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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 the prone position resulting in blindness. With the voluntary efforts of anesthesiologists, nurse anesthetists, and some patients, enough data were collected 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/NINS/index.shtml

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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 133 anesthetics administered and, of those errors, 1 out of 250 is fatal.[1] This translates to nearly 1000 deaths a year in the United States. Acknowledging the 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 Dr. Merry suggested orientation toward managing predictable errors rather than the futile attempt to eliminate all errors. Having a satellite pharmacy in the 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 improve medication safety.

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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 a formal medication safety module reported such reasons as these: medication safety was not a problem, incidents at clinical sites would be handled 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, communication silos, and production pressure. Dr. Cohen suggested that widespread standardization and also the use of pharmacy-prepared bar coded medications 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 and system failure and how this could relate to

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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 the medication administration process (prescribing, transcription, dispensing, and administration—the points at which mistakes occur) are the responsibility 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 interaction with pharmacy service, even if it is an automated dispensing machine or a "smart pump" for a ready-to-use infusion medication.

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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Industry Advises on Prevention of Medication Mistakes

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that the operating room is the most medication-intensive area of the hospital, Ms. Benjamin suggested that now is a great opportunity to coordinate what anesthesia professionals want (medications ready to use, readily available, and easy to store, identify, administer) with what pharmacists want (effective evidence-based processes that are efficient, safe, and compliant with regulatory and accreditation standards and that promote safety through standardization, best practices, security, and control). She concluded with a list of benefits pharmacists can bring to enhance medication safety in the operating room: formulary management; development of evidence-based standard protocols; review of planned/ordered medications for potential problems; analysis of drug use patterns to identify opportunities for improvement; participation in emergencies and maintenance of antidote supplies; support of compliance with regulatory, accreditation, and organizational rules; education on medications, safety programs, and error prevention; and a team culture approach.

Relevant Examples

An example of a safety initiative that could be adapted to operating room medication safety concerns was offered by **Bruce D. Spiess, MD,** from Virginia Commonwealth University and also chair of the FOCUS group (**F**lawless **O**perative **C**ardiovascular **U**nified **S**ystems) of the Society of Cardiovascular Anesthesiologists (SCA). SCA is engaged in a comprehensive longitudinal project to study every conceivable aspect of cardiovascular anesthesia practice utilizing real-time observation as well as literature review to determine why errors occur and develop best practices (with check lists) emphasizing systems, human factors, and the team approach to prevent those errors. A parallel project for operating room medication safety improvement was proposed that would utilize the same design.

A more direct example was presented by **Wilton C. Levine, MD,** clinical director, Department of Anesthesia, Critical Care and Pain Medicine at the Massachusetts General Hospital. Having participated in an exhaustive study of operating room medication practices, he became one of the developers of an anesthesia medication management system that employs a small printer in each anesthesia workstation and a reader that identifies a medication by the bar code on its container and prints a corresponding fully compliant and water proof syringe label in real time ("Smart Label"). He suggested it is impractical to have 100% "ready-to-use" pre-filled syringes for all medications anesthesia professionals use in all anesthetizing locations and that the automated label printer is the application of a technology in place of having a second person check and verify all medications drawn up and administered by an anesthesia professional. The

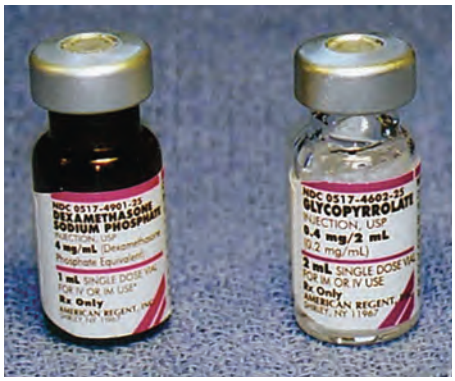

Figure 1. Look-alike medications; left medication is dexamethasone and right vial is glycopyrrolate.

syringe label also has a bar code that is read (with visual and audible confirmation) and recorded by the associated computerized anesthesia automated record/information management system (AIMS). This syringe bar code is easily integrated with AIMS so that at the time of administration, the bar code is scanned to confirm the drug name and concentration, patient allergies, if the syringe has expired, and if the syringe has already been used for another patient. Dr. Levine detailed how this system can also be integrated as the safety system for seamless use with ready-to-use prefilled syringes. He noted that in his institution where some rooms have the technology and others do not, practitioners who have worked with the system always request to be assigned to rooms with the computerized system. He concluded with the belief that technology combined with increased pharmacy services will lead to best (safest) operating room medication practices.

Industry Perspective

Todd N. Jones, RN, director of Marketing, Central Admixture Pharmacy Service (CAPS), a business unit of B. Braun Medical, Inc., described the role of a compounding pharmacy in enhancing operating room medication safety. He suggested there is evidence that standardizing concentrations and diluents improve medication safety, both in general and particularly when transferring patients on life-sustaining infusions from the operating room to postoperative care. Further, he maintained that premixed solutions and prefilled syringes (whether purchased from an outsourced compounding pharmacy like CAPS or prepared in the facility pharmacy) relieve anesthesia professionals of the preparation steps, allowing them to focus more on the patient in the operating room. Another safety issue he commented on was the potential for wrong site/port injection, particularly of dangerous medications accidently injected into an epidural catheter. The potential for separate distinctly incompatible connectors to help prevent such accidents was presented.

Rich Kruzynski, RPh, president of PharMEDium Services, LLC, outlined the extensive market research his company has done on medication administration in the operating room. As a result, his company offers standardized sets of anesthesia medications presented in a standardized array in trays and carts with comprehensive fully compliant labels. Everything is bar coded and compatible with readers utilizing AIMS. Included among the benefits he cited for this approach are full regulatory compliance, lower cost, and the hope for increased medication safety.

Mary Baker, PharmD, medical manager, Global Medical Affairs for Hospira, Inc., addressed the challenges of injectable drug labeling. She suggested that color-coding has drawbacks and that efforts should be directed at making the information in the printing more effectively communicated by the label. Bar coding is essential and standardization of labeling policies is critical, she emphasized.

