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The SAFE-T Summit and the International Standards for a Safe Practice of Anesthesia

by Alan F. Merry, MBChB, FANZCA, FFPMANZCA, FRCA; Walter D. Johnson, MD; Berend Mets, MBChB, PhD, FRCA; Wayne W. Morris, MBChB, FANZCA; and Adrian W. Gelb, MBChB, FRCPC

The following article is a summary of the World Health Organization (WHO) and World Federation of Societies of Anesthesiologists' (WFSA's) "Standards for a Safe Practice of Anesthesia" that was approved by the World Health Assembly in 2018. These standards supplement the 2015 WHO Resolution 68.15, "Strengthening Emergency and Essential Surgical Care and Anaesthesia as a Component of Universal Health Coverage." The article includes a significant *verbatim* portion of the report.

We are publishing this article because of the impact of the WHO standards on anesthesia care and patient safety worldwide. It is provided for information, education, and discussion. Its content does not imply or reflect the opinion of the APSF.

The APSF remains dedicated to its basic vision that *no one shall be harmed by anesthesia care*. We believe that all anesthesia professionals, regardless of their titles and training, play vital roles in providing safe anesthesia and perioperative care. We respect all anesthesia professionals and their important contributions to anesthesia patient safety.

In the eponymous Ellison Pierce keynote lecture at the 2018 Annual ASA Meeting, Dr. Robert Caplan reminded the audience of the mission of the APSF, established by Dr. Pierce, *"that no patient shall be harmed by anesthesia."* It is thus timely to reflect on the first key message of the Lancet Commission on Global Surgery, namely that five billion people do not have access to safe, affordable surgical and anesthesia care when needed.[1]

Convened to address global anesthesia safety standards, the first SAFE-T Summit was hosted by the World Federation of Societies of Anaesthesiologists (WFSA) and the Royal Society of Medicine (RSM) in April 2018 to review progress since the launch of the Lancet Commission's report three years earlier at the same venue. The SAFE-T Summit grappled with the question of measurement and its importance in monitoring and driving improvement in global surgery, obstetrics, and anesthesia. Following from this, the World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) published the International Standards for a Safe Practice of Anesthesia ("Standards") in June 2018.[2,3] These Standards remind us that *"World Health Assembly resolution 68.15 recognizes access to emergency and essential anesthesia and surgical care as an integral part of universal health coverage,"* and, therefore, assert at the outset that *"access to safe anesthesia for essential surgery is a basic human right and should be available to all patients irrespective of their ability to pay."* The Standards are applicable globally, but this document is most relevant to those parts of the world where millions of patients either do not have access to anesthesia care, or when it is

available, face rates of mortality many hundreds or thousands of times higher than those in high-income countries such as the United States.[4] These important opening statements in the Standards set the context for measuring safe anesthesia care.

See "SAFE-T Summit," Page 79

2019 President's Report: Taking Action

APSF's Renewed Commitment to Implementation of Changes That Can Improve Perioperative Patient Safety

by Mark A. Warner, MD, President

Improving patient safety seems so simple since we all share, to various degrees, the desire to help our patients—to guide, escort, and usher them through the perils that come with surgeries and other procedures. APSF's vision that *"no patient shall be harmed by anesthesia"* is clear. Yet why is improving perioperative patient safety so difficult?

For more than a decade, the APSF has used consensus conferences to identify important patient safety issues in anesthesia care (Table 1). The recommendations from those conferences have been based on strong science and have been formatted to be logical, reasonable, and actionable. A close review of these recommendations (available at www.apsf.org) seems to support the first two of these assessments; they appear logical and reasonable. However, they have not been uniformly, and certainly not readily, actionable. Broad implementation of these recommendations would likely have improved the perioperative safety of countless patients.

Beginning with the September 2018 APSF's Stoelting Conference on Medication Safety, the foundation will more vigorously pursue implementation of the recommendations that come from the APSF's annual consensus conferences on patient safety. For this year's conference on medication safety, the recommendations focus on changes that address safety issues related to drugs and their administration. The specific recommendations of the conference are found in Table 2 on page 71. Teams for each of the four major categories have provided an implementation plan for each recommendation. APSF has prioritized these and will now provide the resources needed to move them forward. We will engage with all of the appropriate stakeholders as we address these issues.

Dr. Mark Warner

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The *APSF Newsletter* is the official journal of the Anesthesia Patient Safety Foundation. It is widely distributed to a variety of anesthesia professionals, perioperative providers, key industry representatives, and risk managers. It is published three times a year (February, June, and October). **Deadlines for each issue are as follows: 1) February Issue: November 15th, 2) June Issue: March 15th, 3) October Issue: July 15th.** The content of the newsletter typically focuses on anesthesia-related perioperative patient safety. Decisions regarding content and acceptance of submissions for publication are the responsibility of the editors. Some submissions may go in future issues, even if the deadline is met. At the discretion of the editors, submissions may be considered for publication on our APSF website and social media pages.

Types of articles include:

(1) **Review articles or invited pro-con debates** are original manuscripts. They should focus on patient safety issues and have appropriate referencing (see https://www.apsf.org/authors-guide.php). The articles should be limited to 2,000 words with no more than 25 references. Figures and/or tables are strongly encouraged.

(2) **Q&A articles** are anesthesia patient safety questions submitted by readers to knowledgeable experts or designated consultants to provide a response. The articles should be limited to 750 words.

(3) **Letters to the editor** are welcome and should be limited to 500 words. Please include references when appropriate.

(4) **Dear SIRS** is the "Safety Information Response System." The purpose of this column is to allow expeditious communication of technology-related safety concerns raised by our readers, with input and response from manufacturers and industry representatives. Dr. Jeffrey Feldman, current chair of the Committee on Technology, oversees the column and coordinates the readers' inquiries and the response from industry.

(5) **Invited conference reports** summarize clinically relevant anesthesia patient safety topics based on the respective conference discussion. Please limit the word count to less than 1000.

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APSF Will Take "Action" On Implementing Safety Recommendations From APSF Consensus Conferences

From "President's Report," Cover

Our goal is to develop and then support implementation plans for perioperative patient safety that are actionable—the key being "action." Actions that can improve perioperative patient safety may take many forms, including:

- Improved and expanded dissemination of information about safety issues
- Increased and targeted support for research that generates new knowledge on priority patient safety issues
- Strong collaborations with professional societies, industries, and regulatory agencies to support implementation of perioperative patient safety initiatives

True to our heritage, APSF will be relentless in pursuing actions that improve perioperative patient safety. We look forward to working with all of you on this noble quest.

Dr. Mark Warner is currently President of the APSF and the Annenberg Professor of Anesthesiology, Mayo Clinic, Rochester, MN.

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Table 1. APSF Consensus Conferences 2001–2018

	APSF Stoelting Conferences
2018	*Perioperative Medication Safety: Advancing Best Practices*
2017	*Perioperative Handoffs: Achieving Consensus on How to Get it Right*
	APSF Consensus Conferences
2016	*Distractions in the Anesthesia Work Environment: Impact on Patient Safety*
2015	*Implementing and Using Emergency Manuals and Checklists to Improve Patient Safety*
2014	*Patient Safety and the Perioperative Surgical Home (PSH)*
2013	*Anesthesia Professionals and the Use of Advanced Medical Technologies: Recommendations for Education, Training, and Documentation*
2012	*Perioperative Visual Loss: Who is at risk, What should we tell patients preoperatively, and How should we manage their intraoperative care?*
2011	*Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period*
2010	*Medication Safety in the Operating Room: Time for a New Paradigm*
2009	*Cerebral Perfusion Pressure and the Beach Chair Position*
2008	*Medication Safety and Its Impact on Patient Safety*
2007	*Improving Training in Advanced Anesthesia Technology: Ensuring Patient Safety*
2006	*Patient-Controlled Analgesia and Opioid-Induced Ventilatory Depression: Recognition and Prevention*
2005	*Carbon Dioxide Desiccation*
2004	*The Long-Term Impact of Anesthesia on Patient Outcomes* (and a second one) *Ensuring Patient Safety By Requiring the Use of Audible Alarms*
2003	*Patient Safety and High Reliable Perioperative Medicine*
2002	*Advancing the Use of Anesthesia Information Systems to Improve Patient Safety*
2001	*The Impact of Production Pressure on Anesthesia Patient Safety*

Table 2. APSF's Medication Safety Recommendations 2018

Drug Safety: Identify and promote potentially safer anesthetics

- Encourage reviews and research to assess the risks and benefits of nitrous oxide
- Endorse and encourage the routine use of multimodal approaches for the reduction of postoperative pain
- Endorse and encourage continuous monitoring of oxygenation and ventilation for all perioperative hospitalized patients receiving opioids
- Encourage the FDA to review the hepatotoxicity risk of approved and future volatile anesthetics
- Collaborate with the FDA and convene a work group to identify novel and potentially safer anesthetics for future use in the United States. Examples include inhaled xenon and propofol long chain triglyceride/medium chain triglyceride (propofol-LCT/MCT)

Drug Shortages: Share information, simplify ordering, and establish contingency plans

- Provide up-to-date anesthesia-related drug shortage information on the APSF website and coordinate APSF's efforts with professional and patient safety organizations and regulatory agencies
- Encourage and support efforts to standardize and consolidate concentrations of commonly-used, anesthesia-related drugs
- Encourage the FDA or other appropriate agencies or organizations to develop a manufacturer/supplier quality report card for anesthesia-related drugs
- Collaborate with appropriate organizations to encourage contracting processes that lead to shared risks between health systems and manufacturers and group purchasing organizations for drug shortages and quality issues
- Encourage the FDA to require drug manufacturers to have implementable contingency plans that reduce the risks of drug shortages

Reducing Drug Administration Errors: Standardize procedures and doses, carefully document administration, and simplify preparation

- Encourage and endorse the use of prefilled, sealed syringes and standardized carts, trays, and surface arrangement of drugs in perioperative settings
- Encourage the perioperative practice of identifying and documenting drugs before administering them
- Encourage and support the development of technologies that can identify drugs and their administered doses and directly link these to documentation in electronic medical records
- Develop collaborative efforts with electronic medical record corporations that support drug identification, documentation, and patient safety
- Encourage professional organizations and health systems to support efforts that provide perioperative work environments in which collaboration is encouraged and all individuals are encouraged to identify opportunities to improve patient safety

Standardization and Innovation: Collaborate across specialties and establish consensus for refined standards

- Promote consensus between professional and patient safety organizations on standardization of drug concentrations and labelling of drugs that are used in syringes and infusion administration
- Collaborate with professional and patient safety organizations and encourage health systems and surgical/procedural facilities to standardize the delivery processes of high-risk drugs and drugs in which concentration variations can create high risks to patients
- Develop and support a request-for-proposal and grant(s) for the development of standardized labeling of vials and syringes. The grant(s) would specifically support efforts that integrate the contributions of human factors experts, graphic designers, and clinicians.

Pro/Con Debate: Color-Coded Medication Labels

Pro: Color-Coded Medication Labels Improve Patient Safety

by Luke S. Janik, MD, and Jeffery S. Vender, MD, FCCM

In 2015, the American Society of Anesthesiologists released a statement supporting the practice of user-applied, color-coded medication labels.[1] These labels come in nine distinct colors, each representing a specific drug class according to the American Society for Testing and Materials (Figure 1). However, the Food & Drug Administration[2] and the Institute for Safe Medication Practices (ISMP)[3] have voiced concern over the safety of color-coded labels. They suggest that color-coding may actually contribute to medication errors by acting as a substitute for reading the label. Additional concerns include a limited number of discernible colors, similar appearance of colors, poorly contrasting backgrounds, color-blind clinicians, and a lack of data supporting the practice of color-coding.[3] Although these concerns are understandable, the benefits of color-coding are overlooked. We believe color-coded medication labels improve patient safety.

Figure 1. Color-coded medication labels used in anesthesia.

Research shows that color plays a vital role in the identification of objects. In a classic experiment, subjects were faster to identify objects in color than in grayscale. In turn, they were slowest to identify objects with incongruent color (e.g., blue strawberry).[4] In another study, subjects shown a grayscale image during a functional brain MRI had such distinct activity in the visual cortex that independent experts could correctly determine the color of the object, even though the image was in grayscale (a phenomenon known as "memory of color").[5] However, you don't need sophisticated studies to appreciate the importance of color in the interpretation of your surroundings—you live it every day. Road signs and traffic signals use color to convey meaning.[6] Chefs use color-coded cutting boards to minimize allergy risk.[7] Construction workers wear different colored hard hats to signify their role,[8] and electricians use color-coded circuits.[9] The Department of Defense,[10] the Federal Aviation Agency,[11] National Aeronautics and Space Administration,[12] and virtually every other industry use color-coding to minimize human error. Why? Because color-coding is an essential component of human factors engineering.

Human factors engineering focuses on understanding human strengths, weaknesses, physical limitations, psychology, and fallibility, in order to create systems and devices that minimize human error. The goal of human factors engineering is to design a system that works in spite of human involvement, by decreasing reliance on memory, vigilance, and calculations. This goal is achieved by imposing the principles[13,14] in Table 1.

Color-coded medication labels serve two purposes. First, they act as redundancy cues in object recognition, by conveying the class of the medication through color in addition to lettering. Second, they promote error mitigation. Syringe swaps account for approximately 20% of all medication errors.[15] Color-coded labels aim to contain syringe swaps to medications of the same class. Thus, if a syringe swap does occur, the initial management strategy is likely to be the correct one. For example, prior to performing a spinal you ask a colleague to give fentanyl. Soon after administration, the patient becomes somnolent and apneic. Would you suspect a narcotic overdose? If so, you're not alone. This phenomenon is known as "anchoring bias," in which our initial diagnosis is anchored to a recent event—in this case, the administration of what was believed to be a narcotic. Your first step would likely be to ventilate the patient and give naloxone, while further investigating the cause. After discovering a syringe swap occurred—hydromorphone was given instead of fentanyl—you continue with the current management. Even though the wrong medication was given, your corrective action was appropriate. Color-coded labels contained the error to a narcotic-related adverse event, allowing the "anchoring bias" to work in your favor, instead of against you. Now, imagine that a paralytic agent was actually the culprit. In that case, the initial corrective action may have resulted in a delay of the appropriate management.

Those opposed to color-coded labels argue that they serve as a substitute for reading the label. In fact, they would probably argue that the syringe swap example described above would have been avoided altogether if color labels were not used! By removing the color-coding, the provider would be forced to read the label to identify the medication. In other words, they hope to impose a forcing function at the expense of redundancy cues and error mitigation. There are two flaws in this logic. First, it assumes that color-coded labels lead to an increase in medication errors. If this were true,

See "Color-Coded Label Debate," Next Page

Table 1. Principles Guiding Human Factors Engineering to Reduce Error

Principle	Definition	Example
Standardization	Decreases variability of systems	Preflight checklist use in aviation
Forcing functions	Prevent performance of an undesired action	Impossible to shift gears of a car without applying the brake
Redundancy cues	Convey the same message through multiple routes	Both the color and location of the traffic light have the same meaning
Affordances	Communicate the intended use through inherent characteristics	A door with a push bar implies "push to open"
Natural mapping	Creates an obvious relationship between an object and its controller	Turning a steering wheel to the right turns the wheels to the right
Error Mitigation	Promotes early detection and correction of an error	Medication ordering systems alert a provider when ordering a medication with potential drug-drug interactions

Pro: Color Coded Labels Should Be Used For Anesthesia Drugs

From "Color-Coded Label Debate," Preceding Page

we would expect substantially lower rates of medication errors in hospital units where color-coding is not used. Yet, errors continue to occur in those locations.[16] Even more telling are the results of a clinical trial with over 55,000 anesthetics, reporting zero cases of syringe swaps between drugs with the same color label.[17] In fact, syringe size, not color, was most frequently associated with syringe swap errors.[17] Second, their goal of "forcing" providers to read the label by removing color-coding is well-intentioned, but misguided. Labels with lettering alone are still subject to error. Medication names that are similar in length, share the same first and last letters, or have many characters in common are at risk for misidentification.[18] The ISMP published a list of look-alike drugs, and advised using "tall man letters" to help distinguish these names.[18] However, expecting anesthesia professionals who label their own medications by hand to use standardized "tall man lettering" is impractical.

It's wishful thinking to believe errors would decrease if color labels were abandoned. Yes, we firmly believe every provider should read the label every single time. However, we would be foolish to ignore the lessons learned from human factors engineering and psychology research. How could any provider, at any level of training or experience, administer a medication without carefully reading the label first? Surely, these errors must be due to a lack of vigilance, intelligence, or experience… right? Well, if you have ever driven home only to realize upon arrival that you don't remember going through a familiar intersection or traffic signal, then you've experienced the curious nature of human cognition. Decision-making occurs by two distinct processes: Working memory allows us to perform multiple routine tasks in parallel with little attention, while direct attention is responsible for single, complex tasks that require focus and precision.[13] Faced with multiple simultaneous challenges such as hemodynamic instability, blood loss, metabolic disarray, the need to check labs, etc., the mind simply cannot use direct attention for every task at hand. Whether we care to admit it or not, some tasks will be performed with working memory. Redundancy cues, such as color-coded labels, aid working memory. If color-coded labels are removed, then other less reliable redundancy cues will be substituted to identify the medication, such as syringe size, orientation, and location.

James Reason, PhD, is the psychologist responsible for the famous "Swiss Cheese Model" of error.[19] This model describes how multiple, small failures must align in order for an error to reach the patient. In anesthesia, we strive to create as many layers of defense as possible to prevent errors from reaching the patient. We insist on having two functional blades and handles for laryngoscopy, in case one handle or bulb malfunctions. We use multiple layers of defense in preventing a hypoxic gas mixture: color-coded gas supply lines, the pin-index system, an oxygen sensor, oxygen positioned as the most downstream gas, color-coded flowmeter knobs, and "fluted" oxygen knobs. Simply put, redundancy improves safety.

We share the concerns of the ISMP that there are a limited number of discernible colors, colors may look similar, poorly contrasting backgrounds may affect appearance, and color-blind providers may have a disadvantage. Regarding their claim that data is lacking in support of color-coded labels, we point to a study showing color-coded labels improve proper identification of IV bags, improve identification of errors, and reduce the average performance time of tasks.[20] Color-coded labels may not be perfect, but let's not throw the baby out with the bathwater. Just because a system is not perfect does not mean it has no value. Color-coded labels add "one more layer of cheese" to the defense against medication errors, which may be the difference between an uneventful case and an adverse event.

This pro-con debate is essentially arguing two sides of the same coin. Medication labels are only a small piece of a much larger issue. In addition to syringe swaps, errors result from mistakes in preparation, labeling, vial/ampule selection, route of administration, and communication.[15] As anesthesia professionals, we have a duty to improve the system to minimize human error. Nowhere else in the hospital is a single provider responsible for prescribing, dispensing, preparing, labeling, and administering medications, as well as monitoring for adverse events. Point-of-care label makers, bar code scanning, and prefilled syringes are important safety measures that off-load anesthesia professionals of some of these medication-related tasks and allow second-source verification, decreasing the chance of error. Unfortunately, these devices are not widely used, mainly due to cost constraints. Even with their aid, as long as humans are involved, errors will continue to occur. We support the use of color-coded medication labels, and urge all providers to always read the medication label prior to administration.

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Dr. Janik has no conflicts of interest. Dr. Vender is a consultant for Fresenius-Kabi.

REFERENCES

1. Asahq.org. Statement on labeling of pharmaceuticals for use in anesthesiology. American Society of Anesthesiologists (ASA). 2015; https://www.asahq.org/standards-and-guidelines/statement-on-labeling-of-pharmaceuticals-for-use-in-anesthesiology. Accessed November 9, 2018.
2. Food and Drug Administration. Guidance for industry: safety considerations for container labels and carton labeling design to minimize medication errors. 2013; https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf. Accessed November 9, 2018.
3. Institute For Safe Medication Practices. A spectrum of problems with using color. 2003; https://www.ismp.org/resources/spectrum-problems-using-color. Accessed November 9, 2018.
4. Tanaka, J, Presnell, L. Color diagnosticity in object recognition. *Percept Psychophys.* 1999;61:1140–1153.
5. Bannert MM, Bartels A. Decoding the yellow of a gray banana. *Current Biology.* 2013;23:2268–2272.
6. Federal Highway Administration, Manual of uniform traffic control devices. 2009; https://mutcd.fhwa.dot.gov/pdfs/2009/mutcd2009edition.pdf. Accessed November 9, 2018.
7. The Food Safety Company. Why colour coding is important. 2016; http://www.foodsafety.company/2016/11/why-colour-coding-is-important.html. Accessed November 9, 2018.
8. BuildUK.org. Safety Helmet Colours. 2016; https://builduk.wpengine.com/wp-content/uploads/2016/04/Safety-Helmet-Colours-Build-UK-Standard.pdf. Accessed November 9, 2018.
9. Osha.gov. (2018). Authority for 1910 Subpart S - 1910 Subpart S | Occupational Safety and Health Administration. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10135&p_table=STANDARDS. Accessed November 9, 2018.
10. Department of Defense Handbook. Color and marking of army material (Metric); MIL-STD-1273B (MI) 1995; https://www.alternatewars.com/BBOW/Sources/MIL-HDBK-1473.pdf. Accessed November 9, 2018.
11. Cardosi K, Hannon D. Guidelines for the use of color in ATC displays. Federal Aviation Administration, US Department of Transportation, Research and Special Programs Administration. 1999; http://www.tc.faa.gov/its/worldpac/techrpt/ar99-52.pdf. Accessed November 9, 2018.
12. Standard for color code for shop machinery and equipment, John F. Kennedy Space Center. KSC-STD-0003, 1967; https://ntrs.nasa.gov/archive/nasa/casi.ntrs.nasa.gov/19670027339.pdf. Accessed November 9, 2018.
13. Kohn LT, Corrigan JM, Donaldson MS. "To err is human: building a safer health system." Committee on Quality of Healthcare in America. Institute of Medicine. 1999.
14. Gosbee JW, Gosbee LL. Using human factors engineering to improve patient safety: problem solving on the front line. 2nd ed. The Joint Commission, 2010.
15. Abeysekera A, Bergman IJ, Kluger MT, Short TG. Drug error in anaesthetic practice: a review of 896 reports from the Australian Incident Monitoring Study database. *Anaesthesia.* 2005;60:220–27.
16. Wolfe D, et al. Incidence, causes, and consequences of preventable adverse drug reactions occurring in inpatients: A systematic review of systematic reviews. *PLoS One.* 2018;13:1–36.
17. Fasting S, Gisvold SE. Reports of investigation: adverse drug errors in anesthesia, and the impact of coloured syringe labels. *Can J Anesth.* 2000;47:1060–1067.
18. Institute For Safe Medication Practices. (2018). Special Edition: tall man lettering; ISMP updates its list of drug names with tall man letters. https://www.ismp.org/resources/special-edition-tall-man-lettering-ismp-updates-its-list-drug-names-tall-man-letters. Accessed November 9, 2018.
19. Reason J. *Managing the Risk of Organizational Accidents.* Burlington, VT: Ashgate Publishing Company; 2000.
20. Porat N, et al. Use of colour-coded labels for intravenous medications and lines to improve patient safety. *Qual Saf Health Care.* 2009;18:505–509.

