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## Investigative approaches: Lessons learned from the RaDonda Vaught case

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**Investigative approaches: Lessons learned from the RaDonda Vaught case.**

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### Abstract

Accidental patient harms occur frequently in healthcare, but their exact prevalence and interventions that will best prevent them are still poorly understood. In rare cases, healthcare providers who have contributed to accidental patient harm may be criminally prosecuted to obtain justice for the patient and family or to set an example, which theoretically prevents other providers from making similar mistakes due to fear of punishment. A recent case where this strategy was chosen is the *RaDonda L. Vaught vs. Tennessee* (2022) criminal case. The present article discusses this case and its ramifications, as well as provides concrete recommendations for actions that healthcare organizations should take to foster a safer and more resilient healthcare system. Recommendations include placing an emphasis on just culture; ensuring timely, systems-level investigations of all incidents; creating and facilitating participation in a national reporting system; incorporating Human Factors professionals at multiple levels of organizations; and establishing a national safety board for medicine.

Keywords: patient harm, medical error, medication error, RaDonda Vaught, litigation, criminalization, just culture

## 1. Introduction

For decades, instances of accidental patient harm have been the center of attention for researchers, healthcare institutions, popular media, and even legal proceedings. Recognizing that accidental patient harm has the potential to result in egregious damage and even death, many institutions have attempted to glean insights to accidental patient harm by quantifying adverse events to better understand their prevalence. However, such efforts have been hotly debated, with the true number difficult to ascertain due to the complexity and multifarious nature of harm related to patient care. Initially, it was estimated that approximately 100,000 Americans die annually because of accidental patient harm (Kohn et al., 2000). Subsequent estimates have ranged from 3.6% (Hogan et al., 2015) up to the astronomical third leading cause of death (Makary & Daniel, 2016), with meta-analytic evidence suggesting that fatalities from accidental patient harm account for approximately 12% of in-hospital deaths (Panagioti et al., 2019). In addition to having little agreement on how to measure and quantify accidental patient harm, there is even more ambiguity regarding the factors that contribute to harm (aka root causes) and the appropriate actions that should be taken after harm has occurred.

One sociotechnical model specifically designed for garnering insights about patient safety is the Systems Engineering Initiative for Patient Safety (SEIPS 3.0; Carayon et al., 2020). SEIPS 3.0 posits that individuals along with the processes and tasks, tools and technologies, organizational conditions, and the physical environment all intersect to influence patient safety outcomes related to patients, caregivers, clinicians, and even healthcare organizations. Within the context of this sociotechnical lens, the processes are the means by which a system

accomplishes its goals (Carayon et al., 2020), and the tasks are the specific work actions within the larger set of processes (Holden et al., 2013). The tools and technologies are the physical or cognitive apparatuses used to accomplish the task (e.g., medical devices), and the organizational component refers to the characteristics of the work structure (e.g., scheduling and culture). Finally, the physical environment pertains to the actual space and layout (Holden et al., 2013). Ultimately, all these components intersect with the individuals involved in the provision of patient care to influence outcomes. One example that entails all these components and clearly depicts the consequences of accidental patient harm being poorly understood, investigated, and articulated is the *RaDonda L. Vaught vs. Tennessee* (2022) criminal case. In this example, a nurse in Tennessee was convicted of crimes associated with a patient fatality attributable to patient harm.