Timothy W. Vanderveen, PharmD, vice president, Center for Safety and Clinical Excellence for CareFusion Corp., also stressed the unique challenge of total medication management by a single anesthesia professional in the operating room who usually relies on personal habits and experience to execute the process. Reminders of the widely publicized Indiana deaths from heparin dosage errors in newborns and the story of an Ohio pharmacist sentenced to prison after the death of a child due to a compounding error served to emphasize the great responsibility involved in preparing and administering IV medications. He suggested that bar coding technology and automated drug dispensing cabinets in each operating room would help organize and standardize medication practice, promoting medication safety. He noted the added benefit of such a computerized system for tracking controlled medications and maintaining vigilance for any potential drug diversion by caregivers. Another beneficial technology with beneficial safety implications is smart infusion pumps that decrease chances for dose calculation errors, smooth transitions to and from the operating room for patients on critical infusions, and that perhaps someday in the United States will be utilized to administer target-controlled infusions.

The final podium presentation was from **Mark W. Vaughan,** global product director, Hospital Infusion, Smiths Medical North America, who advocated for smart infusion pumps and technology utilizing standardized drug concentrations that simplify the function of the infusion pumps (which soon will be wireless). Traditional pumps are prone to programming errors that could endanger patients. He also promoted unique connectors that would prevent accidental cross injections among IV, epidural, and enteral infusion lines. With the admonition that "pharmacy is your friend," he again stressed standardization of medication preparations as key to improving OR medication safety.

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Conference Leads to Consensus Recommendations

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Small Groups, Big Assignments

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

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

Consensus Building

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

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

Standardization

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

Technology

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

Pharmacy/Prefilled/Premixed

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

Culture

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

Breakout Sessions Develop Practical Recommendations

"Medication Safety," From Preceding Page

"consensus development" session that was chaired by Dr. Robert A Caplan, MD. Each group's spokesperson presented that group's list of action-item recommendations and then all the attendees voted on setting priorities. During each of the 4 small-group presentations, the attendees had 2 votes each and Dr. Caplan was rigorous in enforcing the idea that an attendee could only vote for 2 ideas on the list from each breakout group, thus facilitating the establishment of the top priority recommendations.

Because the central premise of this conference focused on developing measures above and beyond the basics of medication label format that have been discussed for years, it was nonetheless emphasized in the final consensus-development session that everyone involved must never lose sight of the starting foundation concept that there must be fully compliant labeling of all medication containers and syringes used in the operating room as the nucleus of medication safety efforts (see also the American Society of Anesthesiologists' "Statement on the Labeling of Pharmaceuticals for Use in Anesthesiology").[3-5] However, the role, utility, and feasibility of color coding requires additional study and consensus building.

Due to conceptual overlap some ideas for medication safety "action items" were combined or transferred. The resulting list of the action items (practical recommendations for "predictable prompt improvement" in operating room medication safety in the immediate short-term) is presented in Table 1.

In the consensus session there was agreement that facility administrators must be involved in all major system improvements and should be included on committees and task forces that address medication safety in the operating room. It was noted that administrators tend to pay particular attention to regulations and standards, especially those from CMS and The Joint Commission, because of the potential substantial financial implications of non-compliance. Thus, one major theme was the perceived need to convince regulatory and standard-setting bodies to recognize and focus on medication safety in the operating room.

Significant debate occurred regarding the concept of incentives for engaging and improving medication safety in the operating room. The fact that anesthesia professionals are "fiercely independent" and thus reluctant to change their individual practice habits (as related to medication preparation and delivery) to fit a standardized protocol was noted. A question about the possible value of individual financial incentives to practitioners evoked a reference to the initial push in the mid 1980s for adoption of pulse oximetry and capnography for continuous patient monitoring. Various malpractice insurers gave their clients premium discounts for signing a contract to always use the monitors, which clearly helped increase their implementation at a time before those monitors became undisputed universal standards of care. Opinions from participants were mixed regarding a possible similar approach to programs for medication safety in the operating room. Likewise, widely divergent views were expressed about the concept of "selling" improved medication safety strategies and management systems to facility administrators on the financial grounds of increasing efficiency, production, and revenue—with patient safety improvement as almost a side benefit. That idea was opposed by some attendees who believed that medication error reduction and improved patient safety are the real goals that should remain the primary consideration for everyone, administrators included. One comment to this point related to the beneficial impact of standardization on quality; if a process is standardized, it can be integrated, it can be taught, and it can be measured in order to improve efficiency and safety.

A proposal was floated that practice guidelines involving checklists (analogous to the World Health Organization *Surgical Safety Checklist*) are the clearest, most direct ways to improve medication safety in the operating room.[8] This approach allows practitioners to know what is expected of them and allows compliance, and, particularly, change to be measured by an objective benchmark. Further, even though cultural attitudes on education, accountability ("just culture"), and cooperation are harder to put into guidelines and then measure, it was noted that the U.S. Agency for Healthcare Research and Quality has survey tools to measure safety culture.

Wrap-Up and Future Directions

Dr. Stoelting provided closing remarks, which evolved into a discussion with continued lively audience participation. One theme was the perceived need to convince leaders of relevant major national organizations (professional societies, industrial, regulatory, standards, quality improvement, government, foundations) to become involved as champions for improved medication safety in the operating room and as a source of consensus to help achieve it. APSF was viewed as the logical entity to lead this effort, beginning with dissemination of this report.

There was widespread agreement that individual anesthesia professionals, by definition, will possibly have to surrender some of their "independence" and will need to adapt their personal preferences, styles, and habits (regarding medication preparation and delivery) into more standardized practice patterns (likely involving guidelines, protocols, and checklists) utilizing more standardized medications (involving input from pharmacy services) with more reliance on technology. The involved health care facilities and their administrators are critical to the effort, for both moral support to do the right thing and financial support to help make it happen. It is possible the front-line practitioners in the operating room will take some convincing, but culture can change, just as it did regarding intraoperative monitoring years ago.

