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NEWSLETTER

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2017 Marks 30 Years of APSF Research Grants

by Richard D. Urman, MD; Karen L. Posner, PhD; Steven K. Howard, MD; and Mark A. Warner, MD

The Anesthesia Patient Safety Foundation (APSF) has awarded nearly $12 million in funding for anesthesia patient safety research projects over its 30-year history. There were very few funding opportunities for patient safety research in any specialty, let alone anesthesia, when the research program began in 1985.[1] The term "patient safety" was relatively new, with the specialty of anesthesiology recognized as a health care leader in the adoption of patient safety as an explicit goal of patient care. APSF became the first foundation dedicated solely to patient safety. One of the most important goals of the APSF was to promote research to improve anesthesia patient safety, and the organization devoted significant monetary resources in support of that goal. The first research grants were awarded in 1986.[1] In the early years, small grants of $35,000 were awarded ($74,000 in 2017 dollars adjusted for inflation). The maximum award increased over the years to both keep up with inflation as well as to expand the scope of the projects. Increases in the maximum award amount in 1997 kept up with inflation, while the increase in 2000

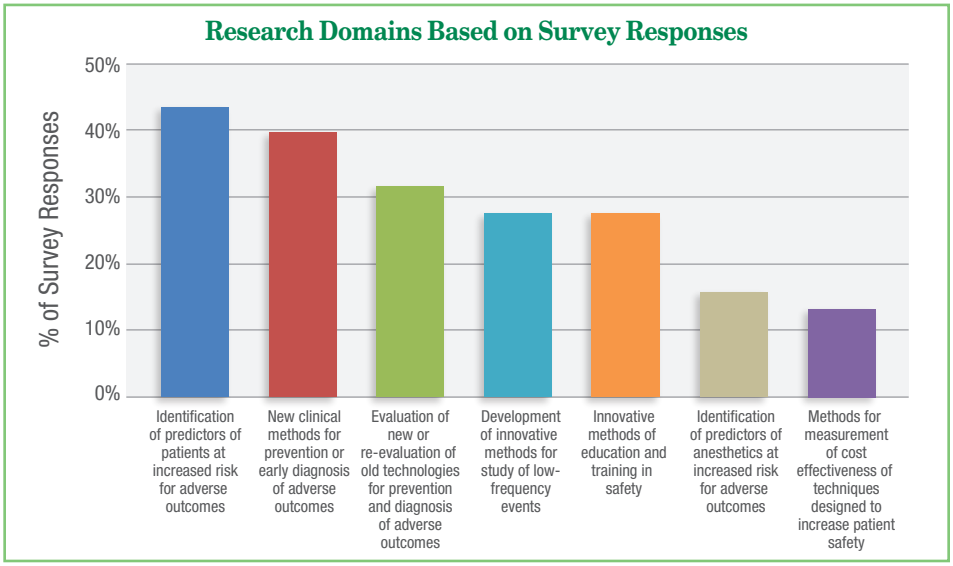

Figure 1: Research domains based on survey responses. Note that some respondents indicated more than 1 category. "Other" = 12% of responses

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Opioid-Induced Ventilatory Impairment: An Ongoing APSF Initiative

by Steven Greenberg, MD, FCCP, FCCM

A substantial number of preventable deaths and other adverse events are associated with opioid-induced ventilatory impairment (OIVI).[1] In fact, opioids are the most common category of drugs prescribed in U.S. hospitals today and the second most common category (hormone and synthetic substitutes being the first) associated with serious patient adverse outcomes.[2,3] While the exact incidence of OIVI in hospitals is difficult to quantify, one study suggested that it may occur in as many as 1 in 200 postoperative patients.[4] Unfortunately, risk stratification and heightened awareness of risk factors does not identify all patients who develop postoperative OIVI.[5]

The APSF's mission is the ongoing improvement of patient safety through advancement of research, education, and quality improvement programs that stimulate ideas for positive safety change. As one step toward fulfilling that mission, the APSF has sponsored two multidisciplinary conferences: the first one in October 2006 in San Francisco and the most recent one in June 2011 in Phoenix. The Phoenix conference was titled, "Essential Monitoring Strategies to Detect Clinically Significant Drug Induced Respiratory Depression in the Postoperative Period." The premise of the conferences was summarized by the statement that, "No patient shall be harmed by opioid-induced respiratory depression in the postoperative period."[5] The consensus of the 136 conference participants was that continuous electronic monitoring should be utilized for postoperative patients receiving opioids. At that time, pulse oximetry was determined to be the most reliable and readily available monitor in those patients not receiving supplemental oxygen.[5] In addition, if supplemental oxygen is being used, the consensus was to use monitors of gas exchange (i.e., capnography) to detect hypoventilation.[5] Although participants recognized that the lack of local resources may thwart universal continuous monitoring, they hoped to see a period when all patients receiving opioids would be monitored for OIVI.[5] As part of its ongoing efforts in this area, the APSF developed an innovative educational video with real-life patient and family experiences involving OIVI (https://www.apsf.org/resources/oivi/). Experts in this field, with the support of APSF, have continued to promote the use of continuous electronic monitoring for those patients receiving postoperative opioids. In addition, several research projects involving OIVI have been funded by the APSF to advance this patient safety topic.

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APSF to Focus on Opioid-Induced Ventilatory Impairment in 2018

"OIVI," From Cover Page

Throughout the year, the *APSF Newsletter* will continue to focus on topics related to the ongoing problem of OIVI. These topics include an examination of the closed claims data involving OIVI, an update on methods for monitoring OIVI, the perspective of the Joint Commission on OIVI, and a review of the impact of perioperative prescribing practices on OIVI. We hope all readers will reflect on their own clinical practices related to opioid administration. In addition, we hope that the information will motivate practitioners and their organizations to address the challenge of reducing harm from perioperative opioid administration.

Dr. Greenberg is presently Editor of the APSF Newsletter *and Vice Chairperson of Education in the Department of Anesthesiology, Critical Care and Pain Medicine at NorthShore University HealthSystem in Evanston, IL. He is Clinical Associate Professor in the Department of Anesthesia/Critical Care at the University of Chicago.*

He has no disclosures pertaining to this introduction.

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We Should Focus On "When" As Well As "Whom" to Monitor for Postoperative Opioid-Induced Ventilatory Impairment

by Lorri A. Lee, MD; Karen L. Posner, PhD; and Karen B. Domino, MD, MPH

Postoperative opioid-induced ventilatory impairment (OIVI) is a preventable cause of high severity injuries to patients and many organizations have focused efforts on this patient safety issue over the last two decades. Progress has been slow in this arena because the low incidence of these events has made outcomes research on specific interventions difficult. The Anesthesia Closed Claims Project utilizes one method to study these rare events by rigorous examination of factors associated with closed anesthesia malpractice claims from professional liability companies that cover approximately one third of anesthesiologists in the United States. The Closed Claims Project identified 92 claims associated with OIVI.[1] Its methodology did not identify the cases where there was no harm from a respiratory event and no claim was filed (e.g., a successful, quick rescue with naloxone), a misdiagnosis as to cause of death or brain injury, the large number of cases that were never pursued in a medicolegal setting,[2] or the cases covered by professional liability companies outside of the Closed Claims Project. Over three-quarters of these 92 OIVI claims involved death or permanent brain damage (Figure 1).[1]

Because of the high severity of injuries related to this complication, many institutional, professional society, and standards-setting organizations have produced guidelines that recommend enhanced postoperative monitoring for high-risk patients receiving postoperative opioids. These guidelines include interventions such as increased assessment checks over shorter intervals, continuous capnography and/or continuous pulse oximetry with centralized alarms, and newer technologies such as the use of electrical impedance to monitor minute ventilation.[3,4] These recommendations are a logical start to this complicated problem; however, identifying all patients at high risk for OIVI is not a simple task. Published studies on this topic using different methodologies and databases have identified numerous risk factors for postoperative OIVI including older age, female sex, obesity, underweight, obstructive sleep apnea, renal impairment, cardiac disease, chronic obstructive pulmonary disease, neurologic disease, diabetes, hypertension, chronic use of opioids preoperatively, and airway surgery.[5-9] Two-thirds of the 92 claims associated with postoperative opioid-induced respiratory depression in the Closed Claims Project were associated with obesity, though 63% were classified as relatively healthy with ASA Physical Status 1-2.[1] Specific gene polymorphisms that alter the metabolism and transport of opioids are increasingly being identified and associated with OIVI.[7,10,11] Clearly, many of these risk factors will be undiagnosed, reducing the accuracy of any potential risk factor checklist. Moreover, postoperative complications that may evolve such as sepsis, acute kidney injury, pneumonia, delirium, and others may influence a patient's susceptibility to OIVI.

Exogenous risk factors for this complication are dependent on the practices and policies of health care professionals and institutions and are equally as important as pre-existing patient conditions. Risk factors that have been cited include the use of general anesthesia compared to neuraxial anesthesia, preoperative administration of long-acting oxycodone or gabapentin, continuous infusion of opioids postoperatively, concomitant administration of other non-opioid sedating medications, multiple postoperative prescribers, and inadequate health care provider education regarding the signs and symptoms of OIVI.[1,12-14] These exogenous risk factors are highly dependent on the skills, experience, and education of each health care professional involved in a patient's care throughout their admission, and the integration and communication between all health care providers, especially when new care guidelines are instituted. Institutional resources such as nurse-to-patient staffing ratios on floors, ongoing provider education at all levels for the signs and symptoms of OIVI, computerized order entry, enhanced electronic monitoring with centralized alarms, and institutional policies surrounding pain management are other significant variables that may influence the incidence of this complication.

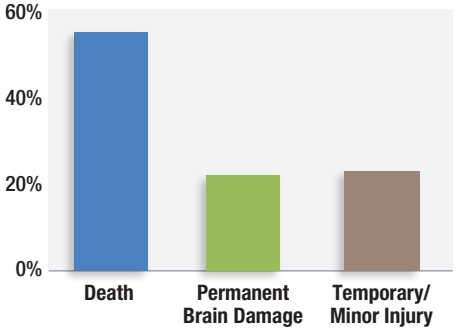

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Figure 1: Severity of injury in 92 claims associated with postoperative opioid-induced ventilatory impairment from the Closed Claims Project.

Given this extensive list of known and unknown contributory factors for postoperative OIVI, health care providers and institutions cannot possibly accurately identify all patients who will develop

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Postoperative OIVI Can Occur Within 15 Minutes of a Nursing Check

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this complication. As the population ages and the obesity and opioid epidemics continue to escalate, and hospital providers care for patients with higher acuity illnesses than in the past, it is likely that the majority of patients will have one or more of these risk factors for OIVI. The recommendation from the APSF and other organizations to institute continuous electronic monitoring for all patients receiving opioids postoperatively would mitigate harm attributable to undiagnosed patient risk factors and variable provider and institutional risk factors.[15] It would avoid confusion surrounding identification of high-risk patients and promote standardization of postoperative care for all patients. As nurses care for more patients, using continuous electronic monitoring of patients with centralized alarms will provide more objective and continuous monitoring of patients. Our study demonstrated that almost one third of the 92 claims associated with postoperative OIVI were discovered to have their critical OIVI event within one hour of their last nursing check and 42% within two hours of their last nursing check (Figure 2).[1] Fluctuating patient conditions and inadequate education for nurses regarding signs and symptoms of OIVI contributed to these findings. These short time intervals argue that physical nursing assessments alone on the floor are not sufficient to detect OIVI when nurses are caring for more than one patient at a time.