Con: Anesthesia Drugs Should NOT Be Color-Coded

by Matthew Grissinger RPh, FISMP, FASCP, and Ronald S. Litman, DO, ML

Color-coding is the systematic, standard application of color to aid in classification and identification. A color-coding system allows people to memorize a color and match it to its function. Color-coding of anesthesia drug labels has been viewed by practitioners as a common-sense approach, and has been promoted by standards created by the American Society of Anesthesiologists[1] and the American Society of Testing and Materials (ASTM).[2] Although color-coding has never been shown to reduce the incidence of medication errors in the operating room (OR), it may mitigate their harm because if there is an accidental syringe swap of medications in the same general class (e.g., opioid for opioid), the adverse effect of the swap may not be as clinically meaningful as a swap with a drug from another class (e.g., neuromuscular blocker).

If color-coding makes intuitive sense, why do the Institute for Safe Medication Practices (ISMP), Food and Drug Administration (FDA), American Medical Association (AMA), and the American Society for Health-System Pharmacists (ASHP) all oppose it? First, color-coding is difficult to maintain, especially when syringes are increasingly being prefilled and prelabeled by a combination of in-house pharmacies and non-hospital-based outsourcers, and then used throughout many parts of the hospital. For example, at the Children's Hospital of Philadelphia, prefilled anesthesia syringes made by an automated robot are supplied with a white label with black letters (Figure 1), and those made by outsourcers may contain differently colored labels because no standardization for color-coding exists (Figure 2). If one relied on color-coding to pick the correct medication each and every time, accidental administration of the wrong medication is inevitable. This was illustrated in a recent case report from the Anesthesia Incident Reporting System, which described what happened when an in-hospital pharmacy took over production of prefilled hydromorphone syringes when their outsourcer had an acute shortage. The new syringes did not contain the usual blue opioid labels and were confused with dexmedetomidine, which was accidentally administered by anesthesia professionals on at least three occasions.[3] In addition, there's a limit to the variety of discernible colors available for commercial use. Subtle distinctions in color are poorly discernible unless products are adjacent to each other.[4,5] The more colors that are used, the greater the risk of confusing a color and its meaning. Clinicians who are color-blind may misidentify color-coded products, leading to a medication error. Relying on color-classification systems as the primary way to identify a drug risks bypassing the recommended three readings of the drug label (Table 1).

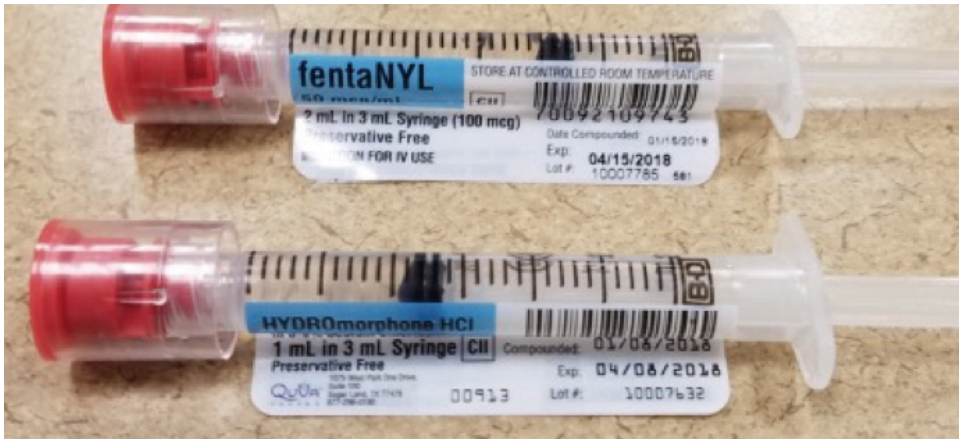

Figure 1. Medication syringes with white label and black letters prepared by hospital pharmacy. Anesthesia professional must have put on an additional colored label.

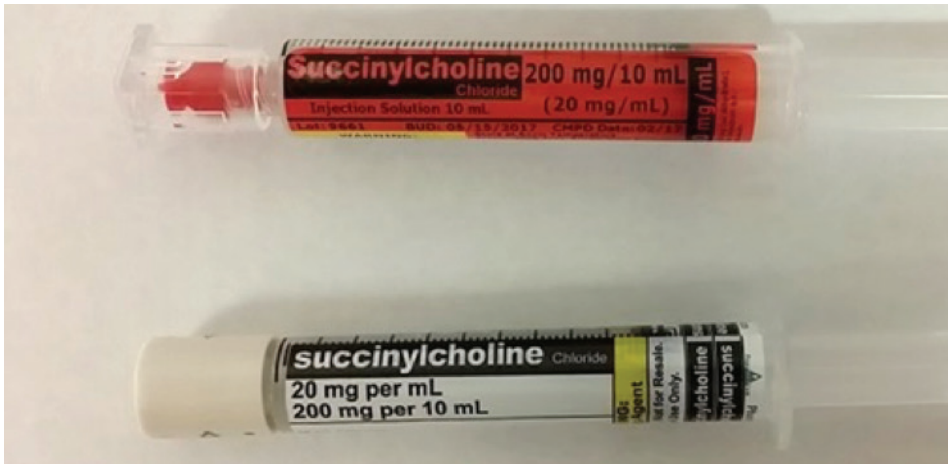

Figure 2. Medication syringes prepared by outsourcers may have different colored labels depending on manufacturer.

Table 1. Three Recommended Readings of the Drug Label

1. When retrieving the drug
2. When preparing and labeling the syringe
3. Before throwing the vial/ampule away

The OR environment is unique with regard to drug preparation. When anesthesia professionals prepare drugs in the OR, they retrieve the medication vial or ampule from a cart, draw up the medication into a syringe, and apply a color-coded adhesive label to the syringe. For most patients, only a single agent within each drug class is prepared. Thus, each drug has its own color, and anesthesia professionals typically know what is in each syringe because they personally prepared it. However, preparing medications at the point of care (i.e., the OR) is an inherently risky endeavor for many reasons, including, but not limited to: unintentional vial swap, accidental failure to label the final medication syringe, and possible contamination of the drug due to preparation in an unsterile environment.

We believe that the future of medication safety in the OR includes the prefilling and prelabeling of medications prior to arrival in the OR. This can be accomplished by an in-house hospital pharmacy, an outsourcing drug distributor, and/or the drug manufacturer. These prefilled syringes, although possibly color-coded by class, could increase the risk of syringe swap because they were not directly prepared by the anesthesia professional, especially if provided in similar-sized syringes and similar labeling formats. For example, it's possible to have three drugs—morphine, fentaNYL, and HYDROmorphone—each with significant potency variations, all in blue labeled syringes in the same physical area. A mix-up of any one of these drugs can cause serious harm to the patient, such as unanticipated respiratory depression leading to anoxia.

See "Color-Coding Label Debate," Next Page

Con: Color-Coded Anesthesia Drug Labels Should NOT Be Used

From "Color-Coded Label Debate," Preceding Page

With drug shortages impacting anesthesia practices, it would also be possible for one concentration of a medication (e.g., morphine 1 mg/mL) to be mixed-up with another concentration of that medication (e.g., morphine 10 mg/mL), yet both would employ the same color scheme. Of course, it is always possible that the hospital pharmacy or outsourcer may accidentally swap medications or labels, but this is much less common because their drug preparation spaces are segregated, as opposed to the OR environment where all drugs coexist in the same physical space.

Finally, these commercially prepared prelabeled syringes may be used in non-OR environments in the hospital by administering nurses or other providers that may not be as familiar with the standard anesthesia colors, which could result in an accidental syringe swap. Within the OR, patients are carefully monitored, and immediate care is available in case of a medication mix-up. Outside the OR, mix-ups can often be difficult to recognize and manage quickly in non-monitored areas; or an error can go unrecognized if syringes are accidentally returned to the wrong storage area or if they are placed on a table with other syringes of drugs in the same class.

The most practical solution to offset the disadvantages of color-coding while enhancing safety is to adopt a technological strategy, such as bar-code scanning (or any similar future technology) of syringe labels to catch inadvertent syringe swaps, thus assuring clinicians that they are administering the correct drug. In essence, color-coding relies on human skills, which are indisputably unreliable.

In summary, we oppose the reliance on color-coded syringe labels because we feel that the colors provide a false reassurance of the content of the syringe, decreasing the chance that anesthesia professionals will read the labels as carefully as they should. As early as 2008, in an *APSF Newsletter*,[6] Dr. Workhoven emphasized that anesthesia professionals do not always read the label because they think that they have time only to recognize the color, shape, or size of the intended drug or syringe. We are now ten years later, and must demand better than our reliance on recognition of colors to keep our patients safe.

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The authors have no financial conflicts of interest to disclose.

REFERENCES

1. Statement on creating labels of pharmaceuticals for use in anesthesiology. 2015; http://www.asahq.org/~/media/sites/asahq/files/public/resources/standards-guidelines/statement-on-labeling-of-pharmaceuticals-for-use-in-anesthesiology.pdf. Accessed October 26, 2018.
2. ASTM, Standard specification for user applied drug labels in anesthesiology. 2017; https://www.astm.org/Standards/D4774.htm. Accessed October 26, 2018.
3. A case report from the Anesthesia Quality Institute, 2018; https://www.aqihq.org/files/AIRS_6.18.pdf. Accessed October 26, 2018.
4. Christ RE. Review and analysis of color-coding research for visual displays. *Human Factors*. 1975;17:542–570. web.engr.oregonstate.edu/~pancake/cs552/guidelines/color.coding.html. Accessed November 19, 2018.
5. American National Standards Institute, Association for the Advancement of Medical Instrumentation. Human factors engineering guidelines and preferred practices for the design of medical devices (ANSI/AAMI HE-48). Arlington, VA: Association for the Advancement of Medical Instrumentation, 1993; pg. 41.
6. Workhoven M. There is no substitute for reading the label. *APSF Newsletter.* 2008;23:19. https://www.apsf.org/article/there-is-no-substitute-for-reading-the-label/. Accessed December 10, 2018.

APSF Sponsors the Trainee Quality Improvement Program for Fourth Straight Year

by Maria van Pelt, PhD, CRNA, and Brian Cammarata, MD

APSF sponsored the fourth annual Trainee Quality Improvement (TQI) Program. For 2018, the APSF Committee on Education and Training expanded the program to three groups of anesthesia professionals. These groups consisted of anesthesiology residents, anesthesiologist assistant students, and nurse anesthesia students. Participants in each track were invited to submit a four-minute video showcasing their best quality-improvement and/or patient-safety projects.

Each group received a robust response and project quality was consistently high. All projects were evaluated in a standardized manner. The physician anesthesia and anesthesiologist assistant program winners were announced at the ASA Annual Meeting in San Francisco, CA. The nurse anesthesia program winners were announced at the AANA Annual Congress in Boston, MA.

The winning TQI resident physician trainee project was submitted by Drs. D. Garcia, D. Wong, and K. Breidenbach from Albert Einstein/Montefiore Medical Center. Their patient-safety video entitled "Intraoperative Cephazolin Redosing—Practice Review and Improvement," described a review and process improvement in their practice of administering preoperative antibiotics in a reproducible and timely fashion. This project resulted in a significant improvement in preoperative antibiotic dosing compliance.

The winning anesthesiologist assistant student project was submitted by J. Rogers, K. Bess, E. Kirst, and A. White from Emory University. This patient-safety video was entitled "Use of the SOAP MEE Checklist during Anesthesia Time Out." The project suggested that students in the program who used the SOAP MEE acronym (Suction, Oxygen, Airway, Positioning, Medications, Equipment, $EtCO_2$) were less likely to miss these key components during anesthesia cases and also more likely to correct them in a timely fashion than those students who did not use SOAP MEE.

The winning nurse anesthesia student project was submitted by L. Easterbrook, RN, BSN, from the Mayo Clinic Nurse Anesthesia Program. This patient-safety video was entitled "Improving Medication Handoff Practices Between Post Anesthesia Care Unit (PACU) Nurses and Anesthesia Providers." After this process was implemented, post-educational observations showed an 80% increased use of the computer for medication reconciliation, correction of errors in charting at the bedside, and increased mention of home medications.

APSF will continue with three parallel tracks for the 2019 program. The following link (https://www.apsf.org/tqi-award-winners/) provides access to the 2018 winning videos. Announcement details for the 2019 QI Program will be available on the APSF website.

Dr. Van Pelt is associate clinical professor and Nurse Anesthesia program director at Northeastern University. She serves as the APSF chair, Education and Training Committee and is a member of the Executive Committee and Board of Directors.

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Neither of the authors have any disclosures to report.

APSF Awards 2019 Grant Recipients

by Steven K. Howard, MD

APSF support of patient safety research has been long guided by the Foundation's Vision Statement that *"no patient shall be harmed by anesthesia"* and the Mission Statement that includes the goal "to improve continually the safety of patients during anesthesia care by encouraging and conducting safety research and education." The APSF has provided over nine million dollars for patient safety research since 1987 in an effort to achieve these goals.

The 2018-19 APSF investigator-initiated research grant program received 29 letters of intent (LOIs) that were submitted in early February 2018. After thorough evaluation, six teams were asked to submit full proposals. On October 13, 2018, the Scientific Evaluation Committee met during the Annual ASA Meeting to make funding recommendations to the APSF Board of Directors. Three recommendations were made and were voted upon favorably.

The principal investigators of this year's APSF grants provided the following description of their proposed work.

Arnoley S. Abcejo, MD

Assistant Professor of Anesthesiology and Perioperative Medicine
Mayo Clinic Rochester

Dr. Abcejo's Clinical Research submission is entitled ***"Neurocognitive Dysfunction after Anesthesia in Patients with Recent Concussion."***

Background: Concussion represents the functional manifestation of traumatic brain injury. This neurologic condition impacts millions of Americans each year—affecting all age groups, genders, and demographic backgrounds. Though most often associated with sports-related injuries and motor vehicle accidents, the most common reason for a concussion is falls. Despite the mechanism, the acute phase after concussive injury results in a myriad of otherwise nonspecific neurologic and cognitive symptoms, i.e., headache, confusion, emotional lability, nausea, memory loss, etc. Despite the resolution of concussive symptoms, however, clinical evidence reveals aberrations in neurophysiologic homeostasis that may persist for days to weeks longer. These changes include cerebral dysautoregulation, changes in cerebral blow flow, and interruptions in cerebral metabolism, blood brain barrier mechanics, and neuronal transmission.

The concept of a "vulnerable brain" in the perioperative period is being investigated in a variety of patient cohorts including children, in those with pre-existing brain injury (i.e., prior stroke, traumatic injury), and in elderly adults. The pathophysiologic changes associated with concussion may result in a "vulnerable brain" state where further insult could uncover, exacerbate, or prolong its symptoms and their sequelae. Exposure to anesthesia and the perioperative setting may pose a significant patient safety risk after concussion. Our group has retrospectively shown that anesthesia after concussion is not uncommon and that many patients with concussion require anesthesia within a month of the concussive injury.[1]

Aims: The overall goal of this project is to determine if the vulnerable brain following concussion is functionally impacted by anesthesia and surgery. To accomplish this goal, a prospective cohort study design will be used to: (1) test the hypothesis that patients with recent concussion experience a greater degree of neurocognitive dysfunction after anesthesia compared to matched patients without concussion and (2) characterize the nature and severity of cognitive deficits that may be associated with anesthesia and surgery in patients with acute concussion. We also want to understand the feasibility of prospectively studying patients with concussion and performance of neurocognitive testing.

Implications: This important work addresses several priorities set forth by the APSF. First, given the worldwide burden of traumatic brain injury, establishing a relationship, or lack thereof, between neurocognitive dysfunction and anesthesia after concussion may provide anesthesia professionals with information to assess their patient's perioperative risk. It may also promote research into optimizing patient care related to safe time intervals between the concussion event and exposure to anesthesia. Second, this pilot work may identify opportunities for promoting brain health initiatives. Specifically, this work may identify neurocognitive testing strategies that can be used in future studies and outline a research strategy for establishing best-practice guidelines and safety standards for anesthesia administration following recent concussion.

Funding: $150,000 (January 1, 2019–December 31, 2020). This grant was designated the APSF/ASA Endowed Research Award. Dr. Abcejo is also the recipient of the Ellison C. "Jeep" Pierce, Jr., MD, Merit Award, which provides an additional, unrestricted amount of $5,000.

REFERENCE

1. Abcejo AS, Savica R, Lanier WL, Pasternak JL. Exposure to surgery and anesthesia after concussion due to mild traumatic brain injury. *Mayo Clinic Proc.* 2017; 92: 1042–1052.

J. Matthias Walz, MD

Professor of Anesthesiology, Surgery, and Perioperative Medicine
University of Massachusetts Medical School

Dr. Walz's Clinical Research submission is entitled ***"Older Adult Safety in Surgery (OASIS): Can a preoperative walking prescription bolstered by pedometer and remote physical therapist coaching improve stamina and mobility in frail older adult surgical patients?"***

Background: Frail older surgical patients face more than a two-fold increase in postoperative patient safety events, including myocardial infarction, deep vein thrombosis, pulmonary embolism, pneumonia, ileus, and others compared with non-frail older adults. Many of these adverse events result from postoperative loss of stamina and poor mobility.[1] Preoperative exercise interventions (i.e., prehabilitation) may better prepare these vulnerable patients for surgery, but there are very few existing studies. The interventions published in the literature thus far fall short of meeting the needs of frail older adults because they include multiple clinic visits which add to the stress of these patients who have multiple other presurgical appointments.

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Moreover, these interventions provide general walking advice, but not goal setting with modern Fitbit-like pedometers or remote coaching by a physical therapist (PT), both of which have been effective in other settings.[2,3]

Aim: The primary objective of this randomized, controlled study is to compare walking with a modern pedometer guided by remote PT coaching versus preoperative general walking advice on postoperative stamina and mobility in frail older adults undergoing colectomy or other intestinal surgery.

Implications: Given the prevalence and elevated risk of postoperative patient safety events in frail older adults, preoperative walking with a modern pedometer and remote PT could have significant positive impact on postoperative health and reduce burden on the health care system. Although we focus on colectomy and intestinal surgeries in this proposal, we believe the same benefits are likely to hold true for a broader population. The number of patients who would potentially benefit from this intervention is likely to be high, and the dividends in terms of averted complications and associated reduction in cost from postoperative utilization is substantial.

Funding: $144,185 (January 1, 2019–December 31, 2020). This grant was designated the APSF/Medtronic Research Award.

REFERENCES

1. Carli F, Scheede-Bergdahl C. Prehabilitation to enhance perioperative care. *Anesthesiology Clinics.* 2015;33:17–33.
2. Bravata DM. Using pedometers to increase physical activity and improve health: a systematic review. *JAMA.* 2007;298: 2296–2304.
3. Fitzgerald GK, White DK. Associations for change in physical and psychological factors and treatment response following exercise in knee osteoarthritis: an exploratory study. *Arthritis Care & Research.* 2012;64:1673–1680.

Nicholas J. Davis, MD

Assistant Professor of Anesthesiology
Columbia University

Dr. Davis's Clinical Research submission is entitled ***"Ultrasound evaluation of gastric emptying time in neonates and infants."***

Background: Preoperative fasting guidelines for all age groups (Practice Guidelines for Preoperative Fasting, updated 2016) have been developed by the American Society of Anesthesiologists to help mitigate the risk of pulmonary aspiration, an infrequent but potentially devastating complication during anesthesia.[1] These recommendations, particularly in the pediatric population, are supported by very limited evidence. NPO guidelines in very young children are six hours for formula feeding and the fasting interval far exceeds the feeding intervals infants normally experience (3–4 hours).[1] Thus, when NPO durations are excessively long, there are real risks of dehydration and possibly hypoglycemia, in addition to being a source of parental dissatisfaction and cause of irritability in young patients. The purpose of this study will be to elucidate gastric emptying times in healthy newborns and infants to support the development of rational fasting guidelines, which would optimize patient safety and well-being, as well as parental satisfaction.