Today, no anesthesia professional begins an anesthetic without complying with universally accepted approaches to intraoperative monitoring. APSF supports a similar approach for medication safety in the operating room that includes the paradigm of **Standardization, Technology, Pharmacy/Prefilled/ Premixed and Culture (STPC)**. The hope is this change will result in a dramatic reduction in the still-persistent medication errors, which result in patient morbidity and mortality.

John H. Eichhorn, MD, Professor of Anesthesiology at the University of Kentucky, served as the first editor of the APSF Newsletter *beginning with its initial publication in March 1986. He remained as editor until 2002 and continues to serve on the Editorial Board and is a consultant to the APSF Executive Committee.*

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To emphasize the urgent need for changes in medication safety practice both nationally and internationally, please see the Letter to the Editor, page 9, "Accidental Intrathecal Injection of Tranexamic Acid for Cesarean Section: A Fatal Medication Error."

Letter to the Editor:

Accidental Intrathecal Injection of Tranexamic Acid in Cesarean Section: A Fatal Medication Error

by Firouzeh Veisi, MD; Babak Salimi, MD; Gholamreza Mohseni, MD; Parisa Golfam, MD; and Azam Kolyaei, BS

To the Editor:

Medication errors from look-alike ampoules continue to cause serious patient harm resulting from lack of systematic medication safety practices. We report a case of a fatal medication error for an emergency cesarean section for term twin delivery.

Case Description: A 21-year-old woman with a 37-wk twin pregnancy came to the hospital emergency department due to painless vaginal bleeding, which started 6 hours prior to arrival. The patient's initial vital signs were: BP=100/70, T=37, HR=94/min, RR=18/min. Fetal heart rates were 140/min and 116/min. Emergency ultrasound revealed decreased amniotic fluid in Twin A and an incomplete placenta previa. The patient's serum hemoglobin was 10 mg/dl. The patient was scheduled for a cesarean section due to vaginal bleeding and placenta previa.

The anesthesiologist decided to administer spinal anesthesia and asked his technician to give him 1.5% bupivacaine. The technician took out an ampoule from a box, opened it, and gave it to the anesthesiologist. The anesthesiologist injected the drug after confirming free flow of cerebrospinal fluid. After injection, the patient was placed in the supine position for prepping and draping. Approximately 3 minutes after injection of the drug the patient began tossing and turning, and complained of severe sharp pain from her waist to her lower extremities. The patient became dysphoric and complained of dizziness. Her vital signs at that time were: RR=18/min, PR=100/min, BP=110/70. There was no demonstrable sensory or motor block in her lower extremities. Consequently, general anesthesia was emergently induced for ongoing vaginal bleeding and fetal distress. Both twins were delivered uneventfully with Apgars of 5 and 6 for Twin A and 8 and 9 for Twin B.

Figure 1. Look-alike ampoules: Tranexamic acid and bupivacaine.

At the conclusion of surgery, the patient developed a tachyarrhythmia at an approximate rate of 280, which was treated with 100mg of lidocaine, as the anesthesiologist discontinued the volatile anesthetic. Approximately 30 minutes after the attempted spinal anesthetic, the patient was noted to have severe jerking motions in her extremities and nystagmus consistent with a seizure. Pupils were alternately dilating and constricting. She received sedative drugs and was mechanically ventilated. Emergency serum electrolytes were within normal limits. She subsequently developed ventricular tachycardia, which was initially responsive to cardioversion. Ventricular tachycardia recurred, and was no longer responsive to cardioversion. Her rhythm progressed to ventricular fibrillation, which was refractory to treatment, and then asystole. CPR was performed for 1 hour without success.

After consultation with a neurologist, the spinal anesthetic was suspected of causing the fatal reaction. After recovering and reexamining the used drug containers, we found an empty tranexamic acid ampoule instead of a bupivacaine ampoule. Tranexamic acid is not a routine drug in our operating room, but it had been used to control a nonobstetric patient's bleeding some weeks ago. Residual unused ampoules previously were put in the drug chest instead of sending them back to pharmacy. When the bupivacaine ampoule was compared to the tranexamic acid ampoule, we found that they both had the same volume / size, color, shape, and font on the label (see Figure 1).

Tranexamic acid is a drug used to inhibit fibrinolysis. It is a drug not typically stocked in the obstetric or other operating room because of its rare usage. Despite this seemingly rare juxtaposition of events in this case report, there are 4 other publications of accidental intrathecal injection of tranexamic acid with resultant seizures.[1-4] Of these 4 reports, 3 patients who had been given a smaller volume of tranexamic acid via intrathecal injection survived with minimal or no permanent sequelae. The 4th patient, who had been given a tranexamic acid dose similar to that in our case report, developed seizures, ventricular fibrillation, and died.

Most drug errors occur during general anesthesia. This may be a reflection of the larger number of general anesthetics performed and the greater number of drugs used during general anesthesia compared to spinal anesthesia. Other drugs, which have mistakenly been injected into the intrathecal space and resulted in death, include contrast agents, muscle relaxants, penicillin, and chemotherapy drugs.

Drug errors may be minimized by the following procedures: 1) a standardized arrangement of drugs in the operating room; 2) reading the drug label prior to drawing up the drug; 3) drug companies creating different (size, color, shape) drug labels and vials; and 4) continuous review of medication errors in hospitals to identify causative associated factors and develop systematic interventions for prevention.

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Dear SIRS

Why Do New Defaults Turn Off CO_2 and Apnea Alarms?

S AFETY
I NFORMATION
R ESPONSE
S YSTEM

Dear SIRS refers to 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 responses from manufacturers and industry representatives. **Dear SIRS** made its debut in the Spring 2004 issue.

Dear SIRS:

GE has proposed "approved" changes to their default ventilator settings on our Aisys anesthesia machines which set the CO_2 and/or Apnea default alarms to OFF when in the manual ventilation mode. I am concerned about the safety of these default settings.

Patricia Roth, MD
San Francisco, CA

Dear Dr. Roth,

Thank you for your concern. We have applied decades of clinical experience and customer feedback to ensure that our anesthesia machines are safe and effective for clinical practice around the world, and additional feedback such as yours is always welcome. I'd like to start by reassuring you that every Aisys machine leaves the factory with Apnea and CO_2 alarms active during manual ventilation. Deliberate action is required by the clinician and/or institution to allow these alarms to be turned off, and even in that case the circumstances are limited as described below.