### **Problem Statement**

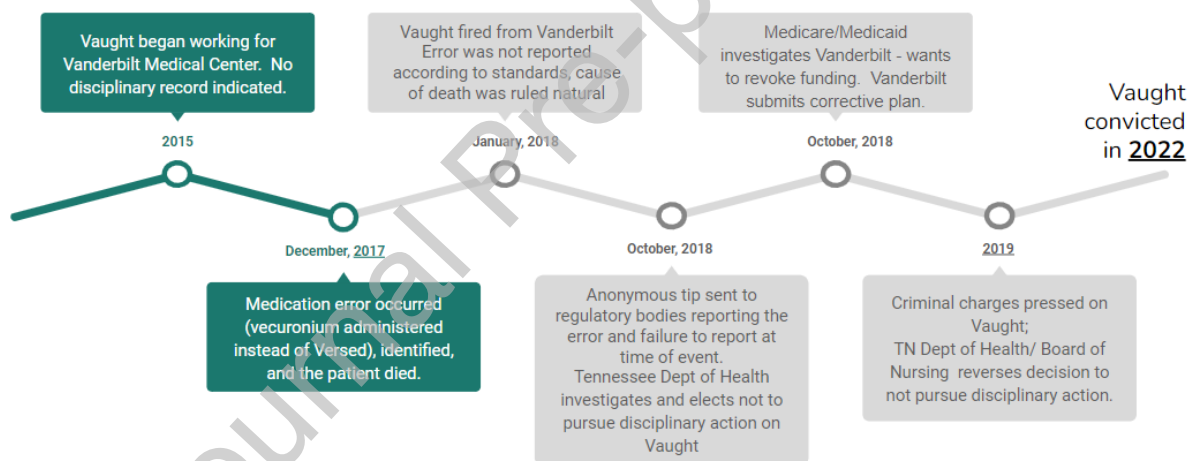
How the incident surrounding RaDonda Vaught was portrayed and tried, along with the verdict and sentencing, have serious negative implications for the entire healthcare industry as well as the public. The purpose of the current paper is to outline the situation and failures in the approach and analysis of the *RaDonda L. Vaught vs. Tennessee* case using the systems engineering initiative for patient safety (SEIPS) 3.0 framework as a guide. To this end, the paper will discuss the event, associated sociotechnical factors based on the SEIPS 3.0 framework, and recommendations to foster a safer and more just healthcare system.

## 2. The Vaught Case – Overview, Key Contributing Factors, and Impact

The following represents a summary vignette of the incident based on the publicly available information regarding the case, primarily relying on the Centers for Medicare & Medicaid Services (2018b) report findings, as it is the most comprehensive and formal document relating to the case. For a visual representation of the timeline of events related to the case, see Figure 1.

**Figure 1.**

Timeline of events related to Vaught's involvement in the patient harm, investigations, and associated litigation.



### 2.1. Overview

On December 26, 2017, RaDonna Vaught was serving as a nurse at Vanderbilt. She was orienting a new nurse and was asked to administer a medication for a patient's claustrophobia in the Radiology PET scan area. Vaught agreed to help, as she and the orientee were already on their way to that department to take care of another patient. Vaught retrieved medication from the electronic dispensing cabinet. They went to the PET scan area, where Vaught confirmed the



patient's identity, prepared and administered the medication. They left for their original tasking, and the radiology technicians then moved the patient to a room to wait for their exam. A short while later, a transporter realized the patient was unresponsive and notified the radiology technicians, who called an urgent code. When the code was announced, Vaught responded and began assisting the response team to stabilize the patient and identify the cause. During this process, another nurse looked more closely at the medication vial, and it became apparent that Vaught had administered vecuronium, a paralyzing agent, rather than the intended sedative Versed. The patient was temporarily revived, then removed from mechanical ventilation and pronounced dead the next day (December 27, 2017). Ultimately, Vaught was criminally prosecuted for this mistake and found guilty of criminally negligent homicide and abuse of an impaired adult (*RaDonna L. Vaught vs. Tennessee*, 2022).

## **2.2. The Investigation and Sociotechnical Factors Related to the Case**

To strengthen patient care while mitigating bias and blame, accidental patient harm should be approached from a systems-perspective (Keebler et al., 2022). Thorough and accurate attribution of causal factors that lead to such harm require rigorous, comprehensive investigation. During and following the event, Vaught admitted she must have made this mistake and filed incident reports accordingly (Office of the District Attorney General, 2019; Centers for Medicare & Medicaid Services, 2018b). Vanderbilt conducted an initial analysis of the event in 2017, and fired Vaught shortly thereafter (Office of the District Attorney General, 2019). Vanderbilt then negotiated a family settlement, did not disclose the incident and incorrectly reported a natural cause of death to governing authorities (Centers for Medicare & Medicaid Services, 2018b, p. 43). An anonymous tip was made nearly a year later, which

prompted the Centers for Medicare & Medicaid Services (CMS) to perform their own independent investigation at Vanderbilt (Centers for Medicare & Medicaid Services, 2018a).