Aims: This study will attempt to determine gastric emptying times in newborns, and infants of ages 3–6 months and 9–12 months, using serial ultrasound assessments of gastric antral volumes. We will test the hypothesis that gastric emptying times after formula feeding are less than the recommended six hours in neonates and young infants.

Implications: If the results document that gastric emptying times are less than six hours for formula-fed newborns and infants, then revisions to NPO guidelines for pediatric patients can be supported. Abbreviating the fasting times in these young children will improve patient and family satisfaction while maintaining patient safety.

Funding: $149,993 (January 1, 2019–December 31, 2020). This grant was designated the APSF/ASA Presidents Research Award.

REFERENCE

1. An Updated Report by the American Society of Anesthesiologists Task Force on Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. *Anesthesiology.* 2017; 126:376-93.

Dr. Howard is a staff anesthesiologist at the VA Palo Alto Health Care System and he is professor of anesthesiology, perioperative and pain medicine at Stanford University School of Medicine. Dr. Howard also serves as current chair of the APSF Scientific Evaluation Committee

Dr. Howard serves on the Board of Directors of the APSF and has no other conflicts of interest to declare.

APSF Corporate Giving Opportunities

APSF is committed to working with all stakeholders to advance patient safety. Your company can support patient safety and education with a gift to the APSF. As a 501c3 charitable organization, APSF can serve your company's corporate responsibility, charitable giving, and research goals.

Companies support the APSF in many ways. Pharmaceutical, medical device, related organizations, and anesthesia practice management companies make it possible for APSF to fulfill its mission to improve continually the safety of patients during anesthesia care by encouraging and conducting:

- safety research and education;
- patient safety programs and campaigns;
- national and international exchange of information and ideas.

With your generous contributions, the APSF can advance its vision that no patient shall be harmed by anesthesia.

If your organization is interested in partnering with APSF to support patient safety, contact APSF President Mark Warner, MD at warner@apsf.org or Sara Moser at moser@apsf.org

Participate in the APSF Corporate Advisory Council

The Anesthesia Patient Safety Foundation invites you to become a member of our Corporate Advisory Council (CAC). When your company becomes a member of the CAC, in addition to the benefits of membership, your company will also be recognized as a supporter of the mission of APSF. Some of the benefits of membership, depending on your level of support and participation, include

- Invitations to participate in the CAC meetings and conference calls, which meet in person once a year to discuss topics pertinent to patient safety and industry
- Recognition in APSF communications, online and in print
- Invitation to APSF events and meetings with executive-level leadership
- Research and collaboration opportunities
- Networking opportunities allowing leaders from corporations and APSF to share ideas and information

For specific information about the benefits of corporate membership, please contact Sara Moser at moser@apsf.org.

Opportunity to Sponsor APSF Stoelting Consensus Conference

The Stoelting Conference, formerly known as the consensus conference, brings a defined group of approximately 125 leaders from perioperative professional organizations such as the American Society of Anesthesiologists (ASA), the American Association of Nurse Anesthetists (AANA), the Association of Operating Room Nurses (AORN), the American Society of Peri-Anesthetic Nurses (ASPAN), and surgical societies together with representatives from anesthesia-related industries and colleagues from insurance, human factors, and legal fields. The recommendations from these conferences have led to significant practice and other changes and improved patient safety. Examples include perioperative fire safety, vision loss, residual neuromuscular blockade, operating room distractions, and, most recently, perioperative medication safety. The 2019 Stoelting Consensus Conference is September 4–5, 2019, at The Camby Hotel in Phoenix, AZ.

Maximum Number of Stoelting Conference Supporters: Four

For more information about the benefits of sponsoring the Stoelting Conference, please contact Sara Moser at **moser@apsf.org**.

Opportunity to Partner with APSF on Patient Safety Research Grants

The APSF has distributed $12 million in funding for anesthesia patient safety research projects over its 30-year history, leading to important discoveries that have changed clinical practices, improved patient outcomes, and supported the career development of anesthesia patient safety scientists. The results of these research grants have made significant contributions to the specialty.

For more information on sponsoring a research grant, please contact Sara Moser at moser@apsf.org.

International Standards for Safe Anesthesia Practice

From "SAFE-T Summit," Cover Page

The current Standards, developed by a multinational, gender-balanced workgroup representing high-, middle-, and low-income countries, build on two previous standards documents endorsed by the General Assembly of the WFSA, but this is the first time these standards have been endorsed by the WHO. The language of the Standards is therefore aligned with that of the World Health Organization (WHO), notably in the use of the terms HIGHLY RECOMMENDED, RECOMMENDED, and SUGGESTED to denote three levels of standards. HIGHLY RECOMMENDED standards are "the minimum expected" and are, in effect, mandatory. The Standards are explicit about this, stating that if these cannot be met, then "the provision of anesthesia should be restricted to procedures that are essential for the immediate (emergency) saving of life or limb." It is, therefore, useful to reflect on a selection of these mandatory standards.

The Standards provide definitions of general anesthesia, levels of sedation, and of the WHO levels of health care facilities. There is considerable variation in the terminology used for different levels of health care facilities around the world, and the document states that it is the type of surgical cases done in the facility that determine the level of the Standards that should apply, rather than the facility nomenclature used by any particular country. This provides a context for the allocation of resources in line with the three levels of the Standards, although it is made clear that the goal should always be to practice to the highest level possible.

The first requirement mandated by the Standards for safe anesthesia care is the continuous presence of an appropriately trained and vigilant anesthesia professional. It is therefore unacceptable for a single anesthesiologist, without other assistant providers, to administer concurrent anesthesia in multiple operating rooms as reported anecdotally around the world. Such practice breaches the first principle of safe anesthetic practice. For example, there is little value in automated or electronic monitoring if a trained anesthesia professional is not present. The mandatory use of an oximeter is *in addition to* the continuous presence of a trained and vigilant anesthesia professional.

In considering the question of how to define a "trained" anesthesia professional, the Standards recognize that many anesthetics are administered by non-anesthesiologists with various levels of training, professional background, and competency. Definitions are provided for the terms used to describe the variety of anesthesia professionals that work with anesthesiologists in meeting the global demand for safe anesthesia. For all types of professionals, *"Formal training in a nationally accredited (postgraduate) education program and documentation of training is HIGHLY RECOMMENDED."* Nevertheless, the WFSA views anesthesia as a medical practice, because of its complexity and potentially hazardous nature. Therefore, these WHO-WFSA Standards state that *"its safe provision requires a high level of expertise in medical diagnosis, pharmacology, physiology, and anatomy, as well as considerable practical skill"* and *"wherever and whenever possible, anesthesia should be provided, led, or overseen by an anesthesiologist,"* where anesthesiologist is defined as a *"graduate of a medical school who has completed a nationally recognized specialist anesthesia training program."* However, the WFSA has issued a statement recognizing that the global gap in access to safe anesthesia care cannot be closed in the foreseeable future by anesthesiologists alone. The importance of teamwork in safe anesthesia and surgery is emphasized. Irrespective of the anesthesia team's composition, patients surely have the right to expect their anesthesia professionals to have successfully completed formal anesthesia training schemes approved by their governing bodies and aligned to the realities of each country.

Furthermore, the authors of the Standards encourage those countries who currently use the term *"an(a)esthetist"* to denote *"anesthesiologist"* to adopt the universal categorization of the terminology of *"anesthesiologist"* proposed, in the interests of standardization. We believe that a single global terminology will contribute to communication with governments and other funding and regulatory agencies and will assist advocacy for the urgent need to address the massive global gap in anesthesia professionals in ways consistent with the mandatory requirement for oversight and leadership by anesthesiologists, outlined above.

The Standards provide a concise outline of the other physical requirements for safe anesthesia, as well as a tabulated list of the necessary medications and intravenous fluids. Readers are referred to the Standards themselves for more detail.[2,3]

The mandatory requirement for the monitoring of tissue oxygenation by pulse oximetry (and continuous clinical observation) was included in the previous edition of these standards and was seen as controversial from two opposing perspectives. From one perspective, it was suggested that this requirement was unrealistic at this time due to limitations in resources of some countries. To some extent this is true, and the Standards are intended to be aspirational, to encourage progress towards acceptable practice. The work of members of the WFSA and Lifebox (of which the WFSA was one of the founding organizations, with the Association of Anaesthetists of Great Britain and Ireland, Harvard School of Public Health and The Brigham and Women's Hospital) has demonstrated and sought to address a global oximetry gap in some 77,000 operating rooms.[5]

Over 20,000 pulse oximeters, supported by considerable training and advocacy, have now been distributed through the efforts of these organizations supported by the American Society of Anesthesiologists and many other anesthesia societies and colleges, notably those from the UK, Canada, Australia, and New Zealand. At the same time, a second group advanced the contrasting perspective that the Standards should have gone further and mandated capnography as well. These commentators argued that the many avoidable deaths associated with undiagnosed esophageal intubation and other ventilation problems are best detected by the continuous monitoring of carbon dioxide.

There was much debate and consultation over whether or not to include capnography during the development of the current Standards. The result of these discussions was that the Standards state, *"If an endotracheal tube is used, correct placement must be verified by auscultation (HIGHLY RECOMMENDED). Confirmation of correct placement by carbon dioxide detection (i.e., non-waveform capnography or colorimetry) is also HIGHLY RECOMMENDED."* The Standards RECOMMEND continuous waveform capnography and state that *"This form of monitoring will be HIGHLY RECOMMENDED when appropriately robust and suitably priced devices are available. Equipment manufacturers are encouraged to address this deficiency urgently."* This formulation reflects the current costs and challenges of providing reliable capnography in resource-poor environments. A proof of concept study has recently been carried out for the provision of capnography in Malawi[6] and work is being initiated by the WFSA to advance the progress of addressing the current deficiency in affordable and robust capnography monitors.[7]

There has been much interest, especially in low- and middle-income countries, regarding the WHO-WFSA Standards and in some countries the national anesthesiology society has submitted them to the ministry of health with a request for formal national adoption.

See "SAFE-T Summit," Next Page

Standards Are Adopted Worldwide to Improve Anesthesia Patient Safety

From "SAFE-T Summit," Preceding Page

The WFSA has also produced an associated checklist tool, the Anesthetic Facility Assessment Tool (AFAT), that allows local, regional, and national inventories of compliance with the Standards and helps to identify gaps that need to be filled.[8] At this time, attempts are being made to integrate AFAT into the WHO Service Availability and Readiness Assessment (SARA) that will be the repository for global health data at WHO, further emphasizing the need to engage health ministries in regular and timely data collection, including all anesthesia indicators.

It is interesting to reflect on the picture painted of global anesthesia presented by the Lancet Commission and reviewed at the April 2018 SAFE-T Summit in the context of the Standards. The Lancet Commission identified six core metrics.[1] Two of these relate directly to the Standards—the specialist surgical workforce density and perioperative mortality. Furthermore, as already intimated, access to timely essential surgery is only of value if that surgery, and the associated anesthesia, is safe, so the Standards inform this metric as well.[1]

In setting the goal of 20 surgical, anesthetic, and obstetric physicians per 100,000 population by 2030, the Lancet Commission was not explicit about how many of these should be anesthetic physicians. In 2017, Kempthorne et al. estimated that over 136,000 additional physician anaesthesia providers would be required to achieve a minimum density of 5 per 100,000 population globally.[9] As indicated, it is clear that the gap in anesthesia professionals will only be closed by training large numbers of nonphysician anesthesia clinicians as well as large numbers of anesthesiologists. The relevant HIGHLY RECOMMENDED Standard is the requirement for an accredited national training program in each case. Investment ensuring that such programs are available for all countries is urgently required.

The current goal for perioperative mortality (defined as "all-cause death rate before discharge in patients who have undergone a procedure in an operating theatre") relates to establishing the capacity to measure and report this nationally. This is a critically important outcome measure, but it will be challenging to meet the target in the proposed time frame and difficult to interpret data in the absence of explanatory information on case-mix and context.

Upon the successful conclusion of the first SAFE-T Summit, the WFSA Board voted to perpetuate annual WFSA SAFE-T Summits in years when there is no World Congress of Anesthesiology. Fittingly, the key themes for the second SAFE-T Summit in London in April 2019 will be access, safety, and equity. Clinicians, administrators, and governments need to work together to ensure that the Standards are a reality for all patients undergoing anesthesia everywhere in the world if we are to achieve the mission of the APSF: "No patient shall be harmed by anesthesia."

Dr. Merry is professor of anesthesiology at the University of Auckland and works clinically at Auckland City Hospital, Auckland New Zealand.

Dr. Johnson is head of the World Health Organization's (WHO) Emergency and Essential Surgical Care (EESC) Programme in Geneva, Switzerland; the World Federation of Societies of Anaesthesiologists has official relations with this programme.

Dr. Mets is a professor and chairperson of the Department of Anesthesiology, Pennsylvania State University, Hershey, PA.

Dr. Morris is a clinical senior lecturer in the Department of Anaesthesia, University of Otago, Christchurch, New Zealand.

Dr. Gelb is distinguished professor (emeritus) in the Department of Anesthesia & Perioperative Care, University of California San Francisco, San Francisco, California.

Dr. Merry has financial interests in SAFER sleep LLC, is treasurer of the World Federation of Societies of Anaesthesiologists, and is on the UK Board of Trustees of Lifebox. Dr. Johnson has no conflicts of interest to declare. Dr. Mets is director of Partnerships for the World Federation of Societies of Anaesthesiologists. Dr. Morris is director of Programmes of the World Federation of Societies of Anaesthesiologists. Dr. Gelb is secretary for the World Federation of Societies of Anaesthesiologists, and a consultant at Masimo Inc.

REFERENCES

1. Meara JG, Leather AJ, Hagander L, et al. Global surgery 2030: evidence and solutions for achieving health, welfare, and economic development. *Lancet.* 2015;386:569–624.
2. Gelb AW, Morriss WW, Johnson W, et al. World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) international standards for a safe practice of anesthesia. *Anesth Analg.* 2018;126:2047–2055.
3. Gelb AW, Morriss WW, Johnson W, et al. World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) International Standards for a Safe Practice of Anesthesia. *Can J Anaesth.* 2018;65:698–708.
4. Walker IA, Wilson IH. Anaesthesia in developing countries-a risk for patients. *Lancet.* 2008;371:968–969.
5. Funk LM, Weiser TG, Berry WR, et al. Global operating theatre distribution and pulse oximetry supply: an estimation from reported data. *Lancet.* 2010;376:1055–1061.
6. Jooste R, Roberts F, Mndolo S, et al. Global Capnography Project (GCAP): implementation of capnography in Malawi—an international anaesthesia quality improvement project. *Anaesthesia.* 2018; Sep 25. doi: 10.1111/anae.14426. [Epub ahead of print]
7. Lipnick MS, Mavoungou P, Gelb AW. The global capnography gap: a call to action. *Anaesthesia.* 2018:doi: 10.1111/anae.14478. [Epub ahead of print].
8. Anesthesia Facility Assessment Tool. https://www.wfsahq.org/resources/anaesthesia-facility-assessment-tool. Accessed December 6, 2018.
9. Kempthorne P, Morriss WW, Mellin-Olsen J, et al. The WFSA global anesthesia workforce survey. *Anesth Analg.* 2017;125:981–990.

2018 APSF/ASA Ellison C. Pierce, Jr., MD, Patient Safety Memorial Lecture: Anesthesia Patient Safety: Sharpening the Vision to Do No Harm

by Steven Greenberg, MD, FCCP, FCCM

The EC Pierce, Jr., MD, Patient Safety Memorial Lecture honors the founding president of the APSF, Dr. Ellison C. Pierce, Jr., for his countless contributions to anesthesia patient safety and his timeless vision that *"no patient shall be harmed by anesthesia."*[1] It is appropriate that this year's honoree, Dr. Robert Caplan, emeritus anesthesiologist at Virginia Mason Medical Center, pioneer in patient safety and former APSF board member was selected to discuss the evolution of how we recognize, manage, and prevent medical errors to reduce harm to, patients. With the mentorship of "Jeep" Pierce, Dr. Caplan has spent much of his career devoting time to moving the needle closer to zero patient harm. First, Dr. Caplan reflected on the importance of Dr. Pierce's words, *"If you hide mistakes, you can't learn from them."*[1] He reported his own firsthand struggles with rising medical errors and a stagnant hospital culture that was not conducive to positive change for patient safety. Dr. Caplan explored the dilemma of Dr. Pierce's vision of "zero patient harm"—immensely difficult to rationalize and achieve, but the only desirable endpoint for patient, provider, and health care.

Dr. Caplan focused the audience's attention on a sentinel event in his own institution where a patient accidentally received intravascular chlorhexidine instead of intravenous contrast. This resulted in the patient's unexpected death from major internal organ injury. As a safety leader, Dr. Caplan and his colleagues looked to the Toyota production line model as a way to systematically reduce medical errors.[2] Every employee was trained to be a safety inspector, using the technique of *source inspection*. This technique focuses on finding and fixing mistakes at a time and place where they can be reversed and remedied, thereby delivering a defect-free product to the patient. Dr. Caplan contrasted *source inspection* from end inspection (Figure 1). End inspection (an audit is the classic example) focuses on the detection of defects that are fixed in the health care product and are difficult to remedy or remove (Figure 2).

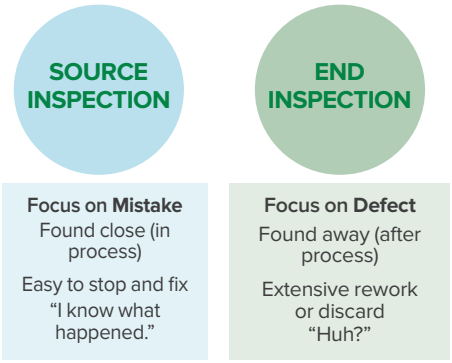

Figure 1. Source vs. End Inspection

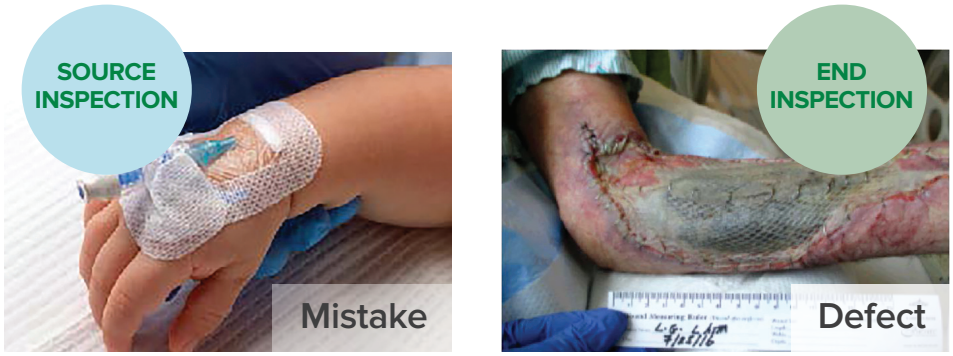

Figure 2. Examples of a Mistake (where a placed intravenous line is infiltrated) vs. a Defect (where the unrecognized infiltrated intravenous line resulted in tissue necrosis of the arm).

Table 1. Six Categories of Disrespectful Behavior

1. Passive disrespect for people and rules
2. Passive-aggressive behavior
3. Demeaning and humiliating treatment of nonphysician providers
4. Disruptive behavior
5. Dismissive treatment of patients
6. Indifference of the "System"

Table 2. Weak and Strong Safety Interventions

Weak	Strong
"Chats," warning letters	Checklists
Signs, computer alerts	Scripted communication
Case conferences	Eliminating look-alike drugs
New policies	Forcing functions/lockouts

Significant roadblocks occurred for Dr. Caplan and his colleagues when implementing safety initiatives. They turned to Dr. Lucian Leape, an internationally renowned leader in patient safety. Dr. Leape helped them understand that widespread provider disrespect is perhaps the most important obstacle to the pursuit of patient safety.[3] In the health care setting, disrespectful behavior typically occurs in six identifiable ways (Table 1).

With Dr. Leape's guidance, Dr. Caplan and his colleagues systematically elevated awareness of disrespectful behavior and promoted respectful alternatives. An especially important lesson was that disrespectful behavior is not just a problem created by *individuals*— it is also a problem created by the *system*. When the *system is indifferent* to weak and wasteful safety measures (chats, posters, announcements, on-line tests, policies that are hard to find or read), providers become discouraged and disengaged from safety work (Table 2). Dr. Caplan invited all members of the anesthesia community to reflect on the pervasiveness of weak and wasteful safety measures, and to consider the possibility that machine learning or artificial intelligence could help us discover more effective ways to find mistakes and deliver defect-free products.

In conclusion, Dr. Caplan challenged health care professionals to go for "zero." Why not identify a specific adverse outcome and eliminate it? This is just what the World Health Organization did with smallpox. Dr. Caplan suggested that there was no reason to delay—our specialty has the talent and leadership in anesthesiology to do it.

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Dr. Greenberg has no conflicts of interest pertaining to this article.

REFERENCES

1. Pierce, EC. The 34th Rovenstine Lecture: 40 years behind the mask: safety revisited. *Anesthesiology.* 1996;84:965–975.
2. Liker, Jeffery (2003), The Toyota Way: 14 management principles from the world's greatest manufacturer, First Edition, McGraw-Hill.
3. Leape LL, Shore, MF, Dienstag JL, et al. Perspective: a culture of respect—part 1 and part 2. *Acad Med.* 2012;87:845–858.