As I am not sure which version of software is currently installed on your Aisys machines, I will use Aisys Version 6.0 software for illustration purposes. We continue to improve the features and functionality with each software release, so I encourage you to consult the User's Reference Manual provided with your machine or with your latest software upgrade for exact details.

In the Aisys machine the Apnea alarm can come from 2 sources, the end-tidal CO_2 measurement from the gas monitor, and the measurement of exhaled volume from the patient. I'll describe each one individually.

In order to turn off CO_2 alarms, including Apnea, during manual ventilation the user must choose to turn them off. The user can do so either in the Start Case menu (where they always default to "On") or in the Alarm Setup menu once the case has started. Switching from manual to mechanical ventilation automatically turns the CO_2 alarms to "On." The CO_2 alarms will stay in the "On" state unless or until the user returns to manual ventilation and again chooses to turn them off using the Alarm Setup menu. Simply switching from mechanical to manual ventilation leaves the CO_2 alarms in the "On" state. The CO_2 alarms cannot be turned off during mechanical ventilation.

The situation with the Volume Apnea alarm depends on how the machine is configured. By putting the machine into "Super User" mode there are

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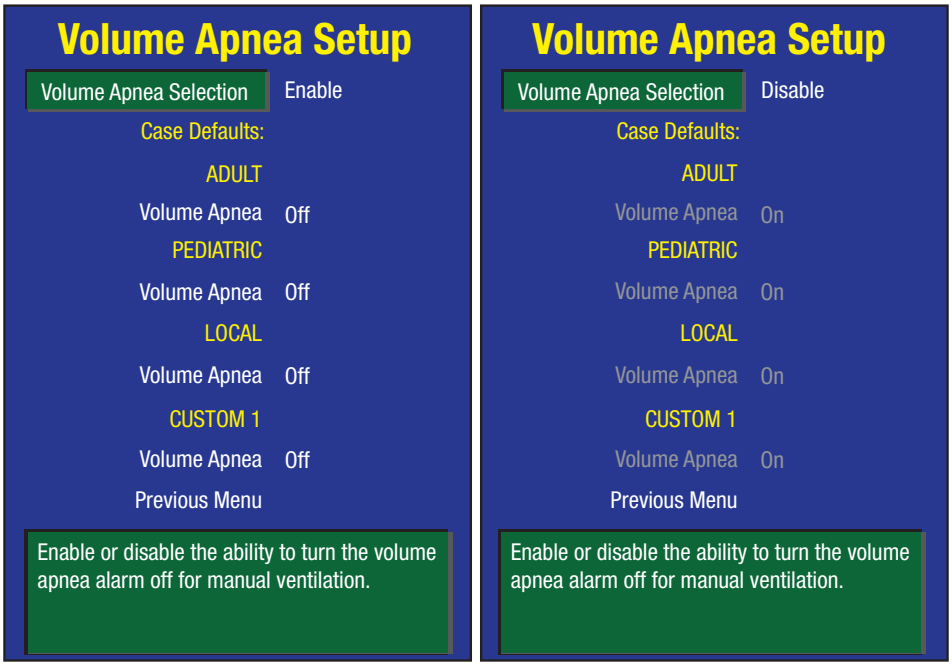

Figure 1. Volume Apnea Setup Menu in "Super User" mode. Left, the hospital has enabled the ability to turn the Volume Apnea alarm off during manual ventilation. Right, the hospital has disabled the selection of Volume Apnea off.

GE Clarifies Defaults and Options

"Dear SIRS," From Preceding Page

many configuration selections available that allow tailoring of the machine to better meet the needs of your particular practice and institutional policies. There are of course factory defaults for all of the configuration selections, but it is always a good idea to review the selections available and decide what is best for your institution. The configuration selections available in "Super User" mode are described in your User's Reference Manual. There are additional configurations that are only available to a trained service person—this could be a GE service engineer or someone in your local biomedical department. One handy feature available to service personnel is the ability to copy a configuration from one machine to another, allowing you to configure your machines identically based on the selections made for your institution.

One of the menus available in "Super User" mode is shown in Figure 1. As you can see, this menu allows configuration of the Volume Apnea selections and default values for each of the 4 selectable case types. If the Volume Apnea Selection is set to disable at the top of the menu—which is the factory default—the menu selections that allow the Volume Apnea alarm to be turned off during manual ventilation will not appear on the menus during clinical use.

Note that even if the Volume Apnea selection is enabled and the default is configured to "Off," when the user switches from mechanical ventilation to manual ventilation a message will appear on the screen saying "Select Yes to turn off the volume apnea alarms during manual ventilation." There are 2 selections available: "Yes" and "No" and the user must select "Yes" to turn the alarm off.

I hope this explanation addresses your concerns, and thank you for the opportunity to remind everyone of the importance of properly configuring the equipment for their needs.

Sincerely,
Kevin Tissot
Engineering Shared Services Manager, Anesthesia Life Support Solutions - GE Healthcare

Note: Dr. Roth has informed us recently that a new version of software from GE Healthcare was installed and solved her concerns.

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Exposure to Ultraviolet Radiation in the Operating Room

Q **Dear Q&A,**

What are the health hazards from UV exposure when UV radiation is used for infection control in the operating room? Could you comment on the effectiveness of sunscreen and Personal Protective Equipment in protecting patients and OR staff? What safety measures should be in place to monitor for photokeratitis, basal cell carcinoma, actinic keratitis, and melanoma?

Kathy Crysel, CRNA
Winston Salem, NC, 27157

A **Dear Ms. Crysel,**

Thank you for your question regarding the hazards of using ultraviolet radiation in operating rooms to control infections.

