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Getting to the Root of the Matter

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Case Objectives

- Appreciate the goals and limitations of root cause analysis
- Outline the steps to conduct root cause analysis

The Case

A 65-year-old man with atrial fibrillation, lung cancer, and chronic renal insufficiency presented to the emergency department (ED) with shortness of breath. His vital signs were significant for a respiratory rate of 32, a temperature of 102.4°F, and an oxygen saturation of 87% on a 100% non-rebreather. A chest X-ray showed a right middle infiltrate. Due to respiratory distress, the patient was intubated.

Shortly thereafter, the patient became hypotensive with a systolic blood pressure (BP) of 65 mm Hg. Fluid resuscitation was continued while BP was supported with phenylephrine and vasopressin. Phenylephrine was changed to norepinephrine. After 8 hours, arterial blood gas test revealed a pH 7.23, Pco_2 23 mm Hg, Po_2 161 mm Hg and base excess –16, lactate 6.2 mmol/L (normal 0.5 – 2.2 mmol/L). A pulmonary artery catheter was placed, and initial numbers were—surprisingly—more consistent with cardiogenic shock than septic shock, with a central venous pressure of 13-17 mm Hg, pulmonary capillary wedge pressure of 19 mm Hg, cardiac index (CI) 1.8 L/min/m^2, and systemic vascular resistance (SVR) of 1500 dynes/sec x cm^{-5} . Norepinephrine was weaned rapidly. The patient remained on vasopressin. An echocardiogram showed global decrease in contractility, with an ejection fraction 45% and mild right ventricular dilatation. Shortly thereafter, it was discovered that the patient had been receiving 0.4 units/min of vasopressin, rather than the intended dose of 0.04 units/min. Vasopressin was discontinued.

Within the next few hours, the patient's condition improved. The CI and mixed venous oxygen saturation increased to 3.8 L/min/m^2 and 75%, respectively, and the SVR decreased to 586 dynes/sec x cm^{-5}. A creatine kinase (CK) peaked to 7236 U/L, CKMB to 37 U/L. The patient was treated with fluids and antibiotics and had an uneventful recovery.

The Commentary

A patient admitted to the intensive care unit (ICU) with septic shock requiring vasopressors appears to have suffered a myocardial infarction (MI) in the course of his treatment. While not terribly surprising, the cause of the MI was likely related to a log increase in the dose of vasopressin because of a prescribing error. This, too, is unfortunately not surprising. Clinicians who regularly care for hospitalized patients—particularly the critically ill—often observe medical mistakes. The magnitude of medical error, the relative contribution of errors to adverse patient outcomes, and the decision to devote substantial resources to prevent errors of unclear significance are often debated.(1) Few, however, would argue that the error in this case should not be investigated. How would you do it? What would you be likely to find? What solutions could be implemented?

Root Cause Analysis

This error would likely have generated a root cause analysis (RCA) if it had occurred in the institutions in which we practice. In health care settings, RCAs are investigations of serious adverse events (or occasionally close calls) performed by a team with expertise in the area of investigation whose members were not directly involved with the error. The team's goal is to determine what happened, why it happened, and what can be done to prevent it from happening again. Rather than focus solely on the individual who wrote the incorrect order, the RCA broadens the focus to examine the "root causes" of the error. Thus, a proper RCA includes an assessment of the environment (e.g., time of day, staffing levels, lighting, product storage and labeling, medication ordering process) in which the error occurred. The theory underlying an RCA is to move the understanding of adverse event analysis away from individual human mistakes that are less actionable to a human factors engineering approach that looks for systems vulnerabilities.(2)

The Investigation

Performing an RCA based on an anonymously submitted case is virtually impossible. Proper system analyses require direct observation of the work environment, interviews with key staff involved in the error (to establish a chronological flow of events), careful review of incident reports from the same ICU looking for similar episodes (or near misses), and intimate knowledge of the institution that would allow for reasonable proposals for change.

We do have a small amount of additional information from this event available to us to review. Pertinent facts include (i) a verbal direction was given by the fellow to the resident to order vasopressin; (ii) the resident directly entered the order into a computerized physician order entry (CPOE) system, which had a menu of several possible doses of vasopressin; (iii) the error went undetected for more than 16 hours; and (iv) the error persisted through the next day's multidisciplinary team rounds, which included physicians, nurses, and possibly pharmacists. In addition, we know that the error was discovered when one of the ICU nurses brought a group of nursing students to the patient's bedside for an introduction to critical care nursing. She pointed out to the students that the patient in this case was receiving the medication vasopressin, at a dose of 0.4 units/min. The ICU fellow, overhearing her instruction, corrected her, saying, "No, the patient is on 0.04 units/min." The fellow then confirmed the dose with the patient's nurse and found that the patient was, in fact, on the higher dose.

Although the information is limited, we will nevertheless attempt to perform an RCA as if this error occurred in our hospital.