Our Own Safety

by Jeffrey Huang, MD, and Anthony Brenner, BS

One physician dies by suicide each day in the United States, equating to roughly two graduating classes of medical students lost per year.[1] Male physicians take their lives at a slightly higher rate compared to nonphysicians, but the rate for female physicians is more than double the rate of their nonphysician counterparts.[2] Although physician suicide has become a disturbingly common occurrence, accounts of these tragedies are described as "unexpected" or "shocking." Such was the case recently in central Florida, when a senior anesthesiologist took his life by his own hand. As word traveled through the hospital corridors, an entire health care community found themselves in disbelief. By specialty, anesthesiologists were second only to surgeons in number of deaths by suicide, according to a registry of data gathered between 2012 and 2018.[3] However, when correcting for the number of active physicians per specialty, anesthesiologists were twice as likely to die by suicide when compared to other physicians.[3] It is time for all anesthesia professionals to manage our own safety just as passionately as we defend the safety of our patients.

DEPRESSION

Physician suicide occurs in the presence of unaddressed risk factors or when multiple risk factors are present. As in the general population, mood disorders and substance abuse are the most common major risk factors in physicians who commit suicide.[4] For example, a postmortem psychological report in a small cohort of physicians who completed suicide identified that two-thirds suffered from either depression or alcohol abuse.[5] Risk of experiencing depression permeates all stages of careers in medicine, including medical school and residency. In fact, medical students and residents are at higher risk of experiencing a depressive episode than physicians further along in their careers.[6,7] In anesthesiology residents across the United States, one study identified 298 out of 1,384 (21%) were at risk for depression, and, of these, 23% reported suicidal ideation at least some of the time.[8] It is unclear whether these data extend into later stages of careers in anesthesia, since there are few studies on depression and suicidal ideation in the specialty as a whole. Furthermore, it is unclear whether this risk for Certified Registered Nurse Anesthetists and Anesthesiologist Assistants is elevated, since studies of depression and the risk of suicide among nonphysician anesthesia providers are lacking. Nevertheless, it is likely that all anesthesia professionals can be affected by this pervasive issue.

Table 1. "SAD PERSONS"[9]

Mnemonic for Suicide Risk Factors	
S	Sex (male)
A	Age >60
D	Depression
P	Previous attempt
E	Ethanol/drug abuse
R	Rational thinking loss
S	Suicide in family
O	Organized plans
N	No support
S	Sickness (debilitating disease)

SUBSTANCE ABUSE

In contrast, the elevated risk of substance abuse has been documented so extensively in anesthesiology that some consider it an occupational hazard. In general, substance abuse makes suicide more likely, and appears as a risk factor in a common screening tool to identify patients at risk for suicide (Table 1).[9] A key factor that increases anesthesiologists' risk of substance abuse is ease of access to addictive medications.[10] Drug handling policies, such as electronic dispensing systems, screening of waste syringes, and lock boxes, have been employed in order to counteract the diversion of these medications for abuse. Despite these efforts, the known incidence of substance abuse remains at roughly 1.6 % of anesthesiology residents and 1.0% of attending faculty. [10,11] Striving to reduce the incidence of substance abuse is critical to reducing the burden of suicide in the field of anesthesiology. While regulations may thwart attempts to obtain addictive substances, other factors such as job stress, work hours, and professional burnout may also be influencing the relationship between anesthesia professionals and substance abuse.

BURNOUT

Burnout, a state of mental fatigue and reduced sense of personal accomplishment, and factors leading to its development have become hot topics in the discussion of physician mental health.[12] This year, the Medscape National Physician Burnout and Depression Report found that 42% of 15,543 physicians reported burnout.[13] Critical care and neurology reported the highest prevalence (48%), while the lowest was reported by plastic surgery, dermatology, and pathology (32%). Prevalence of burnout in anesthesiology was 38% (anesthesiologists represented 6% of all respondents). This same Medscape Report found that 14% of respondents reported both depression and burnout. Although burnout does not necessarily precede depression, a link may exist given the similarity in their symptoms. Early medical trainees consistently report the highest rates of burnout, and the field of anesthesiology is no exception. Among anesthesiology residents, burnout was associated with deviation from best practices in anesthesiology, suggesting that burnout could harm patients in the form of increased rates of medical errors.[8] Furthermore, residents at high risk for depression or burnout demonstrated a higher weekly alcohol consumption and were more likely to abuse tobacco than residents without burnout or depression.[8] Considering anesthesiologists' record with substance abuse, such links should raise a red flag to leaders in anesthesiology and warrant further research on burnout and its role in substance abuse.

PREVENTION

Meaningful improvements in reducing physician suicide rates will require interventions that target the problem at multiple levels. Efforts to educate physicians on warning signs and risk factors should be enhanced and resources should be made readily available so that doctors in distress, or their colleagues, have the means to get help when it's needed most. The American Society of Anesthesiologists (ASA) has taken vital steps after learning that anesthesiologists are the group of physicians most likely to die by suicide. The resource tab on the ASA's website includes a section on suicide prevention resources with direct access to hotlines for those in acute need as well as information on signs, prevention, and education about physician suicide (Table 2). It should be emphasized that these resources will also aid a doctor who sees a colleague in distress but is unsure how to help. The ASA also has assembled an

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Ad Hoc Committee on Physician Well-Being to formulate ways to improve itself as a resource for anesthesiologists who are struggling with depression, substance abuse, and suicide. Furthermore, a panel dedicated to discussing prevention of suicide in anesthesiologists was added to the 2018 Annual ASA Meeting.

Enhancing physician utilization of mental health services can be critical to saving lives. A list of services by state is available on the Federation of State Physician Health Program website (www.fsphp.org). While doctors may be reluctant to seek their own health care, the crux of the problem appears to be resistance to engagement in these programs because of licensure concerns. In one survey, most emergency medicine physicians believed that state agencies or treating physicians will share confidential information with licensing authorities.[14] Additionally, a survey by the American College of Surgeons found that 60% of surgeons with suicidal ideation felt reluctant to seek medical care in fear of jeopardizing their medical licenses.[15] In order to combat this barrier in seeking care, many states have regulations allowing physicians to forgo reporting treatment for mental illness on licensure questionnaires, as long as they are compliant with medical care.[1] Confidentiality and protection will be central to improving physician engagement in their own mental health treatment. Another possibility is that physicians find it challenging to access mental health care due to the time constraints of their clinical duties. Planning leave from work may imperil a doctor's contract, require communicating openly with administration, or pose practical concerns such as loss of income and explaining leave from work to colleagues and family.

Health care providers should not only care for patients, but also for their colleagues and themselves. Prevention is the best form of treatment and accordingly primary prevention of physician suicide should take aim at remolding medicine's culture to place greater emphasis on physician well-being. This will require concerted efforts by medical schools to develop self-awareness among the next generation of doctors and to actively demonstrate self care and teach such practices to their trainees. More immediate solutions might begin with a recognition among health care leaders of the need for benefit packages with built-in time for days off without financial penalty, leave for self-care, or improved access to mental health services by bringing mental health providers into clinics and hospitals to reduce barriers to utilization.

Table 2. Resources for Health Care Professionals

Lifelines	
National Suicide Prevention Lifeline	suicidepreventionlifeline.org 1-800-273-TALK (8255) Text "HOME" to 741741
Suicide Prevention	
NIH National Institute of Mental Health: Suicide Prevention	nimh.nih.gov/health/topics/suicide-prevention/index.shtml
American Foundation for Suicide Prevention	afsp.org/our-work/education/healthcare-professional-burnout-depression-suicide-prevention/
AMA Steps Forward	stepsforward.org/modules/preventing-physician-suicide
ASA suicide prevention resource	asahq.org/in-the-spotlight/suicide-prevention-resources
For Wellness	
American Association of Nurse Anesthetists (AANA) Health and Wellness	aana.com/practice/health-and-wellness-peer-assistance
ACGME Well-Being Initiative	acgme.org/what-we-do/initiatives/physician-well-being
Agency for Healthcare Research and Quality – Physician Burnout	ahrq.gov/professionals/clinicians-providers/ahrq-works/burnout/index.html
Federation of State Physician Health Programs	fsphp.org
E-Couch for Mental Health	ecouch.anu.edu.au/welcome
APA Toolkit for Well-Being Ambassadors	APA-Well-being-Ambassador-Toolkit-Manual.pdf
International Doctors in Alcohol Anonymous	idaa.org

Adapted from material from reference 9: Latha G, Matthew K, Sean B. First aid for the psychiatry clerkship, Fourth edition. McGraw-Hill Education; 2016

For any healthcare professional to die by suicide, multiple stressors must converge and weigh on the mind until the load seems unbearable. If the arc of medical professional suicide is to be bent towards a brighter horizon, real improvements in prevention and treatment utilization must be made.

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REFERENCES

1. Louise B Andrew BEB. Physician suicide. 2018; https://emedicine.medscape.com/article/806779-overview#showall. Accessed September 10, 2018.
2. Schernhammer ES, Colditz GA. Suicide rates among physicians: a quantitative and gender assessment (meta-analysis). *Am J Psychiatry.* 2004;161:2295–2302.
3. Wible P. Keynote: 33 orthopadeic surgeon suicides. How to Prevent #34. 2018; http://www.pamelawible.com/keynote-33-orthopaedic-surgeon-suicides-how-to-prevent-34/. Accessed September 15, 2018.
4. Center C, Davis M, Detre T, et al. Confronting depression and suicide in physicians: a consensus statement. *JAMA.* 2003;289:3161–3166.
5. Hawton K, Malmberg A, Simkin S. Suicide in doctors. A psychological autopsy study. *J Psychosom Res.* 2004;57:1–4.
6. Dyrbye LN, Thomas MR, Shanafelt TD. Systematic review of depression, anxiety, and other indicators of psychological distress among U.S. and Canadian medical students. *Acad Med.* 2006;81:354–373.
7. Goebert D, Thompson D, Takeshita J, et al. Depressive symptoms in medical students and residents: a multischool study. *Acad Med.* 2009;84:236–241.
8. de Oliveira GS, Jr., Chang R, Fitzgerald PC, et al. The prevalence of burnout and depression and their association with adherence to safety and practice standards: a survey of United States anesthesiology trainees. *Anesth Analg.* 2013;117:182–193.
9. Latha G, Matthew K, Sean B. First aid for the psychiatry clerkship. Fourth edition. McGraw-Hill Education; 2016.
10. Tetzlaff JE. Drug diversion, chemical dependence, and anesthesiology. *Advances in Anesthesia.* 2011;29:113–127.
11. Booth JV, Grossman D, Moore J, et al. Substance abuse among physicians: a survey of academic anesthesiology programs. *Anesth Analg.* 2002;95:1024–1030.
12. Lacy BE, Chan JL. Physician burnout: the hidden health care crisis. *Clin Gastroenterol Hepatol.* 2018;16:311–317.
13. Peckham C. Medscape national physician burnout & depression report 2018. 2018; https://www.medscape.com/slideshow/2018-lifestyle-burnout-depression-6009235. Accessed September 15, 2018.
14. Andrew LB. Survey Says: Many EPs suffer in silence. 2006; http://epmonthly.com/article/survey-says-many-eps-suffer-in-silence/. Accessed September 9, 2018.
15. Shanafelt TD, Balch CM, Dyrbye L, et al. Special report: suicidal ideation among American surgeons. *Arch Surg.* 2011;146:54–62.

Perioperative Brain Health—It's Not All Positive Attitude, Exercise, and Superfoods

by Nirav Kamdar, MD, MPP; Lee A. Fleisher, MD; and Daniel Cole, MD

WHAT CAN BE DONE TO PROTECT MY PERIOPERATIVE BRAIN HEALTH?

Sara Lenz Lock, JD, Senior vice president for Policy at the Association of American Retired Persons (AARP), spoke at this year's American Society of Anesthesiologists (ASA) annual meeting in San Francisco, CA, on the crucial topic of perioperative brain health and the patient's concerns regarding the impact of surgery on cognitive function. As a general anesthesiologist who treats a large number of geriatric patients, this question drew one of us (N.K.) to the two-hour, dual-auditorium session hosted by the APSF. A multidisciplinary panel including academic anesthesiologists, researchers, patient engagement and public policy representatives provided some suggestions for management of this increasingly appreciated problem.

Anesthesia professionals and specifically the APSF have a rich patient safety heritage, serving as both leaders and innovators in this field.[1] In many respects, safety is the soul of our specialty. This panel upheld that tradition by examining recent developments in the field of perioperative brain health. The themes of the session addressed three overarching questions: (1) What do patients want to know about preserving brain health before upcoming surgery; (2) What can clinicians do to address brain health perioperatively; and (3) How do clinician's and patient's goals align with smart public policy?

Brain health is a timely topic. Similar to public interest in the neurotoxicity of anesthesia within the pediatric population,[2] it is no surprise that the elderly are interested in the impact of surgery and anesthesia on postoperative cognitive function. The cognitive changes experienced by patients after surgery are not new for anesthesia professionals; we often address concerns about "post-surgical fog" in either pre- or postoperative patient evaluations. Ms. Lock emphasized that patients will turn to their medical providers for answers when their brain health deteriorates. Therefore, patients are likely to inquire about potential risk reduction measures for cognitive dysfunction preoperatively. Similarly, patients might ask about the kind of cognitive effects they are likely to experience after surgery and how long those effects will last.

The conference panelists elucidated the scope of brain health as a patient safety problem, while taking into consideration the demands placed on medical professionals. Dr. Daniel Cole, professor of clinical anesthesiology at UCLA and current APSF vice president, introduced the magnitude of this national problem. He reported that the incidence of postoperative delirium and cognitive dysfunction is between 5-50%[3] and costs the health care system approximately $150 billion.[4]

Dr. Deborah Culley, associate professor of anesthesiology at Brigham and Women's Hospital, discussed practical screening tools that anesthesia professionals can administer to assess the impact of surgery and anesthesia on cognitive function. These tools include the mini-cognition questionnaire[5] (Figure 1) and frailty scoring scale[6] (Figure 2). Dr. Carol Peden, professor of clinical anesthesiology at the University of Southern California, encouraged health care professionals to resist the temptation to immediately incorporate the new prevention and intervention data into strict protocols. Rather she suggested employing core change management principles, which focus on engaging all stakeholders including patients, providers, and policy makers. Brain health of the elderly should continue to be examined as a major public health issue.

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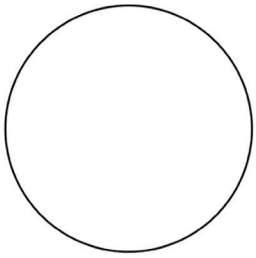
Mini-Cog© — **Instructions for Administration & Scoring** — ID:_____ Date:_____

Clock Drawing — ID:_____ Date:_____



Step 1: Three Word Registration

Look directly at person and say, "Please listen carefully. I am going to say three words that I want you to repeat back to me now and try to remember. The words are [select a list of words from the versions below]. Please say them for me now." If the person is unable to repeat the words after three attempts, move on to Step 2 (clock drawing).

The following and other word lists have been used in one or more clinical studies.[1-3] For repeated administrations, use of an alternative word list is recommended.

Version 1	Version 2	Version 3	Version 4	Version 5	Version 6
Banana	Leader	Village	River	Captain	Daughter
Sunrise	Season	Kitchen	Nation	Garden	Heaven
Chair	Table	Baby	Finger	Picture	Mountain

Step 2: Clock Drawing

Say: "Next, I want you to draw a clock for me. First, put in all of the numbers where they go." When that is completed, say: "Now, set the hands to 10 past 11."

Use preprinted circle (see next page) for this exercise. Repeat instructions as needed as this is not a memory test. Move to Step 3 if the clock is not complete within three minutes.

Step 3: Three Word Recall

Ask the person to recall the three words you stated in Step 1. Say: "What were the three words I asked you to remember?" Record the word list version number and the person's answers below.

Mini-Cog Test	Possible Points	Scoring	Interpretation
Normal Clock Drawing	2	0-2	Higher likelihood of dementia
Word Recall	1 for each word	3-5	Lower likelihood of dementia

Figure 1. The Mini-Cog test. There are three steps that include a score for accuracy of "clock drawing" and "three word recall," resulting in a cumulative score that can increase the detection of cognitive impairment.

Reprinted with permission from Soo Borson, MD. See mini-cog.com for full administration instructions.

Frailty Testing	Possible Points	Scoring	Interpretation
How much of the time during the past four weeks do you feel tired?	1	0	Robust
By yourself and not using aids, do you have any difficulty walking up 10 stairs without resting?	1	1-2	Pre-Frail
By yourself and not using aids, do you have any difficulty walking several hundred yards?	1	3-5	Frail
Do you have 5 or more out of 11 of the listed "illnesses*?"	1		
Have you experienced a 5% weight loss in the last 12 months?	1		

Figure 2. A quick test to assess frailty as a predictor of risk for delirium.

**Illnesses include hypertension, diabetes, cancer, chronic lung disease, heart attack, congestive heart failure, angina, asthma, arthritis, stroke and kidney disease*

Adapted and reprinted with permission from John Morley, MD.[5,6]

Brain Health: An Important Patient Safety Concern

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Dr. Lee Fleisher, chairman of the Department of Anesthesiology and Critical Care at the University of Pennsylvania, illustrated the strategies by which clinicians can engage with geriatric societies and federal partners to help drive clinical culture change. He advocated aligning top-down leadership to promote a strategic agenda around brain health and simultaneously having informal change leaders engaged in clinical practice propagate the strategy leading to a bottom-up cultural change as well. He emphasized working with the geriatric societies to assist in documenting endeavors that address brain health. In this way the impact of brain health efforts will be recognized amongst both clinicians and the public. Finally, Dr. Fleisher also focused on the power of persuasion and urged health care payers to financially incentivize medical professionals to focus on brain health initiatives.

So, where do clinicians go from here in the effort to protect the brain health of patients? Reflections from the audience summarized the challenges to improving perioperative patient brain health (See Audience Generated Reflections).

There is a need to prepare patients with knowledge, active engagement, and medical support to maintain their brain health as they approach major surgery.

For clinicians who treat a larger geriatric population, it was exciting to see the APSF emphasize brain health as a focus of this panel. This year's APSF panel upheld the long tradition of combining clinical science, research, and public policy to achieve anesthesiology's foremost mission: patient-centered, safe surgical care.

Dr. Kamdar is currently the director of Quality in the Department of Anesthesiology and Perioperative Medicine at UCLA Health.

Audience Generated Reflections

Patient advocacy societies must maintain an active list of the most frequent and pertinent questions from patients.

Specialty organizations, such as the APSF, need to invest in developing and evaluating screening tools for brain health, including future technologies such as machine learning-based risk assessment.

There is a need to establish intraoperative brain monitoring standards linked to improved outcomes that can be implemented directly in our operating rooms (i.e., processed electroencephalogram).

Dr. Fleisher is chairman of the Department of Anesthesiology at the University of Pennsylvania Health System.

Dr. Cole is professor of clinical anesthesiology in the Department of Anesthesiology and Perioperative Medicine at UCLA Health. He is vice-president of the APSF.

The authors have no disclosures as they pertain to this article.

REFERENCES

1. Leape LL. Error in medicine. *JAMA.* 1994;272:1851–1857.
2. Grady D. Researchers warn on anesthesia, unsure of risk to children. *The New York Times.* Published December 21, 2017. https://www.nytimes.com/2015/02/26/health/researchers-call-for-more-study-of-anesthesia-risks-to-young-children.html. Accessed November 13, 2018.
3. Postoperative delirium in older adults: best practice statement from the American Geriatrics Society - ScienceDirect. https://www.sciencedirect.com/science/article/pii/S1072751514017931?via%3Dihub. Accessed October 29, 2018.
4. Leslie DL, Marcantonio ER, Zhang Y, et al. One-year health care costs associated with delirium in the elderly population. *Arch Intern Med.* 2008;168:27–32.
5. Borson S, Scanlan JM, Chen P, Ganguli M. The Mini-Cog as a screen for dementia: validation in a population-based sample: Mini-Cog in movies. *Journal of the American Geriatrics Society.* 2003;51:1451–1454.
6. Morley JE, Malmstron TK, Miller DK. A simple frailty questionnaire (FRAIL) predicts outcomes in middle aged African Americans. *J Nutr Health Aging.* 2012;16:601–608.

Drug Shortages: An Ongoing Public Health & Safety Concern

by Tricia Meyers, MS, PharmD, FASHP, FTSHP

Drug shortages have become an ongoing serious public health and safety concern. The severity of annual drug shortages reached a critical level in 2011 and subsequently have slightly declined from 2011.[1] Unexpectedly, in 2017/2018, the shortage of intravenous fluids caused by Hurricane Maria left clinicians across the United States experiencing another serious shortage crisis. The manufacturing facilities were in Puerto Rico, and the hurricane caused a major supply disruption of parenteral solutions. In fact, The Food and Drug Administration (FDA) reported pharmaceutical products manufactured in Puerto Rico account for 10% of all drugs used by Americans.[2] Therefore, drug shortages continue to be a major issue that require urgent solutions. This article will review some of the complex issues as they relate to present-day drug shortages.

Injectable generic medications which are widely used in hospitals, particularly in the operating room, critical care, emergency care, and procedural areas constitute most drug shortages. Unfortunately, there is a limited number of pharmaceutical manufacturers who are involved in the majority of all injectable drug productions. Only one to two producers make the vast majority of injectables.[3,4] Quality problems that occur during the manufacturing process account for the majority of shortages over the last six years.[5] The Government Accounting Office (GAO) reported that 46–55% of sterile injectable anti-infective, and cardiovascular drug shortages between the years of 2012 to 2014 were from manufacturing facilities that had received a FDA warning letter because they failed to comply with manufacturing standards.[6] Examples of quality manufacturing issues are non-sterility (resulting in bacterial or fungal contamination), retained particulate matter (glass, metal, or fiber in vials), crystallization, precipitation, impurities, degradants (leading to less effective drug), and equipment failures.

