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NEWSLETTER

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APSF Hosts Medication Safety Conference

Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

Overview

On January 26, 2010, the Anesthesia Patient Safety Foundation (APSF) convened a consensus conference of 100 stakeholders from many different backgrounds to develop new strategies for "predictable prompt improvement" of medication safety in the operating room. The proposed new paradigm to reduce medication errors causing harm to patients in the operating room is based on **Standardization, Technology, Pharmacy/Prefilled/Premixed, and Culture** (STPC). This new paradigm goes far beyond the important but traditional emphasis on medication label format and the admonition to "always read the label." Small group sessions on each of the 4 elements of the new paradigm (STPC) debated and formulated specific recommendations that were organized and prioritized by all the attendees. The resulting consensus recommendations include:

Standardization

- High alert drugs (such as phenylephrine and epinephrine) should be available in standardized concentrations/diluents prepared by pharmacy in a ready-to-use (bolus or infusion) form that is appropriate for both adult and pediatric patients. Infusions should be delivered by an electronically controlled smart device containing a drug library.
- Ready-to-use syringes and infusions should have standardized fully compliant machine–readable labels.

Technology

- Every anesthetizing location should have a mechanism to identify medications before drawing up or administering them (bar code reader) and a mechanism to provide feedback, decision support, and documentation (automated information system).

Pharmacy/Prefilled/Premixed

- Routine provider-prepared medications should be discontinued whenever possible.
- Clinical pharmacists should be part of the perioperative/operating room team.
- Standardized pre-prepared medication kits by case type should be used whenever possible.

Culture

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

It was agreed that anesthesia professionals will likely surrender some of their "independence," adapting their medication preparation and delivery preferences and habits into more standardized practice patterns (involving guidelines and checklists), utilizing more standardized and premixed medications (input and supply by pharmacy services), and relying more on technology. Facilities and their administrators that are sensitive to the economic value of safety (return on investment) are critical to the effort, for both moral support to do the right thing and for provision of financial support for change. Practitioners in the operating room may take some convincing, but culture and patient safety can improve and medication errors causing morbidity and mortality can be dramatically reduced—just as happened with intraoperative monitoring years ago.

CONFERENCE REPORT

Persistent reports of medication accidents occurring in the operating room with resultant harm or potential harm to patients prompted the APSF to convene a consensus conference of 100 stakeholders from many different backgrounds on January 26, 2010, in

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Inside:

APSF Funds New Registry: The Neurologic Injury after Non-Supine Shoulder Surgery (NINSS) Registry

by Lorri Lee, MD

The *APSF Newsletter* has published numerous articles over the last 2 years on severe brain and spinal cord injuries occurring after shoulder surgery in the sitting or beach chair position. Many of these cases have been associated with the use of deliberate or permissive hypotension, typically at the request of surgeons, to decrease bleeding and improve visualization during arthroscopic shoulder surgery. Several theories exist as to the etiology of these catastrophic neurologic injuries including 1) the loss of venous return and decreased cardiac output in the upright position; 2) loss of a compensatory sympathetic response to positional changes caused by anesthesia; 3) failure to correct for the difference in height between the site of blood pressure measurement and the head level; 4) the use of deliberate or permissive hypotension; 5) dynamic vertebral artery stenosis or occlusion with rotation of the head; and 6) air emboli. These articles have generated significant interest and alarm among the anesthesia and orthopedic communities. Many groups have reported by word of mouth a change in surgical and anesthetic practice based on this information. However, many anesthesia care providers are still being faced with surgical requests for deliberate hypotension in these cases, because of the sparsity of data on this topic.

The APSF Board of Directors Workshop, held last October in New Orleans, further explored this potentially lethal, yet preventable, patient safety issue by inviting numerous national and international experts on the topics of cerebral perfusion, cerebral function monitoring, deliberate hypotension, and shoulder surgery. Most speakers and attendees agreed that the use of deliberate hypotension in these shoulder surgery cases in the sitting position should be discouraged until we have better research on this topic. One of the suggestions for future research from the breakout groups at the workshop was to create a national voluntary registry to collect these rare cases of neurologic injury after non-supine surgery (NINSS).

In follow-up to the workshop recommendations, the APSF has funded the creation of the NINSS Registry in collaboration with the ASA Closed Claims Project at the University of Washington. It will be modeled after the ASA Postoperative Visual Loss Registry, with the goal of identifying common perioperative characteristics that may guide future research. Prior to data from the ASA Postoperative Visual Loss Registry, the anesthesia community was being blamed for inadequate protection of patient eyes in

to identify that the most common cause of postoperative visual loss after spine surgery was being caused by something other than globe compression. Once this information was well dispersed, other perioperative events and characteristics began to emerge as potential predisposing risk factors, such as duration of surgery and magnitude of blood loss.