The development of virulent bacteria that are resistant to multiple antimicrobial treatments is occurring around the world[1] and one of the proposed solutions to minimize wound infections is exposure to ultraviolet radiation. Ultraviolet germicidal irradiation (UVGI) appears to be effective in reducing the risk of surgical site infection[2-4] including MRSA. The routine use of ultraviolet radiation in orthopedic operating rooms is well known and has been recently investigated by National Institute for Occupational Safety and Health.[5]

Ultraviolet radiation can be divided into 3 regions of the ultraviolet spectra as illustrated in Table 1. The most common wavelength in operating rooms because of its germicidal effects is 254 nanometers, in the UV-C range, which is also invisible to humans. All of the UV wavelengths can be responsible for health risks dependent upon the intensity and wavelength of the source, distance from the source, and length of exposure to the source. Table 1 also summarizes the hazards.[5]

Table 1: Ultraviolet Radiation Wavelength and Corresponding Tissue Damage

Band	Wavelength	Primary Visual Hazard	Other Visual Hazard	Other Hazards
UV-A	315-400nm	Cataracts of lens		Skin cancer, Retinal burns
UV-B	280-315nm	Corneal injury	Cataracts of lens, Photokeratitis	Erythema, Skin cancer
UV-C	100-280nm	Corneal injury	Photokeratitis	Erythema, Skin cancer

Ocular damage generally begins with photokeratitis, but can also result in keratoconjunctivitis and photo-keratoconjunctivitis depending upon the dose and length of exposure. Symptoms may not be evident until 6-12 hours after exposure and may include an abrupt sensation of sand in the eyes, tearing, and eye pain, possibly severe. These symptoms generally resolve within 24-48 hours, leaving no permanent damage. Eye damage can be completely avoided by wearing protective eyewear in any and all cases where direct UVC energy may be present.

Cutaneous damage consists of erythema; it's like sunburn with no tanning. Acute overexposure to UV-C energy can be incapacitating, but generally regresses after several days, leaving no permanent damage, possibly because of limited depth of skin penetration. Skin damage can be completely avoided by covering all exposed skin in any and all cases where direct UV-C energy may be present. While keratoacanthoma-like tumors appeared in rats exposed to UV-C, and squamous-cell carcinoma and fibrosarcoma appeared in mice, UV-C has not been shown to be associated with melanoma or basal cell carcinoma.[6] There are no conclusive data to link UV-C to skin cancer in humans.

Exposure threshold limit values for UV radiation have been established by the American Conference of Governmental Industrial Hygienists.[7] The Occupational Safety and Health Administration (OSHA) has not established a standard for safe exposure to ultraviolet light. However, the National Institute for Occupational Safety and Health (NIOSH) developed a permissible exposure limit at a wavelength of 254 nanometers (the peak intensity of most UV-C germicidal lamps) which is 0.2 microwatts/cm^2 for 8 hours. The severity of effects from UV light are dependent upon the intensity and wavelength of the source, distance from the source, length of exposure to the source, sensitivity of the individual, and the presence of sensitizing agents.[5]

The National Institute for Occupational Safety and Health studied a Boston Hospital that used UV-C radiation produced by ceiling mounted UV lamps in orthopedic operating rooms. Personal dosimetry was employed to measure UV-C exposure in 3 orthopedic operating rooms. Orthopedic OR staff wore scrub shirts and a warm-up jacket or surgical gown to make 2 layers of personal protective equipment. Dosimetry measurements indicated safe levels of UV-C measured at the skin of the shoulder (under 2 levels of personal protective equipment). However, UV-C exposure was 6-28 times the NIOSH recommended

See "Q&A," Next Page

Numerous questions to the Committee on Technology are individually and quickly answered each quarter by knowledgeable committee members. Many of those responses would be of value to the general readership, but are not suitable for the Dear SIRS column. Therefore, we have created this simple column to address the needs of our readership.

Q&A

UV Effects Dependent Upon Several Factors

"Q&A," From Preceding Page

exposure limit when dosimeters were placed on the surface of the personal protective equipment. Not all surgical hats, gowns, and masks protect adequately from UV-C radiation.

In summary:

The severity of effects from UV light are dependent upon the intensity and wavelength of the source, distance from the source, length of exposure to the source, sensitivity of the individual, and the presence of sensitizing agents.[5] Sun screen is not recommended as a reliable method of protection from UV-C. NIOSH recommends a UV-C and Personal Protective Equipment training program for employees who will be exposed to UV-C in the operating room. Personal Protective Equipment must be approved for use in the UV-C environment. The recommendations include establishment of a medical surveillance program for all OR personnel exposed to UVGI with periodic skin screenings.[6]

A. William Paulsen, Ph.D.
Chair, APSF Committee on Technology
Vice President of Education
South University, Savannah, GA

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Letter to the Editor

Chlorhexidine-Alcohol Preparation Solution Contributes to Risk of Combustion

To the Editor:

A recent article in the *New England Journal of Medicine* recommends chlorhexidine-alcohol as a surgical site preparation solution.[1] However, the use of an alcohol-based preparation solution represents a step backwards in terms of operating room fire safety because it increases the risk of combustion. Thus, important safety measures must be undertaken to prevent the occurrence of operating room fires when an alcohol-based preparation solution is used. Such fires have already been reported.[2,3] The alcohol-based preparation solution must be applied without pooling and allowed to completely dry before surgery begins. When the site of surgery is near an open source of oxygen such as a nasal cannula and an ignition source such as cautery is employed, extreme care must be used to prevent the occurrence of a fire.

Mitchel B. Sosis, MS, MD, PhD
Holy Redeemer Hospital and Medical Center
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Letter to the Editor

Non-Opiate Analgesics & CPAP May Prevent Postoperative Respiratory Depression

To the Editor:

After reading Dr. Eichhorn's review of the 2009 ASA meeting patient safety exhibits and Dr. Overdyk's letter regarding postoperative opioid use in the winter 2009-2010 *APSF Newsletter*, I'd like to add the following thoughts. We do have better ways of reducing postoperative pain and opiate-associated respiratory depression; they were demonstrated at last year's ASA meeting. Specifically, using non-opiate analgesics reduces postoperative opiate requirements and therefore opiate-associated side effects. In the scientific exhibits the group from Temple (or Hahnemann) University demonstrated the use of postoperative intravenous ketamine infusion as an effective and safe alternative to systemic opiates. Clearly, other available modalities of providing better and safer analgesia exist (e.g., regional anesthesia and other systemic non-opiate analgesics).[1,2] We should pursue the use of these and other analgesic alternatives.