The critical time period for use of continuous electronic postoperative monitoring is primarily within the first 24 hours postoperatively as data from the Closed Claims Project demonstrate that 88% of these events occurred within that time frame (Figure 3).[1] Moving from the noisier and higher stimulation area of the recovery room with 1:1 or 1:2 nurse-to-patient ratios to the floor where patients will have less stimulation and less intensive monitoring by nurses is a high-risk time. Our study revealed that 13% of these OIVI events occurred within two hours of moving to the floor. These findings are consistent with other studies that have found that the first 24 hours is the highest risk period for OIVI for postoperative patients.[16-18]

Lastly, continuous electronic monitoring with centralized alarms would theoretically be able to alert providers of other evolving postoperative complications that can alter respiratory and heart rates and oxygen saturation such as sepsis, hypovolemic shock, pneumonia, and other illnesses. Taenzer and colleagues successfully demonstrated this concept when they instituted electronic surveillance with continuous pulse oximetry with centralized alarms.[19,20] They noted a significant reduction in ICU transfers from the floor by 50%, a reduction in rescue events by 60% from baseline, and decreased mortality from opioid-related causes. The economic return on investment was also highly significant with an estimated savings of $1.48 million from reduced ICU transfers within their initial study unit.[21] This figure did not take into account any potential reduction in lifelong expenses for patients from reduced morbidity or for institutional medicolegal defense. Data from the first 24 hours and further could be utilized to determine when a patient can be weaned from continuous electronic monitoring.

In summary, risk stratification for OIVI is important for perioperative management of anesthetics and medications, but it cannot be done with high reliability. The concept of using only pre-existing patient conditions and illnesses for identifying which patients require continuous electronic monitoring postoperatively negates the significant impact that the health care setting (providers and institution) places on patients for development of OIVI in a variable fashion. Continuous electronic monitoring of oxygenation and/or ventilation for all postoperative patients receiving opioids for at least the first 24 hours would simplify and standardize postoperative care and potentially reduce the incidence of postoperative OIVI and other complications. Initial efforts in resource-limited institutions to increase monitoring for patients for OIVI may focus on patient risk factors, but organizations should aim for the ultimate goal of monitoring all patients receiving opioids postoperatively.

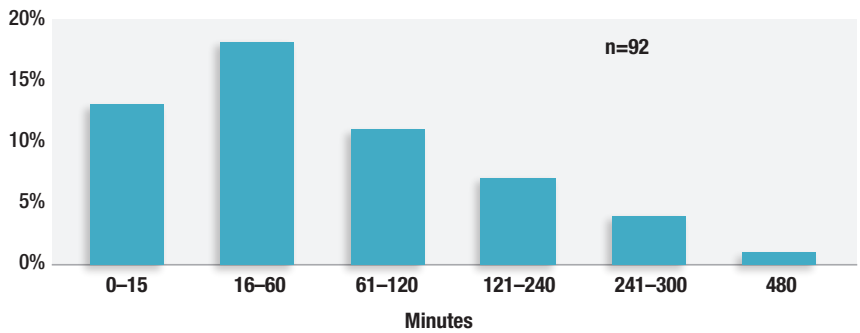

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Figure 2: Time between last nursing check and discovery of opioid-induced ventilatory impairment in 92 claims. Claims with unknown timing (n = 39) and not applicable (at home, n = 3) not shown.

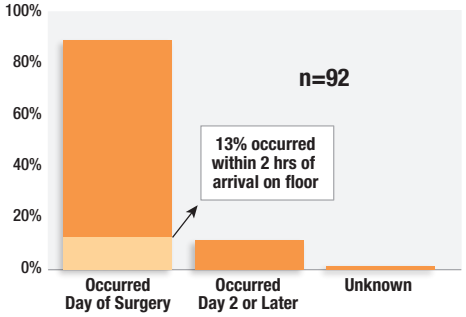

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Figure 3: Postoperative timing of opioid-induced respiratory depression in 92 claims from the Closed Claims Project.

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APSF Grant Program Has Impact on Patient Safety

"30 Years of Grants," From Cover

went beyond inflation to a maximum of $65,000 in 2000 ($92,000 in 2017 dollars). A major increase in award amounts in 2007 resulted in the current award limit of $150,000, double the initial award amount (adjusted for inflation) from the inception of the program 30 years ago.

In addition to changes in the maximum allowable budget per grant, APSF has increased the total number of awards in years when sufficient organizational funds were available. Funding for anesthesia patient safety research has now expanded from strictly APSF funds to grant awards sponsored by the American Society of Anesthesiologists (ASA), industry, and other donations. The 2017 funding cycle included awards sponsored by the ASA (APSF/ASA President's Research Award and Endowed Research Award), industry (APSF/Medtronic Research Award), and donations (APSF Ellison C. Pierce, Jr., MD, Merit Award).

The program has also expanded over time from solely scientific research projects to encompass educational research and curriculum development. Special requests for proposals (RFPs) targeting selected areas of interest are periodically solicited, as are Safety Scientist Career Development Awards to promote career development in anesthesia patient safety research. Annual funding amounts for all projects over the years (in 2017 dollars) ranged from $145,000 to >$1,200,000, with an average total of $400,000 per year over the APSF grant program's 30-year history.

APSF has reviewed the progress and impact of its grant program at various intervals.[1,2] In the spring of 2017, the APSF conducted a survey of past and current research grant and Safety Scientist Career Development Award recipients going back to 1986 when the first grant was awarded. The survey was emailed to all living principal investigators (PIs) whose contact information was available—a total of 113 individuals representing 118 awards. The goal of the survey was to evaluate and further promote the effectiveness of the APSF Research Program. A total of 76 responses from 71 different PIs (some individuals had received funding more than once) were received and analyzed. The results are described in the following sections.

APSF Grant Program 2017 Survey Results

Types of Grants Awarded

The grants covered a variety of research topics related to patient safety (Figure 1) and a number of grants addressed more than one patient safety domain. As reported by the respondents, the most common domains included identification of predictors of patients at increased risk for adverse outcomes (43.4%), new clinical methods for prevention or early diagnosis of adverse outcomes (39.5%), evaluation of new or re-evaluation of existing technologies for prevention and diagnosis of adverse outcomes (31.6%), development of innovative methods for the study of low-frequency events (27.6%), innovative methods of education and training in patient safety (27.6%), and methods for measurements of cost-effectiveness of technologies designed to increase patient safety (13.2%).

Survey responses also indicated specific study categories (Figure 2). Top categories were human factors or human performance (43.4%), outcomes or incident measurement (40.8%), risk assessment or risk factors (34.2%), monitoring and injury prevention (30.3%), prevention of specific complication or injury (30.3%), and education or training (29%).

Study methodologies varied, most frequently representing clinical trials (34.2%), simulation or

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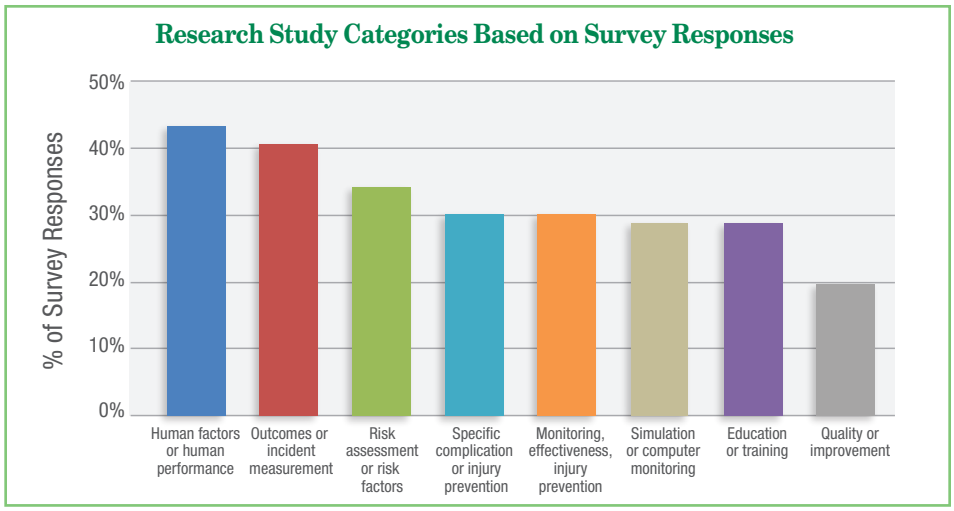

Figure 2: Research study categories based on survey responses. Note that some respondents indicated more than 1 category. Only top 8 responses are included in this figure.

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APSF Grant Program Covers Wide Variety of Research Topics

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computer modeling (30.3%), non-clinical human subject studies (26.3%), database analysis (18.4%), and medical records review (13.2%) as shown in Figure 3.

Grant Results and Impact on Anesthesia Patient Safety

When asked about major findings of the project and associated changes to anesthesia practice, education, or public policy, investigators reported a wide range of impact on patient care. Many APSF-funded projects have led to direct improvements in patient safety. Earlier projects supported human factors research, crisis management and simulation, checklists, device development, and patient monitoring and alarm generation. One project used human factors techniques for measuring intraoperative vigilance by embedding vigilance probes in the workplace. Another research grant aided in funding a study that applied cognitive analysis techniques to investigate how clinicians think about respiratory function and what the cognitive challenges are for assessing patient ventilation status. The analysis was then used to map the demands of ventilation-related events and the effectiveness of medical equipment in supporting clinical decision-making.

Several simulation-based projects have been funded by the APSF. These projects addressed issues such as improving technical performance skills, team dynamics and crisis resource management, facilitated simulation use in educational assessment, and health systems integration. APSF has also funded a number of education-related grants, including an examination of the impact of long work hours on performance and on the learning of anesthesia providers. Other education-oriented studies created a web-based program for ultrasound training and validated methods for assessing performance of first-year anesthesia residents to ensure minimum levels of competency. This latter project developed simulation-based assessment metrics to identify anesthesia residents who may not have attained sufficient skills expected for their stage of training. Another grant was used to design and build an adjustable airway task trainer able to assume numerous anatomic configurations and to model four laryngoscopic views using combinations of unfavorable airway factors. This model subsequently has been used in multiple research projects, supported several publications and grants, and proved useful in resident training.[3]

Other important perioperative safety topics supported by APSF funding have included an investigation of postoperative delirium and cognitive dysfunction after cardiac and noncardiac surgery, such as the effects of surgery and anesthesia on postoperative cognitive dysfunction and the onset and progression of Alzheimer's disease; the effects of perioperative hypothermia on bleeding and wound infection; novel approaches to difficult airway recognition and management; and identification of the incidence and risk factors associated with perioperative vision loss.

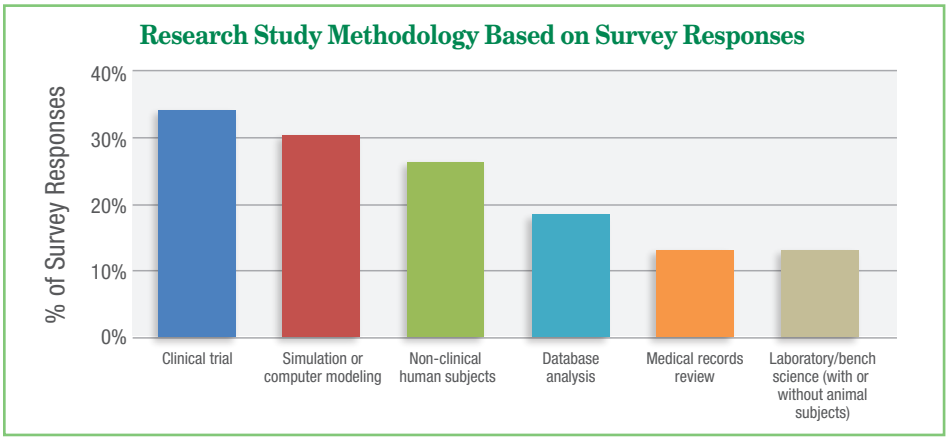

Figure 3: Research study methodology type based on survey responses. Note that some respondents indicated more than 1 category. "Other" = 14% of responses

APSF-funded projects continue to address a wide variety of important perioperative safety issues and stimulate broad areas of continued research. Recent examples include opioid safety in children and adults, better ways of risk assessment and monitoring for postoperative respiratory depression, as well as strategies for improving perioperative outcomes through preoperative evaluation including frailty, nutritional status, obstructive sleep apnea, and cognitive status. Techniques to improve communications in emergent situations have been studied and implemented, including studies on the effectiveness of emergency manuals and other decision aids, handoffs, and transitions in critical care. Given the increasing importance of big data in outcomes research, APSF funding has recently enabled one investigator to integrate several distinctly different patient databases that existed at one institution and to pursue large-scale epidemiologic studies of perioperative outcomes. Investigators have used intraoperative physiologic markers such as heart rate variability and vasoactive drug use patterns to identify risk factors for postoperative deterioration. Another recent grant provided the initial funding to develop a collaborative implementation research program within a large network of hospitals. This program integrated information systems to disseminate evidence-based practice and answer research questions to which multisite big data resources are uniquely suited.