The unpredictability of shipments adds to the difficulty of managing drug shortages. For example, hospitals can receive products in very limited supply one week and then may not have any additional supply for weeks until they receive another shipment.

Another problem is secondary shortages. This occurs when a drug is on shortage and hospitals purchase alternative drugs in the same pharmacologic category and the new demand for the alternate agent causes another shortage.[3]

Additionally, once a shortage occurs, it does not necessarily occur at the same time or rate across the country. This is due to the varied distribution of the available drug. For instance, one hospital may receive supplies and another hospital may not be able to obtain that same supply. Although a drug may have a supply disruption, it may be available in a variety of strengths, packages, and/or concentrations. An increased risk of medication errors can result when using different drug presentations due to clinician unfamiliarity.[3]

The Institute for Safe Medication Practices (ISMP), a global leader in medication safety, surveyed patient safety officers, pharmacy leaders, and purchasing agents from August to October 2017 on their opinions regarding drug shortages.[7] Although shortages were occurring across all treatment categories, emergency care was the area that respondents noted had the most drug shortages, and anesthesia care was noted as the second most prevalent area to experience drug shortages. The respondents overwhelmingly felt that care of patients has been compromised due to the shortages. Seventy-one percent of those surveyed were unable to provide patients with the recommended drug or treatment and approximately half of respondents commented that patients received a less effective drug.[7]

Hospitals, pharmacies, and professional organizations have developed strategies and guidelines to manage the limited supplies of medications during drug shortages. Multiple strategies are used for each drug that has a supply disruption. Resource intensive actions by pharmacy are listed in Table 1 and may be used regularly or daily, depending on the drug, to mitigate the shortages.[7]

Table 1. Resource Intensive Actions[7]

- Ration drugs
- Establish criteria for use
- Search literature to determine whether lower doses or shorter duration may have desired clinical effect
- Contact suppliers repetitively
- Review manufacturer/wholesaler ordering sites daily
- Communicate information on shortages/respond to numerous questions from clinicians
- Change par levels on automated dispensing cabinets (ADCs)
- Remove/re-add inventory to ADCs
- Purchase more expensive products
- Borrow or purchase from another health system
- Purchase different strengths/concentrations
- Compound unavailable products in-house

GOVERNMENT AND NATIONAL ORGANIZATIONS RECOGNIZE DRUG SHORTAGE CRISIS

When a drug is in shortage, it has an impact on all health care delivery systems from public and private hospitals to VA hospitals and the United States military.[5] At the 2018 American Medical Association Annual Meeting, new wording was added to policy declaring that drug shortages are now an urgent public health concern. The AMA will be asking the Department of Health and Human Services and the Department of Homeland Security to examine the problem as a national security initiative, and to consider vital pharmaceutical production sites as critical infrastructure. The AMA is responding to the ongoing national drug shortages that threaten patient care and safety.[8]

On September 20, 2018, Drug Shortages as a Matter of National Security: Improving the Resilience of the Nation's Health Care Critical Infrastructure Summit was held in Washington DC. The summit was hosted by the American Society of Health-System Pharmacists, American Hospital Association, American Society of Anesthesiologists, American Society of Clinical Oncology, and Institute for Safe Medication Practices. The groups discussed solutions to the persistent shortages of critical lifesaving medications that dangerously hinder patient care. The participants' plan was to develop actionable solutions to safeguard patients by having a secure and stable supply of medications. One of the participants at the summit, then ASA President James Grant, MD, stated that 98% of anesthesiologists across the country have experienced drug shortages.[9] The attendees developed 19 recommendations. See list at: https://www.ashp.org/-/media/assets/advocacy-issues/docs/Recommendations-Drug-Shortages-as-Matter-of-Natl-security.ashx?la=en&hash=FA494117C6255A5493F77B67EDE39DD28B790FAD

At the 2018 APSF-sponsored Stoelting Conference in Scottsdale, AZ, speaker Erin Fox, PharmD, BCPS, FASHP, senior director of Drug Information & Support Services at the University of Utah Health, stated the rate of new shortages

See "Drug Shortage," Next Page

Drug Shortages

From "Drug Shortages," Preceding Page

is increasing and long-term active/ongoing shortages are not resolving.[10] Health care organizations have developed and implemented recommendations and expended significant efforts to prevent shortages from causing medication errors. However, many of these recommendations may not address the pervasive manufacturing quality problem. Dr. Alice Romie's and Dr. John Beard's articles (pages 87 and 89, respectively) in this issue present views on solutions from the manufacturer's perspective.

Drug shortages can affect patients and providers on a daily basis. The impact on the nation's health care system continues to be significant.

REFERENCES

1. American Society for Health Systems Pharmacist. Drug shortages. Drug shortage statistics. https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics. Accessed October 30, 2018.
2. U.S. Food and Drug Administration. FDA statement. Statement from FDA commissioner Scott Gottlieb, MD, on FDA's continued assistance following the natural disaster in Puerto Rico. October 6, 2017. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm579493.htm. Accessed November 1, 2018.
3. Fox E, Burganda S, Jensen V. Drug Shortages: A complex health care crisis. *Mayo Clin Proc.* 2014: 89;361–373.
4. Woodcock J, Wosinska M. Economic and technological drivers of generic sterile injectable drug shortages. *Clin Pharmacol Ther.* 2013; 93:170–6.
5. Drug shortages roundtable: minimizing the impact on patient care. *Am J Health-Syst Pharm.* 2018;76:816–20.
6. U.S. Government Accountability Office. Drug shortages: certain factors are strongly associated with this persistent public health challenge (GAO-16-595, July 2016). www.gao.gov/assets/680/678281.pdf. Accessed November 2018.
7. Institute for Safe Medication Practices. Drug shortages continue to compromise patient care (January 11, 2018). https://www.ismp.org/resources/drug-shortages-continue-compromise-patient-care. Accessed November 9, 2018.
8. American Medical Association. Press Release. New AMA Policy reflects frustration over ongoing drug shortages. June 12, 2018; https://www.ama-assn.org/new-ama-policy-reflects-frustration-over-ongoing-drug-shortages. Accessed September 8, 2018.
9. American Society of Health-System Pharmacists. Press release. Summit on drug shortages to examine impact on national security and health care infrastructure. Sept. 20, 2018; https://www.ashp.org/news/2018/09/19/summit-on-drug-shortages-to-examine-impact-on-national-security-and-health-care-infrastructure. Accessed November 21, 2018.
10. Fox E. Drug Shortages. APSF Stoelting Conference. Sept. 2018. Phoenix, AZ. https://www.apsf.org/presentation/drug-shortages/. Accessed November 21, 2018.

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She has served on the advisory board of Neumentum.

Fresenius Kabi Response to Drug Shortages

by Alice Romie, PharmD

As a global health care company with a significant focus on sterile injectable medicines, Fresenius Kabi understands the responsibility of producing high-quality products in a reliable manner.

The sterile injectable process and production planning are very complex, so when there is a shortage in the market, there are a significant number of steps needed to continue to manufacture products and adjust production schedules to help address shortages.[1] Determining what will be filled, packaged, and shipped for the day or week can be a challenge because of line constraints. It is a daily art of prioritizing and weighing multiple factors to make the right decision, and knowing and accepting that, as one manufacturer, we can only do so much.

Unlike past shortages, which occurred in one category or drug class, the current challenge is broad, impacting more product categories,[2] including IV solutions, antibiotics, neuromuscular blocking agents, and opioids. The immediate steps we have taken—and are taking—to help in the short-term are significant, and the investments we are taking to help improve supply reliability long-term are even greater. In fact, our manufacturing plan and investments were in place prior to 2017 and have been a critical part of our long-term expansion plans in the U.S.[3]

In January 2016, Fresenius Kabi acquired a facility in Wilson, North Carolina, that produces prefilled syringes.[4] Since then, Fresenius Kabi has increased production of the Simplist® prefilled syringes significantly, providing many products routinely used in the OR including sedatives, induction agents, and opiates that have been in short supply. This increase requires substantial investment in staffing, training, accreditation, and quality processes to maintain the stringent current good manufacturing practices (cGMP) standards necessary to supply quality product.[5] In 2017, the Wilson plant operated essentially five days a week. Today, with the appropriate staffing and processes in place, the plant operates seven days a week, with significantly increased workflow efficiency and increased production. Although many patients and clinicians have benefited from the increased supply that we've produced, there is still greater demand. The shortfall created by the shutdown of a large manufacturing facility is far too great for one manufacturer to surmount. A large manufacturing facility may have many production lines, whereas other manufacturers may only have few lines and would therefore need to prioritize what is produced on each line on a daily basis.

Fresenius Kabi produces injectable drugs across the world, including three sites in the U.S., and since 2014, production at these sites has grown significantly.[6] We are continuing to implement plans to expand our capacity and improve workflow. We have not only increased production of current products, but we've continued to launch new products, like glycopyrrolate vials,[7] atropine vials,[8] and many other anesthesia products to meet the needs of providers and their patients.

In addition to our current and future internal investment, we are committed to working with national organizations and regulatory bodies to manage the drug shortages and mitigate these issues moving forward. We are also in constant communication with providers, government agencies, the American Society of Health System Pharmacists (ASHP), the Institute for Safe Medication Practices (ISMP), and the American Society of Anesthesiologists (ASA) to prioritize and address shortages wherever possible. Our dedication to our customers and their patients include helping to address the ongoing shortage challenges.

Dr. Romie is currently director of Professional Strategies at Fresenius Kabi, USA, LLC, Lake Zurich, Illinois.

REFERENCES

1. https://www.npr.org/2018/07/20/629942414/doctors-raise-alarm-about-shortages-of-pain-medications
2. https://www.mayoclinicproceedings.org/article/S0025-6196(13)01043-4/pdf
3. https://www.businesswire.com/news/home/20160817005556/en/Fresenius-Kabi-Announces-Major-Investment-U.S.-Manufacturing
4. https://www.in-pharmatechnologist.com/Article/2017/11/22/Fresenius-Kabi-investing-100m-and-adding-445-jobs-in-North-Carolina
5. https://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm
6. https://www.pharmaceutical-technology.com/projects/fresenius-kabis-pharmaceutical-manufacturing-facility-expansion-melrose-park-illinois/
7. https://www.businesswire.com/news/home/20180718005233/en/Glycopyrrolate-Injection-USP-Fresenius-Kabi
8. https://www.businesswire.com/news/home/20180719005042/en/Atropine-Sulfate-Injection-USP-Fresenius-Kabi

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Intravenous Solutions Shortages:
A Manufacturer's Perspective on the Past, Present, and Future

by JW Beard, MD, MBA

As the second largest supplier of intravenous (IV) solutions to the US market and the only IV solutions producer not to experience significant production challenges over the past year, we at ICU Medical, Inc., believe we can make a valuable contribution to the discussion of drug shortages.

We recognize that the stakes for our patients and country are high and are fortunate to have participated in the American Society of Health-System Pharmacists (ASHP)/American Society of Anesthesiologists (ASA) Summit on Drug Shortages, September 20, 2018, in Washington, DC.[1] As reflected by the attendees at the summit, a concerted effort with collaboration across multiple stakeholder groups is required to resolve these complex issues. The stakeholders are diverse and include patients, clinicians, professional societies, manufacturers, hospital systems, group purchasing organizations, and regulatory bodies—just to name a few. In this article, we will review the present understanding of the history of IV solutions as a pharmaceutical category, discuss the IV solutions marketplace today, and the steps we believe are required to move to a state of reliable, high-quality supply.

A wide array of drug shortages have affected health care delivery in the US, with many sharing common features. Drivers of shortages have included product discontinuations, manufacturing quality issues, and natural disasters.[2,3] Recent shortages have been most acutely experienced in generic, sterile injectable products where margins are slim and production is consolidated to a small number of manufacturers.[2,3]

The recent shortages of small volume parenteral (SVP) IV fluids were driven by the manufacturing disruption from Hurricane Maria superimposed on reduced supply due to manufacturer quality issues.[3] The reduced supply of SVP products, including normal saline, led to widespread disruption in the delivery of health care in the US and globally as these products are used for hydration and preparation of numerous additional widely used medications.

Without adequate substitute products, clinicians faced difficult choices, including rationing IV fluids and utilizing workarounds. With a focus on SVPs, an understanding of the history of these products is essential to interpret recent events and the challenges going forward.

Today's IV solutions manufacturing industry is the result of decades of decisions and "looking the other way" by manufacturers and purchasers. In the case of IV fluids, purchasers range from the individual medical clinic to large health systems and Group Purchasing Organizations (GPOs). Historically, IV fluids were treated as "medical-surgical" items rather than capital-intensive pharmaceutical products. Instead of searching for market equilibrium ensuring the stability of business, manufacturers have operated without price transparency or logic as IV solutions were co-mingled with other supplies such as infusion pumps and IV tubing and provided at a discount. In parallel, purchasers of these products demanded and utilized concessions when comparing product offerings and making buying decisions.

While the contract bundles promised savings for the purchaser, IV fluids were bought and sold at artificially low prices and slim margins. These forces have led to a liter of saline costing less than a liter of many brands of bottled water. Intense cost pressure has impacted the geographic location of manufacturing plants, where tax incentives, labor market conditions, and transportation expense have contributed to favorable economics, such as in Puerto Rico.

Over time, the production has become concentrated and constrained, with nearly all IV solutions in the US market being manufactured by three companies: ICU Medical, Baxter and B. Braun—with Baxter concentrating its SVP manufacturing in Puerto Rico.[3] Growth of supply has been limited as the financial conditions of the market discourage new entrants and reduce the incentive to expand manufacturing beyond obligated volumes.

Regulatory and quality requirements contribute additional cost and complexity to the industry. IV fluids are regulated as pharmaceutical products and carry all of the capital investment requirements of sterile injectable medications despite being sold at relatively low prices. Over the last twenty years, the cost of the pharmaceutical ingredients and the plastics to produce a unit of saline has slowly increased while the cost of appropriate regulatory and quality maintenance has increased several-fold. For example, changes in raw material suppliers and improvements to manufacturing equipment can require significant qualification studies and data collection in advance of regulatory submission to ensure the changes do not impact the safety, efficacy, purity, or quality of these pharmaceutical products. Additionally, changes impacting globally registered products may involve generation of multiple data sets and regulatory filings due to lack of regulatory harmonization.

The steady rise in regulatory requirements, plus the high stakes of maintaining compliance in a changing environment add an additional barrier to growing the supply.

ACTIONS TO IMPROVE THE SUPPLY OF IV SOLUTIONS

Despite these challenges, the reliable, high-quality supply of IV solutions is realistic and coping with shortages can be improved.[4] Manufacturers can offer more price transparency to illustrate the stand-alone value of the category and sign reciprocal agreements to back up the supply chain. Customers can use their market power to source IV solutions from two or more suppliers, offer long-term commitments for predictable contracts and value the category as a pharmaceutical product.

Manufacturers can develop contingency plans including developing excess capacity and redundant manufacturing locations. Additional product stock can be distributed and held throughout the health care supply chain to sustain clinical operations during shortages.

MITIGATING THE IMPACT OF SHORTAGES

Techniques for conserving fluids, such as conversion from IV to oral therapy and vigilant discontinuation of nonessential infusions, should be implemented into clinical practice. Evidence-based medication handling should be followed including considerations for improved utilization of single-use vials, extending product use dates, and empowering pharmacists to bring techniques forward to maximize supply management.

LONG-TERM MARKET AND SUPPLY STABILITY

Developing the manufacturing capacity to reliably meet the needs of our health care system is possible; however, it is virtually impossible for manufacturers to turn this capacity on and off quickly due to significant labor, capital, and regulatory requirements. We are looking to bring pragmatism and transparency to the economics of the industry that will help ensure that this capacity is utilized more consistently and intelligently by the market overall, helping to minimize the impact of future production shortfalls in the market.

Long-term continuity of supply will come from demand stability and valuing these products as a capital-intensive pharmaceutical category. Until that day arrives, contingency planning for management of shortages will continue including transparency, communication, and collaboration across diverse stakeholder groups to serve the needs of our patients and clinicians.

Dr. Beard is currently the medical director of ICU Medical, Inc.

REFERENCES

1. ASHP, 9/19/18 Press Release. Summit on drug shortages to examine impact on national security and health care infrastructure. https://www.ashp.org/news/2018/09/19/summit-on-drug-shortages-to-examine-impact-on-national-security-and-health-care-infrastructure. Accessed December 17, 2018.
2. Drug shortages roundtable: minimizing the impact on patient care. *Am J Health Syst Pharm.* 2018;75:816–820.
3. Mazer-Amirshahi M, Fox ER. Saline shortages—many causes, no simple solution. *N Engl J Med.* 2018;378:1472–1474.
4. Fox ER, McLaughlin MM. ASHP guidelines on managing drug product shortages. *Am J Health Syst Pharm.* 2018;75:1742–1750.

Q&A

Disposable Laryngoscopes: Should We Use Them?

Q Dear Q&A,

I wanted to propose a couple of questions/concerns with regards to disposable laryngoscope blades:

1. Have you had any complaints from others about disposable blades?
2. Our experience is that they tend to be flimsy and feel like they are susceptible to breakage with too much pressure.
3. The use of these laryngoscopes has resulted in several missed intubations and we are uncertain as to whether this is related to a new user learning curve or poor quality. There have also been some associated complications including; broken teeth, pinched lips and tongue and tonsillar rupture.
4. The idea of a single use item to protect patients is important, but at what cost? I wonder why we would fill the landfills with more plastic that won't break down. Single use requires that each blade be taken apart to remove the batteries each time and be disposed of separately, so now we have more bins to work around not only for storage of all the sizes, but for disposing.
5. Why stop using what has worked for many years?
6. Does it cost the institution more money to process the blades than to buy the disposable ones? I have heard that the traditional blades/handles are very difficult to process and sterilize.
7. Can we not find an alternative mechanism by which to clean the blades?

In conclusion, are disposable laryngoscopes really safer than resuable ones for our patients?

From: Anonymous author

A Editorial Response:

Thank you for sending your concerns about the disposable laryngoscope blades currently in use at your institution. APSF has not received similar reports to date but clearly the adequacy of devices for safe airway management is a central concern to anesthesia practice. You raise two questions that are relevant to clinical practice and patient safety:

1) What is the value of using disposable laryngoscope blades in general practice?
2) Are there deficiencies with the design of the blade you are currently using?

With regard to the latter question, if there have been no patient injuries or deaths, the FDA Medwatch Database can be used to report[1] clinical care concerns for medical devices. Anyone can enter information about a medical device to that database. If there has been a death or serious injury, the facility and manufacturer are required to enter a report to the FDA Maude Database.[2] The ECRI Institute also maintains a database of device problems and readily accepts user reports into their database.[3] ECRI has not had reports to date of patient injury related to single-use laryngoscopes.

The general question about the value of disposable laryngoscopes in clinical practice is challenging practices around the country. The reprocessing requirements for reusable laryngoscopes have added significant cost and complexity to managing these devices such that disposable laryngoscopes are economically attractive, notwithstanding the environmental and clinical care considerations. Reprocessing requirements are based upon concerns for patient safety related to the infection risk of reusable laryngoscopes. Whether or not the infectious risks outweigh the risks of suboptimal airway management, or the environmental impact, remains to be proven, although clearly an airway complication that resulted from an inferior disposable laryngoscope would seem to outweigh the potential infection risks. There is some literature comparing the environmental impact of reusable and disposable laryngoscopes, which can be found at the ASA website under *Greening the OR*.[4] The authors of that document favor reusable devices.

One large study from France randomized patients for emergency intubation to either reusable or disposable laryngoscopes.[5] The study found the clinical performance to be better with the disposable version. They did not evaluate the infectious concern. This finding does underscore the fact that there are disposable laryngoscopes available that should perform the same as our reusable devices, if not better.

One suggestion is to contact the manufacturer about any quality concerns that might be addressed. Another option is to look at some of the other disposable laryngoscopes available and to promote a trial of some alternative devices. There are several alternative devices available, and you may find one or more to be suitable for your practice.

These resources may be helpful. In addition, in this issue of the *APSF Newsletter*, Dr. Jodi Sherman, an expert in this particular field, provides her perspective on this important patient safety matter (see next page). Thank you again for taking the time to report your concerns.

Dr. Jeffrey M. Feldman, MD, MSE, is chair of the APSF Committee on Technology and professor of clinical anesthesiology at Children's Hospital of Philadelphia, Perelman School of Medicine, Philadelphia, PA.

Dr. Feldman serves as a member of the Clinical Advisory Board, ClearLine MD, Boston, MA. Dr. Feldman has received consulting compensation from Dräger Medical, GE Medical, and Medtronic.

REFERENCES

1. FDA Medwatch Database. https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home. Accessed December 10, 2018.
2. FDA Maude Database. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. Accessed December 10, 2018.
3. ECRI Institute Database of Device Problems. https://www.ecri.org/pages/ReportADeviceProblem.aspx. Accessed December 10, 2018.
4. Axelrod D, Bell C, Feldman J, et al. Greening the Operating Room. Report of the Task Force on Environmental Sustainability Committee on Equipment and Facilities. https://www.asahq.org/resources/resources-from-asa-committees/environmental-sustainability/greening-the-operating-room. Accessed December 10, 2018.
5. Amour J, Le Manach YL, Borel M, et al. Comparison of single-use and reusable metal laryngoscope blades for orotracheal intubation during rapid sequence induction of anesthesia. *Anesthesiology.* 2010;112:325–332.