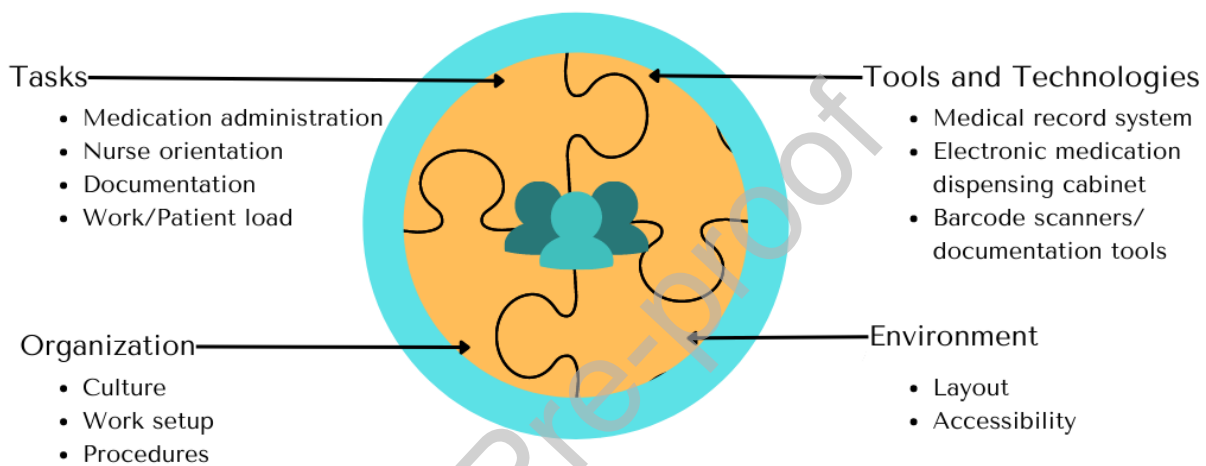
Ultimately, CMS deemed Vanderbilt's investigation and response to the incident was insufficient to generate appropriate safety improvements capable of preventing such an incident from reoccurring (Centers for Medicare & Medicaid Services, 2018b, p.26). Thus, they threatened to revoke funding until Vanderbilt was able to produce an action plan to implement safety improvements (Centers for Medicare & Medicaid Services, 2018b). Based on the publicly available information from the hospital's initial event analysis (Centers for Medicare & Medicaid Services, 2018b, p. 22; pp. 29-38), many of these initial response failures may have stemmed from the Vanderbilt analyses' focus on the individual provider mistakes, rather than systemic issues that contributed, which is a common shortcoming of hospital-initiated event analyses and responses (Peerally et al., 2017; Keebler et al., 2022). Additionally, the criminal investigation conducted by the Tennessee Bureau of Investigation (TBI) focused solely on the mistakes that Vaught made without consideration of the systems-level issues, and nor was evidence of these systemic issues presented in her defense (ISMP, 2022).

There is merit in better understanding such systemic factors that likely contributed to the patient's harm to emphasize what may have been revealed by a more comprehensive and timely investigation. Although we are limited to the information that was documented and made publicly available, it is possible to consider a broad array of the factors that might have contributed, and thus demonstrate that the legal and organizational responses to the incident exclusively targeting Vaught were inappropriate. Thus, with these limitations in mind, we have

utilized the SEIPS 3.0 framework to identify and organize demonstrable issues, which are illustrated in Figure 2 and further described in subsequent sections.

**Figure 2**

Factors involved in the patient harm based on the SEIPS framework:



### **2.3.1. Technology and Tools**

The tools and technologies are the physical or cognitive apparatuses used to accomplish tasks, such as medical devices, computers, the electronic health/medical record system (EHR, EMR), electronic medication dispensing cabinets and their associated interfaces (Holden et al., 2013). Many of these technologies, and the interactions between them, played a role in this event. To begin, recent changes in this medical record system likely contributed. Vanderbilt was in the process of a large-scale transition in their medical record system for the two months

preceding the incident in December of 2017 (Johnson & Ehrenfeld, 2018). Due to this transition, workarounds and overrides were reportedly commonplace when interacting with the medical record system during this period (Kelman, 2022a). There is supporting evidence that this patient case alone required 20 overrides for necessary medications during their stay (Kelman, 2022b). As a result, within this context, the warnings provided to Vaught would not have been abnormal or unique at the time, nor accurately prescriptive in the majority of cases. The informativeness of warnings has been identified as one of the top contributors to whether front-line staff appropriately respond to them (Rayo & Moffatt-Bruce, 2015). Thus, the front-line workers were dismissing such warnings without much consideration (Kelman, 2022a), which is a well-established repercussion of high volumes of warnings in medical records related to drug safety (Payne et al., 2015).