The NINSS Registry is a voluntary registry collecting all cases of new or worsened central (brain or spinal cord) neurologic injury after shoulder surgery in the non-supine position. The injury must occur either during surgery or within the initial 24 hrs postoperatively; and the minimum patient age is 12 years. Exclusion criteria include 1) any case where direct surgical trauma could cause cerebral or spinal cord injury; 2) perioperative cardiac arrest, intraoperative hypoxic events, or uncontrolled surgical hemorrhage; 3) lack of adequate medical records including preoperative history and exam, anesthetic record, and postoperative follow-up and studies. Case submissions are voluntary and anonymous, with IRB approval for this study from the University of Washington. Please visit our website at www.asaclosedclaims.org and click on the brain and spinal cord icon to direct you to submission forms. The direct link is http://depts.washington.edu/asaccp/NINS/index.shtml. It is only with the help of our dedicated professionals in the anesthesia community that we can collect enough information to offer guidance on the topic of blood pressure management in the beach chair position.

Dr. Lee is Co-Editor of the APSF Newsletter, *Director of the NINSS Registry, and Associate Professor of Anesthesiology at the University of Washington, Seattle, WA.*

NINSS Registry

Neurologic Injury after Non-Supine Shoulder Surgery

Click on the link below to submit cases of central neurologic injury (brain or spinal cord) occurring after shoulder surgery in the non-supine position.

http://depts.washington.edu/asaccp/

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Medication Safety Conference Develops New Strategies

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Phoenix, Arizona. The goal of the conference was to create actionable statements that could result in "predictable prompt improvement" of medication safety in the operating room.

Multiple reports and analyses of "syringe swaps" and incorrect syringe labels, look-alike labels, look-alike medication vials and ampoules, incorrect injection sites (into epidural or arterial catheters), and infusion pump confusion or programming errors have appeared in the *Anesthesia Patient Safety Foundation Newsletter* and other journals in recent years.[1-3] APSF conducted its 2008 Annual Workshop on "Innovations in Medication Safety in the Operating Room," with the report of this meeting being published in the Winter 2008-09 *APSF Newsletter*.[3] Other reviews and editorials have considered distinctive label format for medication containers and syringes, uniform drug labeling standards, and a more universal role of pharmacy services.[4-7] While all those are relevant, little, if anything, has changed. Operating room medication errors continue to occur, many with significant morbidity and/or mortality. Anesthesia professionals in the operating room have a unique role and responsibility in that they are the only medical personnel who prescribe, secure, prepare, administer, and document medications—a process that can take up to 41 steps—usually within a very short time interval.[2] In addition these steps occur in real time, autonomously, often in a distracting environment, and typically without standardized protocols.

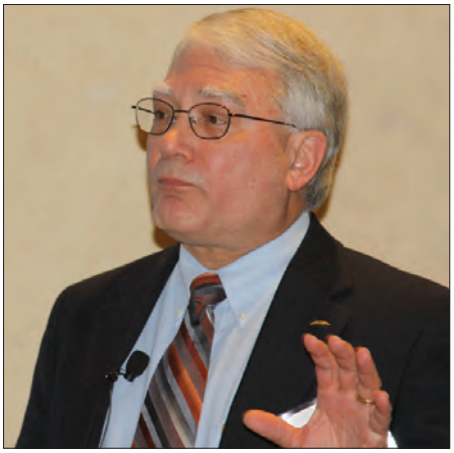
Because past efforts to improve medication safety have not been particularly successful, the purpose of this conference was to develop new ideas and approaches. Reference was made to the quotation popularly attributed to Einstein that the definition of insanity is doing the same thing over and over and expecting a different result. The conference title was "Medication Safety in the Operating Room: *Time for a New Paradigm.*" The theme of the "new paradigm" had 4 elements: **Standardization, Technology, Pharmacy/Prefilled/Premixed and Culture (STPC)**, representing a new 4-pronged approach to the persistent problems of medication safety in the operating room.

