needed to label an activity as criminal. But since the advent of powerful machines that, through individual behaviors, could cause significant harm, an *evil mind* is no longer required for an action to be considered a crime. For example, automobile drivers who have been involved in an accident that caused the death of another individual might be prosecuted in most states for vehicular homicide, even if the death resulted from a human error. The reality is that mere human error that randomly occurs in well-meaning people is now considered "criminal" in various circumstances where public safety is an issue. For those unlucky enough to make one of these errors, criminal charges may only be an indictment away.[7]

Sidebar 3 Updated *Guidelines for the Safe Use of Automated Dispensing Cabinets*

Recent tragic events involving automated dispensing cabinet (ADC) overrides have brought a renewed focus on the safe use of ADCs. With this technology being used for medication distribution in more than 80% of hospitals and health systems, ISMP believes organizations have an obligation to ensure that the implementation of ADCs and the management of ADC overrides are optimized in a manner that promotes safe patient outcomes. In addition to the event in Tennessee that led to the indictment of nurse RaDonda Vaught (see main article), headlines out of Ohio this past week describe at least 34 near-death patients who were intentionally prescribed large doses of opioids and sedatives while under the care of a physician, for the stated purpose of providing comfort care. All 34 patients are deceased; of these, 28 received excessive and potentially fatal doses. In many cases, the large doses of opioids were prescribed as emergency medications in a way that facilitated ADC access using override functionality, bypassing the need for prospective review by a pharmacist.

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However, normal human biases make it difficult for healthcare leaders to learn from the mistakes of others. Too often, leaders assume that a catastrophic medication error that has happened in another facility will not happen in their facility. If it does, leaders may be unable to effectively cope with it, underestimate its full effects, and resort to punitive personnel actions that are conveniently quick and easy, yet wholly ineffective and often unfair. Or, leaders and others, including the criminal justice system, may overlook latent system failures that contributed to an error and instead focus only on the frontline nurse's active failure to follow the "five rights."

Yes, RaDonda did not complete verification of the five rights, which is a failing with ANY medication error. But the five rights are merely broadly stated goals that offer no procedural guidance on how to achieve them. Simply holding nurses accountable for following the five rights fails miserably to ensure medication safety. They are not intended to be an individual behavioral model for achieving medication safety but rather goals for which organizations must accept responsibility and design safe systems in which they can be achieved.[15]

We urge leaders to push aside the natural tendency to believe published events are rare and instead recognize that errors are inevitable. Leaders must be proactive with system design improvements by learning and benefiting from the lessons learned by others when medication errors happen. Please don't wait for another patient to die, or another frontline practitioner to be brought up on criminal charges, before acting. Leaders are the owners of systems and are not off the hook, even though much of the dialog currently surrounds an individual frontline nurse. Accountability for safety must be shared, and leaders are ultimately responsible for system design as well as subsequent design changes that are needed to improve safety within their organizations. Perhaps criminal indictment of frontline practitioners in the wake of an error would not occur if leaders took ownership of, and addressed, imperfect systems at the outset.[16]

⑤ We urge leaders to avoid the severity bias and establish a Just Culture.

When a patient dies as a result of an error, it is human nature to react to the egregiousness of the injury.[7] Although we have a tendency to view errors leading to harm as more blameworthy and punishable than the same errors that do not lead to harm,[17] allowing a severity bias to drive the response is not fair to the workforce and does not maximize safety.

To be fair, or just, human error should be consoled as long as the individual's behavioral choices were not reckless. The quality of one's behavioral choices should dictate accountability, not the human error itself or the severity of its outcome. In contrast to the criminal system, the question within a Just Culture is not whether harm occurred, but whether the individual *consciously* disregarded what he or she *knew* to be a substantial and unjustifiable risk. This question is associated with conscious disregard of a known risk, not conscious disregard of a policy, procedure, or "safeguard." Policy, procedure, and "safeguard" deviations are often at-risk, rather than reckless, choices where the risk is not seen or mistakenly believed to be insignificant or justified.[18] Most at-risk behaviors are caused by system failures that practitioners must work around, often on a daily basis, to get the job done—such as obtaining a medication by override because it can't seem to be found in the patient's profile. The practitioner who engages in at-risk behavior should be coached to see the risk associated with the choice, AND the system failures that are driving that behavior must be remedied.

Allowing the severity bias to drive error responses is also ineffective with respect to safety improvements. The "no harm, no foul" mentality of waiting for patient injury before taking action belies logic when pursuing safety.[17] Looking the other way when non-harmful errors happen leaves the outcome to a matter of luck. If you are lucky,

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Managing ADC overrides safely is an important area of focus in our newly updated 2019 edition of the ISMP ***Guidelines for the Safe Use of Automated Dispensing Cabinets***, which are available at www.ismp.org/node/1372. The newly revised ***Guidelines***, which were first created in 2009, include input from members of the Medication Safety Officers Society (MSOS), as well as ADC vendors, BD and Omnicell. The updated document, which also underwent public comment and review, is designed to support organizations in the safe use of ADCs through the adoption of standard practices and processes. The ***Guidelines*** include best practices associated with both structural elements (e.g., environmental conditions, system security, and cabinet configuration and functionality) and system design elements (e.g., optimal inventory management, stocking and return processes, and procedures for safe product withdrawal). The latter topic includes a focus on managing system overrides safely. We hope all organizations will prioritize implementation of the systematic recommendations outlined in these important ***Guidelines***.