The name lookup function for drugs within these systems exacerbated such issues. The medication dispensing cabinet system was programmed such that drugs in the profile would default to appearing only by their generic, rather than brand names. In this case, that meant that the ordered drug, stated as “Versed” in general communications and orders in the medical record, needed to be looked up by its generic name, “Midazolam,” to appear in the default search functions of the medication dispensing system (Centers for Medicare & Medicaid Services, 2018b, p. 37). Since Vaught did not recognize this, it caused her to be unable to find the medication via direct search in the patient’s profile on the dispensing cabinet. This precursor issue underpins why Vaught performed the initial override to get to the larger list of medications.

A final issue that contributed to this incident resulting in patient harm was the inaccessibility of other tools that could have caught and prevented the error from occurring. Barcode scanners, a tool providers use to either crosscheck a medication with the medical record before administering and/or aid with documentation after the procedure, have been demonstrated as an effective tool for reducing medication administration and documentation errors such as this one (Truitt et al., 2016). Although these scanners were present in many other places in the hospital, they were not available to Vaught in the radiology department (Centers for Medicare & Medicaid Services, 2018b, p. 32). Because these tools were not available, Vaught was unable to perform any systematized crosschecks prior to administering the incorrect medication. Her only mechanism to catch the error was based on the five rights of medication administration (right patient, right drug, right time, right dose, and right route), which are considered broad goals that lack direct procedural guidance, and are insufficient for preventing patient harm when providers lack appropriate knowledge and support structures to carry out these checks effectively (Grissinger, 2010; ISMP, 2022). Therefore, the institutions' overreliance on inconsistent processes and failure to provide appropriate tools contributed further risk of patient harm occurring following Vaught's initial oversight.

A more systems-focused analysis of this event might have involved investigations regarding the relative frequency of provider overrides across the hospital, as well as the relative informativeness of the warnings within these systems. Such investigations have been recommended and utilized to improve monitoring and alert policies in hospitals, and could have provided vital insights as to whether the warning was likely to be noticed and acted on by other providers in Vaught's position (Rayo & Moffatt-Bruce, 2015; Rayo et al., 2015). Additionally,

information regarding the effectiveness of barcode scanners in other hospitals or departments (i.e., in preventing wrong drug administration) to elucidate the baseline risk of not having barcode scanners in the radiology department (e.g., Kung et al., 2021; Burkoski et al., 2019; Truitt et al., 2016).

### **2.3.2. Tasks**

In addition to the many issues related to the technology and tools available to Vaught, there were also task-related issues that contributed to this incident. In this context, tasks are the specific work actions individuals engage in within the larger set of processes at an organization (Holden et al., 2013). During a shift, nurses are responsible for a variety of concurrent and time-sensitive tasks (Douglas et al., 2017; Michel et al., 2021). As a nurse, Vaught was no exception with having to multi-task under time constraints. At the time, her tasks included administering the medication to this patient, conducting a procedure on another patient, and orienting a new nurse. Many of these tasks competed with one another, contributing additional vulnerability to errors and patient harm.

For example, Vaught was actively explaining procedures to the orientee while selecting the medication in the electronic dispensing unit (Centers for Medicare & Medicaid Services, 2018b, p. 54). This caused a distraction to her normal processes and added to her cognitive load, which would have increased the potential for error (Hayes et al., 2015; Parry et al., 2015). Vaught was completing this medication administration on the way to a procedure with another patient as no other nurses (including the patients' assigned nurse and the nurses in radiology) were able to do so at the time. The other nurses' lack of availability is suggestive that there may have been a poor nurse-patient ratio set up by the organization. The lack of available

nurses is, unfortunately, a common issue, as data from the U.S. Department of Health and Human Services has identified a gap between the available nurses and the demand for nurses since 2015 (US DHHS, 2017). Consequently, these shortages have implications, such that nurses report having insufficient time to complete their tasks, therefore, experience a sense of time pressure (de Casterle et al., 2020; Vinckx et al., 2018). High patient to nurse ratios (more patients to fewer nurses) have been previously identified as a risk factor for elevated medication administration error rates (Parry et al., 2015). Furthermore, there was a danger that this patient's exam would need to be rescheduled if the medication was not administered in a timely manner (Centers for Medicare & Medicaid Services, 2018b, p.13). Because the medication had to be administered immediately and no additional nurses were available, Vaught was experiencing time pressure to address multiple patients (and thereby reduce monitoring time) to compensate, which ultimately increased the potential for patient harm.

A more systems-focused investigation of this event should have produced evidence regarding the nurse-to-patient ratio at the time, along with the relative normality of this ratio for safe patient care. Additionally, this situation warranted an investigation into potential conflicts between nurses related to task assignments, procedural expectations, and experience that may have shaped the execution of these tasks, which is discussed further in the Organization section.