Robert K. Stoelting, MD, APSF president, served as the overall moderator for the intense 1-day conference. He opened with the video *Beyond Blame*, produced in 1997 and distributed by the Institute for Safe Medication Practices. The video contains interviews with an anesthesiologist, an ICU nurse, and a pharmacist, each of whom was involved with a fatal medication error. The video stresses, "It could happen to anyone." Despite the passage of 13 years the issues in the video remained highly relevant in 2010. Dr. Stoelting also noted the often-cited statistic that there is 1 significant anesthetic medication error in every general value of evidence-based medicine, he stressed that the traditional approach involving multiple randomly controlled prospective blinded trials simply cannot apply to preventing rare unpredictable adverse events—and that waiting or hoping for such results can actually be counterproductive for safety. He emphasized that safety is doing the right thing because it makes sense. Dr. Stoelting noted that anesthesia safety has been improved by many small steps over the years, that have made a big difference in the aggregate.

Dr. Stoelting introduced a novel format consisting of 20 invited speakers from widely varying disciplines and backgrounds (clinical anesthesia, research [including human factors], surgery, operating room nursing, administration, pharmacy, regulators, and the pharmaceutical/medication device industry). Each speaker had a 15-minute time slot—but all with the same topic: *"Time for a New Paradigm: Standardization, Technology, Pharmacy, Culture."* Each was asked to address relevant elements of the paradigm from their special perspective. Following these 20 presentations the entire assembly was divided by interest and expertise into 4 small group breakout sessions, one for each component of the STPC paradigm. The assignment to each group was to generate a list of actionable items in order of impact that, if implemented, would produce "predictable prompt improvement" in operating room medication safety. A final combined session set the stage for development of consensus statements as the primary product of the conference.

World Class Experts

The keynote speaker was **Alan F. Merry, MBChB,** head of anesthesiology at the University of Auckland, New Zealand, former chair of the Patient Safety Committee of the World Federated Societies of Anesthesiologists, and founder of Safer Sleep, LLC, a company that provides technology intended to increase anesthetic medication safety. He cited the recently adopted "Guidelines for the Safe Administration of Injectable Drugs in Anaesthesia" from the Australian and New Zealand College of Anaesthetists that focus on standardization of medication administration as opposed to the traditional approach of each practitioner independently making these decisions. He also noted that the International Standards Organization most recent publication regarding content of adhesive syringe labels includes the class of drug ("induction agent," "muscle relaxant,") as well as the drug name along with space to write the concentration and date and, also, a bar code. Another component of standardization is in the anesthesia workspace, in that he suggests a uniform arrangement of medications, syringes, empty drug containers for every case by every provider. Because of human nature, errors will occur at points in the drug administration process, and operating room area is a forward step. Having medication containers come into the operating room with attached peel-off detailed labels ready to go on the syringe is another related step. Application of the increasingly effective "checklist mentality," especially if a second person or a device such as a bar-code reader with spoken voice repetition of the name checks the drug about to be given, was emphasized. Finally, from a "culture" perspective, he noted that anesthesia professionals may exhibit problems with denial and also believe they are all above average, but that these features must be overcome with a genuine reporting system that recognizes and records errors, enabling analysis and subsequent system modification to prevent repetition.



Donald E. Martin, MD

Systematic improvement of the human performance required in anesthetic drug administration was the theme of **Donald E. Martin, MD,** from Penn State College of Medicine. The usual human factors associated with accidents, led by inattention (but also failures of memory, knowledge, or motivation), are associated with drug errors in the operating room. He presented an analysis of the 41 steps involved in first-time administration of a drug during an anesthetic and noted 36 were automatic behavior with muscle memory and 5 required conscious attention, decisions, and judgment—a setup for inattention to the 5 critical steps. Ways to help direct attention by the anesthesia professional to the key parts of drug administration were presented, including both ergonomics of the anesthesia workspace (a recurrent point from many presentations) and larger and louder stimuli to target multiple senses. Dr. Martin made analogies to function in the cockpit of a commercial airliner, particularly noting the beneficial use of checklists and also the concept of the "culture of safety" where individual autonomy of action is surrendered and the prescribed "standard operating procedure" is the only acceptable behavior. He ended with a plea to involve the entire operating room team in the effort to

Experts Offer Insight into Causes of Errors

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Robert A. Caplan, MD

Robert A. Caplan, MD, member of the APSF Executive Committee and medical director of Quality at Virginia Mason in Seattle, in a particularly poignant presentation, emphasized the importance of the "culture" of medication labeling by recounting a tragic accident that occurred in his organization in 2004. A patient who was undergoing an interventional radiology procedure accidently received a fatal injection of chlorhexidine (a prep solution) instead of contrast dye because both solutions were in similar, unlabeled containers on the procedure table. As a result of this event, the leadership and safety teams at Virginia Mason made several key discoveries about the existing "culture" of medication labeling. First, medication labeling was regarded as desirable but not mandatory. Second, the strongest motivation for not labeling was convenience. And third, it was not possible to justify non-labeling behavior with clinical, ergonomic, or economic arguments. As a result, Virginia Mason developed an explicit, standardized process for medication labeling. The process is now used throughout the organization. Dr. Caplan noted that this event and its associated lessons have accelerated the implementation of other related safety strategies.