SAFETY brief

More on fuzzy matching. Since publishing our ***Safety Brief*** in the January 31, 2019, newsletter about Epic's "fuzzy matching," we learned of some improvements made by the company that seem to reduce the risk of selecting an incorrect medication. Briefly, if a practitioner misspells a medication name when entering orders or searching for medications, fuzzy matching refers to the software generation of an algorithm-based list of what the system "thinks" the practitioner is searching for; however, the list includes near hits that may not be an exact match. ISMP has received reports of concerns from Epic users about the risk of selecting something other than what was intended because the list includes look-alike drug names.

The good news is that, soon after publication of our ***Safety Brief***, Epic users told us that the company had recently tweaked the algorithms used for fuzzy matching, which eliminated some of the examples of problem drug names we provided in the brief. However, the bad news is that, even

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the patient is unharmed. If you are unlucky, the patient is harmed. If you are really unlucky, you may even spend time in jail for being human.

We cannot wait for harm to address risky systems or behaviors. Nor can we repeatedly engage in risky choices, then unjustly punish the unlucky few who have been involved in events that resulted in significant harm.[7] Avoiding the severity bias and establishing a Just Culture is paramount to safety.

Our support for RaDonda in no way lessens our condolences to the patient's family or minimizes the pain her family will forever bear from losing a loved one to a medical error. Our hearts and prayers go out to the patient's family as well as to RaDonda and her family.

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ISMP Medication *Safety Alert!* Acute Care (ISSN 1550-6312)

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with the recent improvements, similar-looking names are still presented to users with fuzzy matching. For example, users will still see cyclosporine listed when the tuberculosis drug cycloserine is spelled incorrectly as "cyclosorine." As one of our readers mentioned, this is quite different than older paper-based ordering systems that did not automatically suggest look-alike names to the prescriber that could also be confused by a pharmacist. Now, the potential for medication errors is an unanticipated consequence of electronic health records with enabled fuzzy matching. So, our concern remains. We still do not think fuzzy matching for medications is wholly safe.

Special Announcements

Free ISMP webinar

On **March 14, 2019**, from 1 to 2 p.m. ET, ISMP will be presenting a **FREE** webinar thanks to support from Baxter on ***Designing Reliable Practices for IV Push Medication Use: A Focus on Safe Administration***. Join nurse faculty from ISMP as they describe the often-unrecognized risks associated with intravenous (IV) push practices, provide related national survey results, and discuss the recommendations from the ***ISMP Safe Practice Guidelines for Adult IV Push Medications***. The faculty will also describe a national gap analysis tool that will help to assess and improve the safety of IV push practices (see below). For details, visit: www.ismp.org/node/1377.

Gap analysis tool deadline approaching

ISMP has launched a new tool to help healthcare facilities identify and manage risks associated with the use of intravenous (IV) push medications in adults. The ***ISMP Gap Analysis Tool (GAT) for Safe IV Push Medication Practices*** is available at no charge, thanks to support from the Baxter Healthcare Corporation. Healthcare facilities that submit their findings to ISMP anonymously via a secure online portal by **March 31, 2019**, will receive a gap analysis score and will have access to aggregate data after the submission period. To access the tool, visit: www.ismp.org/node/1188.

ISMP Safe Medication Management Fellowships

ISMP is now accepting applications for three unique **Fellowship** programs commencing in **2019**

ISMP Safe Medication Management Fellowship

Location and Term: This 12-month Fellowship commences July 2019 at the Horsham, Pennsylvania (near Philadelphia) office of ISMP. Relocation to the Horsham/Philadelphia area is required.

Description: Now in its 27th year, this Fellowship offers a **nurse, pharmacist, or physician with at least 1 year of postgraduate clinical experience** an unparalleled opportunity to work collaboratively with the nation's experts in medication safety to assess and develop interdisciplinary medication error-prevention strategies. This Fellowship is open to US citizens (or applicants with a valid US visa).

FDA/ISMP Safe Medication Management Fellowship

Location and Term: This 12-month Fellowship commences August/September 2019. The Fellow will spend 6 months at the Horsham, Pennsylvania (near Philadelphia) office of ISMP and 6 months at the Silver Spring, Maryland (near Washington, DC) office of the US Food and Drug Administration (FDA). Relocation to the Horsham/Philadelphia and Silver Spring/Washington, DC, area is required.

Description: This Fellowship, open to a **healthcare professional with at least 1 year of postgraduate clinical experience**, is a joint effort between ISMP and FDA's Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis. The Fellowship allows the candidate to benefit from ISMP's years of medication safety experience along with FDA's valuable regulatory experience focused on medication error prevention.

ISMP International Medication Safety Management Fellowships

Location and Term: These 1- and 2-year Fellowships commence summer/fall 2019 at the Horsham, Pennsylvania (near Philadelphia) office of ISMP. Relocation to the Horsham/Philadelphia area is required.

Description: These Fellowships, open to **healthcare professionals with an advanced degree and at least 1 year of experience in an acute care setting**, will help train medication safety leaders seeking long-term careers at an international level. The Fellows will be involved in global medication safety initiatives, address worldwide safety issues, and help increase global reporting of medication errors. All applicants must be **fluent in written and spoken English and be a US citizen or have official documentation** to remain in the US for the duration of the Fellowship and to travel internationally.

A competitive stipend is provided with all Fellowship programs.

How to Apply

Information and an application can be found at: www.ismp.org/profdevelopment/.
An application can also be requested by calling 215-947-7797.

The application deadline for all Fellowship Programs is March 31, 2019.