Grant Program Impact on Patient Safety Research

In addition to exploring the direct impact of APSF grants on improving patient safety, the survey also inquired about the role the grant program had on an individual's career in patient safety. Overall, the respondents praised the program as helpful to both beginners and established researchers. Many described unique opportunities afforded by the grants to receive mentorship as well as to mentor others.

APSF grants have contributed to developing patient safety research expertise beyond the principal investigator. For example, one respondent commented that, in addition to studying an important clinical question, APSF funding "allowed the support of junior faculty who gained academic experience and publications. All have progressed in their careers and continue as investigators." APSF funding has also helped many investigators establish collaborations with colleagues nationally and internationally, maintain an academic career, and engage in projects for which there otherwise would be no or limited funding available. According to another respondent, "APSF funding not only made the work possible, but it validated the notion of patient safety research (i.e., simulation, decision-making, cognitive aids, etc.) as an appropriate line of academic endeavor." There are even instances where the funding allowed the investigator to initiate a completely new and innovative line of research and move beyond basic science to translational research involving human subjects.

Having dedicated, protected time from clinical duties is often necessary for pursuing an academic career. APSF funding has helped secure academic time for the vast majority of investigators and this time has been instrumental in getting their projects completed and advancing their careers in patient safety. The ability to do research is becoming much more difficult in the current academic environment where clinical productivity has become the priority of many institutions. One respondent commented that, "As research faculty are becoming a smaller fraction of our academic population in anesthesia... these grants are becoming increasingly more important to the survival of our academic missions." As many as 86% of prior recipients who responded to the survey are still actively involved in patient safety research and other similar activities not directly related to clinical work.

One important metric of any research grant program is whether it has led to additional extramural funding for the investigator. For many respondents,

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initial APSF grant support contributed to additional peer-reviewed funding. Approximately 68% of applicants conducted additional related studies following up on their APSF grant activities. The National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), Patient-Centered Outcomes Research Institute (PCORI), other government organizations such as NASA and the Veterans Administration, nonprofit foundations, professional societies, and industry have served as additional funding resources. Overall, APSF funding has resulted in a significant "return on investment" as evidenced not only by follow-up funding successes, but also by development of patient safety careers, high-impact peer-reviewed publications, and clinical practice improvements adopted by our specialty to improve patient safety.

Future Directions

The APSF leadership is using the information obtained from this survey to gain perspective on the successes of this long-standing grant program and to address unmet needs with future awards aiming to further advance perioperative patient safety.

The importance of mentorship was a significant theme in many of the responses as a major factor in successful completion of projects and subsequent successes of grant recipients as patient safety researchers. Thus, the APSF is reviewing opportunities to bring prior grant recipients together and create a network of patient safety leaders, mentors, and educators. In the survey, we proposed an idea for creating an Anesthesia Patient Safety Leaders Alumni Network (APSLAN)—an active community of prior and current grant recipients to promote stronger engagement with APSF and across the specialty. Specifically, a network such as APSLAN holds the potential to stimulate and promote future patient safety initiatives and create a formal mechanism for mentoring a new generation of patient safety researchers. An overwhelming number of respondents (~ 80%) expressed interest in participating. More information about this important initiative will be forthcoming.

In summary, during its 30-year existence the APSF grant program has funded many successful research projects that have produced significant improvement in perioperative patient safety. The grant program has also helped to nurture the careers of patient safety scientists by helping them to develop qualitative, clinical, and educational research skills. APSF funding has provided the support needed by a majority of grant recipients to successfully pursue additional large patient-safety-oriented awards from federal agencies, foundations, and industry. Our survey results show significant overall satisfaction with the program and the desire by many prior recipients to stay engaged with APSF to help shape the future of perioperative patient safety research. The APSF is grateful to its individual and practice donors, corporations, and anesthesia organizations for their continued support.

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Disclosures: Dr. Richard Urman has received APSF research funding in the past, and Dr. Steven Howard currently chairs the APSF Scientific Evaluation Committee. Neither Dr. Karen Posner nor Dr. Mark Warner have any disclosures with regards to the content of the article.

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HCA-Infections: Can the Anesthesia Provider be at Fault?

by Richard C. Prielipp, MD, MBA, and David J. Birnbach, MD, MPH

Richard C. Prielipp, MD, MBA, FCCM, professor of Anesthesiology at the University of Minnesota, introduced this provocative and timely topic on October 21, 2017, at the ASA Annual Meeting by noting that two million hospitalized patients develop healthcare-associated infections (HCAI) annually, contributing to over 90,000 deaths each year in the United States.[1] The source of these infections may be unknown, but the consequences are profound, including increased costs, selection pressure for drug resistant organisms, patient and family dissatisfaction, increased morbidity and mortality, and even potential liability. Surgical site infections (SSI) are especially relevant to the anesthesia community, as they account for 20% of all HCAI. Indeed, SSI afflict 1–3% of all surgical patients, increasing the hospital length of stay (LOS) from 3 to 10 days and increasing mortality 2- to 10–fold.[1] Because the majority (60% or more) of SSI are considered preventable, payers and insurers may no longer cover the incremental cost of approximately $20,000 per episode.

Heightening the concern of anesthesia professionals, Dr. Prielipp noted a recent study that identified bacterial contamination of drugs during routine administration of anesthesia in the operating theater. Over 6% of microbial filters placed in standard IV tubing of anesthetized patients were contaminated with *Staphylococcus (S.) capitis*, *S. hemolyticus*, *Corynebacterium*, and *Bacillus* species.[2] Equally alarming, 2.4% of fluid samples from the residual drug within syringes at the end of cases grew these same organisms, plus *Staphylococcus aureus* and *S. hominus*. Thus, there seems little doubt that anesthesia caregivers have a substantial stake in understanding and preventing SSI (Figure 1).

Silvia Munoz-Price, MD, PhD, enterprise epidemiologist and professor of Medicine, Division of Infectious Diseases at the Medical College of Wisconsin, led an engaging discussion of the interactions between anesthesia professionals and operating room equipment, the anesthesia machine, monitor surfaces, vascular catheters, stopcocks, and intravenous tubing. She noted the frequency of these interactions during 8 hours of operating room (OR) observation during which the anesthesia provider touched surfaces 1,132 times, completed 66 stopcock injections, and inserted 4 vascular catheters. Unfortunately, appropriate hand hygiene preceded only a small fraction of these anesthesia actions.

In addition, Dr. Munoz-Price enlightened the audience of approximately 250 participants about key features of environmental disinfection ("room cleaning" between patients). Surfaces in a typical OR are likely to grow pathogens such as methicillin-resistant *Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), methicillin-sensitive Staphylococcus aureus (MSSA), E. coli*, and *Acinetobacter spp*. **after room cleaning**! Decontamination of the environment becomes critical as additional evidence highlights that the probability of bacterial growth in injection stopcocks is a function of the number of bacterial colonies infesting the anesthesia machine as well as baseline hand contamination of anesthesia providers.[3] Dr. Munoz-Price described the "Fecal Patina," as the coating of enteric organisms that are not only limited to the patient's skin, but also are on common surfaces in the health care environment that are touched and contaminated by patients and health care providers. Clinicians will likely identify several avenues to improve disinfection practices in their own institution to battle this "Fecal Patina in the Anesthesia Work Area."[4]

David J. Birnbach, MD, MPH, Miller Professor of Anesthesiology, senior sssociate dean for Patient Safety and vice provost at the University of Miami, illustrated how readily—and rapidly—anesthesia providers' hands can contaminate the anesthesia work surfaces within a few minutes after routine induction and endotracheal intubation.[5,6] Dr. Birnbach presented data concerning contamination of presumably clean OR surfaces following intubation and showed powerful visual evidence of contaminated areas using fluorescent techniques. Of particular interest, Dr. Birnbach showed evidence of 100% contamination of the IV hub, anesthesia circuit, and anesthesia cart (Figure 2). In addition, he showed

Figure 1: Intraoperative photograph of the anesthesia work surface during the maintenance phase of a routine general anesthetic. Note two medication syringes are uncapped (circled highlights) while in close proximity to the patient's airway equipment.

Expert panelists fielded questions from the audience at the APSF-sponsored conference (at the 2017 ASA Annual Meeting in Boston, MA) entitled "Postoperative Infections: Can the Anesthesia Provider Be at Fault?" From Left to Right: Daniel Sessler, MD; G. Burkhard Mackensen, MD, PhD; Silvia Munoz-Price, MD, PhD; Richard C. Prielipp, MD, MBA; and David J. Birnbach, MD, MPH.

compelling evidence of contamination of unused syringes, suggesting that all syringes (even if unused) be discarded at the end of each case. Several recommendations were made regarding methods to reduce OR contamination, including the potential advantages of anesthesia professionals wearing double gloves during intubation.[6,7]

Dr. Birnbach completed his talk with a discussion of neurologic infections due to contamination by the anesthesia professional. He highlighted several cases of meningitis where the causative bacteria were isolated from the anesthesiologist's nasopharynx[8] and informed the audience about the scientific literature suggesting the importance of routinely wearing masks during placement of neuraxial blockade.

G. Burkhard Mackensen, MD, PhD, FASE, professor in the Department of Anesthesiology and Pain Medicine at the University of Washington, and chief of the Division of Cardiothoracic Anesthesia, provided an illuminating discussion regarding reusable vs. disposable laryngoscopes. Flexible and rigid laryngoscopes—both blades and handles—are classified as semicritical devices (because they contact mucous membranes), and therefore require both cleaning and **high-level disinfection or sterilization**. He cited the deaths of two infants in a California neonatal ICU due to an outbreak of *Pseudomonas aeruginosa* attributed to reusable laryngoscopes used during their hospitalization.[9] However, many institutions are discovering that the cost of reprocessing reusable laryngoscopes to this new standard is substantial. While cost allocation data depend on your specific organization, adopting single-use products may actually be quite favorable and even less expensive. Table 1 compares several aspects of these two laryngoscope options.

Daniel Sessler, MD, discussed hypothermia and other related factors as he highlighted several confounding variables related to SSI. He began by noting how general and neuraxial anesthetics profoundly impair thermoregulatory control. Consequently, nearly all unwarmed surgical patients become hypothermic. Intraoperative hypothermia results initially from a core-to-peripheral redistribution of body heat; thereafter, it results from heat loss

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exceeding metabolic heat production.[10] Randomized trials have shown that mild hypothermia increases blood loss and transfusion requirements,[11] promotes surgical site infection,[12] and slows drug metabolism thereby prolonging recovery. Professional groups in various countries have, therefore, published guidelines indicating that core temperature should be monitored during both general and neuraxial anesthesia, and that surgical patients should be kept normothermic.