Secondly, we should encourage the use of immediate postoperative continuous positive airway pressure (CPAP) for patients following abdominal surgery in the obese population or those with sleep apnea. Two disposable CPAP masks were presented by vendors at the meeting. Recent literature supports immediate and continued use of CPAP.[3,4] Now with the availability of inexpensive disposable masks, such treatment is readily available.

Both the use of non-opiate analgesics and postoperative CPAP will help reduce postoperative respiratory failure. Let's use them!

Fred Rotenberg, MD
Providence, RI

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Web Application to Track Patient Safety During Sedation

The University of Alabama at Birmingham (UAB) has launched a free web application for tracking and notification of events that occur during procedural sedation and analgesia (PSA). Participating institutions have the ability to access their confidential data, run personalized reports, track user-defined metrics and comply with Joint Commission standards for tracking and notification of events that occur during PSA.

The number of noninvasive and minimally invasive procedures performed outside the traditional operating room has grown over the last several decades. These procedures performed in doctor's offices, same-day surgery centers, procedural suites, or other non-operating room hospital sites, usually do not require general anesthesia. PSA may include a combination of sedative and analgesic agents and is administered by a medical professional who often times has no formal training in anesthesiology.

End-users at participating institutions will complete a short online case report form for each PSA administered. The web application transfers the unidentified information into a database that may be queried securely by program administrators at participating institutions. No HIPAA-protected information is retained within the database. The institution may then use the data for internal reviews of practices and standards or for reporting to accreditation agencies such as Joint Commission. Events that occur during PSA initiate an automated notification to pre-designated institutional personnel. In addition to events that occur during PSA, the application tracks interventions required and monitoring modalities utilized.

SafeSedation was developed by Chad Epps MD, Departments of Anesthesiology and Clinical & Diagnostic Sciences and is supported by a grant from Oridion Capnography, Inc. Under UAB IRB approval, Dr. Epps will use the unidentified aggregate patient data to take an across-the-board look at PSA safety and the way it is currently administered and monitored. To view a demonstration video and sign up for a free account, go to www.SafeSedation.org.

Letter to the Editor:

Growing Pains: Unavoidable Collateral Damage or Time for a Warning?

To the Editor:

There is no question that videolaryngoscopy (VL) has become one of the preferred methods for performing endotracheal intubation; its use has extended beyond perceived "difficult" patients, in the controlled setting of the OR, to use in the emergency department and also by paramedics in the field. The majority of the literature is positive, but as with other topics in medicine—especially when concepts or devices are relatively new—positive reports are reported more commonly than negative ones.

Recently I learned of a complication, a soft palate perforation during a routine, atraumatic, single attempt oral intubation requiring surgical repair, which occurred to one of my colleagues using a GlideScope. This prompted me to review the literature on the subject and much to my surprise I found several similar cases and descriptions of this complication, more commonly with the use of the GlideScope, but more recently with the McGrath VL as well.[1-5] There are multiple potential predisposing factors to consider. Unfortunately, the sources are case reports, making assumptions or conclusions difficult. However, 2 factors stand out that I believe should be further scrutinized: 1) all cases involved the use of a stylet; its rigidity and angle of configuration vary (most reports claim that the tip of the stylet did not protrude beyond the tip of the ETT); and 2) when using indirect laryngoscopes such as VL (unlike when direct laryngoscopy is used), the user is looking at a screen rather than directly at tissue, and also the introduction of the tube is "blind" until the tip makes its appearance as it passes to the oropharynx. Therefore, during this journey, especially if there has been difficulty or multiple intubation attempts, it is possible for trauma to oropharyngeal structures to occur as the literature suggests.

Understanding that a Pandora's Box is about to be opened, should we modify our practices and use these devices in a different manner? For example, only looking to the screen once we have directly watched the blade pass behind the tongue? Is this an indication of things to come and channeled devices provide some advantage in this regard? Should we look further into VL and stylet use, its shape, angle, and rigidity? Should a warning be sent stating there are cases of palatal damage with the use of these devices, or is this just due to growing pains, or collateral damage from the use of these novel devices and there is no reason to be concerned?

Felipe Urdaneta, MD
Gainesville, FL

Dr. Urdanetta has no financial relationship with any manufacturer of airway equipment or airway devices.

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Letters to the Editor

An example of yet another medication error—of sorts!

Gas Cylinder Colors ARE NOT an FDA Standard!

To the Editor:

In a recent submission to the *APSF Newsletter*, we discussed one application of color coding in anesthesiology practice, specifically how a mislabeled vaporizer was not detected because clinicians relied on the color of the vaporizer and not the label with the name of the anesthetic.[1] We recently discovered in our operating rooms an example of the converse, an important component that was properly labeled, but improperly colored.

An "E" cylinder fitted to the air yoke of an anesthesia machine was a primer-grey color, not the expected yellow color that indicates medical air in the United States (Fig. 1). There was even a bit of dust on the dome of the tank, indicating that the tank had been on the machine for some time. The cylinder was labeled "Medical Air," and delivered an FIO_2 of 0.21 and no carbon dioxide when analyzed by the gas analyzer on the anesthesia machine. Comparison with an "E" cylinder of carbon dioxide showed the 2 shades of grey were different (Fig. 2).

It may be a surprise to most practitioners that color coding of medical gas cylinders is not mandatory in the United States. The FDA has only made recommendations in agreement with the Compressed Gas Association (CGA) that "each container is of the proper color to correspond to any color-coding system employed, such as that recommended by the CGA in its pamphlet C-9, *Standard Color Marking of Compressed Gas Cylinders Intended for Medical Use in the United States.*"[2] It is up to individual suppliers of medical gas to follow or ignore the tank color guidelines.

Figure 1: From left to right, properly colored and labeled oxygen cylinder and nitrous oxide cylinder next to a gray, improperly colored medical air cylinder that should be yellow.

In conclusion, we remind our colleagues that color coding of medical gas cylinders is not required by regulation and tank color can be misleading. Gas cylinder content should always be carefully verified by close inspection of the tank label.