Roots of the Problem

A different aspect of the question was addressed by **Maria Magro, CRNA,** who is a member of the APSF Executive Committee and program director, Nurse Anesthesia, at the University of Pennsylvania School of Nursing. She described the national survey of CRNA training programs she and 2 colleagues conducted regarding formal training in anesthesia medication safety practices. Results revealed the impression that drug errors observed or committed by CRNA students are under-reported and that medication safety can be a stronger component of the curriculum. The 44% of training programs that did not have bar code medication administration systems in place there, and the ICU nurses entering the program would already have medication safety skills. Support was generated through the survey process for a nationally standardized curriculum as well as generous use of simulation to teach safety skills for medication administration to CRNA students.

Maria Magro, CRNA

Jerry A. Cohen, MD

Jerry A. Cohen, MD, first vice-president of the American Society of Anesthesiologists and from the University of Florida, stated that fragmentation of the approach to medication safety problems is itself a significant problem. He maintained, the Swiss-cheese model of human error and accidents notwithstanding, that attempting to isolate root causes obscures complex interactive pathways (system function) that lead to errors. He cited a host of individual factors that can contribute to medication errors, particularly failure to standardize the operating room environment, especially the anesthesia work area, which leads to chaos and distraction and an equally long list of barriers to improvement, especially resistance to checklists, compliance with bar code readers as part of electronic anesthesia records and information management systems would be central to efforts to improve medication safety in the operating room. He concluded with a plea for studies to generate data to guide implementation and also stimulate appropriate standards and regulations that will govern practice.

A different take on human factors engineering was provided by **John W. Gosbee, MD,** of the University of Michigan who presented an elaborate "equation" describing operating room medication errors, in which the probability of confusion was the product of 6 factors: "sound alike, look alike, location expectation, location trust, work flow expectation, and work flow trust." He analyzed and provided examples of each factor in the anesthesia work station environment in a typical operating room. More emphasis came on the context of medication use in the work area than on labeling itself. He suggested that very simple factors such as strict standardization of the anesthesia work space, especially the location of stored medications, would help improve safety now while more complex technologic solutions involving barcodes, readers, and computerized records are developed and rigorously tested for efficacy.

Allied Perspectives

The public policy component was provided by **Nancy Foster,** vice president for Quality and Patient Safety Policy for the American Hospital Association. She noted that facility administrators are always interested in patient safety, but clinicians need to be more skilled at presenting safety proposals, particularly involving resource allocation, as imperatives that lead to "win-win" situations. She suggested one useful strategy is to "engage" administrators by including them on quality improvement teams and safety task forces and then give them specific goals and assignments that are achievable, thus reinforcing their stake in establishing a safety culture and improvement of outcome. Also, Ms. Foster noted the trend of greater integration of health professionals, physicians in particular, into the internal institutional organization, which should increase the receptivity of administrators to safety proposals. She concluded with a reminder that administrators are sensitive to the public's perception of their facility and that the public today finds failure to attempt to improve patient safety as totally unacceptable.

A surgical perspective on OR medication safety was offered by a member of the APSF Board of Directors, **William P. Schecter, MD,** from UCSF and San Francisco General Hospital. He functionally provided a "morbidity and mortality conference" based on operating room medication errors he had witnessed over the years. At the outset, he noted the tension and complex interaction between human error

Pharmacists Weigh in on Medication Error Prevention

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different types of medication errors (wrong drug or dose or route, and adverse reactions). He also applied the STPC paradigm to each case to dissect out causes that could be corrected with those elements. In all cases, there were both human factors and system components as root causes. In nearly all the cases, standardization of practice and protocols would have helped to prevent the error. The eerily familiar theme of accidental injection of a toxic substance into an inappropriate injection port with catastrophic outcome figured in 3 of the cases. Adherence to strict labeling policies and physical segregation of toxins were the suggested remedies.