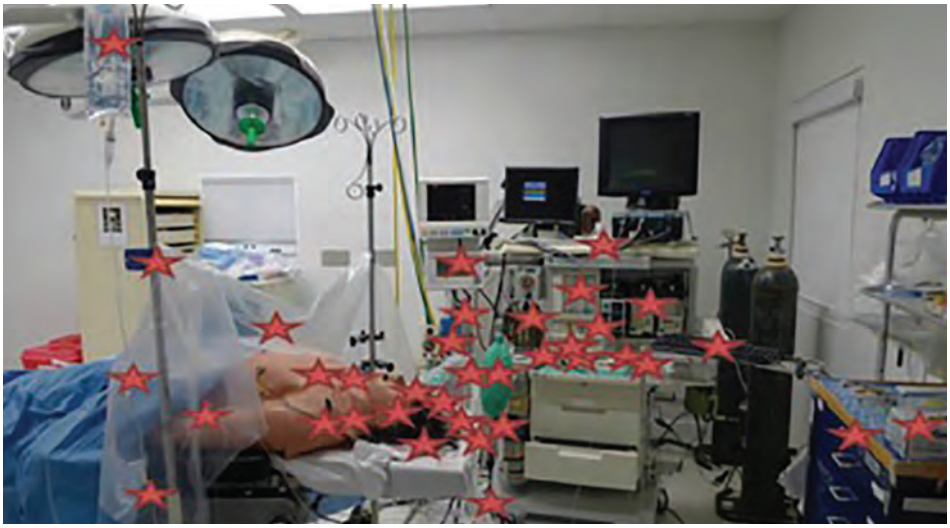
Forced-air warming (FAW) is by far the most commonly used intraoperative warming system worldwide, but clinicians are free to adopt any system that keeps patients normothermic. In recent years, there has been some concern that forced-air might disturb laminar flow and thus promote infection during orthopedic procedures. In fact, Brandt and colleagues suggested that laminar flow increases infection risk,[13] presumably by detaching bacteria-laden particles from the heads of surgeons and scrub nurses, and driving them directly into the surgical wound. However, the only clinical study of forced-air and laminar flow showed that there was no interference whatsoever.[14] Supporting this conclusion, the United States Food and Drug Administration in August of 2017 provided the following guidance: "The FDA has been unable to identify an association between forced-air (FAW) and surgical site infection. Therefore, the FDA continues to recommend the use of thermoregulating devices (including forced air thermal regulations systems)."

In addition, to the effects of hypothermia on infection risk, Dr. Sessler provided evidence to support the following concepts:

1. Timely antibiotic administration helps to reduce surgical site infections.[15]
2. Supplemental oxygen does not seem to reduce risk of infection.[16]
3. Little evidence supports which fluid strategy and what type of fluid may reduce infection risk.[17,18]
4. Smoking increases infection risk but it is presently unknown if perioperative cessation reduces this risk.[19]

The panelists concluded by answering questions from the engaged audience of approximately 250 participants.

Dr. Richard C. Prielipp is Professor of Anesthesiology at the University of Minnesota in Minneapolis. He serves on the Board of Directors of the APSF.



Reproduced and modified with permission. Birnbach DJ, Rosen LF, Fitzpatrick M, et al. Double gloves: a randomized trial to evaluate a simple strategy to reduce contamination in the operating room. *Anesth Analg* 2015;120:848–52.

Figure 2: Anesthesia residents (unaware of the study design) performed routine induction of general anesthesia with endotracheal intubation in a high-fidelity simulator. Invisible fluorescent dye—secretly painted in the "patient's mouth"—was traced to an alarming multitude of anesthesia work surfaces within six minutes of the start of anesthesia (each star indicates contamination by the oral tracer).[6]

Dr. David J. Birnbach is Miller Professor of Anesthesiology, Senior Associate Dean for Patient Safety and Vice Provost at the University of Miami. He serves on the Board of Directors of the APSF.

Both report no COI relevant to this presentation.

The opinions expressed in this article are not necessarily those of the Anesthesia Patient Safety Foundation. The APSF neither writes nor promulgates standards, and the opinions expressed herein should not be construed to constitute practice standards or practice parameters. Validity of opinions presented, drug dosages, accuracy, and completeness of content are not guaranteed by the APSF.

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Table 1: Comparison of Reusable to Disposable, Single-Use Laryngoscopes

Traditional, Reusable Laryngoscopes	Single Use ('Disposable') Laryngoscopes
Batteries wear out, need replacement	Batteries always brand new
Bulbs dim and eventually burn out	Light source always new
On-off switch prone to wear and failure	Switch is new; testable while still in package
Handles require disassembly to disinfect	No cleaning or maintenance of device
Requires sterilization or high-level disinfection after each use	Provided sterile in new, transparent package
Costs rise rapidly with newly required processing and sterilization	Costs at parity or even less expensive depending on the institution[20]
Performance is well known with a familiar feel	Performance now usually rated at parity with reusable laryngoscopes[21]

President's Annual Report: "That No Patient Shall Be Harmed By Anesthesia…"

by Mark A. Warner, MD, President, Anesthesia Patient Safety Foundation

The Anesthesia Patient Safety Foundation's (APSF's) vision statement is clear, "That no patient shall be harmed by anesthesia." What does that mean, though? In the past, many anesthesia professionals, especially in the U.S., interpreted it to mean that no patients shall be harmed in the well-defined intraoperative period, plus perhaps in the immediate postoperative few hours when patients were in a postoperative care unit and their care was still somewhat the responsibility of anesthesia professionals. Does that simple interpretation still hold today as the definition and practice of anesthesia evolve?

We are increasingly aware that the impact of anesthesia extends well beyond operating rooms. For example, cognitive and immunologic impairments associated with the perioperative period can exist far beyond the time that we have an ability to measure the residual pharmacokinetics of any of our anesthetic medications. Our resolve that no patients shall be harmed and our subsequent actions in response to that resolve should now overlay many aspects of preoperative evaluation and management, the intense period of intraoperative and immediate postoperative care, and the prolonged postoperative period. Our expectations and those of our patients and health care colleagues are far different today than three decades ago when the APSF was started.

The APSF's primary mission remains to continually improve the safety of patients during anesthetic care by encouraging and conducting:

- Safety research and education
- Patient safety programs and campaigns
- National and international exchanges of information and ideas

The mission has not changed. However, when applying the mission to today's expectations of anesthesia professionals and trainees, APSF needs to ensure that its activities span the extended range of perioperative care and involve collaboration with the full spectrum of colleagues in all fields and industries that impact our patients' care. There are important questions to be answered and issues to be addressed. Several of these involve changing behaviors and expectations of anesthesia professionals:

- *Culture of Safety:* Anesthesia professionals must support environments that allow all health care providers to speak out for patient safety. The "captain of the ship" ethos should be long gone and anesthesia professionals must be willing to be collegial but assertive in establishing a culture in which everyone is expected to contribute to the safety of patients.
- *Clear Communications:* Failure to effectively communicate is the primary factor in the majority of health care safety adverse events. Anesthesia professionals must take a lead in improving perioperative communications, including ensuring appropriate handoffs of care during the many transitions that occur during the perioperative period.
- *Advocacy for Patient Safety:* Anesthesia professionals must identify opportunities for improving patient safety and advocating for actions by their professional organizations and local facilities. For example, we know that increased monitoring can reduce the risk of postoperative opioid-induced ventilatory impairment but we have not consistently or effectively advocated for national or local practice guidelines that would address this potentially catastrophic issue. We have not presented a persuasive, coherent initiative that would propel industries and government agencies to develop less dangerous analgesics and better ventilatory monitoring. There are independent efforts but no coordinated strategies.
- *Self-Improvement:* Anesthesia professionals need to lead by example. Some of our daily practice patterns may contribute to patient harm. Drs. David Birnbach and Richard Prielipp led a fascinating APSF panel at the 2017 American Society of Anesthesiologists' Annual Meeting on the impact of anesthesia professionals and the potential spread of infection during the intraoperative period. Adherence to optimal perioperative infection control practices will aid in improving patient safety. We can contribute to perioperative infections…and better practices may reduce that problem. We simply must continue to improve. Our patients can be harmed by our complacency.

The APSF has primarily been focused on the U.S. for the past several decades. This focus is changing to meet our founding mission to increase the international exchange of patient safety ideas. By the end of 2018, the *APSF Newsletter* will be published in multiple languages. These newsletter translations, along with translated safety videos, will appear on the APSF website (apsf.org) as they become available and will increase the exchange of ideas with an estimated 350,000 anesthesia professionals worldwide. Anesthesia patient safety must be a universal mission.

Dr. Mark Warner, APSF President

In the coming years, APSF will increase its focus on the full spectrum of perioperative safety issues and increase its advocacy for patient safety, even when it may not be popular. It's the right thing to do for our patients…and for our profession.

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

Dr. Warner has no disclosures with regards to the content of the article.

2017 APSF/ASA Ellison C. Pierce, Jr., MD, Patient Safety Memorial Lecture: *Anesthesia Patient Safety: Closing the Gap Between Perception and Reality*

by Robert K. Stoelting, MD, Past President, APSF

The APSF/ASA Ellison C. Pierce Patient Safety Memorial lecture is dedicated to recognizing the contributions to anesthesia patient safety of Ellison C. Pierce, Jr., MD, the founding president of the Anesthesia Patient Safety Foundation (APSF) in 1985 (Figure 1). The APSF is a proud example of anesthesia's contributions to medicine and the history of APSF's formation deserves to be part of the heritage for all anesthesia professionals.

A challenge in addressing anesthesia patient safety issues is closing the gap between what we know (perception and recognition of the safety issue) and the institution of best practices (change in behavior, investment in technology) that will decrease the likelihood of adverse events (reality). Too often the "dangerous intersection" phenomenon persists where the risk of an adverse event is recognized (e.g., flash fire in at-risk patients, opioid-induced ventilator impairment in patients receiving opioids), but the steps for creating a safer intersection (limited open delivery of supplemental oxygen, objective monitoring of oxygenation in the postoperative period) do not occur until after the adverse event (Table 1).

Closing the loop on identified patient safety issues is reflected by changes in behavior and/or investment in technology that facilitates institution of best practices that should predictably decrease the likelihood of an adverse event. This goal may be approached by different paths based on the unique needs, resources, and patient population of each anesthetic practice (Table 2). Endorsement as best practice by anesthesia professional associations in the form of standards, practice guidelines, and practice advisories is a traditional approach and one in which our professional associations have been recognized as leaders by organized medicine.

Dr. Robert Stoelting, Past President of the APSF, giving the APSF/ASA Ellison C. Pierce, Jr., MD, Patient Safety Memorial Lecture, entitled "Anesthesia Patient Safety: Closing the Gap Between Perception and Reality," at the 2017 ASA Annual Meeting in Boston, MA.

In addition to statements from professional anesthesia associations, an effective approach to bringing best practices to everyday patient care could be endorsement by individual anesthesia groups and practice management companies (Table 2). For example, objective monitoring of neuromuscular blockade could become a "policy" for all members of a group independent of personal views on the need for this strategy. The reality of leaving a safety intervention to individual choice is no longer reasonable. Alternatively, a policy for monitoring neuromuscular blockade would not be relevant for a practice profile that did not include patients routinely receiving neuromuscular blocking drugs.

Figure 1: Ellison C. Pierce, Jr., MD, founding President of APSF.

Ultimately, closing the gap between perception and reality for instituting best practices that will most likely decrease the likelihood of adverse anesthesia events depends on the individual anesthesia professional's "buy-in" to known safety practices and recommendations. "Only you can help (Figure 2)."

Dr. Stoelting is immediate Past President of the APSF.

He has no disclosures as it relates to this article.