Reusable vs. Disposable Laryngoscopes

by Jodi Sherman, MD

To understand reusable and disposable laryngoscope safety, it is helpful to review both Center for Disease Control and Prevention (CDC) infection risk classification[1] as well as device procurement criteria: safety, efficacy, ease of use, cost, and regulatory compliance.[2]

Tongue blades come in contact with mucous membranes and are considered intermediate risk or semi-critical. They therefore require a minimum of high-level disinfection, typically performed in the Central Sterilization and Supply Department (CSSD).[1] Handles come in contact with skin, and historically have been considered low risk or noncritical. They therefore require a minimum of low-level disinfection, typically performed using a chemical cloth wipe in the operating room.[2]

The CDC language on laryngoscope handle classification is vague, and thus the CDC defers to device manufacturer "Instructions for Use" (IFU) to determine risk level.[1] IFUs are intended to describe manufacturer-approved alternative methods for cleaning equipment that meet CDC compliance, and it is up to the institution to choose which method to use.[3] Oversight bodies, such as The Joint Commission, are tasked with enforcing CDC regulations and recently started holding facilities accountable for laryngoscope IFUs. CDC deference to industry for risk determination has invited potential "up-classification" of device risk and therefore disinfection requirements. Thus, while manufacturers are not infection experts, many are now starting to include intermediate risk designations on laryngoscope IFUs, even though historically handles have been safely treated as low risk. This means that facilities now have two choices to remain in regulatory compliance: send the handles to CSSD for a minimum of high-level disinfection, or switch to single-use disposables (SUDs). Many facilities may be electing to do the latter, owing mostly to convenience.[2] The letter on page 90 of this issue of the *APSF Newsletter* raises many typical concerns regarding taking the expedient route.

There are multiple small studies demonstrating inferior SUD blade performance in the peer-reviewed literature owing to the higher deformability of the blade/joint, especially those comprised of plastic materials. Increased deformability makes vocal cord visualization more difficult.[4] Institutions electing to use SUDs may for this reason opt for "disposable" steel; however, this is an even more concerning material from an environmental perspective.[4] The International Standards Organization (ISO) determines performance criteria necessary to achieve FDA approval of equipment. Of note, the ISO 7376 standards permit tongue blade tip excursion of up to 1 cm. While traditional reusable steel devices have much less tip excursion, SUDs can take advantage of the permissible "wiggle room" to save on materials. SUDs can be made to approximate reusable

laryngoscopes, but it requires higher quality materials and cost increases.

Disposable laryngoscopes are often perceived to be cheaper than reusable alternatives, due to CSSD reprocessing labor and material costs. However, when considered across an entire institution, the cost of SUDs can exceed the lifecycle costs of an equivalent number of reusable laryngoscopes. Assuming average CSSD laborer salary of $50,000 per annum, standard cleaning times, and including periodic refurbishment, Sherman and colleagues estimated that reusable handles would be more economical than SUDs if they last through at least 4–5 uses, and reusable blades, 5–7 uses. Typical steel reusable devices are rated for thousands of uses, and thus the advantage over disposables can be considerable. In terms of infrastructure complexity, treating reusable laryngoscope handles and blades is likely a very small fraction (e.g., 2%) of CSSD facility duties.[4]

Environmental health is a new safety consideration. It's not just about what goes to the landfill, but also natural resource extraction, manufacturing, packaging, transportation, use/reuse, and eventual waste management—the entire life cycle. Sherman and colleagues performed a life cycle assessment and found that SUD rigid laryngoscope handles and blades result in 16–25 and 6–8 times more greenhouse gas (GHG) emissions using standard U.S. energy mix, respectively, when compared to alternative reusable cleaning scenarios. Of the reusable reprocessing options, surprisingly, low-level disinfection of the handle resulted in slightly higher GHG emissions than high-level disinfection, despite lower cost.[4]

There is a disturbing trend towards single-use disposable materials throughout the world. Pollution is a leading cause of non-communicable disease, responsible for an annual 9 million deaths, or 16% of annual deaths globally.[5] Climate change has been called the number one public health issue of the 21st century.[6] Plastics are so pervasive in our environment that they are now prevalent in our tap water, table salt,[7] and stools.[8] Patient safety considered in its broadest context includes public health. You are correct to question the safety of disposable laryngoscopes. Not only do SUDs have a significantly negative environmental impact compared with reusable laryngoscopes, analysis of the entire life cycle indicates that SUDs do not achieve the intended impact of reducing cost.

Dr. Sherman is presently associate professor of anesthesiology, Yale School of Medicine and associate professor of epidemiology in environmental health sciences, Yale School of Public Health. She is also co-chair of the ASA Subcommittee on Environmental Health.

Dr. Sherman has no conflicts of interest.

REFERENCES

1. Rutala WA, Weber D. The Healthcare Infection Control Practices Advisory Committee (HIPAC): Guideline for disinfection and sterilization in healthcare facilities. Centers for Disease Control, 2008.
2. Sherman JD, Hopf HW. Balancing infection control and environmental protection as a matter of patient safety: the case of laryngoscope handles. *Anesth Analg.* 2018;127:576–579.
3. Global Harmonization Task Force. Label and instructions for use for medical devices, 2011.
4. Sherman JD, Raibley LA IV, Eckelman MJ. Life cycle assessment and costing methods for device procurement: comparing reusable and single-use disposable laryngoscopes. *Anesth Analg.* 2018;127:434–443.
5. Landrigan PJ, Fuller R, Acosta NJR, et al. The Lancet Commission on pollution and health. *Lancet.* 2018;391:462–512.
6. Costello A, Abbas M, Allen A, et al. Managing the health effects of climate change. *Lancet.* 2009;373:40.
7. Kim JS, Lee HJ, Kim SK, et al. Global pattern of microplastics (mps) in commercial food-grade salts: sea salt as an indicator of seawater MP pollution. *Environ Sci Technol.* 2018;Oct 16. doi: 10.1021/acs.est.8b04180. [Epub ahead of print].
8. Schwabi PL, Koppel S, Konigshofer TP, et al. Assessment of microplastics concentrations in human stool—preliminary results of a prospective study. *United European Gastroenterol J.* 2018;6:A127.

Drug Diversion in the Anesthesia Profession:
How Can the Anesthesia Patient Safety Foundation Help Everyone Be Safe?
Report of a Meeting Sponsored by the Anesthesia Patient Safety Foundation

by Maria van Pelt, PhD, CRNA; Tricia Meyer, MS, PharmD; Rigo Garcia, MSN, MBA, CRNA; Brian J. Thomas, JD; Ronald S. Litman, DO, ML

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Diversion in the workplace can adversely impact the safety of health care professionals and patients. The Anesthesia Patient Safety Foundation (APSF) believes that substance use disorder, diversion in the workplace, and their potential adverse effects on patient safety need to be addressed through open discussion, education, research, policy, and possible other interventions. To make progress in this area, the APSF convened a conference entitled "Drug Diversion in the Anesthesia Profession: How Can APSF Help Everyone Be Safe?" in Phoenix, AZ, on September 7, 2017 (Supplemental Digital Content, Document, http://links.lww.com/AA/C616). It was comoderated by the authors. APSF President Mark A. Warner, MD, welcomed >50 participants who represented large anesthesia group practices and practice management companies. The attendees participated in a half-day conference to discuss relevant anesthesia patient safety issues related to the opioid epidemic and, specifically, drug diversion in the health care workplace.

The workshop was introduced by a multidisciplinary panel of experts who provided information on patient and health care worker (HCW) safety implications associated with drug diversion. The goal of the workshop was to develop (broad) recommendations to reduce the associated risks to providers and patients from drug diversion. The conference started with a series of informational presentations by diverse stakeholders with associated audience response polls followed by panel discussions and small group breakout sessions.

DISCUSSION

Despite an extensive awareness of the prevalence of substance use disorder in health care professionals and data demonstrating that substance misuse is an occupational hazard for HCWs and those in training, little progress has been made improving the prevalence, education, and outcomes. Substance use disorder is a problem that continues to impact society. It is estimated that 10%–15% of HCWs, including anesthesia professionals, will misuse drugs or alcohol at some time during their career.[1] It has been suggested that substance use disorder is the most frequent disabling illness in HCWs. There clearly is a need for multidisciplinary coordination of efforts to reduce drug diversion within the health care workplace as highlighted in the presentations at the workshop.

DRUG DIVERSION

"Drug Diversion from the Health Care Workplace: A Multi-Victim Crime," Keith H. Berge, MD (Mayo Clinic, Rochester, MN), noted that not only do addicted HCWs divert drugs from their employers to support their addiction, but they also divert drugs from their patients. This poses a major patient safety risk and exposes patients to blood-borne pathogens as evidenced by the outbreaks of infections associated with diversion.[2] Dr. Berge supported the notion that it is a multivictim crime that places patients, addicted HCWs, their coworkers, their employers, and society at risk and emphasized that vigilance is mandatory. Moreover, he advocated for policies and procedures within health care institutions for dealing with investigations and managing possible outcomes of confirmed diversions.[3]

SECURING NARCOTICS

"Securing Narcotics: Standard of Care Evolves in Wake of Hepatitis C Outbreaks," Brian Thomas, JD (Preferred Physicians Medical, Overland Park, KS), provided a medicolegal perspective on drug diversion and tampering by highlighting three high-profile cases in which hospital employees infected patients with blood-borne pathogens. The hospital employees stole the anesthesia providers' narcotics that were left unsecured, injected themselves, refilled the syringes with saline, and returned them to be administered to patients. These incidents resulted in dozens of patients being infected with life-threatening Hepatitis C, multiple lawsuits, medical and nursing board investigations, and widespread negative publicity for the involved health care providers and facilities.[4] He discussed that in medical negligence litigation, the standard of care is defined by expert opinion and testimony. In light of recent highly publicized cases, the consensus among anesthesiology experts is all schedule 3 and 4 narcotic medications should be kept in locked, enclosed areas when not under the direct control of anesthesia professionals. He also offered risk management strategies that included carefully reviewing and adhering to all hospital/facility drug storage and security policies, never leaving controlled substances or medications likely to be diverted unsecured and unsupervised, carefully considering whether to keep controlled substances or medications likely to be diverted on your person once dispensed, reporting any suspicious behavior or activity if you suspect drug diversion, and implementing workplace drug testing policies.

WHY AND HOW DRUG DIVERSION OCCURS

"The Silent Epidemic: Drug Diversion in the Health Care Setting," Tricia Meyer, PharmD (Scott & White Temple Medical Center, Temple, TX), pointed out how common theft/diversion of controlled substances is in the health care workplace and that it may be attributed to the high-risk settings and easy access to drugs in these areas.[1,5] There are several other potential reasons, including self-medicating for personal health problems, cultural acceptance of pharmacological agents to cure ills, pain reduction, overwork, sleep deprivation, availability and access, advanced parenteral administration skills, believed immunity to drug abuse, and exposure to death and dying.[6,7]

The Joint Commission sets expectations of medication security in their Medication Management Standards to ensure that hospitals secure medications in protected areas and keep them locked when necessary, in accordance with law and regulation, to prevent diversion.[8] Each organization is then responsible for developing a controlled substance diversion prevention program that complies with federal and state laws and regulations. In addition, a hospital should use technology and ongoing surveillance to consistently review procedure compliance and effectiveness, strengthen controls, and seek to proactively stop diversion.[7]

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However, many health care systems have inconsistencies in their oversight of controlled substances, poor accountability, inconsistent compliance with regulatory requirements, processes favoring convenience over control, inconsistent and delayed consequences, lax processes, and a culture of reluctance to speak up that can enable diversion. In her presentation, Dr. Meyer noted that the goal is to reduce the number of employee diversions, the lag time between employees beginning diversion and discovery, and reduction of the number of vials/tablets/syringes diverted by addicted employees. There are opportunities for diversion at almost every step of any medication use process.

Diversion can occur at procurement, preparation/dispensing, prescribing, administration, and waste/removal of controlled substances. Each of these represents a theft risk point, and safeguards must be in place at each step.

THE IMPAIRED PROVIDER

"Catch Me, (If You Can)," Rigo Garcia, CRNA (Parkdale Center for Professionals, Chesterton, IN), shared his personal journey with substance use disorder and experience as the co-founder and executive program director of a center that specializes in diagnosis, treatment, monitoring, and advocating for the addicted professional and their families. In his presentation, Mr. Garcia described the inconsistencies and noncompliance in organizational regulatory requirements that enable addicted HCWs access to misuse controlled substances. He advocated that because HCWs remain at higher risk of substance use disorder due to easy access to medications, expert knowledge in how to use them, and increasingly stressful jobs, proper treatment followed by an accountability monitoring program are essential for sustained sobriety. Mr. Garcia stressed that a punitive-only approach to managing the impaired provider has been proven to be ineffective over the past 50 years and is detrimental to those who desire to seek help voluntarily.

THE OPIOID SOMMELIER

"Are Opioids Necessary for Surgical Patients?" Ronald S. Litman, DO, ML (The Children's Hospital of Philadelphia, Philadelphia, PA, and the Institute for Safe Medication Practices, Horsham, PA), shared his perspective that any attempt to prevent diversion of opioids in the perioperative environment may ultimately be unsuccessful if it relies on education, surveillance, or vigilance because these all are historically unreliable in producing changes in behavior. Dr. Litman made the provocative recommendation that the only reliable way to prevent diversion by anesthesia professionals is to remove their ability to access and administer opioids. Although opioids are traditionally used as part of a balanced anesthetic technique, their intraoperative use has not been definitively associated with improved outcomes. In fact, the blinded substitution of β-blockers for opioids has resulted in less postoperative opioid use.[9,10]

Therefore, Dr. Litman introduced the concept of the "opioid sommelier," a health care professional who is designated to administer opioids in the perioperative environment. This method would be designed to eliminate opioid diversion by anesthesia and other operating room personnel. It would potentially decrease first-time opioid use by HCWs if the drugs are not available to individual personnel. Several obstacles would need to be overcome due to the current standard of care that requires each anesthesia professional to administer their own opioids. These include identifying specific opioid sommeliers, defining their credentials and responsibilities, determining how these people would prioritize opioid administration, and attaining buy-in from all perioperative personnel.

Table 1. Attitudes About Substance Use Disorder and Drug Diversion

Statement to Which Audience Members[a] Responded	Agreement (n = 51), %
Addiction is a choice and not so much an actual disease.	7%
Drug diverters display patterns and behaviors that make them relatively easy to identify.	6%
Drug diversion from the health care workplace is a rare event.	18%
The impaired anesthesia professional who is found to be diverting medication should be confronted by human resources, facility security, and their direct supervisor. They should be escorted to their locker to clean it out immediately and immediately sent home pending further investigation.	37%
Operating rooms are "secure areas."	9%
Anesthesia professionals should keep prepared syringes on their person.	50%
The theft of 1 oxycodone is a crime that MUST be reported to the Drug Enforcement Agency (United States) within the business day.	84%
Anesthesia practice groups should develop and implement drug testing policies.	92%
Most health care workers who divert drugs are caught by self-reporting.	0%
Surgical procedures can be done without opioids.	77%

[a]The attendees represented clinical operations of health care facility, administrative operations of health care facility, and research operations of health care facility, corporate, or other business environment. More detailed demographics of the participants were not available. The 51 attendees consisted of 66% anesthesiologists, 15% nurse anesthetists, 4% nurses, 4% nonclinical health care professionals, and 11% corporate/industry professionals.

RECOMMENDATIONS

Audience polling throughout the meeting revealed attitudes and priorities about substance use disorder in anesthesia providers and drug diversion in the perioperative environment (Table 1). The most agreed upon action item (92% agreement) was for anesthesia practice groups to develop and implement drug testing policies. However, as previously discussed in articles published in *Anesthesia & Analgesia*, the practicalities of implementing such a system are not always straightforward.[11,12] As a result of the presentations, and further discussions during small breakout sessions, our diverse group of stakeholders put forward a broad portfolio of recommendations (Table 2).

In summary, substance use disorder is an addiction and, as with any addiction, it is a disease. Its diagnosis, management, and treatment will vary depending on the severity of the disease. Effective means of treatment must focus on recognition that substance use disorder is not curable and requires lifelong surveillance. Equal emphasis must be placed on prevention. Substance use disorder and diversion of medications in the workplace can adversely impact the safety of health care professionals and patients. Health care organizations have an opportunity to implement positive change by implementing a culture of safety and accountability.

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cation and Training Committee and is an Executive Committee and Board of Directors member.

Dr. Meyer is currently regional tirector of Pharmacy at Baylor Scott & White Medical Center-Temple and associate professor of Anesthesiology at Texas A&M College of Medicine. She has served on the advisory board of Neumentum, and she is on the APSF editorial board.

Mr. Garcia is chief executive officer of Parkdale Center, Addiction Treatment for Professionals.

Mr. Thomas is vice president of Risk Management at Preferred Physicians Medical (PPM), a professional liability company for anesthesiologists, in Overland Park, KS. Mr. Thomas is a member of the APSF editorial board.

Dr. Litman, DO, ML, is medical director of the Institute for Safe Medication Practices and professor of anesthesiology and pediatrics at the Perelman School of Medicine at the University of Pennsylvania and an attending anesthesiologist at the Children's Hospital of Philadelphia.

Drs. Van Pelt, Meyer, and Litman have no disclosures as they pertain to this article. Mr. Garcia is on the speakers bureau for Alkermes. Mr. Thomas has no dislosures as they pertain to this article.

REFERENCES

1. Wright EL, McGuiness T, Moneyham LD, et al. Opioid abuse among nurse anesthetists and anesthesiologists. *AANA J.* 2012;80:120–128.
2. Schaefer MK, Perez JF. Outbreaks of infections associated with drug diversion by US health care personnel. *Mayo Clin Proc.* 2014;89:878–887.
3. Berge KH, Dillon KR, Sikkink KM, et al. Diversion of drugs within health care facilities, a multiple-victim crime: patterns of diversion, scope, consequences, detection, and prevention. *Mayo Clin Proc.* 2012;87:674–682.
4. Thomas BJ. Securing narcotics: standard of care evolves in wake of hepatitis C outbreaks. *Anesth Law.* 2013:1–5.
5. Baldisserri MR. Impaired healthcare professional. *Crit Care Med.* 2007;35(suppl):S106–S116.

Table 2. Recommendations and Associated Potential Interventions for Health Care Facilities or Health Systems

Recommendations	Potential Interventions
Develop a prevention focus related to substance use disorder and diversion within health care organizations.	Develop a Clinician Wellness Committee within the procedural practice.
Provide a comprehensive educational program related to substance use disorder to reduce the stigma associated with it and to promote a culture of safety.	Develop educational modules and build a culture of safety that addresses the factors that increase the risk for substance use disorder.
Develop clear policies related to drug diversion and substance misuse.	Convene a multidisciplinary group to review best practices and develop policies for the prevention and detection of drug diversion and substance misuse in procedural practices; this should include a drug diversion team that investigates missing drug events.
Health care organizations should identify and provide appropriate recommendations related to "process of reporting" and treatment options for all anesthesia professionals.	Develop an information tool kit and designate a resource person within each anesthesia group and health care organization.
Develop a comprehensive approach to managing the key areas of focus related to substance use disorder.	Annual competencies modules related to wellness, substance use disorder, diversion, and treatment options should be available and widely communicated within health care organizations.
Develop a comprehensive requirement for new employee reference checks (including clarity on any gaps in employment).	Standardize a comprehensive reference checking process.
Develop consistency across all health care institutions as it relates to oversight of controlled substances.	Create and uphold a well-defined policy for institutional oversight of controlled substances.
Prioritize compliance and accountability.	Standardize drug testing policies.
Intensify research and learn from all health care disciplines.	Multidisciplinary collaborations to facilitate research, education, and policy development.

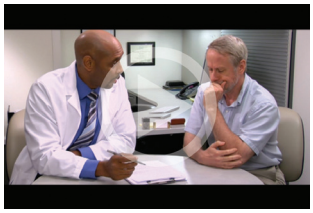
6. Desmond J. University of Michigan Injury Center-Opioid Overdose Summit. December 8, 2015; https://www.slideshare.net/UMInjuryCenter/health-system-response-to-opioid-overdose-diversion-by-jeffrey-s-desmond-md. Accessed August 30, 2017.
7. Brummond PW, Chen DF, Churchill WW, et al. ASHP guidelines on preventing diversion of controlled substances. *Am J Health Syst Pharm.* 2017;74:325–348.
8. Joint Commission. Medication Management Standard MM-1. Comprehensive Accreditation Manual for Hospitals. Oakbrook Terrace, IL: Joint Commission Resources; 2016.
9. Chia YY, Chan MH, Ko NH, Liu K. Role of beta-blockade in anaesthesia and postoperative pain management after hysterectomy. *Br J Anaesth.* 2004;93:799–805.
10. Collard V, Mistraletti G, Taqi A, et al. Intraoperative esmolol infusion in the absence of opioids spares postoperative fentanyl in patients undergoing ambulatory laparoscopic cholecystectomy. *Anesth Analg.* 2007;105:1255–1262.
11. Rice MJ, Grek SB, Swift MD, Nance JJ, Shaw AD. The need for mandatory random drug testing in anesthesia providers. *Anesth Analg.* 2017;124:1712–1716.
12. Berge KH, McGlinch BP. The law of unintended consequences can never be repealed: the hazards of random urine drug screening of anesthesia providers. *Anesth Analg.* 2017;124:1397–1399.