The Institute for Safe Medication Practices (ISMP) was represented by **Allen J. Vaida, PharmD**, its executive vice president. The ISMP focus is on the system causes of medication errors and resulting system changes that must be implemented along with education to prevent recurring patterns. Dr. Vaida stressed employing an open environment of sharing errors internally and externally to safety organizations for learning, sharing, and bringing about change. He noted relatively poor compliance with labeling policies and procedures during drug administration and also showed many examples of striking look-alike drug vials (and noted the disproportionately great number of look-alike accidents involving muscle relaxants). He also stressed that clinicians (working to achieve consensus with pharmacists and manufacturers) need to establish and accept a relatively limited set of standardized concentrations for drugs. At a 2008 national consensus conference on the safety of intravenous drug delivery systems, there was a clear preference for manufacturer-prepared completely ready-to-use IV medication in all settings, although increased cost and potential inapplicability (such as for seldom-used but necessary drugs in the anesthesia operating room armamentarium) are drawbacks of that approach if standardization is not agreed upon. Dr. Vaida also noted a clear preference for satellite pharmacies in operating room suites but noted that when that is not possible, there must be organized involvement from pharmacy for anesthesia services in the operating room to support medication safety.

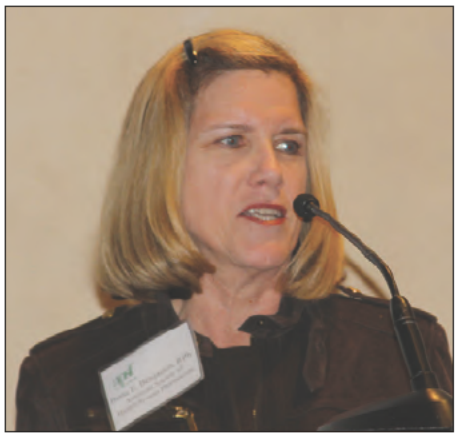
Pharmacy Practices

Philip J. Schneider, RPh, associate dean of the University of Arizona College of Pharmacy, noted that evidence-based best practices known to improve medication safety, particularly unit dosing, have been in place for medication administration in hospitals for decades, but those concepts are not applied in the operating room. He noted that all of the key parts of

of the anesthesia professional in the operating room, preventing the traditional safety checks present in other settings. He suggested that providing "ready-to-use" medications in the operating room whenever possible that are prepared by outsource specialty companies who do that exclusively should decrease medication errors in the operating room.

Patricia C. Kienle, RPh, an industry representative holding the position of director, Accreditation and Medication Safety for Cardinal Health, Inc., stressed the need for standardization of all the key functions in the very complex task of anesthetic medication administration in the operating room, illustrating her point with multiple photos of actual anesthesia workstations with what seemed like quasi-chaotic hodgepodges of medication storage and administration. However, she asserted that color-coding of medication containers may not be a help and may actually be a detriment in some cases. She also noted the USP practice standard for sterility of "compounded preparations" and suggested that the traditional 100 ml bag of phenylephrine made up from an ampoule by many anesthesia professionals at the start of a work day does not meet that standard.

Andrew J. Donnelly, PharmD, director of Pharmacy at the University of Illinois Medical Center at Chicago, emphasized that cost of medications and associated personnel is a huge issue today for health care institutions facing budget constraints. Further, he also noted that the unique medication use process for anesthesia in the operating room has minimal involvement of pharmacy and lacks the normal checks and balances. He advocated for a much more robust presence of pharmacy service in the operating room, even without a satellite pharmacy, in order to gain the benefit of a team approach with the pharmacist functionally as the "Perioperative Medication Safety Officer" inculcating a culture of safety. This would involve allergy verification, dissemination of drug information, formulary management, facilitation (shortages; look-alike, sound-alike), quality improvement projects, and even research projects. Dr. Donnelly cited survey research showing that "ready-to-use" medications are strongly preferred by practitioners, leading to the idea that collaboration between anesthesia professionals and their pharmacists should lead to consensus on which medications are provided in ready-to-use form in that operating room. He also favored standardization of medications and concentrations, throughout an institution and even across the entire industry. He commented on the large number and quantity of medications in the usual anesthesia workstation, suggesting this is often wasteful and potentially dangerously confusing—the preferable alternative being greater reliance on and



Bona E. Benjamin, RPh

Another advocate for improving operating room medication safety by "teaming up for innovation" with pharmacists and making them an integral part of the operating room team was **Bona E. Benjamin, RPh**, who is director of Medication-Use Quality Improvement for the American Society of Health-System Pharmacists, an organization that recently held an "IV Safety Summit." She cited several studies showing the cost and outcome benefits of pharmacist involvement in medication administration, including specifically one large 2007 study of surgical patients showing those without pharmacist-managed antimicrobial prophylaxis had 52% higher death rates from surgical site infections, 10% longer length of stay, and 7% higher drug charges. Noting

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