#### **2.3.4. Organization**

The organizational component of the SEIPS 3.0 model refers to characteristics of the work structure, such as scheduling, role and responsibility designations, procedures, and culture embedded in the organization. A number of procedural ambiguities and inconsistencies

likely exacerbated many of the technology-, and task-related issues described above. For instance, research has specified that role ambiguity is negatively related to a variety of factors within medicine, such as increased conflict (Sanli et al., 2021) as well as increased stress, poor organizational commitment, decreased job satisfaction, and higher levels of burnout (Cengiz et al., 2021). Pertaining to this incident, there was ambiguity regarding whether this specific patient needed to be monitored for Versed administration, as well as whose responsibility it would have been to make that decision. The nurses in radiology refused to administer the medication upon request due to an inability to monitor; in contrast, several people (including Vaught) were told that patient monitoring was not needed in this circumstance (Centers for Medicare & Medicaid Services, 2018b, p. 11 and 13). Levels of procedural standardization and provider collaboration influence provider adherence to safety-related practices, including patient monitoring (Vaismoradi et al., 2020). According to the CMS report, a specific monitoring protocol was not explicitly documented in Vanderbilt's procedures (Centers for Medicare & Medicaid Services, 2018b, p. 3 and p. 6). Thus, in this case, the lack of explicitly documented procedural guidance and inadequate collaboration between the providers contributed additional risk of patient harm.

Organizational designations of roles and responsibilities specific to Vaught's role relative to the other nurses responsible for the patient's care likely contributed further to this issue. The "help-all" nurse was not a universal role across the hospital, and Vaught stated in interviews that there was not a job description for the role (Centers for Medicare & Medicaid Services, 2018b, p. 11 and 37). Individuals in this role were not assigned to specific patients to take care of during a shift, but were instead expected to assist other nurses in the care of their assigned



patients at the direction of a staff leader (Centers for Medicare & Medicaid Services, 2018b, p. 105). The extent of their expected involvement in various tasks and the day-to-day variability in such tasks for this role was not made public knowledge. However, since these individuals are not assigned specific patients, these individuals may have fewer interactions with patients and less patient-specific knowledge that may be relevant for clinical judgements needed for them to independently complete their assigned duties (e.g., deep level understanding of the patient condition, status, or a given procedure/medication for a specific patient's case).

For instance, nurses' ability to appropriately identify a deteriorating patient is often rooted in intuition based on deviations from the patient or case profile's typical clinical status (Odell et al., 2009; Halverson & Tilley, 2022). This process requires the nurse to have a deep level expertise of such features to detect deviations. Vaught would have been less likely to have deep level expertise, given that she was a help-all nurse with less than 3 years of experience at the hospital. Further, research has demonstrated that providers with less experience have more difficulty and less certainty when making medical decisions compared to more experienced providers, and inexperienced providers ignore conflicting information more often than experienced providers (Tabak et al., 1996; Carroll & Sanchez, 2020). Consequently, it is possible that the more familiar nurse (the patient's assigned nurse) recommended that monitoring was not needed (as is suggested by language from interviews in the CMS report; Centers for Medicare & Medicaid Services, 2018b, p. 11 and 13). A more familiar nurse stating that monitoring is not necessary would have been particularly powerful in influencing Vaught's behavior to move outside of what might otherwise be nurses' standard of care practices for monitoring patients following medication administration. Thus, the unclear responsibilities

between these patient care roles related to medical decisions and administration procedures would have further increased the potential for patient harm in these circumstances. A more systems-level investigation of this event might have produced information relating to the relative experience of the nurses on shift (with regard to the patient, drug administration for this and other drugs, and years in active practice), teamwork dynamics, standard day-to-day task expectations and variability specific to the “help all” nurse role (e.g., orienting new employees, administering medications) to validate whether these factors played a significant role in the incident.

### **2.3.3. Environment**

The procedural ambiguities discussed in the previous section may have been further influenced by the environment associated with the radiology department where the medication was administered. In the SEIPS 3.0 model, the environment pertains to the physical features of the space, including features such as noise, lighting, and layout in areas where tasks are carried out (Holden et al., 2013). Although perhaps often overlooked, the physical layout of the healthcare facility has serious implications for adverse events and patient safety. Ulrich and colleagues (2004) conducted a review of over 600 studies and found evidence that the physical layout is related to the effectiveness of delivering care along with overall healthcare quality. Relating to this incident specifically, the environment influenced staff members’ ability to monitor the patient’s wellbeing.