Table 1: Closing the Loop for APSF Safety Initiatives: Dangerous Intersection Phenomenon

- Identifying the safety risk is **NOT** the problem
- Recognizing the possible solution to the safety risk is **NOT** the problem
- The problem is **Closing the Loop** between the safety risk, its solution, and acceptance of practices that will reduce the risk of an adverse event

Table 2: Closing the Loop for APSF Safety Initiatives: Options For Instituting Best Practices

- Endorse best practices by **professional associations** (standards, practice guidelines, practice advisories)
- Create vehicles to increase awareness among **individual anesthesia professionals** (experts' conferences, written reports vs. educational videos, social media)
- Accept as best practices by **large anesthesia groups/practice management companies**
- **Educate Patients** (asking the "right" questions)

Figure 2. Closing the Loop for APSF Safety Initiatives: Only You Can Help

Presentation of the APSF Collaborative Panel on Neuromuscular Blockade and Patient Safety at the 2017 ASA Annual Meeting

by Glenn Murphy, MD

At the 2017 ASA Annual meeting in Boston, MA, the APSF Collaborative Panel on Neuromuscular Blockade and Patient Safety presented the results of a survey conducted to assess practitioners' attitudes towards dosing, monitoring, and reversal of neuromuscular blockade. In addition, the results of four Expert Discussion Groups, which were established to determine the key issues related to perioperative neuromuscular management, were reviewed in the session.

The primary objectives of the project were to identify the key risk factors in anesthetic-related morbidity and mortality associated with use of neuromuscular blocking agents; describe current practices of intraoperative neuromuscular monitoring; assess the incidence of postoperative residual neuromuscular blockade (PRNB); determine factors potentially responsible for the variations in practice with regard to neuromuscular management and monitoring; and describe changes in practice that will decrease residual neuromuscular block and improve patient safety.

Dr. Sorin Brull presented the results of the survey that was distributed to 50,690 anesthesiologists, nurse anesthetists, anesthesiologist assistants, and PACU nurses. The response rate to the survey was 5.7% (2,897 respondents). Sixty-four to 72% of respondents noted that they perceived the incidence of PRNB to be 1–10%. In contrast, numerous studies from medical centers around the world have demonstrated that 30–50% of patients are admitted to the PACU with PRNB.[1] Although many of the respondents believed that PRNB was a rare event, 31–43% stated that residual paralysis can have a significant negative effect on patient outcomes. Forty-five percent of respondents reported assessing recovery of neuromuscular function using clinical tests (e.g., 5-second head lift) or a peripheral nerve stimulator. In addition, 8–51% of respondents believed that clinical tests were very or moderately reliable in excluding incomplete neuromuscular recovery. However, significant muscle weakness may still be present (TOF ratios as low as 0.4) when these methods are used.[2] While the responses varied between individual providers, 88% of responding anesthesiologists had at least 1 peripheral nerve stimulator per operating room. Only half of the departments had any quantitative monitors (devices which measure and display a train-of-four (TOF) ratio from 0–1.0 or 0–100% in real-time—Figure 1). The primary reason stated for not using quantitative monitoring was the lack of availability of the devices.

Previous surveys have revealed that routine pharmacologic reversal is used in only 18–32% of practices in the European Union and United States.[3] In the APSF survey, the primary reason noted for omitting reversal agents was the timing since last dose. However, clinical investigations have described significant incidence of PRNB nearly 3 hours after receiving even a small dose (25 mg) of rocuronium.[4] Furthermore, most respondents stated that the minimal degree of neuromuscular recovery prior to neostigmine reversal was a TOF count of 1–2. Though somewhat controversial, some studies have suggested that it may not be possible to achieve adequate recovery within 1 hour at a TOF count of 1 to 2, and that neostigmine should not be administered until a TOF count of 4 is present.[5] Thirty-five percent of respondents noted that an alternative, sugammadex, was either unavailable or its use was restricted by the pharmacy to specific clinical situations or patient populations.

At PACU admission, most clinicians provided information about the muscle relaxant and reversal agent given intraoperatively, but little other data were provided. One-half of the PACU nurses stated that reversal drugs were given to 1–5% of patients after admission. Although clinical tests of muscle strength were performed by 57% of PACU nurses, few (10%) used quantitative, objective monitors (and most nurses receive no training in using these devices). Overall, 75% of responding anesthesia professionals agreed that the American Society of Anesthesiologists (ASA), the American Association of Nurse Anesthetists (AANA) and the American Academy of Anesthesiologist Assistants (AAAA) should collaboratively develop clinical practice guidelines for perioperative monitoring of neuromuscular function.

From Left to Right: Dr. Mohammed Naguib (Professor of Anesthesiology, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Cleveland, Ohio) and Dr. Sorin Brull (Professor of Anesthesiology at Mayo Clinic, Jacksonville, FL) are convening after their 2017 ASA Annual meeting lecture entitled "Assessing and Analyzing the Perceptions of Perioperative Professionals on Neuromuscular Blockade Monitoring and Residual Neuromuscular Blockade."

In addition to the findings of the survey, the conclusions of the four Expert Discussion Groups were presented. The groups were composed of anesthesiologists, nurse anesthetists, PACU nurses, pharmacists, and anesthesiologist assistants. The first group was assigned to address the question of what the most important patient safety issues are related to PRNB. The group noted that there were a number of provider knowledge deficits, including reliance on clinical (head-lift) and subjective (peripheral nerve stimulator-PNS) tests, use of facial muscles instead of the hand for monitoring, the misconception that monitoring is not required if sugammadex is used, and the perception that residual block is rare, and if it occurs, it is not clinically significant. Furthermore, many clinicians do not recognize that PRNB may result in postoperative adverse respiratory events, pneumonia, prolonged PACU length of stay, and unpleasant symptoms of muscle weakness. The second group addressed barriers to the use of subjective and objective monitoring devices. The belief that PNS provide data that indicate ade-

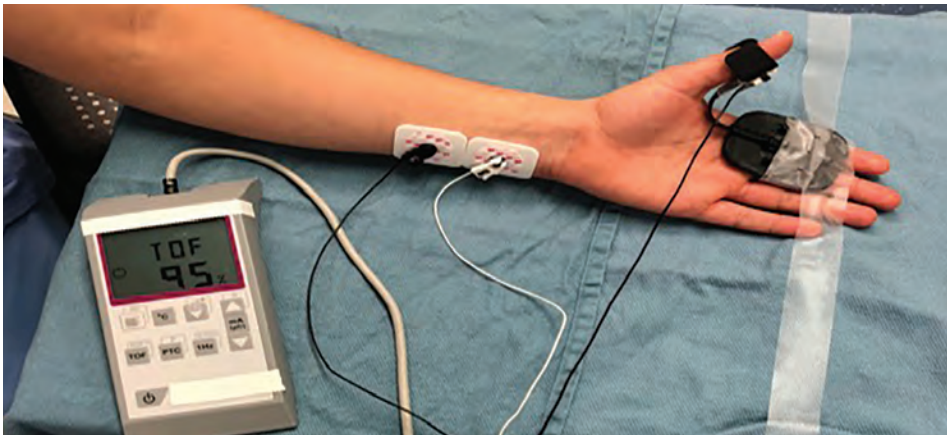

Figure 1: Depicts a quantitative neuromuscular blockade monitor being applied to the subject's ulnar nerve.

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Neuromuscular Blockade Panel Recommendations

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quate recovery and that improper application of devices may fail to detect significant PRNB was discussed. Barriers to the use of objective quantitative monitors include lack of user-friendly devices, cost, unfamiliarity with quantitative technology, lack of appropriate training, and the fact that objective monitors are not considered standard of care. Group three recommended that details about dosing, monitoring, and reversal of neuromuscular blockade should be provided to PACU nurses during transfer of care. Group four addressed education and training requirements which included limitations of clinical tests and subjective (qualitative) evaluation; advantages of quantitative monitoring; proper application (site) of stimulating electrodes; responses of various muscle groups being monitored; importance of documenting baseline TOF ratios; and limitations of neostigmine reversal (depth of block, time to peak onset, ceiling effect). In addition, the group emphasized the importance of documenting competency validation in the use of monitoring at the institutional level.

Dr. Mohamed Naguib concluded by providing recommendations from the Collaborative Panel on perioperative neuromuscular management. These included

1. **Quantitative (objective) monitoring should be used whenever a neuromuscular blocking drug (NMBD) is administered. These devices should be available at all anesthetizing sites, and information recorded should be incorporated into electronic medical records. Electromyography technology may provide advantages over other categories of monitors.**
2. **During the period of transition to quantitative monitoring , the use of a peripheral nerve stimulator (PNS) in any patient receiving a NMBD is "mandatory."**
3. **Clinical signs do not guarantee complete resolution of postoperative residual neuromuscular blockade (PRNB), and no longer have a place as the sole determinant of adequate recovery of neuromuscular function.**
4. **Professional organizations should develop practice standards and guidelines detailing how best to monitor and manage perioperative administration of NMBDs.**

The session concluded with a summary of the findings of the Collaborative Panel. The Panel noted that a majority of all practitioners think that PRNB is a very significant or moderately significant safety issue that impacts patient outcomes; this validates the purpose of the panel and likely confirms the need for clinical practice guidelines. Equipment availability for anesthesia providers still appears to be an issue, especially with regards to quantitative monitoring. Of note, a significant proportion of practitioners think monitoring is not needed with sugammadex, although no reasoning was provided for this response. Very little information is communicated to PACU nurses regarding intraoperative neuromuscular management, and this information gap must be addressed. In addition to clinical guidelines, educational guidelines are needed for anesthesia providers and PACU nurses. Finally, the survey indicates that 75% of practitioners agree that clinical guidelines are needed, which validates the need for (and acceptance of) guidelines.

Dr. Glenn Murphy is Director of Anesthesiology Research at NorthShore University HealthSystem and is Clinical Professor in the Department of Anesthesia/ Critical Care at the University of Chicago.

Dr. Murphy discloses that he is on the advisory board of Merck and has served as a consultant for Merck.

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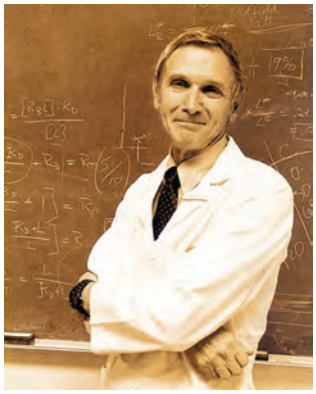
In Memory of Richard J. Kitz, MD

by Jeffrey Cooper, PhD



Dr. Richard J. Kitz

We mourn the unexpected passing of Dr. Richard J. Kitz on September 19, 2017, at the age of 88. As chair of the Massachusetts General Hospital Department of Anesthesia, Critical Care and Pain Medicine for over 25 years, he was the mentor of many leaders of anesthesia departments throughout the world and responsible for many aspects of the professional evolution of the specialty. Unbeknownst to many, Dr. Kitz was a pioneer of anesthesia safety, and he played an important role in the founding of the APSF. His dedication to patient safety can be seen in his dedication to full transparency within his department and his encouragement of research on human error in anesthesia. He was also the instigator of a meeting that proved to be catalytic to anesthesia patient safety—the International Symposium for Preventable Anesthesia Mortality and Morbidity (ISPAMM), held in Boston, MA, in 1984.* It was at ISPAMM that APSF founding president Ellison (Jeep) C. Pierce, Jr., conceived of the idea of the Foundation. During a trip to the UK the prior year, Dr. Kitz gave a lecture to the Royal College of Anesthetists, where he spoke about the studies led by his department that were exploring the relatively new topic of anesthesia errors and preventable adverse outcomes. Sir Cecil Grey, the pre-eminent anesthetist at the time in the UK, suggested that Dr. Kitz convene a conference to gain more insight into the extent of the problem and possible solutions. On his return to the U.S., Dr. Kitz brought the suggestion to Dr. Jeffrey Cooper and Dr. Pierce. The three worked together to organize ISPAMM, with representatives from around the world and supported by several corporate sponsors. The idea of the APSF was hatched from conversations held at ISPAMM. Dr. Kitz was one of the original APSF Board members. He was a committed advocate for patient safety and especially the foundational research in his department. A more extensive obituary of this remarkable anesthesiologist leader can be found at: http://www.massgeneral.org/anesthesia/assets/pdfs/Richard-Kitz-Obituary.pdf

*Keats AS. International Symposium on Preventable Anesthesia Mortality and Morbidity. Meeting Report. *Anesthesiology* 1985:63:349-50.

