Anesthesia Quality Institute®
American Society of Anesthesiologists®

Learning From Others: A Case Report from the Anesthesia Incident Reporting System

Case 2021-4: Measure Twice, Cut Once

Laboring patient received epidural for labor analgesia. After epidural placement and dosing, patient became hypotensive. Ephedrine and NeoSynephrine were then used to treat the hypotension. After NeoSynephrine administration, the patient became hypertensive and was reporting chest and arm pain and headache. Also, during this time period fetal distress was noted and patient underwent emergent cesarean section under general anesthesia. Patient and infant did well. Apgars were 8,9 but cord gas did show acidosis. After event, it was noted that NeoSynephrine was only diluted to 1 mg/ml instead of 100 mcg/ml.

Contributing factors: *NeoSynephrine must be diluted twice – to 1 mg/ml, then to 100 mcg/ml.*

Hurrying due to symptomatic hypotension in laboring parturient.

Multiple health care workers and family at bedside leading to distraction.

Lessons learned: *Slow down when diluting medication and double check dilution.*

Minimize distractions during preparation and administration of medication.

Double dilution of vasoconstrictors has a long history in anesthesia, with virtually every anesthesia provider at some point performing this task. Like many tasks in anesthesia, this one is not complex. Taking a 10 mg/mL to a 0.1 mg/mL solution (100 micrograms per mL) via a two-step dilution of 1 mg/mL to 0.1 mg/mL and then, with nine more mL of saline, to a 0.01 mg/mL (or 100 mcg/mL) is straightforward. The steps are linear and the same every time, and the error of omitting the second dilution falls into what James Reason defines as a skill-based error, with a slip or lapse in a routine that we have done many times before (Human Error. 1990). In Dr. Reason's framework of cognitive errors, skill-based errors are joined by rules-based errors and knowledge-based errors.

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Conference Leads to Consensus Recommendations

"Medication Safety," From Preceding Page

Small Groups, Big Assignments

Predictably, each of the 4 group breakout sessions: **Standardization, Technology, Pharmacy/Prefilled/Premixed, and Culture,** generated intense debate. There was a specific assignment to generate up to 3 primary actionable recommendations that could produce "predictable prompt improvement" in operating room medication safety. There was also the requirement to balance the often contradictory considerations of the clearly ideal top-priority beneficial measures vs. the realistic practicality of potential for implementation in the short-term future. Thus, the discussions involved a great many back-and-forth swings of argument and opinion.

The Standardization Group, led by **Patricia A. Kapur, MD,** APSF Executive Committee member, considered what degree of standardization would be achievable for which components of the operating room medication process and how that could be accomplished. The Technology Group, led by **George A. Shapiro,** APSF executive vice president, eventually decided to leave the issue of configuration of medication containers to the Standardization Group and focus on hardware and software that could prevent drug errors. The Pharmacy Group, led by **Sorin J. Brull, MD,** chair of the APSF Scientific Evaluation Committee, struggled with the balance of roles between the anesthesia professional in the operating room in real time and the related supporting pharmacist as far as maximizing safety of medication procedures. The Culture Group, led by **Robert C. Morell, MD,** editor of the *APSF Newsletter,* debated what would be the best target mindset to promote operating room medication safety and then how best to achieve that goal.

Consensus Building

After the breakout sessions the 4 groups reassembled in the main meeting room for the final

See "Medication Safety," Next Page

Table 1:
Consensus Recommendations for Improving Medication Safety in the Operating Room

Standardization

1. High alert drugs (such as phenylephrine and epinephrine) should be available in standardized concentrations/diluents prepared by pharmacy in a ready-to-use (bolus or infusion) form that is appropriate for both adult and pediatric patients. Infusions should be delivered by an electronically-controlled smart device containing a drug library.
2. Ready-to-use syringes and infusions should have standardized fully compliant machine–readable labels.
3. *Additional Ideas:*
   a. Interdisciplinary and uniform curriculum for medication administration safety to be available to all training programs and facilities.
   b. No concentrated versions of any potentially lethal agents in the operating room.
   c. Required read-back in an environment for extremely high alert drugs such as heparin.
   d. Standardized placement of drugs within all anesthesia workstations in an institution.
   e. Convenient required method to save all used syringes and drug containers until case concluded.
   f. Standardized infusion libraries/protocols throughout an institution.
   g. Standardized route-specific connectors for tubing (IV, arterial, epidural, enteral).