Within this context, staff members could see the patient while they were waiting; however, their view was restricted to only a small camera-based view which did not permit them to passively assess key vitals such as respiratory status (Centers for Medicare & Medicaid

Services, 2018b, p.12). Additionally, the patient was not attached to any form of monitors that could have been utilized (or adequately seen by staff members) to observe vital signs throughout the duration of the waiting period and thus notice when she stopped breathing (Centers for Medicare & Medicaid Services, 2018b, p.12). Finally, the patient was not accompanied by a family member for their transport or permitted to stay with them during the waiting period (ISMP, 2022). Family members have been recommended as part of comprehensive surveillance programs for hospitalized and elderly patients, and have been reported to successfully detect adverse events and facilitate provider intervention (Khan et al., 2017; Stockwell & Gill, 2010). Given that respiratory rate is one of the most significant contributors for predicting serious events (e.g., cardiac arrest; Cretikos et al., 2008), the inability to monitor respiratory rate through any of these alternative mechanisms exposed the patient to greater risk of harm.

A more systems-focused investigation might have sought to understand whether these environmental constraints intersected with the procedural ambiguities related to monitoring discussed in the previous section; for example, if there was an incorrect assumption by overseeing staff that radiology technicians or family would be in the room with the patient throughout the duration of the procedure. If this were the case, they may have been under the mistaken impression that these individuals could have served sufficient monitoring agents based on the profile of the drug that was intended to be administered.

### **3.Recommendations**

Despite the gaps in the investigation of RaDonda Vaught, we have identified many systemic issues that influenced her behavior and made it far more likely for this mistake to occur and cause harm to the patient. We hope this evidence is sufficient to cause doubt that this was the result of true negligence, and thereby encourage readers to question the validity of the verdict she received. The remainder of the paper will be devoted to discussing five efforts all healthcare organizations and the healthcare industry should consider pursuing to prevent a similar tragedy in the future.

#### **3.1.Emphasize just culture.**

This case ended in the firing, license revocation, and criminal prosecution of a well-meaning provider who freely admitted to their error, demonstrated honesty and genuine efforts to rectify their mistake. Her conviction does nothing to motivate or guide us toward improved patient safety and more resilient healthcare systems (Hollnagel et al., 2006) and will only serve to decrease the safety of the system by increasing the barriers providers already perceive to reporting events that could lead to improvements in the system's safety (Hammoudi et al., 2018). Evidence demonstrates that punitive or blame-centric approaches to harm that focus on the providers' role inhibit incident reporting due to fears of damaged reputation, threat of malpractice lawsuits, high expectations of the patient's family/society, possible disciplinary action by licensing boards, threats to job security, and expectations/egos of other team members (Sexton et al., 2000; Kaldjian et al., 2006; Hartnell et al., 2012; Bell et al., 2017; Hammoudi et al., 2018). Ultimately, if the healthcare community retains shaming of patient harm and errors, they will be underreported. Without reporting, improvements in the system

will be limited to lessons learned from severe cases that result in patient harm that are traceable to an identifiable mistake, such as this one. This outlook is less than ideal, as it relies on severe harm occurring to instill improvements that may remain insufficient to protect all future patients, and unfairly penalizes providers based on chance outcomes. Just culture represents a shift away from blame culture by prescribing a balance of appropriate accountability and incident reporting (Khatri et al., 2009; Woods et al., 2010). Just culture necessitates that patient harms are investigated beyond individual errors committed by front-end providers, focusing on educational and system improvements capable of preventing such harm in the future (White and Delacroix, 2020). To this end, application of a just culture requires investigation of all incidents, thus, bringing us to our second recommendation.

### **3.2.Ensure timely, systems-level investigations of all incidents.**

The criminal investigation took place over a year after the event, focused solely on the actions Vaught took that lead to patient harm, and entirely overlooked the systems issues that contributed to the event. Vanderbilt's investigation and response to the incident, though both more timely and systemic, was similarly lacking. Although the hospital implemented some changes prior to the intervention of CMS (e.g., education for staff members regarding the default selection systems in the dispensing cabinet, replacement of vecuronium on the override list with a faster acting drug, and barcode scanners in the radiology department) , their timeline to implement system changes extended several months, and was ultimately deemed insufficient by CMS authorities (Centers for Medicare & Medicaid Services, 2018b, pp. 29-38). The CMS report states, "based on standards of practice, document review, review of hospital policies and procedures, medical record review, and interview, the hospital failed to ensure

that the Quality Assurance and Performance Improvement (QAPI) program thoroughly analyzed a critical adverse event and all the causes, and implement preventive actions that inducted adding additional safety parameters associated with overriding paralytics and other High Alert medications from an automated dispensing cabinet (ADC) to ensure that a similar critical adverse event could not reoccur” (p. 26). Furthermore, the failure of the institution to accurately report the incident to governing authorities greatly extended the investigative timeline, which likely increased the potential for key details of the case to be misrepresented and contribute to the inappropriate legal actions.