APSF Website Offers Online Educational Videos

Visit the APSF website (www.apsf.org) to view the following Videos

Opioid-Induced Ventilatory Impairment (OIVI): Time for a Change in the Monitoring Strategy for Postoperative PCA Patients (7 minutes)

Perioperative Visual Loss (POVL): Risk Factors and Evolving Management Strategies (10 minutes)



APSF Presents Simulated Informed Consent Scenarios for Patients at Risk for Perioperative Visual Loss from Ischemic Optic Neuropathy (18 minutes)

APSF Presents Prevention and Management of Operating Room Fires (18 minutes)

APSF Grant Alumni Academy: "Serve as a Mentor and Be Mentored"

by Richard D. Urman MD, MBA, FASA, and Jeffrey B. Cooper, PhD

The APSF Board of Trustees recently approved the establishment of the APSF Grant Alumni Academy (AGAA). The vision of the AAGA is an organized, active community of prior and current research and career development grant recipients who are strongly engaged with APSF. AGAA members will promote the mission of APSF related to safety research, education, mentorship, safety programs, and campaigns, and facilitate an exchange of information and ideas about those topics. Short- and long-term goals are outlined in Table 1. The goal of the workshop held during the ASA Annual meeting in San Francisco in October 2018 was to introduce AGAA to the alumni and begin to deepen their engagement with APSF.

During the workshop, Dr. Mark Warner delivered an introductory statement outlining the importance of engaging a wider patient safety community and how it fits into the strategic mission of APSF, as well as his expectations from AGAA. Dr. Richard Urman then spoke about the rationale for forming the AAGA and described its vision and short- and long-term goals. Dr. Jeffrey Cooper described how the APSF research program began over 30 years ago and that it has provided support for well over 115 principal investigators and many more co-investigators. It has led to substantial learning about a spectrum of topics, including many that have found their way into practice either directly or indirectly such as identification of predictors of patients at increased risk for adverse outcomes, prevention or early diagnosis of adverse outcomes, methods for study of low-frequency events, education and training in safety (especially simulation-based training), and measurements of cost effectiveness of technologies designed to increase patient safety.[1]

Most importantly, the APSF research program has seeded anesthesia patient safety with many leaders both in research and clinical application. The program continues to be strong and vibrant but there is much more room to grow. Dr. Cooper emphasized the need to mentor up-and-coming perioperative patient safety scientists, and that AGAA was formed to both recognize and honor those who have been awarded grants over the years and to elicit support to continue the success. Dr. Karen Domino gave an overview of how APSF grant support helped advance her academic career as well as the value of good mentorship, while Dr. Steven Howard discussed the current state of the APSF grant program and highlighted its successes.

We are compiling a comprehensive list of all prior grant and career development recipients to facilitate communication among members, including the use of social media. We hope to provide resources for both mentees and mentors, as much of the discussion revolved around capacity-building to enable mentorship of those interested in patient safety. We strategized about specifically how to engage those who want to be mentored (e.g., trainees and junior clinicians and scientists) and those who want to serve as mentors. We will be reaching out to potential mentors who might be willing to serve in a variety of roles ranging from being an informal career advisor to a research collaborator. All agreed that good mentorship is about helping the mentee learn and refine new skills, two-way communication and availability, open-mindedness, setting expectations, building collaborator networks, and providing honest and timely feedback. We also discussed how to best achieve short- and long-term outcomes and successes of funded research and impact on patient safety, how to best act as a resource for the APSF leadership to assist with their strategic initiatives (e.g., education, research, affiliations), and finally, how alumni can facilitate fundraising and organizational development activities.

You can expect to hear more from us in the coming months as we further develop our priorities and activities. We also encourage you to contact us with any suggestions or interest in being involved.

Table 1. AGAA Short and Long-term Goals

1. Create an organized community/network of "alumni" volunteers previously or currently supported by APSF.
2. Highlight short- and long-term outcomes/successes of funded research and impact on patient safety.
3. Facilitate fundraising activities with the help and support of alumni volunteers.
4. Engage, through mentorship, anesthesia trainees and junior practitioners interested in clinical innovation and research aspects of patient safety.
5. Act as a resource for the APSF leadership to assist with strategic initiatives (Education, Research, Special Projects, Fundraising).

Dr. Urman is associate professor of Anaesthesia at Harvard Medical School in the Department of Anesthesiology at Brigham and Women's Hospital, Boston, MA.

Dr. Urman has received APSF research funding in the past.

Jeffrey Cooper is past executive vice president of the APSF, and he has been an active member of the APSF Executive Committee from 1985 to October 1, 2018. He is also professor of anaesthesia at Harvard Medical School in the Department of Anesthesia, Critical Care & Pain Medicine, Massachusetts General Hospital, Boston, MA.

The authors have no conflicts of interest to disclose.

REFERENCE

1. Urman RD, Posner KL, Howard SK, Warner MA. 2017 marks 30 years of APSF research grants. *APSF Newsletter.* 2018;32:61–63. https://www.apsf.org/article/2017-marks-30-years-of-apsf-research-grants/. Accessed December 10, 2018.

Simulation Is a Critical Tool for Advancing Patient Safety—Available to Everyone Regardless of Location or Resources

by David M. Gaba, MD

Patient safety comes from using all available mechanisms to avoid harming patients while trying to cure or help them within the health care system. Simulation—defined as a **"technique and not a technology"** [1] for creating and using interactive and immersive experiences that recreate or stimulate recall of real-world experiences—is a critical tool used to enhance patient safety.[1,2] Simulation is useful in many ways, but in part because it allows one to do things that are impossible in real life. There is no risk to any patient, and, unlike real clinical care teaching, there is no pressure for efficiency. One can pause, stop, and start a simulation at will. Perhaps most importantly, simulation errors occur and can play out to their ultimate conclusion, whereas with a real patient, others would need to intervene to protect the patient.

While many people think of simulation as involving computer technology and robotics, it is actually an ancient technique made possible by human beings' innate ability to recall past events and imagine events that have not yet occurred. Because of these abilities, a number of mental activities that require minimal or no technology are in fact "simulations" they are available to everyone regardless of location, wealth, or technological savvy.

Here are five types of non-technological simulation:

- **Storytelling:** Clinicians have always told stories about their challenging cases. When one hears such a story, he or she may contemplate, "What would I do if faced with the situation described?"
- **Verbal Simulation** ("What if"): An individual can pose a situation (true, fictitious, or both) to another person probing to describe both his or her own thoughts and actions. Often this is done more systematically than just telling the story.
- **Role-playing:** This occurs when one "assumes the role" of someone else, sometimes in an unfamiliar position. Role playing allows one to practice the actual thinking and communication with others.
- **Encounters with (Standardized) patient actors:** The role of the patient (or family member, or others) is played by an actor. The "standardized patient" is a specially trained professional whose experience and training allow for portrayal of diverse people and personalities. In addition, these individuals may be trained to evaluate or score the clinician about certain medical or interpersonal skills demonstrated in the encounter.
- **Procedural training using food items:** For many clinical procedures there may be no better simulator than food—either the animal part analogous to the human part, replicating the anatomy, or sometimes a non-realistic food item that has some useful characteristics. An example of the latter is the use of a watermelon to aid the training of novices in epidural catheter placement (the rind of the watermelon replicates the firmness of the ligamentum flavum and then provides an excellent loss of resistance when penetrated).

Some of these simulation modalities can be enhanced when combined with a small amount of technology. Verbal simulations can be enhanced by showing diagrams or photos of monitor screen vital signs or patient anatomy. Certain inexpensive smartphone apps can show a monitor with a variety of moving waveforms, with the values changeable by a corresponding app on another person's phone.

TECHNOLOGY SIMULATION TYPES

Relying solely on verbal simulation may not address the complexities of real (anesthesia) patient care. As expected, there are no simulations with actors or students allowing themselves to be anesthetized solely for educational purposes. Therefore, there are some simple "technologies" (e.g., mannequin; monitor app) that have been very useful in low-resource environments. A few examples worth mentioning are the "Helping Babies Breathe" program, which uses a very simple mannequin (Laerdal Medical, Inc., Stavanger, Norway) that is essentially a simple, but ventilatable, head with the "body" made up of a special plastic bag that when filled with warm water expands to mimic a newborn's thorax, abdomen, and limbs (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/helping-babies-survive/Pages/Helping-Babies-Breathe.aspx). An extension of this simple technology is used for simulating post-partum hemorrhage and consists of a delivery "pouch" that can be worn by someone playing the mother. Both of these simple devices also come with a curriculum. The typical targets for these simple and relatively inexpensive devices are local birth attendants. More sophisticated, but still relatively simple, devices may be appropriate for hospital personnel in low-resource settings.

For those with more resources there are a variety of mannequin-based simulators and task trainers of varying complexity. An exciting new set of technological simulation modalities are just beginning to emerge, offering types of "virtual reality" (VR) ranging from simple to complex. In one approach, an online "virtual world" is created on the computer screen replicating a clinical environment, with the primary participant in the simulation controlling an "avatar" on the screen which can interact with a patient, administer drugs and utilize supplies and equipment. Currently one of the most advanced of these systems—SimSTAT™ *(https://www.asahq.org/education-and-career/educational-and-cme-offerings/simulation-education/anesthesia-simstat)* has been developed for the American Society of Anesthesiologists (ASA),

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which offers it to anesthesia professionals for a fee. A more challenging VR approach uses head-mounted displays, audio, and hand-held controllers to provide a fully interactive multiple-participant immersive patient care environment. Systems of this type are just becoming available for acquisition and use for teaching by clinical simulation faculty.

Simulation is for all fields of health care, especially for highly dynamic areas like anesthesiology, intensive care, emergency medicine, and neonatology. The target audience for simulation are often experienced personnel, often involving teams composed of members from many disciplines or even whole work units. For such purposes, the goals of the simulation are typically only partially focused on the medical and technical details of patient care situations. Instead, they are primarily focused on dynamic decision making, including "crew resource management," teamwork, ethical issues, and communication, including having difficult conversations with patients or families.

SIMULATION HAS MANY PURPOSES

The use of simulation for education and training seems obvious, but it can also be used for a number of other purposes to affect patient safety in different ways. These include simulation for quality and risk management, to help understand—prospectively and retrospectively—what problems exist or what factors contributed to an adverse outcome.[1,2] Simulation is used in this area to elucidate what "human factors" affect the ability of clinicians to work effectively, and how care processes can be improved. Simulation can also be used to help design new medical equipment in order to make it easier and safer to use; regulatory bodies increasingly expect to see data from realistic simulations demonstrating that the design holds up well even in stressful time-critical situations. Simulation can have a role in the assessment of performance by clinicians—this topic is very complex and an ongoing field of research.[1,2]

One of the important uses of simulation for quality and safety is to conduct **"in situ"** simulations, meaning "in place"—in an actual patient room/bed/OR, etc. (or if necessary "peri-situ" to the clinical work unit but in a conference room or corridor).[1] These simulations challenge providers in their actual working environment, using real equipment coupled with current clinical care practices. The purpose is to identify what works well and what does not ("systems probing").[1,2]

One important caution in using in situ simulation is that it is inappropriate to secretly "grade" a participant during a "training session." That is, participants should be made aware when they are being evaluated. Violating this rule risks breaking the trust needed for clinicians to engage fully in training via simulation.[3]

DOES SIMULATION IMPROVE PATIENT SAFETY?

There is good evidence that using simulation as part of a larger bundle focused on central venous cannulation can improve patient outcome.[4,5] But this is a very narrow practice area, involving a relatively simple task, and occurs in a context in which the outcomes are well known and already measured on a regular basis. The same certainty regarding the benefit of simulation has not been demonstrated for many safety issues that are uncommon, involve complex care processes, and with many confounding factors separating the work of clinicians and the ultimate patient outcome. We can actually design studies for evaluating simulation in these more complex situations, but they would take a decade or more to complete, with thousands of clinicians, patients, and financial resources required. To date almost all simulation interventions have been:

- Applied infrequently
- Often with relatively low-intensity curricula
- With little reinforcement in real work
- With no coupling to performance assessment of clinicians or systems
- In only a few disciplines/domains (anesthesiology is one, but fewer than 30% of practicing anesthesiologists have actually ever undergone a meaningful simulation beyond ACLS)*
- Small studies with short time horizons (days, weeks, months)

CONCLUSION

Simulation is an important technique to address issues of patient safety. We need to think of its benefits with a long-term view, as an ongoing career-long activity for all clinicians. Because the techniques are not necessarily dependent on expensive technologies, they can be used in a wide variety of clinical settings whether high- or low-resource. The growth of simulation use has come largely from clinicians' perceived benefit obtained via direct experience with it rather than from definitive evidence of its impact (which is hard to come by) or by any regulatory drivers. It has not been necessary to count the lives saved in order to convince many institutions to adopt these techniques. There is a saying so profound that it is present in both the Hebrew Talmud and the Muslim Quran that "whoever saves a life, it is as if he has saved all of mankind." Based on anecdotes and the evidence that does exist we can be confident that many hearts, brains, or lives have been saved directly and indirectly by the use of simulation. It is this spirit that motivates the many anesthesia professionals and those in other arenas of health care to continue their efforts to use these techniques to their maximum effect.

Adapted by the author from his presentation at the International Forum on Perioperative Safety & Quality, October 12, 2018, San Francisco, CA.

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His disclosures relevant to this article are

1) *Dr. Gaba receives an annual honorarium from the Society for Simulation in Healthcare as the founding editor-in-chief of the peer-reviewed journal* Simulation in Healthcare.
2) *Dr. Gaba receives an annual honorarium from the ASA as a member of the Simulation Editorial Board.*
3) *Dr. Gaba receives royalties on the sale of the textbook* Crisis Management in Anesthesiology.

*Personal communication with author, unpublished data.

REFERENCES

1. Gaba DM. The future vision of simulation in healthcare. *Simul Healthc.* 2007;2;126.
2. Rall M, Gaba D, Dieckmann P, Eich C. Patient simulation. Miller's Anesthesia (8th edition). Edited by Miller R. Philadelphia, Saunders, an imprint of Elsevier Inc., 2014.
3. Gaba DM: Simulations that are challenging to the psyche of participants: how much should we worry and about what? *Simul Healthc.* 2013;8;4–7.
4. Barsuk JH, McGaghie WC, Cohen ER, et al. Simulation-based mastery learning reduces complications during central venous catheter insertion in a medical intensive care unit. *Crit Care Med.* 2009;37;2697–2701.
5. Barsuk JH, Cohen ER, Potts S, et al. Dissemination of a simulation-based mastery learning intervention reduces central line-associated bloodstream infections. *BMJ Qual Saf.* 2014;23;749–56.

The Ellison C. Pierce, Jr., MD, Award for Best Abstract in Patient Safety:

Using Audit and Feedback to Reduce Avoidable Transfusions in Cardiovascular and Thoracic Surgery

by Aishwarya Vishwanath, BS, and Philip E. Greilich, MD, MSc

Red blood cell (RBC) transfusions are known to be overused nationwide, with cardiac surgery specifically noted to use 10–15% of the United States blood supply.[1,2] Transfusions given in the perioperative setting are associated with high cost and adverse outcomes.[3,4] Patient blood management is a multifaceted strategy to reduce the use of avoidable transfusions, thereby potentially mitigating the risk of complications. Audit and feedback,[5] a robust component of a blood management strategy, provides clinicians with information designed to change their transfusion behavior and related processes within their organization.

Investigators from the University of Texas Southwestern Medical Center hypothesized that implementation of an audit and feedback system would reduce the rate of avoidable transfusions for patients undergoing cardiovascular and thoracic surgery. Before this hypothesis could be tested, a feasible instrument needed to be developed to facilitate successful implementation in the future.[6] The aim of this study was to determine the measurements of meaning and preferred usage of this audit and feedback instrument, the Transfusion Dashboard. A 16-question REDCap survey[7] was used to collect data from anesthesiologists and surgeons through interviews, small group discussions, and electronic mail. Survey questions addressed management of preoperative anemia, restrictive transfusion practice, and the most effective use of the audit and feedback tool. The Transfusion Dashboard was constructed based on results from this survey.

The results suggested that the following blood utilization metrics were most likely to change these surveyed physicians' transfusion practice: the percent of patients receiving any RBC transfusion, the percent of RBC transfusions with hemoglobin greater than 8 g/dL, the mean number of RBC units transfused per patient, and the total number of RBC units transfused indexed by 1000 inpatient days. The Transfusion Dashboard displays this longitudinal population-based blood utilization data and is able to compare risk-adjusted metrics between peers of the same service line. We found that clinicians who participated in the survey preferred to review the Transfusion Dashboard on a quarterly basis for self-evaluation and on a biannual basis to identify trends in practice. We also found that physicians preferred to use the Transfusion Dashboard to visualize departmental blood utilization data over a rolling period of two years. This instrument displays this data on process control charts that are capable of showing significant changes in practice over a prolonged time period.

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CONCLUSION

Physician engagement appears to be an effective means for designing an acceptable audit and feedback system. Based on individual feedback from service line anesthesiologists and surgeons, the willingness of physicians to change their transfusion behavior and advocate for institutional change also appears high. Successful implementation and widespread adoption of an audit and feedback system is critical to achieving sustainable change.

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An earlier version of this project was presented at the Institute for Healthcare Improvement 2017 Student Symposium.

The authors have no disclosures.

REFERENCES

1. Shander A, Aronson S, Berger JJ, et al. Appropriate blood management. In: National Summit on Overuse. Chicago, IL; 2012.
2. The Society of Thoracic Surgeons Blood Conservation Guideline Task Force. 2011 update to The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists blood conservation clinical practice guidelines. *Ann Thorac Surg.* 2011;91:944–982.
3. McEvoy MT, Shander A. Anemia, bleeding, and blood transfusion in the intensive care unit: causes, risks, costs, and new strategies. *Am J Crit Care.* 2013;22:eS1–eS14.
4. Loor G, Rajeswaran J, Li L, et al. The least of 3 evils: exposure to red blood cell transfusion, anemia, or both? *J Thorac Cardiovasc Surg.* 2013;146:1480–1487.
5. Meybohm P, Richards T, Isbister J, et al. Patient blood management bundles to facilitate implementation. *Transfus Med Rev.* 2016;31:62–71.
6. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health.* 2011;38:65–76.
7. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform.* 2009;42:377–381. Grant: CTSA NIH Grant UL1-RR024982.

Anesthesia and Nosocomial Infections

Have you ever wondered about the role that anesthesia care plays in the spread or prevention of nosocomial infections? On December 11, 2018, the Society for Healthcare Epidemiology of America (SHEA) issued guidelines on the prevention of infection in the operating room anesthesia work space. The guidelines were authored by representatives from SHEA, the Anesthesia Patient Safety Foundation (APSF), the American Society of Anesthesiologists (ASA), and American Association of Nurse Anesthetists (AANA). Given the lack of empiric evidence on this topic, the guidelines were developed using evidence synthesis, and surveys of the membership of ASA, AANA, the American Association of Anesthesia Assistants (AAAA), and the SHEA research network. The guidelines also considered practical considerations, expert opinion, and theoretical rationales. The guidelines, which give recommendations about hand hygiene, environmental disinfection, and continuous improvement, are **available from the *journal Infection Control & Hospital Epidemiology***.[1]

1. Munoz-Price LS, Bowdle A, Johnston BL et al. Infection prevention in the operating room anesthesia work area. *Infect Control Hosp Epidemiol.* 2018;11:1-17.

Multidisciplinary Disaster Planning for Obstetrics

by Gillian Abir, MBChB, FRCA, and Kay Daniels, MD

INTRODUCTION

Obstetric health care professionals and facilities that provide maternity care offer services to a population that has many unique features warranting additional consideration.[1] Compared with other patient cohorts, pregnant women, unborn infants, and neonates are more vulnerable to acute and long-term effects from disasters , both natural (e.g., earthquakes, hurricanes) and man-made (e.g., terrorism). An obstetric-specific triage tool and stratification of maternity hospital's levels of care should enable safe and rapid evacuation and transfer of patients. Disaster preparedness and regular training of staff are necessary to assure and facilitate a seamless process during an event.

DISASTER PLANNING FOR OBSTETRICS IS UNIQUE

Pregnant and peripartum women are unique patient cohorts with specific needs, the majority of which are not encompassed in a generic disaster plan. The key to a successful outcome is including these unique requirements in any preplanning and training, thereby ensuring a rapid response and recovery. The plan needs to provide care for the broad range of acuity levels seen in obstetric patients, from a laboring patient, to a patient who had a normal vaginal delivery, and to a patient who is undergoing emergency cesarean delivery with neuraxial or general anesthesia. Caring for both the mother and fetus/infant with varying levels of acuity is an added challenge which must be considered when/if evacuation is required. Vital to the plan is a system in place that will assure an obstetrical patient is evacuated to the facility best equipped to care for her and her fetus/infant. To accomplish this, the American College of Obstetricians and Gynecologists and the Society of Maternal-Fetal Medicine published a consensus describing levels of maternal care hospitals.[2] Obstetric disaster planning needs to be multidisciplinary with involvement from: the obstetric team; anesthesiology team; neonatology team; labor and delivery nursing team; labor and delivery management team; and office of emergency management (if applicable).

ANESTHESIOLOGY INVOLVEMENT IN OBSTETRIC DISASTER PLANNING

The anesthesiology team can contribute to disaster planning and preparedness by providing specialized knowledge related to ongoing care and observation of patients who have received neuraxial analgesia for labor or surgical anesthesia (neuraxial or general anesthesia); airway equipment; monitoring requirements for specific patient groups (e.g., patients with cardiac or respiratory disease); and safe transportation of all patient groups.