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Lexington, KY

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Figure 2: Two different shades of gray.

Is Hydromorphone PCA Safer Than Morphine PCA?

To the Editor:

Concerning respiratory depression with patient controlled analgesia (PCA),[1] there is reason to suspect hydromorphone may be inherently safer. Hydromorphone has a more rapid and complete penetrance to the central nervous system. Hence, peak effect occurs in about 10 minutes. With morphine and its metabolites, you may achieve 70% of its peak effect in 10 minutes, but the peak effect may not occur for up to 90 minutes. Hence, if you titrate to effect with 10 minute lockouts, with morphine, you are setting up for a delayed overdosage, but not with hydromorphone. Has there been a study comparing the safety of hydromorphone (Dilaudid) vs. morphine PCA?

Jonathan Roth, MD
Philadelphia, PA

Reference

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Hospital Coalition Group Endorses APSF Recommendations for PCA Monitoring

The Indianapolis Coalition for Patient Safety (ICPS) comprised of chief executive, medical, nursing, quality, and pharmacy officers from 7 Indianapolis Health Systems has studied and endorsed, in principle, the APSF recommendations for monitoring patient controlled analgesia (PCA) in the postoperative period.[1,2] In January 2010, ICPS approved the following "Opioid-Induced Respiratory Depression" document consisting of "Facts, Recommendations, and Immediate Steps for Coalition Members."

Facts

(1) Opioid-induced respiratory depression in postoperative patients occurs at an unknown incidence. Rates quoted in the literature range from 1-40% depending on the definition used. At least 3 Coalition hospitals have experienced known or suspected significant events related to opioid-inducted respiratory depression.

(2) Rates of opioid-induced respiratory depression are known to be higher among patients receiving continuous opioid infusions compared to PCA. By extension an opioid dosage regimen that is not related to demand by the patient (infusions or single injections in the neuraxis, transdermal techniques) may also put patients at increased risk of respiratory depression.

(3) The literature has delineated patient populations likely to be at higher risk for respiratory depression with postoperative opioids, including patients with sleep apnea, the opioid-naïve (for reference, a patients is considered not opioid-naïve if they have been receiving any form of opioid for 7 or more days preoperatively), the elderly and infirm, and those receiving other CNS depressants. However, patient not in these higher-risk groups can also suffer this complication.

(4) It appears that monitoring of patients receiving postoperative opioids can detect otherwise-unrecognized respiratory depression. It is unclear whether this recognition (and, presumably, intervention) will improve final outcomes, but it seems probable.

(5) Oximetry, while ubiquitous, easy to use, and relatively inexpensive, is a relatively poor detector of respiratory depression/hypoventilation, particularly in the presence of supplemental oxygen.

(6) Capnography is the most reliable detector of hypoxia and hypoventilation. It is unfortunately more difficult to use, less comfortable for the patient, and is prone to false positives related to equipment failures. Capnography is presently rarely used in hospitals outside of operating room settings, and implementation outside of ICU and PCU settings may be difficult. The capital requirements for monitoring all postoperative patients with capnography may be very large.

Recommendations

(1) Hospitals should develop an action plan with a timeline for implementation of monitoring for postoperative respiratory depression. It would be rational to begin with identified higher-risk patients.

(2) Ideally, patients would be monitored with both oximetry and capnography. If supplemental oxygen is **not** being administered, monitoring with only oximetry is acceptable. If supplemental oxygen is administered, monitoring with capnography with or without oximetry is desirable.

(3) A closed-loop system, which stops or pauses opioid dosing if respiratory depression is detected, is desirable. Systems are most ideally centrally monitored. In any case, alarms should be audible or otherwise available to the primary caregiver, and a mechanism for prompt response should be in place.

(4) Better screening for known factors that increase risk should be conducted on all patients, not just those who are pre- or postoperative.

(5) Coalition hospitals should reexamine the use of continuous-infusion PCA techniques, especially in patients known or considered to be at risk for sleep apnea and opioid-naïve patients. Consider whether continuous PCA infusions should carry automatic stop dates, limitations on duration, or requirement for reevaluation of the patient prior to continuing.

(6) Emphasis should be placed on administering supplemental oxygen only to patients where it is needed to maintain acceptable oxygen saturation.

(7) Hospital staff should be educated in the manifestations of this complication and how to monitor for it. Significantly, the treatment of hypoxemia in patients receiving opioids will generally include supplemental oxygen, which, in the absence of a concomitant intervention to support ventilation, is the wrong response in patients who are hypoxemic due to opioid-induced respiratory depression.

(8) Non-opioid pain relief techniques (regional and local anesthesia, nonsteroidal medications) should be encouraged to decrease opioid requirements.

(9) Selection of patients suited to PCA techniques should be better defined, and hospitals should revisit who is pushing the PCA button.

Immediate Action Steps for Coalition Members

(1) PCA: Reevaluate use of non-demand pain therapies for acute postoperative pain (continuous infusion PCA or neuraxial, transdermal, single shot neuraxial). Develop criteria for suitability of patients for PCA based on ability to self-dose, and consider limitations on duration of PCA. Develop family education materials to discourage family administration of PCA medications.

(2) Encourage use of non-opioid pain therapies (regional and local infiltration anesthesia/analgesia, nonsteroidal analgesics when appropriate, and other non-opioid adjuvants).

(3) Discourage use of routine postoperative oxygen supplementation, particularly if oximetry is used for postoperative monitoring of ventilation.

(4) Educate bedside caregivers on the possibility and recognition of respiratory failure with hypercapnea despite the absence of arterial hypoxemia, as when supplemental oxygen is being administered. Emphasis should also be placed on understanding that postoperative desaturation may be due to hypoventilation, and that the addition of supplemental oxygen or increased flow rates of supplemental oxygen are not necessarily the correct treatment.