As an example of a likely misrepresentation, there is evidence that the prosecution may have obtained incorrect information related to Vaught’s actions at the time that would have falsely depicted her to the jury as negligent. Although the CMS investigation revealed evidence that Vaught only dismissed a generic warning related to overrides (which were commonplace at the time according to eyewitness testimonies; Centers for Medicare & Medicaid Services, 2018b, p. 33; Kelman, 2022a), the prosecutorial discovery documents indicate that she dismissed a warning specific to the paralytic and respiratory depressant status of vecuronium, along with the need to ventilate, through the dispensing cabinet interface (Office of the District Attorney General, 2019, warning #4 on p. 50). However, based on Vanderbilt’s corrective action plan submitted to CMS, a warning with this specific phrasing was only proposed as an addition to be implemented in their systems in November of 2018, nearly one year after the event took place (Centers for Medicare and Medicaid Services, 2018b, p. 43 and 29). This suggests the prosecution may have based pieces of their investigation on the updated systems that included safety improvements, which is plausible given that the prosecution did not begin

the process of investigating Vaught's role in the incident until December 2018 (one year after the event and shortly following the projected implementation timeline of the corrective action plan; Office of the District Attorney General, 2019). Thus, the lack of timely, comprehensive investigation into this incident severely hinders the conclusions that could be drawn about Vaught's true culpability.

A more thorough investigation of the incident at the time of the event may have identified some of the gaps in relevant information and validated the systemic causes mentioned in previous sections. This may have led to more timely and comprehensive improvements in the hospital's systems to mitigate harm that could potentially occur for future patients, and likely a fairer criminal investigation surrounding Vaught. However, we recognize that it is difficult for the existing organization and culture to change if it is left to investigate itself for such issues. This brings us to our third recommendation.

### **3.3. Refine and bolster participation in a national reporting system.**

Such systems may aid harm prevention by enabling more widespread learning from instances of harm, which theoretically would allow institutions to identify likely patient safety issues and intervene before harm occurs. At present, existing calls for such a system remain inadequately answered (e.g., Toussaint & Segel, 2022). The Institute for Safe Medication Practices houses one reporting mechanism where providers can report medication errors on a national level (ISMP, n.d.). However, this database is restricted to medication errors, which is only a fragment of the incidents and potential patient harms that could be improved in healthcare. Patient Safety Organizations present another mechanism for providers to report such incidents, which are intended to collaborate with healthcare institutions to improve

patient safety, as well as receive and collate incident information to the national level using Network of Patient Safety Databases (NPSD; US Department of Health and Human Services, 2019).

There are a multitude of barriers to healthcare organizations adequately utilizing these services (US Department of Health and Human Services, 2019). Many of these reporting systems place a significant burden of reporting, as well as correctly identifying and portraying factors that were involved in the harm, on the healthcare provider/reporter. Additionally, front-end providers are often unsure what constitutes an adverse event or harm that should be reported (Hammoudi et al., 2018). This uncertainty in defining what constitutes accidental patient harm affects the entire field, including the front-line providers and researchers alike (Papanicolas & Figueroa, 2019). These issues present major barriers to reporting practices (Hammoudi et al., 2018), which may be mitigated by hospitals formally integrating human factors professionals into these processes to increase the feasibility and accuracy of these reports, as well as reduce the burden of reporting on the front-end providers. This brings us to our fourth recommendation.

#### **3.4. Incorporate Human Factors professionals at multiple levels of organizations.**

The seminal work “to err is human” (Kohn et al., 2000) emphasizes how the use of human factors experts in other high-risk industries has contributed to a reduction in the number of safety incidents. The integration of scientific knowledge of human capability and limitations together with operational goals guide system designs that position the human operator in the center, and thus, result in a safer work environment. Human factors tools and methods add a unique perspective to the design of systems that rely on human operators



which enable efficient and effective identification of systems and organizational issues that contribute to patient harm (Edwards et al., 2017; Keebler et al., 2022).