Getting Started

The RCA team is usually led by a member of the institution's patient safety or quality improvement program who has expertise in conducting these analyses. This individual is responsible for ensuring that the process focuses on systems, rather than individual, actions. For a case such as this, other members of the team should include an ICU physician, as well as representatives from ICU nursing (both the nurse manager and a staff nurse), the pharmacy, and the ED (where vasopressor medications are often initiated). Importantly, an ICU fellow as well as a medical resident who has recently rotated through the ICU should also be a part of the RCA team.

Gathering Data

Once established, the RCA team generates a differential diagnosis for systems factors that may have contributed to the error. The Table outlines investigation domains generated in this case after considering the myriad underlying causes of the error. Ultimately, each domain is assessed for contribution to the error and priority for change. The first step in this process is to develop a timeline of events related to the patient's care. As much as possible, every provider contact with the patient (from physician to patient transport personnel), every order, every test, and every response to a test should be charted. The timeline can be used to observe all the steps involved in the care of the patient and better evaluate what contributed to the incorrect dose being administered. Based on additional data provided by the case submitter and our own experience, the most important contributing factors were:

- There were no ICU protocols for high-risk procedures or for the use of high-risk drugs;
- There was poor staff/trainee teamwork skills;
- There was no systematic process in the ICU for reviewing key aspects of patient care during daily rounds;
- There were no nursing guidelines or protocols for use of vasopressor medications; and
- There was no process in the pharmacy to highlight medications used in differing doses for different indications.

Analyzing Contributing Factors

Most ICUs emphasize high quality and safe care; increasingly, ICUs are committed to creating a culture of safety. While many ICUs have developed processes and protocols related to high-risk procedures such as central line insertion or endotracheal intubation, in our experience, few have done the same for high-risk medications. Preventable adverse drug events are a common type of error seen in the ICU setting.(3-6) One recent study of errors associated with long ICU work hours concluded that medication errors were the most common mistake seen.(7) Fortunately, most errors are caught, and those that are missed usually do not lead to adverse outcomes. However, this may not apply to certain high-risk medications (e.g., intravenous potassium chloride or insulin) (4), *justifying a more aggressive approach toward preventing errors in their use*. We believe that vasopressin should be considered a high-risk medication, since it has a narrow therapeutic window and is known to cause the serious adverse cardiovascular effects seen in this

patient when recommended doses are exceeded.(8,9) As a result, most guidelines and systematic reviews of the use of vasopressin for septic shock do not recommend it for use as a first-line vasopressor, and, when used, recommend it be started at very low doses and not be titrated above 0.04 units/min.(10) All ICUs should have protocols in place to handle such high-risk medications. This ICU did not.

The vasopressin order was incorrectly written by a resident physician after he received a verbal order from his supervising critical care fellow. A full discussion of issues related to the human factors and teamwork problems in this case is beyond the scope of this commentary but has been reviewed in a past WebM&M case.(11) Although we do not know exactly what the fellow said to the resident, it is unlikely that the fellow asked the resident whether he understood the order, had used vasopressin previously in patients with septic shock, or had concerns about writing an order for this particular drug. We suspect that only a handful of teaching hospitals routinely require that verbal orders given by a supervising physician be “read back” by the trainee.

The ICU physician rounding process, while very structured in time and clinical content, rarely includes a regular assessment of medication doses, drug interactions, or key error prevention and patient safety steps (e.g., daily assessment of the need for continued venous or urinary catheterization).(12) Additionally, pharmacists may not regularly round with the team or routinely review all prescribed medications; such rounding has been demonstrated to be associated with a reduction in medication errors.(13) Finally, trainees should be taught that the differential diagnosis for unusual clinical findings (such as the pulmonary artery catheter revealing cardiogenic shock in this case) should be expanded to include iatrogenic causes such as medication error.

The nurse caring for this patient administered the incorrect dose of vasopressin. In fact, the incorrect dose was given for more than 16 hours, which means that more than one nurse was involved in the error. It was not until a nurse was discussing the medication dosing with nursing students that the incorrect dose was overheard by the fellow and the error recognized. Although it is tempting to lay the blame entirely on a lack of knowledge about vasopressin, the focus on systems and environmental issues would likely reveal that nurses in this ICU did not follow set protocols related to the use of vasopressors, did not systematically review doses of medications during nursing sign-out, and—in contrast to what happens with blood transfusions—did not regularly use a process of “double-checking” whether the right drug is being given to the right patient at the right dose.

Pharmacy issues also figured prominently in this error. The institution had a computerized physician order entry (CPOE) system, but, as has been noted previously (14), merely implementing a CPOE system or a patient bar coding system will not eliminate medication errors. In this case, vasopressin was available in two doses in the CPOE system. A dose of 0.04 units/min was available for treating shock, and 0.4 units/min for gastrointestinal hemorrhage and variceal bleeding. This CPOE system, like most at this point, did not ask for the indication, nor did it flag the order for pharmacist review despite the known risks of the higher dose of vasopressin.