The time elapsed since neuraxial labor analgesia placement is a major consideration when determining the OB TRAIN (Obstetric Triage by Resource Allocation for Inpatient) status of the patient, which determines the most appropriate mode of transportation for the patient in the event of evacuation (Figures 1a and 1b).

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Figure 1a. OB TRAIN Antepartum and Labor

Transport	CAR (Discharge)	BLS	ALS	SPC	SHELTER IN PLACE
Labor Status	None	Early	Active	At risk for en route delivery	If delivery is imminent, 'Shelter in place' and TRAIN after delivery
Mobility	Ambulatory*	Ambulatory or Non-ambulatory	Non-ambulatory	Non-ambulatory	
Epidural Status	None	Placement >1 hr **	Placement >1 hr **	N/A	
Maternal Risk	Low	Low/Moderate	Low/Moderate	High	

BLS = Basic Life Support (Emergency Medical Technician-staffed ambulance); ALS = Advanced Life Support (Paramedic-staffed ambulance); SPC = Specialized (must be accompanied by MD or Transport Nurse).

*Able to rise from a standing squat.

**Epidural catheter capped off.

Figure 1b. OB TRAIN Postpartum

Transport	CAR (Discharge)	BLS	ALS	SPC
Delivery	VD >6 hr or CD >48 hr	VD >6 hr or CD >48 hr	Complicated VD or CD	Medically complicated
Mobility	Ambulatory*	Ambulatory or Non-ambulatory	Ambulatory or Non-ambulatory	Non-ambulatory
Post Op	Non CD surgery >2 hr**	>2 hr from CD	<2 hr from CD	Medically complicated
Maternal Risk	Low	Low/Moderate	Low/Moderate	High

BLS = Basic Life Support (Emergency Medical Technician-staffed ambulance); ALS = Advanced Life Support (Paramedic-staffed ambulance); SPC = Specialized (must be accompanied by MD or Transport Nurse); VD = Vaginal delivery; CD = Cesarean delivery.

*Able to rise from a standing squat.

**If adult supervision is available for 24 hours.

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Obstetric Disaster Planning

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A period of one-hour following neuraxial block placement was identified as a limiting factor for triage group allocation, as the majority of complications/side effects and drug-related etiologies (e.g., local anesthestic systemic toxicity, anaphylaxis) will usually have occurred during this time-frame.[3] In the event of evacuation, labor epidural infusions should be discontinued and the epidural catheter capped to decrease the acuity-level for the mode of transportation required. Alternative modes of analgesia can be offered to patients prior to re-dosing of the epidural catheter (if required) at the receiving institution, depending on local protocols. Examples include intravenous fentanyl boluses or intravenous patient-controlled analgesia using remifentanil.

The anesthesiology team should be prepared to provide clinical care in austere conditions. Airway equipment, anesthesia-related and suction equipment, monitoring modalities, intravenous fluid, and medication supplies all should be available (Table 1 and Figure 2).[4]

MULTIDISCIPLINARY OBSTETRIC DISASTER PLAN TOOLS

Institutions should have generic disaster plans established, and in addition should have obstetric-specific tools (Table 1). On-line tools developed to guide hospital-based evacuation or shelter-in-place for obstetric units are available.[4]

OBSTETRIC DISASTER PREPAREDNESS TRAINING

Disaster preparedness training can be delivered in various formats, such as: on-line information through government-funded resources; medical and nursing societies; and in some areas, simulation-based multidisciplinary training is available.[5-9] Simulation-based training can be organized at the department/institution level, or interagency drills in collaboration with hospitals, emergency services, and disaster organizations on a county level.[10]

CONCLUSION

Multidisciplinary obstetric disaster preparedness is essential for all institutions. Obstetric and neonatal patients are unique and require individual consideration. Disaster planning, including incorporation of OB TRAIN and other obstetric-specific tools, awareness of local maternity hospital's levels of care, health care provider training, and knowledge of local resources will help provide optimal patient care in the event of any disaster situation.

Table 1. Depicts Key Components of an Obstetric Disaster Planning Tool

Disaster plan tool	Description
Disaster plan binder	Each unit should have a designated binder that contains relevant forms and instructions pertinent to the disaster plan. Paper format is recommended in preparation of a power outage or cyber-attack.
Disaster box	Equipment specifically designated for use in a disaster should be stored in labeled boxes. The box should be stored in an accessible location in each unit and only retrieved during a disaster. Recommended items include paper forms; flashlights; headlamps; non-rechargeable batteries; handheld doppler transducers; Grab-and-go bags; and vests.
Disaster roles	Leadership roles are fundamental in any emergency situation, and should be titled using nomenclature used by the Hospital Incident Command System (HICS) to avoid confusion. The Unit Leader's role should be assigned to the most knowledgeable individual(s) on the unit. Further roles are the assistant unit leader (obstetric resident and/or team leader nurse), anesthesia professional, triage physician or nurse, bedside nurses, nursing assistants/technicians, and clerk.
Job action sheet (JAS)	JASs are role-specific instructions with the purpose to ensure all tasks are completed, ideally within the predetermined time-frames: immediate (operational period 0–2 hr); intermediate (operational period 2–12 hr); and extended (operational period >12 hr, or as otherwise determined by the Hospital Command Center).
Obstetric triage	A major step in planning evacuation is patient triage. Vehicle numbers and availability will most likely be limited. The triage system can be used to determine the resources required and the optimal order of evacuation to allow a quick and appropriate evacuation of patients.[11-13]
Census worksheet	Mother and infant data sheet containing protected health information such as name, medical record number, date of birth, and also current physical location and planned destination (for tracking).
Department damage map	A plan that shows every staff room, patient room, and common area within the unit to identify useable (safe) vs. non-useable areas (unsafe due to debris, flooding, electrical hazard, etc.).
Grab-and-go bag	An empty backpack (not pre-filled due to perishable items) containing a list of essential supplies should be available for individualized patient care, including items for an off-site delivery. This individualized Grab-and-go bag will accompany the patient at the time of either shelter-in-place off the unit, or evacuation. (Figure 2).
Transfer form	A paper form with pertinent medical information should be available and given to the patient at the time of transfer, allowing optimal patient care to be continued at the receiving hospital.
Transfer orders form	Orders specific to maternal and fetal monitoring (if applicable), fasting/nutrition status, medications, and intravenous fluid administration.
Medication conversion instructions	Common obstetric medications should be listed with dose conversions from intravenous to intramuscular administration.
Regional hospital's levels of care	A list of regional hospitals should be available documenting essential information such as distance, phone number, maternal level of care, and neonatal level of care, in order to send patients to the proper hospital with the most appropriate level of care and to avoid maternal-neonatal separation. When patients are transferred to other institutions, it is essential to have an effective patient tracking system in place so the sending institution knows where each patient has been admitted to avoid maternal-neonatal separation, follow up with aspects of clinical care, and send test results, etc.
Maternal discharge form and checklist for well-baby discharge	List of criteria that need to be met prior to discharge of a well baby.

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Both authors have no disclosures as they pertain to this article.

REFERENCES

1. Hospital disaster preparedness for obstetricians and facilities providing maternity care. Committee Opinion No. 555. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2013:121:696–99.
2. Levels of maternal care. Obstetric Care Consensus No. 2. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2015;125:502–15.
3. Di Gregorio G, Neal JM, Rosenquist RW, Weinberg GL. Clinical presentation of local anesthetic systemic toxicity: A review of published cases, 1979 to 2009. *Reg Anesth Pain Med.* 2010;35:181–7.
4. Disaster planning for obstetrical services. https://obgyn.stanford.edu/divisions/mfm/disaster-planning.html. Accessed November 2018.
5. The Department of Homeland Security. https://www.ready.gov. Accessed April 2018.
6. American Red Cross. How to prepare for emergencies. http://www.redcross.org/get-help/how-to-prepare-for-emergencies. Accessed April 2018.
7. Disaster Management and Emergency Preparedness. American College of Surgeons. https://www.facs.org/quality-programs/trauma/education/dmep. Accessed April 2018.
8. Center for Domestic Preparedness. Federal Emergency Management Agency. https://cdp.dhs.gov. Accessed April 2018.
9. National Incident Management System (NIMS). Federal Emergency Management Agency. https://training.fema.gov/nims/. Accessed April 2018.
10. Jung D, Carman M, Aga R, Burnett A. Disaster preparedness in the emergency department using in situ simulation. *Adv Emerg Nurs J.* 2016;38:56–68.
11. Daniels K, Oakeson AM, Hilton G. Steps toward a national disaster plan for obstetrics. *Obstet Gynecol.* 2014;124:154-158.
12. Cohen RS MB, Ahern T, Hackel A. Disaster planning - triaging resource allocation in neonatology. *J Invest Med.* 2010;58:188.
13. Lin A, Taylor K, Cohen RS. Triage by resource allocation for inpatients: a novel disaster triage tool for hospitalized pediatric patients. *Disaster Med Public Health Prep.* 2018;31:1–5. [Epub ahead of print].

Figure 2. OB Anesthesiology Grab-and-go Bag List:

	Airway:	Location/Notes
☐	Ambu bag x2	From epidural cart or on wall in LDR hallway
☐	O_2 tank x2 + wrenches	Dirty utility room across from LDR X (Door code xxxx)
☐	Laryngoscope + Blade x2	
☐	ETT x2	
☐	NRB mask x3	
☐	Oral airways	
☐	Proseal LMA #3, #4, #5	
☐	Bougie	
	Suction:	
☐	Portable Suction machine	Top of code cart (across from LDR X)
	Monitors:	
☐	Propaq + power and monitor cables	Anesth Tech Rm
☐	Portable SpO_2	Top of OR X Anesthesia machine
	IV:	
☐	IV start equipment	
☐	Normal saline or lactated ringers 1000 ml bag x4	
☐	IV blood tubing x2	
	Meds:	
☐	Omnicell Keys 1. Pick up key packet from Main Pharmacy for anesthesia cabinets and/or nursing cabinets 2. Insert appropriately labelled keys into top + bottom locks on front panel 3. Retrieve needed drugs 4. Keep track of drugs administered and associated MRNs 5. Give key to Pharmacists or RN Manager	
☐	Propofol + Succinylcholine	
☐	Labetalol	
☐	Pitocin	
☐	PPH Kit x2	Med room + PACU Omnicells only
☐	Emergency medications: Epinephrine/ Atropine/Phenylephrine/Ephedrine	
☐	SL NTG	
	2% lidocaine/epinephrine/bicarbonate 10 ml syringes x2	
	Other:	
☐	10 ml syringe x 20	
☐	18G needle x 20	
☐	25G needle x 10	

Gas Shut-Off Valves: Turn off if smoke or fire present, once off, only engineering can turn back on.	
PACU/Triage rooms/US room:	Just outside PACU
LDR rooms:	Between break room and double doors to OR
OR X:	Just outside OR X
OR Y:	Just outside OR Y
OR Z:	Just outside OR Z

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On Reducing Fixation Errors

by Rafael Ortega, MD, and Kunwal Nasrullah, BA

Although it has been nearly twenty years since the publication of the Institute of Medicine's landmark publication "To Err is Human," medical errors continue to be a leading cause of patient morbidity and mortality.[1] Studies have estimated human error accounts for 87% of all medical errors[1,2] with varying prevalence stratified by specialty and clinical situation (lower than 5% in radiology to as high as 10–15% associated with emergency medicine care).[2,3] In anesthesia, human errors have been shown to account for up to 83% of errors, with fixation errors among the major culprits.[2-4] The reasons for why human errors continue to be prevalent are varied, but include the complexity of the OR environment, the acuity of crisis situations, and psychophysiologic variables that are unique to individuals and teams.[2-4]

Fixation errors are a type of cognitive error in which individuals and teams focus on one aspect of a situation, while ignoring more relevant information.[3-7] These errors have been categorized into three different types: a) "this and only this" errors occur when only one diagnosis or solution to a problem is considered, b) "everything but this" errors occur when the correct diagnosis or solution is not considered, and c) "everything is okay" errors occur when a problem is not acknowledged.[4,6] Cases 1 and 2 (Figures A & B) typify perioperative care situations where different types of fixation errors occurred. These events galvanized health care professionals from our institution to embark upon a patient safety transformation, which has led to the publication of an innovative educational tool. This teaching instrument consists of a hybrid book, entitled *Ok to Proceed? What every health care provider should know about patient safety,* which blends printed text with multimedia, and reviews a variety of patient safety topics, including fixation errors.[6] In this article, we focus on fixation errors and detail why innovative strategies for addressing them are so important to patient safety.

CASE 1:
An eight-year old boy who underwent appendectomy.

Soon after the procedure, he suffered a surgical complication that required parenteral nutrition. A series of errors led to the preparation of a mixture containing ten times the prescribed potassium concentration, and the patient suffered a cardiac arrest. Vigorous resuscitation efforts failed.

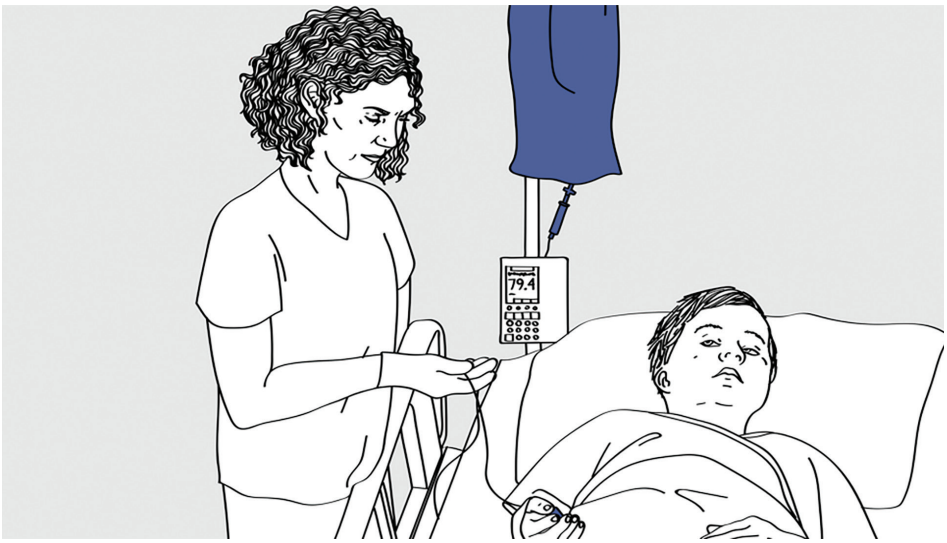

Figure A. A nurse checking the IV line after beginning transfusion of an IV fluid. However, the child is accidentally given a preparation containing ten times the prescribed potassium concentration.
Reproduced and modified with permission from authors and the Boston Medical Center.

Evaluation:

The health care team suffered an "everything but this" fixation error by failing to consider hyperkalemia as a cause of the patient's cardiac arrest.

CASE 2:
A healthy middle-aged man presented for oral surgery.

This patient required nasotracheal intubation for the procedure. After the laryngoscopist advanced the tube into the trachea under direct visualization, it was difficult to ventilate the lungs. The team believed that the reason for airway resistance was bronchospasm. Fixated on this diagnosis, the team did not entertain the possibility that the tube could have been kinked within the trachea or other causes of an inability to adequately ventilate. The patient died due to anoxia.

Evaluation:

The OR team was victim to a "this and only this" fixation error when they concluded that bronchospasm was causing the airway resistance.

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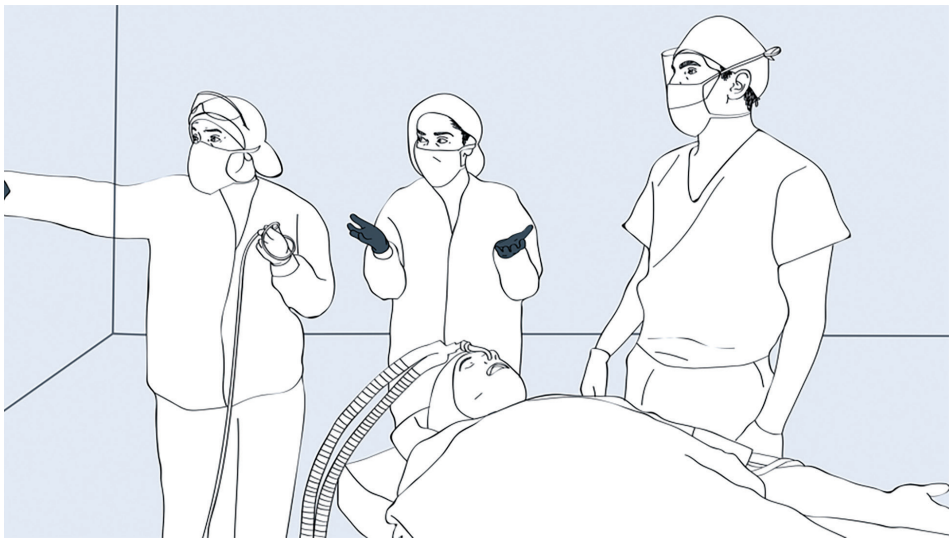

Figure B. OR team fixated on bronchospasm as the cause of airway resistance after a nasotracheal intubation.
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Fixation Errors

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Fixation errors have also been called "anchoring" errors or "tunnel vision"[2,4,5,7] and can be broadly considered as human errors of *insight*. For this reason, much of the research about fixation errors has been in the fields of cognitive psychology and aviation safety.[4,5] The work of Fioratou and colleagues elucidate how experience and knowledge work against us and can result in fixation errors.[5] In medicine, as in other fields, we rely on our prior experience to help us approach new situations; this is known as heuristic or experiential learning. In the case of fixation errors, our experiences bias us to the new situation, making us cling to a conclusion even when presented with information to the contrary.[3-7,9] It is as if we *anchor* to an idea. The reasons for this are varied but include availability bias (tendency to overvalue examples that come easily to mind), prior experience, mental shortcuts, and the high cognitive load of complex environments (e.g., operating room).[1,4]

It is difficult for both trainees and seasoned anesthesia professionals to identify and then rectify a fixation error due to the focus on heuristic training. Thus, it is very important to encourage learning tools that teach "outside-the-box" or "lateral" thinking, which have been shown to circumvent fixation errors.[5,9-10] The most important strategy for overcoming fixation errors is *awareness*.[5,9,10] This is promoted by articles such as this one, patient safety learning material, didactics, and simulations.[9] Individuals must be made aware of what fixation errors are, led through exercises where fixation errors have occurred, and work through these errors in simulations. Through exposure, trainees and professionals alike are taught that shortcuts and obvious conclusions can be pitfalls leading to fixation errors.[5] Therefore, they must employ strategies that may help to mitigate these errors. These strategies are included in Table 1.[5,9–11]

Table 1. Strategies for Overcoming Fixation Errors

Rule out the worst-case scenario
Accept that the first assumption may be wrong
Consider artifacts as the last explanation for a problem
Do not bias team members with a previous conclusion

OBTAIN A SECOND OPINION

In making fixation errors, goal-directed behavior is curtailed.[5] In these cases, even trial and error procedures can yield useful information[5] and participants should consider not repeating the same actions if they yield the same results. Rather, they should entertain the possibility of a fixation error, and change their strategy, particularly in the face of unfavorable results.

Preventing medical errors requires thinking beyond the field of health care and promoting novel educational and cognitive strategies which counteract cognitive errors to create high accountability networks.[3,7,12] Our institution is using this approach and creating patient safety initiatives using the book as an innovative alternative to address these complex challenges. This teaching tool capitalizes on the power of storytelling, multimedia, diagrams and digital animation, and is based on real medical errors, engaging players at all levels of health care. Lastly, we are committed to studying the impact of these tools on provider understanding of patient safety issues and, ultimately, their performance.

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REFERENCES

1. Walsh T, Beatty PCW. Human factors error and patient monitoring. *Physiological Measurement.* 2002;23:111–132.
2. Saposnik G, Redermeier D, Ruff CC, et al. Cognitive biases associated with medical decisions: a systematic review. *BMC Medical Informatics and Decision Making.* 2016;16:138.
3. Stiegler MP, Neelankavil JP, Canales C, et al. Cognitive errors detected in anaesthesiolgy: a literature review and pilot study. *British Journal of Anaesthesia.* 2012;108:229–235.
4. Chandran R, DeSousa KA. Human factors in anaesthetic crisis. *World Journal of Anesthesiology.* 2014;3:203–212.
5. Fioratou E, Flin R, Glavin R. No simple fix for fixation errors: cognitive processes and their clinical applications. *Anaesthesia.* 2010;65:61–69.
6. Ortega R. Fixation errors. In: Lewis K, Canelli C, Ortega R, eds. OK to proceed? What every health care provider should know about patient safety. 1st ed. Boston, MA: *Boston Medical Center.* 2018:64–69.
7. Arnstein F. Catalogue of human error. *British Journal of Anaesthesia.* 1997;79:645–656.
8. Lewis K, Canelli C, Ortega R, eds. OK to proceed? What every health care provider should know about patient safety. 1st ed. Boston, MA: Boston Medical Center; 2018.
9. Brindley PG. Patient safety and acute care medicine: lessons for the future, insights from the past. *Critical Care.* 2010;14:217.
10. Carne B, Kennedy M, Gray T. Review Article: Crisis resource management in emergency medicine. *Emergency Medicine Australia.* 2012;24:7–13.
11. Rall M, Gaba DM. Human performance and patient safety. In: Miller RD, Eriksson LI, Fleisher LA, et al., eds. *Miller's Anesthesia.* 7th ed. Philadelphia, PA: Churchill Livingston; 2010:93–149.
12. Stiegler MP, Tung A. Cognitive processes in anesthesiology decision making. *Anesthesiology.* 2013;120:304–17.

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