Technology

1. Every anesthetizing location should have a mechanism to identify medications before drawing up or administering them (bar code reader) and a mechanism to provide feedback, decision support, and documentation (automated information system).
2. *Additional Ideas:*
   a. Technology training and device education for all users, possibly requiring formal certification.
   b. Improved and standardized user interfaces on infusion pumps.
   c. Mandatory safety checklists incorporated into all operating room systems.

Pharmacy/Prefilled/Premixed

1. Routine provider-prepared medications should be discontinued whenever possible.
2. Clinical pharmacists should be part of the perioperative/operating room team.
3. Standardized pre-prepared medication kits by case type should be used whenever possible.
4. *Additional Ideas:*
   a. Interdisciplinary and uniform curriculum for medication administration safety for all anesthesia professionals and pharmacists.
   b. Enhanced training of operating room pharmacists specifically as perioperative consultants.
   c. Deployment of ubiquitous automated dispensing machines in the operating room suite (with communication to central pharmacy and its information management system).

Culture

1. Establish a *"just culture"* for reporting errors (including near misses) and discussion of lessons learned.
2. Establish a culture of education, understanding, and accountability via a required curriculum and CME and dissemination of dramatic stories in the *APSF Newsletter* and educational videos.
3. Establish a culture of cooperation and recognition of the benefits of STPC within and between institutions, professional organizations, and accreditation agencies.

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Consensus Recommendations for Improving Medication Safety in the Operating Room (*APSF Newsletter* 2010;25).

As shown in the table, Kahneman divides our day-to-day cognitive processes (and actions) into fast and slow thinking (Thinking, Fast and Slow. 2011), while Stanovich and West use the terms System I (fast) and System II (slow) (*Behav Brain Sci* 2000;23:645-726). System I thinking and actions are associative, unconscious, effortless, and come after many repetitions of a task or multiple exposures to a certain pattern (if bradycardic, give atropine); System I includes Reason's skill based and rule-based errors. System II thinking or actions are slow and reflective, deductive, conscious and effortful (first attempts at intubation). It is no wonder that humans much prefer to live in the world where our stored schema run subconsciously, even as we carry on conversations, or monitor vital signs. However, each of these basic types of thinking are inherently at risk for specific errors. For System I thinking common errors include that we run a schema at the wrong time (give atropine for bradycardia caused by electrocautery interference of a pacemaker), or that the schema is interrupted mid-stream, and when we return to it, we either enter a step too early or too late, omitting a step. In the case of severe hypertension noted above, the second step, that of diluting the 1 mg/mL solution once more, was omitted.

Although there is not a plethora of case reports of this type of error in the literature, virtually every provider of some experience knows of a local case or two of errors in dilution or has been called to assist when an error has occurred and the team must manage severe hypertension or, in this case, significant fetal distress. In pediatrics, the dangers are more prevalent and often more serious due to the need for dilution of nearly all medications and the narrow therapeutic range in our tiniest patients. In a study by Avidan, faculty and residents were asked to calculate the correct dilution for a number of

In the Know: Monoclonal Antibody Therapies

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diminution of activity against known variants (*Science* February 2021). The single domain antibodies are able to lock the spike protein in an "active" configuration, which results in the receptor binding domain cleaving from the protein as shown in Figure 2. The result is an inactive, noninfectious spike.

Quoting the authors: "Perhaps, in the future, a positive rapid SARS-CoV-2 test outcome will go hand in hand with an easily administered, affordable, subcutaneous injection or nebulized inhalation of an antibody targeting highly conserved epitopes not recognized by the human immune system." In other words, as soon as you have a positive test, you are given a nebulized treatment rendering it impossible for the COVID-19 to progress.

Why are deaths so high?