Systems Solutions

Unfortunately, we have no randomized trials of safety solutions to help guide the changes that need to be made. We thus must rely on the data generated by the RCA to identify the key steps that contributed to the

error, propose reasonable systems-based solutions, implement the changes, and then re-evaluate the process to ensure we have not created more problems than we have solved. In this case, we would propose the following changes:

- Most institutions respond to such errors by patching small leaks in the systems that have created the error. Some have argued that the most important and most long-lasting changes result not from patches, but from complete system redesign.(4) We agree. Most institutions, however, are reluctant to commit the resources and effort required for such changes. In this case, a multidisciplinary team could redesign the entire medication delivery process in the ICU. The process could include complete medication reconciliation and review at patient entry and exit into the ICU, an intervention that is beginning to occur at some institutions.(15) An ICU safety officer (or pharmacist, if only focusing on medications) would round with the team, reviewing all medications (indication, dose, interactions) as well as other non-medication-related patient safety measures (e.g., urinary and vascular catheter management, elevation of head of bed in mechanically ventilated patients, prevention of venous thromboembolism). At minimum, a review of medications and doses by the team should happen every morning (perhaps twice daily in an ICU) on rounds and should include a pharmacist.(13,16)
- High-risk medications need to be treated similarly to high-risk procedures. Perhaps there should be “time outs” prior to high-risk medication administration, similar to what happens with blood transfusions, to ensure we are giving the correct medication to the correct patient at the correct dose. In the case of vasopressors, standard dosing scales that attempt to prevent overdoses should be programmed into IV pumps.
- Adopting processes from the aviation field, teamwork training should be considered for all physicians, nurses, trainees, and other staff who work in the ICU. Such training would include role-playing and simulations that markedly improve team dynamics and communication.
- A forum should be created that allows residents, fellows, nurses, pharmacists, and other team members to openly discuss errors. Such discussions could take place during an occasional morning report or a morbidity and mortality conference. This will increase the likelihood that constructive changes will be made.(17)
- The CPOE system should remind the ordering physician that a drug such as vasopressin (and others like it) has more than one indication, and then it should query the indication and provide a suggested dose. Computer-generated recommendations that are overridden by the physician ideally would be flagged for immediate pharmacist review. In addition, smart systems could include admitting diagnoses and, by combining that with patient location (ICU or ward), flag a drug or dose as potentially incorrect, thereby triggering a review.

The RCA: Important Limitations and Caveats

Although the value of RCA has not been confirmed in carefully conducted clinical trials in a health care environment, we believe that these analyses serve a useful purpose in error reduction when used appropriately. RCA works best in assessing rare events—such as wrong-site surgery or egregious medication misadventures that lead to fatal overdoses—rather than common patient safety problems (e.g., hospital-acquired infection, contrast-induced nephropathy, delirium in a hospitalized patient) that are more amenable to an approach based on principles of clinical epidemiology (i.e., surveillance, benchmarking,

intervention, re-evaluation).(18) Proposed system-based solutions need to be feasible. There are no greater barriers to changing safety culture than those created by silly, time-consuming, and ineffective safety protocols, especially those developed by managers who no longer are clinically engaged in the tasks they are modifying. Asking clinicians to jump through bureaucratic hoops in the name of patient safety squanders the good will of the staff, thereby making useful error-reduction strategies challenging, if not impossible, to implement. We thus believe that nearly all clinical leaders—nurse managers, safety officers, physician executives—should be required to perform some clinical work in the setting they are managing. Finally, we suggest that all changes be re-evaluated periodically to ensure the new process is indeed safer and achieving the desired outcomes.

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Table

Table. Investigating the Error

Domain of Investigation	Contribution to Error	Priority for Change
General		
Timeline of events	N/A	N/A
ICU protocols for high-risk processes/use of high-risk medications	No checks and balances for high-risk medications	High

Division of labor between ICU/ER for patients admitted to ICU	Unclear: Incorrect doses ordered in ER may persist after transfer to ICU: NC	Low
ICU safety culture	No focus on routine prevention	High
ICU environment (lighting, layout, etc.)	Unknown	Low
Physician/Resident Practice		
Medication ordering process	Unclear roles and expectations for fellow/resident/nursing	Medium
Communication practices	No “read-back” on verbal orders	High
Staff/trainee working relationships	No teamwork training/unclear roles/no use of simulation	Medium
Supervision of trainees	No routine assessment of knowledge/understanding	Medium
Trainee work hours	Work hours mandated: Unclear contribution	Low
Knowledge assessment	No formal training/guidelines for pressor use	Medium
Rounding practices	No systematic review of medications/doses/interaction	High
Nursing		
Staffing levels	Adequate: NC	Low
Management support/training	Supportive environment/regular orientation for new nurses: NC	Low
Infusion practices	No specialized infusion pumps for pressors	Medium

Protocols for pressors	No nursing guidelines/no “double-check”	High
Task design and clarity	Process for administering meds not standardized/no formal design	Low
Pharmacy		
Where/how meds stocked	Different doses of drug drawn from same vial	Medium
How are meds ordered/delivered	CPOE (no hand-writing issues)/pressors drawn up in ICU, not pre-mixed	Medium
How are meds with different doses for different indications handled	No computer alert for different doses/different indications	High
How are dose errors communicated when discovered/suspected	No routine system for suspecting errors/communication is pharmacist dependent	Medium

N/A: non-applicable; NC: non-contributory.

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