Jeffrey Cooper is immediate past Executive Vice President of the APSF. He is also Professor of Anaesthesia at Harvard Medical School in the Department of Anesthesia, Critical Care & Pain Medicine, Massachusetts General Hospital, Boston, MA.

He has no conflicts of interest to declare.

Monitoring for Opioid-Induced Respiratory Depression

by Rajnish K. Gupta, MD, and David A. Edwards, MD, PhD

In 2006 and 2011, the Anesthesia Patient Safety Foundation (APSF) convened multidisciplinary conferences to address the serious patient safety issue of Opioid-Induced Ventilatory Impairment (OIVI).[1] Given the significance of the problem, and that no best monitor exists for detection of OIVI associated-adverse events, the consensus recommendations from the 2011 conference participants were that, until better monitors exist, continuous pulse-oximetry (preferably with centralized alarms and paging systems) should be used for monitoring patients not receiving supplemental oxygen, and ventilation monitors (capnography) are suggested for those receiving supplemental oxygen.

It is now 2017, and, in the context of the national discussion surrounding the opioid crisis, it is more relevant than ever to review the current state of monitoring for OIVI and provide updated evidence-based recommendations.

Incidence of Opioid-Induced Ventilatory Impairment

It has long been a challenge to accurately measure the incidence of OIVI and then to subsequently measure the safety advantage of a new monitoring protocol or technology. Inconsistent taxonomy for respiratory depression in the literature hinders comparative studies.[2] The different definitions used as surrogates for identifying respiratory depression make determination of the actual incidence challenging. Some surrogate measures for defining respiratory depression include hypoxemia, hypopnea, hypercapnic hypoventilation, decreased respiratory rate, and minute ventilation, among others.[2] Definitions used to characterize hypoxemia in the literature range from 80–94% SpO_2.[3] With the caveat that many different measures are used for respiratory depression, the incidence of OIVI reported ranges between 0.15% and 1.1% of all post-surgical patients.[3-8] While estimates of the incidence of OIVI vary based on the definitions employed, recent studies continue to report the incidence of OIVI within this same range.[2] It seems clear that the taxonomy and outcome measures for respiratory depression must be standardized so that research focusing on risk reduction can make relevant advances. In addition to determining "what to monitor," we must decide when monitoring is needed (addressed in a companion article on page 59) as well as the appropriate tools to reduce the incidence of OIVI.

When is Monitoring Needed

Somnolence and sedation are the most common precursors leading to OIVI.[2,9] Regular monitoring by nursing staff is currently the primary means of monitoring for this phenomenon. Determining the needed frequency of nurse evaluation requires achieving a balance between minimizing patient interruption, interference with nursing workflow, and staffing expenditures. For postoperative patients, the first four hours after post-anesthesia care unit (PACU) discharge is the time period associated with the highest rates of sedation, and the first 12 hours after surgery are when over half of OIVI events occur. In addition, 75% of all OIVI events occur within the first 24 hours after surgery.[2] Based on the timing of postoperative OIVI, a greater emphasis on monitoring the first 24 hours is likely to be helpful in reducing adverse events from opioids.

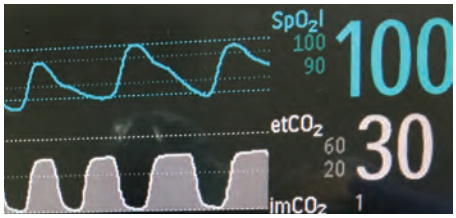


Figure 1: Depictions of continuous pulse oximetry and capography waveforms.

In 2014, The Centers for Medicare and Medicaid Services (CMS) updated their recommendations for hospital administration of opioids to include serial nursing assessments with blood pressure, temperature, pulse, respiratory rate, pain level, respiratory status, and sedation level.[10] However, the optimal frequency of assessments has not been established and likely depends on a variety of factors including the type of pain, the adequacy of initial pain relief, the presence of side effects, comorbidities, and changes in clinical status. For patients receiving neuraxial opioids, the American Society of Anesthesiologists Task Force on Neuraxial Opioids and the American Society of Regional Anesthesia and Pain Medicine suggests monitoring q 1 hour for the first 12 hours, q 2 hours for the next 12 hours and q 4 hours afterward if no opioid-related complications occur.[11] In contrast, a CMS-supported expert panel recommended that for any opioid administration a monitoring frequency of q 2.5 hours (to allow for documentation delays) for the first 24 hours and q 4.5 hours afterwards. However, during a survey of CMS hospitals, only 8.4% of patient encounters with IV opioid PCA met the q 2.5 hour standard and only 26.8% met the more relaxed q 4.5 hour standard.[12] Because of the variation in monitoring recommendations from different organizations, different patient risk factors, different anesthetic plans, variable prescriber and nursing education regarding OIVI, and variable nurse-to-patient ratios, continuous electronic monitoring postoperatively for all patients receiving opioids is likely to simplify care and improve the detection of OIVI.

How Should Patients Be Monitored—Monitoring and Alert Systems

Regardless of the particular electronic monitoring system employed to detect OIVI, the method of alerting health care professionals when these events occur must be addressed in order to ensure an effective system. Establishing an evidence-base of monitoring alerts that are useful for detecting OIVI is a critical need. Inadequately established alert thresholds lead to alarm fatigue, patient and staff irritation, and complacency; all of which can make even the most effective monitoring system completely ineffective in achieving the desired outcome.[2]

Ideally, monitoring systems should use multiple parameters in concert to detect whichever indicator of respiratory depression may arise first and employ combinations of measures to accurately identify an impending event. In the past, threshold alarms have been fairly simplistic and prone to error.

Pulse oximetry is the most commonly available monitor of respiratory depression presently used in hospital systems. However, threshold alarms for pulse oximetry are often the most problematic. Setting the threshold too high leads to frequent false positives while setting it too low can result in late responses to respiratory depression. Administration of supplemental oxygen complicates the monitoring issue because it can delay detection of depressed ventilation and further impair hypoxic respiratory drive.[13]

Capnography used alone also has limitations. Capnography is typically qualitative instead of quantitative in non-intubated patients, thereby providing an indication of the presence of carbon dioxide during normal ventilation, relative changes in exhaled carbon dioxide, and some information about respiratory rate. However, detecting changes in CO_2 values, either reduced or increased, can be problematic and inaccurate. Still, capnography can be useful as a monitor for respiratory rate since the periodic nature of CO_2 exhalation and the drop to zero during inhalation provide a clear demarcation of respiratory cycling. Upper thresholds for respiratory rate can also be used with capnography to detect hyperventilation.

Combining respiratory rate with oximetry and capnography helps to provide additional information for detection of OIVI as well as other disease processes (Figure 1). Three patterns of respiratory depression resulting in unexpected death have been described by Curry et al.[14] Type I is a Hyperventilation Compensated Respiratory Distress (e.g., from sepsis, pulmonary embolus, or congestive heart failure). In Type I, patients have a stable oxygen saturation initially and decreasing $PaCO_2$ as metabolic acidosis sets in and compensatory hyperventilation begins. Rapid respiratory rate is a hallmark of this type of respiratory failure. Eventually a slow desaturation precedes a precipitous decline in

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OIVI Monitoring and Alert Systems

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SpO_2 when the ventilatory response to worsening acidosis fails. Most current monitors have low respiratory rate alarms but not necessarily rapid RR alarms or the high setting detects respiratory failure too late. Type II respiratory depression is a Progressive Unidirectional Hypoventilation or CO_2 narcosis event. In this case, often due to opioid or other sedative overdose, patients have a rise in $PaCO_2$ (and $EtCO_2$) first due to decreased minute ventilation, often while the SpO_2 is still >90%. Type III respiratory depression is a Sentinel Rapid Airflow/Oxygen Saturation Reduction with Precipitous SpO_2 Fall that can be observed in patients with obstructive sleep apnea. In this situation, the patient is dependent on the arousal state to maintain oxygenation. If there is arousal failure, precipitous hypoxemia develops during apnea that can lead to a sudden arrest.

There is currently no proven single monitoring system or set of alarm thresholds able to detect all respiratory patterns that result in unexpected death events. Overall sensitivity to impending events may be increased by using multiple monitors to detect patterns of change.

Newer Monitoring Technologies and Alert Algorithms

As discussed above, workforce limitations often exist for achieving the high frequency and consistent monitoring required to accurately capture adverse events and single monitor alarms are limited in their ability. Efforts are ongoing to develop and validate newer monitors with smarter alert systems.

Algorithms that combine multiple individual physiologic parameters to produce a single "superfusion" threshold may increase the sensitivity of threshold systems while still avoiding false alarms. One example is the Modified Early Warning Score (MEWS).[14] The MEWS is a simple additive threshold alarm that combines multiple monitors into one number for documentation and alerts. Future smart algorithms should analyze patterns of change with combinations of vital signs rather than simply adding thresholds of single monitors. These systems should predict the trajectory towards respiratory depression before an event occurs, allowing for early responses and less morbidity.

Integrated medication delivery systems and monitoring such as capnography and pulse oximetry combined with IV PCA devices allow for monitoring and response to be tied together.[15] A monitor that can integrate multiple sensors and, through the use of a pattern recognition algorithm, detect early signs of respiratory depression can functionally lockout the delivery of additional opioid while alerting medical personnel.[16]

Respiratory rate can be measured during capnography with changes in airflow from the CO_2 sampling line. However, alternative methods of detecting respiratory rate have also been evaluated. Acoustic monitoring is appealing since it can be performed without direct patient contact. This method is particularly attractive in children since maintaining a sampling line on a child can be difficult.[17] However, acoustic monitoring has thus far been fraught with errors leading to alarm fatigue.[18] Radar systems that monitor ventilation by mounting a sensing system in the wall or ceiling of the room are being evaluated, but are also limited by movement errors and false alarms.[19]

Bioimpedence is a technology that uses changes in electrical conductance of the chest obtained with surface electrodes to estimate respiratory rate, minute ventilation, tidal volume, and apnea events. Studies have shown that this type of respiratory volume monitor (RVM) can detect changes in minute ventilation and impending respiratory depression more rapidly and to a greater degree than capnography alone.[20] One study found that RVM can detect the onset of respiratory depression more than 12 minutes before the onset of desaturation.[21] In particular, patients receiving supplemental oxygen frequently showed signs of low minute ventilation using RVM without any desaturation alarm occurring. One of the major problems with current implementations of the bioimpedence monitors is the need for the surface electrodes placed on the

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Table 1: Pros and Cons of Continuous Electronic Monitors

MONITOR	PARAMETERS	PROS	CONS
Pulse Oximetry	SpO_2 HR	• Inexpensive, widely available • Well tolerated • Incorporated into wearables for comfort & mobility	• Poor monitor with supplemental O_2 • Threshold alarm - results in false positives and delayed detection depending on where threshold is set
Capnography	$EtCO_2$ RR	• Good for ↓ and ↑ RR • Detects apnea • Useful with suppl. O_2	• Sampling line not well tolerated • Qualitative • Expensive • Not widely available • Simple threshold alarm
Combined Threshold (MEWS)	RR HR (SBP UOP Temp Neuro Status)	• Multi-parameter input • More sensitive to ↓ RR • ↓ delay to intervention • ↓ delay for ICU transfer	• Requires integrated electronic health record • Sum of simple threshold alarms • Requires robust hospital response protocols
Integrated Delivery and Monitoring Devices	SpO_2 $EtCO_2$ RR	• Monitor tied to drug delivery • Use of algorithms • Interrupt drug delivery before notifying clinicians	• Expensive • Not widely available • Both CO_2 sampling line and oximeter required
Acoustic Monitor	RR	• Better tolerated (e.g., children) • Detects ↓ and ↑ RR • Detects apnea	• Prone to motion & noise artifacts • High false positives • Alarm fatigue
Radar Monitor	RR	• No patient contact • Better tolerated (e.g., children) • Detects ↓ and ↑ RR • Detects apnea	• Prone to motion artifacts • High false positives • Alarm fatigue
Bioimpedence	RR TV MV	• ↑ sensitivity to ↓ ventilation • Detects apnea • Detects ↓ ventilation before ↓ SpO_2	• Expensive • Cumbersome to wear • Prone to motion artifacts • High false positives • Alarm fatigue • False negatives with obstructive apnea
Inductance plethysmography & audiometry	RR SpO_2 Airway Patency	• ↑ sensitivity to ↓ ventilation • Detects apnea • Detects obstructive apnea • Detects ↓ ventilation before ↓ SpO_2 • Detects isolated ↓ SpO_2	• Expensive • Cumbersome to wear • Prone to motion artifacts • High false positives • Alarm fatigue