Monoclonal antibodies have been available since late November. Since effective therapy has been available, why did COVID-19 deaths surge to new peaks in January? One reason, of course, is that cases surged because of SARS-CoV-2 seasonality as well as the superspreading events of the Thanksgiving and Christmas holidays. However, even with surging cases, shouldn't deaths have decreased dramatically with the availability of these cocktails?

This hasn't been well studied, but several explanations have been floated in the media as to why deaths are surging and antibody cocktails sit, unused, on pharmacy shelves (*N Engl J Med* 2021;384:289-91; asamonitor.pub/2N3kSZZ):

1. Treatment for COVID-19 is advancing so fast that many clinicians are not aware that these are available.
2. There is a mistaken belief that these are for inpatient use. That may arise, in part, because the approved cocktails must be given by I.V. infusion. However, the intent is for the drugs to be administered to outpatients early in the course of the disease.
3. The reason to give the cocktails early in therapy is that they must be given before the immune system goes haywire. As COVID-19 progresses from moderate to severe disease, end-organ damage changes from viral-induced to autoimmune injury. At that point, decrease viral load is of limited benefit.

William Haseltine was right: monoclonal antibodies have been quickly developed. They have the potential to radically change therapy. As always, science has progressed faster than clinical medicine. Monoclonal antibody cocktails should be considered on the initial presentation of any patient with COVID-19 at risk for serious illness. ■

medication infusions: only 15% got all dilutions correct (faculty were not better than residents), and incorrect calculations ranged from a drug concentration 50 times too low and up to 56 times too high (*J Clin Anesth* 2014;26:276-80).

Errors of dilution are, in fact, so common that virtually all medication safety guidelines call for the removal of all concentrated medications from the anesthesia medication trays (or Pyxis) and suggest that only the appropriate dilutions are provided. In 2010, the Anesthesia Patient Safety Foundation included a solution to dilution errors as one of their Consensus Recommendations for Improving Medication Safety in the Operating Room, stating: "*High alert drugs (such as phenylephrine and epinephrine) should be available in standardized concentrations/dilutions prepared by pharmacy in a ready-to-use (bolus or infusion) form that is appropriate for both adult and pediatric patients*" (*APSF Newsletter* 2010;25). The same consensus recommendations state that "*routine provider-prepared medications should be discontinued whenever possible*," and "*no concentrated versions of any potentially lethal agents [should be] in the operating room*." A report of survey results from 34 pediatric hospitals in 2014 found that 27 of the 34 did supply vasopressors in prefilled syringes – but clearly seven hospitals still were asking their anesthesia teams to prepare dilutions of these high-risk medications, and all of the 34 required at least one medication to be prepared by the anesthesia provider (*Jt Comm J Qual Patient Saf* 2014;40:471-5). In 2017, Wahr and colleagues published a review of literature and expert-based recommendations for medication safety in the OR, which included that "*pharmacy provides diluted high-risk drugs*" and "*no concentrated drugs are in cart inventory*" (*Br J Anaesth* 2017;118:32-43).

Table 7.1 The two systems that describe the ways in which we think, and their relationship to the terminology used by James Reason

System I: Fast and Automatic	System II: Slow and Reflective
Associative	Deductive
Unconscious	Conscious
Effortless	Effortful
Uses pattern recognition and rules	Uses logic and works from first principles
Feed-forward	Feed-back
Informed by the individual's mental model of the situation	Informed by the individual's mental model of the situation
Terminology used in Reason's Generic Error Modeling System	
Skill-based Rule-based	Knowledge-based

Source: Synthesized from various sources: Reason 1990 (6), Kahneman 2011 (9), Thaler and Sunstein 2008 (10).

The two systems that describe the ways in which we think, and their relationship to the terminology used by James Reason (Reprinted with permission from Merry and Wahr) (Medication Safety during Anesthesia and the Perioperative Period. In press, 2021)

"At this point, there appears to be little good reason to continue the practice of having anesthesia providers perform dilution of high-risk vasoactive agents."