Human factors professionals are educated in methods that enable thorough investigation into the influence of relevant factors we identified related to this case, including considerations related to human-computer interaction, teamwork, and warning/notification labels and systems along with many others. Additionally, since human factors education is rooted in psychology, these practitioners have greater understanding of how bias may impact both decisions and judgements and can readily incorporate methods that reduce their potential to influence investigation findings (e.g., Keebler et al., 2022). Incorporating human factors professionals in adverse event investigatory committees has improved investigation thoroughness in the medical domain (Keebler et al., 2022).

Further, these professionals may present ideal candidates for positions that are devoted to documenting, investigating, and liaising with PSOs while retaining individual providers' confidentiality. Intentional integration of these positions may serve to mitigate many of the existing barriers healthcare communities face in performing thorough investigations and utilizing PSOs to their full potential, as well as reduce some of the national reporting challenges associated with deidentification processes (US Department of Health and Human Services, 2019). Tiered reporting mechanisms may be considered to address issues discussed related to reporting systems, whereby front-end providers submit abbreviated notifications to embedded human factors professionals in organizations, who then conduct hospital-wide investigations to formally validate the issues, identify improvement mechanisms, and submit de-identified information to national organizations. Their ability to de-identify the data earlier in the process,

with maximum situational context, may permit the data to become more useful when elevated to the context of the national database. However, to facilitate the incorporation of these individuals into investigations and maximize benefits derived, incidents and corresponding safety improvements must be disseminated, organizations held accountable for their implementation, and those involved in incidents (including organizations) protected from criminal and civil lawsuits. This brings us to our final recommendation.

### **3.5. Establish a national safety board for medicine.**

Others have called for a regulatory agency, such as a National Patient Safety Board (NPSB), to be established that would facilitate change in organizations by providing teams of experts that can recommend targeted changes for hospitals to improve patient safety (Toussaint & Segel, 2022). In fact, there is a House Bill that was recently proposed to formally establish an NPSB as the national investigatory body (National Patient Safety Board Act, 2022). The present case serves as an excellent demonstration of why such a board is necessary and how it has the potential to substantially reduce patient harm across the country.

Relating to this incident, the ISMP had previously identified many mix ups between vecuronium and Versed that resulted in patient harm, which had prompted them to recommend hospitals aggressively restrict access to vecuronium (and other neuromuscular blockers, such as rocuronium, the drug that replaced vecuronium on the override list) to prevent these incidents from occurring (ISMP, 2016). The fact that Vanderbilt failed to adequately identify and integrate this established recommendation before patient harm occurred is concerning. In this case, the hospital was not able to self-identify or implement

established practice recommendations until they were investigated by a government body that was able to inform them of the oversight.

This type of oversight has not been exclusive to this hospital (ISMP, 2022), which reflects the practical constraints and ambiguity all hospitals face when attempting to provide high quality care to patients in dynamic, unpredictable environments. A national patient safety board may be able to smooth this process by more effectively educating organizations, creating scaffolding that encourages participation in PSOs, and facilitating organizations' implementation of the learning achieved through these systems. Such changes may be accomplished by direct collaboration of NPSB teams with healthcare organizations, as well as through partnerships with medical drug and device companies to generate standards that enhance safety across hospital systems.

#### **4. Conclusions and Impact Statement**

Healthcare is a complex system, there is arguably no way to eliminate all patient harm and safety-related incidents (Meddings et al., 2020; Stockwell et al., 2022). However, we should design the system in a way that makes it less likely for latent factors to facilitate accidental patient harm and more resilient to harms when they occur. The attack of RaDonda Vaught is contradictory to these efforts, and has had serious negative impacts on the community with many anecdotal reports of providers choosing to leave healthcare professions in response to this verdict (Kelman & Norman, 2022). As a community, we *must* take steps to reverse this tragedy. Involving human factors experts in areas of design and operation of healthcare processes, independent investigation and governing board committees to respond to incidents, as well as litigation proceedings, are the first steps our industries need to take to affect a better

work environment that is safer for both patients and clinicians. Creating an independent governing body to investigate accidents, collaborate with health care institutions, and facilitate industry-wide solutions is yet another step towards this goal. Finally, we need to adopt a just culture that seeks opportunity for change when accidental patient harm occurs rather than blame and shame of the individuals involved. Together, these actions can reduce the number of victims of patient harm and lead to a more resilient healthcare industry.

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#### Declaration of interests

- ☐ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.
- ☒ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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