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Letter to the Editor:

Syringe Labeling Made Simple

To the Editor:

Syringe swap is one of the most common causes of medication error in the practice of anesthesia.[1]

These errors are rarely published since they are either of little consequence, are professionally uncomfortable to admit, or result in litigation that inhibits outcome reporting. We are aware of several cases that fit this description. Ephedrine and cefazolin injected into the epidural space were cases that had no consequence. Vecuronium mixed and immediately injected intravenously by an exhausted anesthesiologist into a conscious patient resulted in harm. The intent was to give cefazolin. Thirty-four milligrams of epinephrine in an unlabeled syringe left on the prep table was mistaken for bupivacaine and was injected into the knee of a patient under general anesthesia. Myocardial infarction, pulmonary edema, and cardiopulmonary failure resulted. A properly labeled syringe of mivicurium was injected in error into the caudal epidural space of a young patient by an anesthesiologist who misread the label, hand written by another anesthesiologist as "Marcaine." Neuraxial injury was purported to be a consequence.

These cases had common characteristics. In every case the medication was drawn into an unlabeled syringe either with the intent of subsequently finding and applying the correct label, hand writing the label, or of never labeling the syringe at all but instead immediately administering the medication. A propagating factor in most was the absence of a proper preprinted label immediately available for the medication at issue.

Complications from unlabeled or mislabeled syringes has in part prompted the Joint Commission on Accreditation of Healthcare Organizations to create National Patient Safety Goal 03.04.01: "Label all medications, medication containers (for example, syringes, medicine cups, basins), or other solutions on and off the sterile field." Suggestions for compliance have included special label printers[2,3] and computerized barcode systems.[4] A common institutional remedy is to threaten disciplinary action against individual anesthesiologists for "not labeling your syringes" while simultaneously failing to make proper labels available. And the unfortunate selection by JCAHO of unlabeled propofol syringes as appropriate for administrative sanction[5] reduces the issue to farce when in fact a real problem exists.

With the Medication Safety in the Operating Room Conference having been held in January, we would like to offer a simple, practical, and low cost approach that allows for compliance with the JCAHO standard, will likely reduce medication errors, and can be implemented using existing infrastructure in any hospital.

It is so simple it can be stated on only a few words: **"A re-usable syringe-compatible label is applied (by the pharmacy or the manufacturer) over the cap of every injectable medication used in the operating room."** This solution both provides the right label for the right medication and also compels the anesthesiologist to remove the label to access the drug. The most obvious place to put the label is on the empty syringe that is about to be filled. This eliminates the error of "I filled the syringe but there was no label." Roche has recently adapted this idea for some vials of midazolam as depicted in Figure 1.

Should the FDA require this type of packaging for all injectable medications? We think so. A standardization of the size, color, and font of labels for all injectable drugs, detachable from the top of the vial, would make proper syringe labeling a quick, uniform, effective, and safe process.

Figure 1. Top photo demonstrates medication vial with reusable adhesive medication label. This label is removed from the vial and applied to the syringe that was used to draw up the medication.

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Medical Student IV

Bruce P. Kingsley, MD
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A Statement by the Executive Committee of the APSF

From time to time, the Anesthesia Patient Safety Foundation reconfirms its commitment of working with all who devote their energies to making anesthesia as safe as humanly possible. Thus, the Foundation invites collaboration from all who administer anesthesia, all who supply the tools of anesthesia, and all who provide the settings in which anesthesia is practiced, all individuals and all organizations who, through their work, affect the safety of patients receiving anesthesia. All will find us eager to listen to their suggestions and to work with them toward the common goal of safe anesthesia for all patients.

Letters to the Editor:

Distractions in the Operating Room:

Should the Use of Personal Computers Be Banned during the Administration of Anesthesia?

To the Editor:

Due to the availability of wireless technology, the personal laptop computer is making its way into operating rooms. While useful in many instances, it can be a distraction as well as taking up space and obscuring the view of the monitoring array. Slagle and Weinger[1] note that with the introduction of electronic patient care information, the opportunities and allure of electronic non-patient care activities, e.g., web surfing, are increasing.

A few reports of cell phone texting during driving and operating heavy machinery and trains have made headlines. One car magazine conducted a test to determine how long it takes to hit the brake when sober, when legally drunk at 0.08 alcohol level, when reading e-mail, and when sending a text. When driving 70 miles per hour on a deserted air strip a driver reacted slower when texting and e-mailing than when legally drunk.[2] The results:

Unimpaired: 0.54 seconds to brake

Legally drunk: add 4 feet

Reading e-mail: add 36 feet

Sending a text: add 70 feet

It is intriguing to consider whether parallels can be drawn between texting and driving and computer use during the administrations of anesthesia.

The introduction of new technology and the impact it has on a multitude of actions is not declared until someone or something is involved in an incident that causes attention. A recent example occurred when 2 pilots apparently became so engrossed in the use of laptop computers that they overshot their destination. They were so focused on their laptops that they were out of communication with air traffic controllers and their airline for more than an hour. They didn't realize their mistake until contacted by a flight attendant about 5 minutes before the flight's scheduled landing.[3] A Federal Aviation Administration (FAA) Administrator commented that, "The pilots forgot that their first job was to focus on flying the plane." He continued, "I can't regulate professionalism. With everything we know about human factors, there are still those who just ignore the common sense rules of safety." He also noted that the pilots lost total situational awareness.[4]

Routine intraoperative anesthesia care has already been compared to aviation and both have been described as consisting of hours of boredom punctuated by moments of terror.[1] These examples invoke the need to question the activities of anesthesia providers. Should they surf the internet and answer e-mail during surgery? Can they be trusted to monitor themselves so that they do not become detached? This author is aware of at least one institution that has addressed the issue of intraoperative personal computer use by establishing a policy prohibiting it. This was enacted after an anesthesia provider failed to observe that the surgery had ended because his attention was diverted by the use of his computer.

Policies and procedures are developed to establish uniform protocols for every patient. Policies help to dictate actions and reinforce the decision making process as well as ensure performance is consistent and meets the institution's and patient's needs.

Hospitals have a huge role to play in the provision of a safe health care environment. Since clinical training and experience do not necessarily address use of intriguing new technologies, having a policy of no personal internet use would enhance patient safety. All members of the OR team would be focused on the patient, increasing the safety of the patient as well as promoting a sense of teamwork.

Steven Dean, CRNA, MS
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