As we can see from this report, a case recently submitted to the AIRS database, anesthesia providers at some hospitals continue to be required to prepare dilutions of high-risk medications on a day-to-day basis, despite the risk. The reporters(s) in this case cited, appropriately, the contributing causes of time pressure (hurrying) and distractions (multiple people at the bedside) and concluded that the lessons to be learned are to "slow down" and "avoid distractions." These are nice sentiments, but unlikely to be possible in any anesthesia setting, where multiple medications are administered in the midst of distractions and under considerable time pressure. In addition, the comments essentially represent a "try harder" approach, which we know is useless when it comes to errors that grow out of the subconscious – the conscious mind does not keep a leash on the subconscious, as anyone who has fought to recall the name of a familiar song or book. By definition, the subconscious exists out of control of the conscious mind. Therefore, although "thinking about how we think" or metacognition can help alleviate some cognitive errors, in general, a conscious effort to never make an error in a System I task is a fool's errand.

The task cited in this report very neatly represents what Dr. Reason called error traps: "*The same situation keeps producing the same errors … even though quite different people are involved. That surely indicates we are dealing with error prone circumstances rather than error prone people. We are dealing with error traps*" (The Human Contribution: Unsafe Acts, Accidents and Heroic Recoveries. 2008). It should be clear that, if the same situation keeps producing the same error, we surely should take a systems approach to eliminating that situation, such as providing prefilled syringes of the appropriate dilution. Multiple manufacturers offer prefilled syringes like this; in addition, virtually any pharmacy can prepare these dilutions of high-risk medications in a quiet environment where a double check is available (and often mandated by policy).

Why then do hospital leaders continue to ask our anesthesia providers to undertake this risky business? Cost is the most commonly cited reason, although perhaps an unfounded one. The difference between a vial of concentrated phenylephrine is about $2.80, a prefilled syringe providing a concentration of 100 mcg/mL is $4.80. The pharmacy director may see a 2X cost, but the additional cost really disappears when one considers the labor costs associated with anesthesia providers performing the dilutions and the waste involved in drawing up a medication that may not be needed. One study found that savings associated with waste alone made prefilled syringe costs comparable to provider prepared syringes (*Ann Fr Anesth Reanim* 2009;28:211-4); another compared the system vulnerabilities in provider prepared versus prefilled and identified eight system vulnerabilities in using prefilled syringes versus 21 in using provider prepared (*Anesthesiology* 2016;124:795-803). At this point, there appears to be little good reason to continue the practice of having anesthesia providers perform dilution of high-risk vasoactive agents.

The event detailed above is clearly an error on the part of the anesthesia provider, but the refusal of hospital leadership to provide prefilled syringes of vasoconstrictors is more a violation than it is an error. As detailed by Merry and Wahr, "*the distinguishing feature between an error and a violation is that in an error, one tries to do the right thing but actually does the wrong thing, whereas in a violation, one deliberately does the wrong thing (although without malevolent intent)*" (Medication Safety during Anesthesia and the Perioperative Period. In press, 2021). In this case, the decision to not provide appropriate syringes represents a deviation from practices that medication safety experts have deemed necessary to maintain safety. As Merry and Wahr point out, people who violate generally believe that the violation will cause no harm – clearly leaders who choose to "save costs" by requiring providers to mix their own medications believe, although against all evidence, that the providers will do so perfectly every time. It becomes our responsibility, then, to vigorously put forth the argument that we cannot be expected to do this dangerous practice perfectly and that great harm lurks. This case put a mother and a baby at unnecessary risk; it is time to implement what we know to be those practices "deemed necessary to maintain the safe operation of a potentially hazardous system" (Medication Safety during Anesthesia and the Perioperative Period. In press, 2021). ■

Review of unusual patient care experiences is a cornerstone of medical education. Each month, the AQI-AIRS Steering Committee abstracts a patient history submitted to the Anesthesia Incident Reporting System (AIRS) and authors a discussion of the safety and human factors challenges involved. Real-life case histories often include multiple clinical decisions, only some of which can be discussed in the space available. Absence of commentary should not be construed as agreement with the clinical decisions described. Feedback regarding this article can be sent by email to **airs@asahq.org.** Report incidents or download the AIRS mobile app at **www.aqiairs.org.**