SpO_2 – peripheral oxygen saturation
HR – heart rate
$EtCO_2$ – end-tidal carbon dioxide
RR – respiratory rate
SBP – systolic blood pressure
UOP – urine output
TV – tidal volume
MV – minute ventilation
ICU – intensive care unit

Advantages and Disadvantages of Available OIVI Monitoring

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patient to be physically connected to a device that analyzes the motion. In addition, non-respiratory motion such as coughing or moving can create false signals. Lastly, chest wall movement without air exchange as occurs with airway obstruction can also fool some bioimpedence devices (Table 1).[17]

More complex integrated systems that combine respiratory inductance plethysmography with audiometry and pulse oximetry are very sensitive for detecting respiratory depression, but the current systems are very cumbersome, difficult for patients to wear, are subject to motion artifacts, and have similar limitations with false chest wall movements such as coughing or crying, as with other bioimpedence devices.[17]

Conclusions: An Ideal Future

In an ideal future, no patients will be harmed by postoperative OIVI. To achieve this goal, we will need alternative analgesics that are as effective as opioids but do not cause respiratory depression. Until then, we need to mitigate the risk of the opioid medications we currently use. This will be done through intelligent use of nursing resources combined with advanced monitoring systems that are sensitive in detecting impending respiratory events. To facilitate this future, key shareholders should help delineate a taxonomy for opioid-related adverse events including respiratory depression, with accompanying guidelines and outcome measures.

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Neither author has any conflict of interest to declare as it relates to this article.

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Vision

The vision of the Anesthesia Patient Safety Foundation is to ensure that no patient shall be harmed by anesthesia.

& Mission

The APSF's Mission is to improve continually the safety of patients during anesthesia care by encouraging and conducting:

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

Dear SIRS

Ball-Bearings From MRI Anesthesia Machine Writing Tray Slide Found Near MRI Scanner

Dear SIRS:

I am writing to describe an incident we experienced at Connecticut Children's Medical Center that has implications for MRI safety. Following inhalation induction inside the MRI scanner room of a 12-year old patient, I heard a few bangs that sounded like objects being sucked into the magnet. Upon closer inspection, I observed several ball bearings lying on the ground and others that had apparently rolled across the floor and were pulled up the side of the magnet. We evacuated the patient and woke her up uneventfully. We use a Dräger Fabius MRI compatible anesthesia machine which is located approximately 5–10 feet from the entrance of the 1.5T magnet. This machine is equipped with several drawers and a shelf all of which have slides and encased ball bearings. Dräger Medical and Siemens Medical have both been informed of the incident.

Michael Archambault, MD
Connecticut Children's Medical Center
Hartford, CT

Reply:

Dräger would like to thank the Anesthesia Patient Safety Foundation (APSF) for the opportunity to respond to the above submission.

The authors describe a situation where, after induction, the clinician heard a few bangs that sounded like objects being sucked into the magnet. The clinician looked to the ground and saw ball bearings lying on the ground. Upon inspection, one ball bearing was found attached to the MRI magnet. No patient injury was reported.

The clinician reported that the source of the ball bearings was believed to have come from one of the drawers, which utilizes ferromagnetic ball bearings. The facility wanted to continue using the device so all the drawers, the writing tray, and all the slides were removed from the machine as a precaution. The machine passed all self-tests, and the hospital personnel performed additional testing between Fabius MRI and MRI machine successfully.

Prior to outlining Dräger's findings during the investigation, it is important to clarify that contrary to the Fabius MRI being reported as "MRI Safe" during this submission, the Fabius MRI is instead

WARNING
The Fabius MRI anesthesia machine has been tested with magnets with field strengths of 1.5 tesla and 3 tesla by a fringe field strength of 40 mtesta (400 gauss). Use of the machine at higher strengths could result in ventilator and device malfunction. Additionally, unmanageable attractive forces could lead to serious injury.

Figure 1: Warning from Fabius MRI Instructions For Use (IFU).

"MRI Conditional" (please see warning from the Fabius MRI IFU) in Figure 1. This clarification is important in that the Fabius MRI is cleared from use "with magnets with field strengths of 1.5 tesla and 3 tesla by a fringe field strength of 40 mtesla (400 gauss). The use of the machine at higher strengths could result in ventilator and device malfunction. Additionally, unmanageable attractive forces could lead to serious injury."

To provide further clarity:

- **MR Safe**—the device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individual, but may affect the quality of the diagnostic information. The MRI conditions in which the device was tested should be specified in conjunction with the term *MR safe* since a device which is safe under one set of conditions may not be found to be so under more extreme MRI conditions.
- **MR Conditional**—An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR).

In this case, upon inspection of the Fabius MRI, the Dräger Service technician found that the writing tray of the Fabius MRI was damaged, and this damage led to the ball bearings in the writing tray slide being "dislodged" from the Fabius MRI machine (Figure 2).

Dräger completed further investigations on the ball bearings in question and found that, even when outside of the anesthesia machine, the ball

Figure 2: This figure depicts the ball bearings that were retrieved near and on the side of the MRI scanner by the provider.

bearings are not attracted to the magnet when kept outside of the 400 gauss line. This is consistent with the findings reported by the clinician, which said that ball bearings remained loose on the floor (beyond the 400 gauss line). These findings lead Dräger to believe that upon the ball bearings being dislodged from the Fabius MRI, at least one ball bearing infringed on the 400 gauss line, leading to the ball bearing being attracted to the magnet.

Dräger has no explanation on how the writing tray slides were damaged, which is a requirement for the ball bearings to become dislodged from the anesthesia device. The slides are approved for 25kg, and the writing tray is labelled with a "max. 10 kg" load. Additionally, the writing tray passed a load test "four times" the labelled load. Finally, since the Fabius MRI was introduced 10 years ago, this is the only reported destruction of the writing tray slides.

In summary, Dräger would like to thank the authors for sharing this unique scenario to the anesthesia community. It underscores the importance of understanding the risk associated with utilizing equipment inside an MRI environment, and the difference between an "MRI Safe" and "MRI Conditional" device.

Thank you,
David Karchner
Director of Marketing, Dräger, North America

See more "Dear Sirs," Next Page

SAFETY INFORMATION RESPONSE SYSTEM

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. Dr. Jeffrey Feldman, current chair of the Committee on Technology, is overseeing the column and coordinating the readers' inquiries and the responses from industry.

Dear SIRS

Airway Topicalization Atomizer Parts Break Off in Patient's Airway

Dear SIRS:

Topical anesthesia of the upper airway for awake intubation is often accomplished by spraying local anesthetics through an atomizer.[1] In our institute, we routinely utilize EZ-Spray™ (Figure 1) (Alcove Medical Inc., Saratoga Springs, UT). Here we report an event in which the nozzle part of the EZ-Spray™ unexpectedly broke off during routine topicalization for an awake intubation. In this situation, the EZ-Spray™ was powered by 15 L/min of oxygen delivered from an E O_2 cylinder. Immediately after the breakage, patient spit out two components of the EZ-Spray™ (Figure 2). Since these two pieces were the only pieces missing and were retrieved in full, and the patient was not coughing and reported no feelings of foreign body in his throat, no imaging of the chest or bronchoscopic exam of his tracheobronchial tree were performed. The originally planned awake intubation and the intended procedure were subsequently accomplished uneventfully. Fortunately, this event resulted in no harm to the patient; however, we would like to take this opportunity to raise the awareness of this potential equipment malfunction. To avoid any related aspiration, we recommend:

1) Check the integrity of the atomizer before spraying.
2) Search for the small components shown in the picture if breakage does happen.
3) If a part is missing:
   A) The patient's oral cavity should be thoroughly searched for any residual components of breakage.
   B) If all components cannot be located, a radiograph of the oropharynx, and/or lung should be obtained, and a bronchoscopic examination should be performed which should reveal the metal and plastic components if they have been aspirated, and allow for extraction.
4) We also recommend reviewing similar equipment failure related events and reporting them in FDA's Medsun system. (https://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/default.htm)

Figure 1: Normal EZ-100 Power Sprayer.

Dr. Mi Wang is a staff anesthesiologist in the Department of Anesthesiology at the Cleveland Clinic, Cleveland, OH.

Dr. Piyush Mathur is a staff anesthesiologist in the Department of Anesthesiology at the Cleveland Clinic, Cleveland, OH.

Dr. Basem Abdelmalak is Professor of Anesthesiology and Director of Anesthesia for Bronchoscopic Surgery and the Center for Sedation in the Department of Anesthesiology at the Cleveland Clinic, Cleveland, OH.

None of the authors have any conflicts of interest as they relate to this article.

Reference

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Reply:

Alcove Medical, Inc., received notification of the occurrence cited by the Cleveland Clinic providers on June 13, 2017. However, our initial response was based on the understanding that the EZ Spray product referred to was an EZ-103-A, a reposable power sprayer. After receiving photographs of the Power Sprayer involved, however, we now realize Dr. Wang was referring to our EZ-100, a one-time use Power Sprayer.

From Dr. Wang's report, it seems apparent that somehow the EZ-100 Power Sprayer used by Dr. Wang was not bonded properly. If properly bonded, it would be impossible for the plunger rod and spring to be ejected.

We have since reviewed our assembly safety and inspection procedures and have added and implemented the following: Instead of two tests for function and one for visual quality we have instituted a third "hands on test" where all bonded joints are manually checked for adhesion and strength. Then, they are visually inspected before being processed for shipment.

We believe this safety policy will help insure increased quality and safety in all of our products.

Our single use power sprayer, EZ-100, was designed specifically for difficult airway management. Its single use, patented, closed system prevents the possibility of cross-contamination and provides the benefit of deep, penetrating atomization. The EZ-100 nozzle extender is bonded to the body. The whole Power Sprayer is discarded after each use.

Alcove Medical is an American-based family business and has never before had any incident of any kind with any of its products since its inception in 1997. We appreciate the opportunity to respond to this matter and to be able to explain the procedures and safety policies put in place in regards to EZ-100 Power Sprayer assembly and all Alcove products.

Thank you,
John K. Bullock, COO
Alcove Medical, Inc.

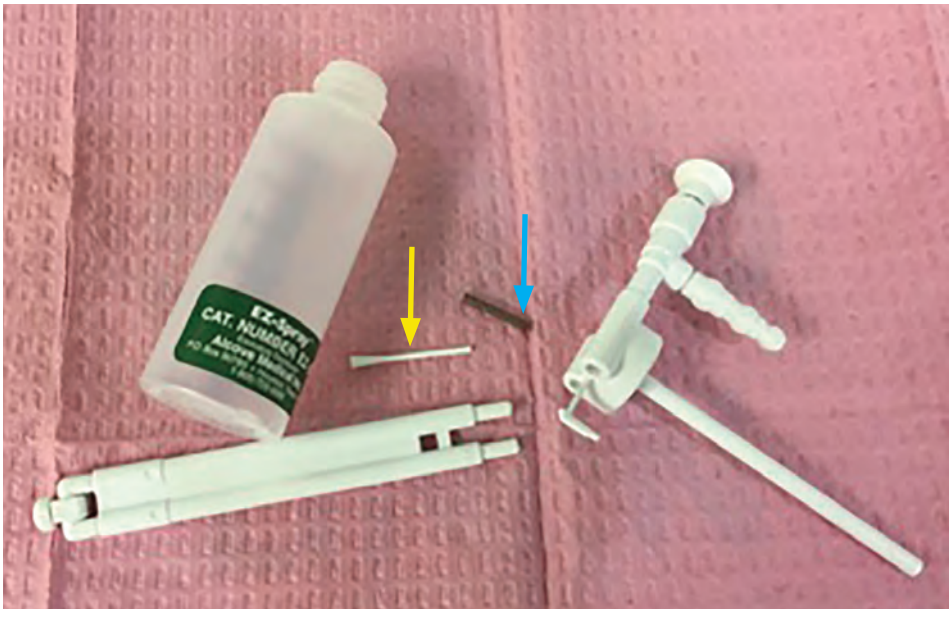

Figure 2: This figure represents the components of the EZ-Spray™ atomizer. The Blue arrow points to the spring, while the yellow arrow points to the pushrod. Both small components were spit out by the patient after EZ-Spray™ breakage.

2018 Corporate Giving Opportunities

Your company can support patient safety and education with a gift to the Anesthesia Patient Safety Foundation. As a 501c3 charitable organization, APSF can serve your company's corporate responsibility, charitable giving and research goals.

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

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

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

If your organization is interested in partnering with APSF to support patient safety, contact the APSF office at moser@apsf.org or warner@apsf.org

Participate in the 2018 APSF Corporate Advisory Council

The Anesthesia Patient Safety Foundation invites you to become a member of our 2018 Corporate Advisory Council (CAC). When your company becomes a member of the CAC, in addition to the benefits of membership, your company will also be recognized as a supporter of the mission of APSF. Some of the benefits of membership, depending on your level of support and participation, include

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

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

Opportunity to Sponsor APSF Stoelting Consensus Conference

The Stoelting Conference, formerly known as the Consensus Conference, brings a defined group of approximately 125 leaders from perioperative professional organizations such as the American Society of Anesthesiologists (ASA), the American Association of Nurse Anesthetists (AANA), the Association of Operating Room Nurses (AORN), the American Society of Peri-Anesthetic Nurses (ASPAN), and surgical societies together with representatives from anesthesia-related industries and colleagues from insurance, human factors, and legal fields. The recommendations from these conferences have led to significant practice and other changes and improved patient safety. Examples include perioperative fire safety, vision loss, residual neuromuscular blockade, and operating room distractions. The 2018 Stoelting Consensus Conference is September 5–6, 2018, at the Royal Palms Resort in Phoenix, AZ and is entitled "Perioperative Medication Safety—Advancing Best Practices."

Maximum Number of Stoelting Conference Supporters: Four

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

Sponsorship of Translations of the *APSF Newsletter*

One of APSF's key initiatives is to improve the international exchange of patient safety information and ideas. To accomplish this in 2018, we are working with our colleagues and industry partners to make perioperative patient safety information, guidelines, and recommendations easy to obtain worldwide. The seven translated languages will include Chinese, Spanish, Portuguese, French, Arabic, Russian, and Japanese. Data from the World Health Organizations suggest that 95% of the world's anesthesia professionals will comprehend articles in English or in one of these languages.

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


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Anesthesia Patient Safety Foundation（APSF）は、日本麻酔科学会（JSA）と連携し、日本語版APSFニュースレターを作成し、配布することにしました。JSAの安全委員会がこの企画を担当します。共通した目標は、周術期の患者の安全教育を改善することです。APSF Newsletterの読者は、12万2千人以上おりますが、各国で25万人までの拡大を目指しています。今後は、さらにスペイン語，中国語，ポルトガル語，アラビア語，ロシア語の5か国語で発行する計画があります。このプロジェクトの日本における第1版をこのたび出版できる運びとなりました。今後も、充実した内容になるように努めてまいりたいと思います。

APSF Newsletter日本語版　編集担当：

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Steven Greenberg, MD, FCCP, FCCM

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First Japanese edition of selected articles was published in November 2017.

Opportunity to Partner with APSF on Patient Safety Research Grants

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

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

2018 APSF Grant Recipients

by Steven K. Howard, MD

The APSF's mission statement explicitly includes the goal to continually improve the safety of patients during anesthesia care by encouraging and conducting safety research and education. Since 1987, the APSF has funded safety projects totaling over nine million dollars.

The 2017-2018 APSF investigator-initiated grant program had 34 letters of intent submitted with the top scoring grants undergoing statistical review as well as detailed discussion among members of the Scientific Evaluation Committee. The top nine scoring grants were invited to submit full proposals, and eight of them were submitted for final review and discussion on October 21, 2017, at the ASA Annual Meeting in Boston, MA. Two proposals were recommended to the APSF Executive Committee and the APSF Board of Directors for funding and both received unanimous support. This year's recipients were John Fiadjoe, MD, from the Children's Hospital of Philadelphia and Randy Loftus, MD, from the Department of Anesthesiology at the University of Iowa.

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

John E. Fiadjoe, MD

Associate Professor of Anesthesiology and Critical Care Medicine
The Children's Hospital of Philadelphia

Dr. Fiadjoe's Clinical Research submission is entitled ***"The Videolaryngoscopy in Small Infants (VISI) Trial."***

Background: Approximately 1.5 million infants undergo surgery requiring general anesthesia each year in the U.S.; the majority require tracheal intubation (TI). Intubation-associated adverse events in infants are underappreciated because of low case volumes and a lack of high-quality studies. Direct laryngoscopy (DL) is the standard for initial TI attempts in infants. It is highly effective, but is difficult to master, requiring 45–57 attempts to become proficient.[1,2] Infants are vulnerable during TI because of their rapid hemoglobin desaturation. Securing the airway on the first pass is the best practice to minimize complications; however, initial attempts in infants are often made by trainees who lack the kinesthetic skill to secure the airway rapidly. Videolaryngoscopy (VL) improves trainee coaching during TI, and the shared view reassures the supervising clinician that the tracheal tube is appropriately placed. We discovered in a multicenter study of children with difficult airways that the number of TI attempts is a critical modifiable risk factor for severe adverse events such as hypoxemia, bronchospasm, laryngospasm, and cardiac arrest. Multiple attempts (>2) were independently associated with complications (OR 3.1, 95% CI 2.1–4.6; $p < 0.0001$).[3] In 1,343 healthy infants with normal airways presenting for elective surgery, we found (unpublished data) from electronic medical record data that 16% required more than one intubation attempt and (371 of 1,134) 32.7% of children with one attempt experienced severe hypoxemia compared to (101 of 210) 48.1% of those with multiple attempts. These results likely overestimate the incidence of severe hypoxemia ($SpO_2 < 90\%$ for more than 1 minute) because of tourniquets applied for intravenous access and other artifacts. Nevertheless, the differences between the two conditions (multiple vs. single attempt) are likely accurate. Taken together, the literature on the impact of multiple TI attempts is consistent. In emergency rooms, intensive care units, and operating rooms, multiple TI attempts increased complications including dysrhythmia, hypotension, hypoxemia, unrecognized esophageal intubation, regurgitation, airway trauma, dental or lip trauma, mainstem intubation, and cardiac arrest. There is a knowledge gap regarding the safest device to secure the airway of infants with normal airways with the least number of attempts.

Aims: To determine if a non-angulated VL as the first attempted device improves first pass TI success in infants ≤12 months of age with a normal airway exam, defined as a patient without craniofacial abnormalities such as micrognathia, mild-face hypoplasia, or limited mouth opening. We hypothesize that using a non-angulated VL for the first intubation attempt will be associated with fewer intubation attempts. We also hypothesize that using a non-angulated VL for the first intubation attempt will be associated with less hypoxemia.

Implications: Our project could potentially lead to a reduction in multiple TI attempts, consequent hypoxemia, and associated complications. Our results could be applied to all areas where infants require TI including neonatal and pediatric ICUs, emergency departments, hospital floor units and even intubations in the field. Forty percent of pediatric surgical cases in the United States are managed in adult hospitals by clinicians who lack the requisite pediatric TI experience. VL may close the skill gap for these clinicians and improve the safety of infant intubation.

Funding: $149,702 (January 1, 2018—December 31, 2019). This grant was designated as the APSF/Medtronic Research Award. Dr. Fiadjoe is also the recipient of the Ellison C. "Jeep" Pierce, Jr., MD, Merit Award, which provides an additional, unrestricted amount of $5,000.

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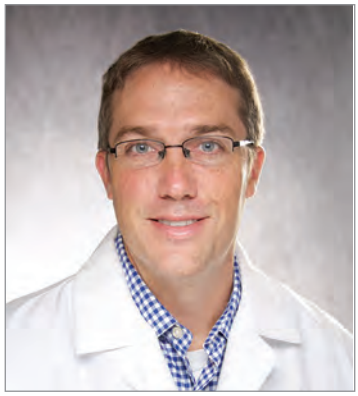

Randy W. Loftus, MD

Assistant Professor of Anesthesiology and Critical Care Medicine
University of Iowa Hospitals and Clinics

Dr. Loftus' Clinical Research submission is entitled ***"Reducing Perioperative S. aureus Transmission via Use of an Evidence-Based, Multimodal Program Continually Optimized by Innovative Surveillance (OR PathTrac)."***

Background: A decade of research has examined the magnitude and implications of bacterial transfer in the anesthesia work area environment. The conceptual framework is that if anesthesiologists, historical and current leaders in patient safety, can establish a better understanding of how bacterial pathogens are transmitted and cause disease in our environment, then we can use this information as a platform to guide perioperative improvements in

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Grant Recipients Focus on Pediatric Airway Management Safety and Perioperative Infection Control

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patient safety. We have developed and validated a model for the study of intraoperative bacterial cross contamination that has firmly established the need for a multimodal program designed to maximally attenuate intraoperative bacterial transmission and the development of postoperative health care-associated infection (HAI) development. In response, we have generated an evidence-based bundle that incorporates advances in intravascular catheter design and handling, hand hygiene, environmental cleaning, and patient decolonization. We have more recently developed an innovative platform for active surveillance of bacterial transmission to measure the fidelity of bundled components for the purpose of early fatigue identification and mitigation. The surveillance platform uses a systematic phenotypic and genomic approach, bringing genomic analysis to the patient bedside to improve basic preventive measures. We now plan to leverage the evidence-based bundle along with active surveillance of *S. aureus* transmission to reduce perioperative transmission and subsequent infection development.

Aims: Our primary aim is to reduce perioperative *S. aureus* transmission. We hypothesize that this approach will reduce *S. aureus* transmission by at least 30%. Our secondary aim is to reduce postoperative HAIs. We hypothesize that this approach will reduce surgical site infections (superficial and deep) by at least 40%. An evidence-based bundle incorporating improvements in intravascular catheter design and disinfection, hand hygiene, environmental cleaning, and patient decolonization will be implemented to maximally attenuate perioperative bacterial transmission and subsequent infection development. In parallel, an evidence-based surveillance system (OR PathTrac) will be implemented to continually track perioperative bacterial transmission dynamics. Bacterial transmission events mapped by OR PathTrac that are linked to failures in hand decontamination, intravascular catheter hub disinfection, environmental cleaning, and/or patient decolonization efforts will be used by an infection-control perioperative team to design and to measure the effect of targeted improvements in bundle component(s). Improvements may include, but are not limited to, individual and group level feedback, environmental reorganization, and equipment redesign. All efforts will be customized by surveillance data, and ongoing surveillance will monitor the effect of proactive improvements. Ultimately, OR PathTrac will provide a mechanism for continued optimization of the evidence-based bundle throughout implementation, and, as primary and secondary aims are reached, a mechanism to measure the relative effectiveness of bundle components.

Implications: This work serves to address a major agenda put forth by the Centers for Disease Control (CDC) including the prevention of infections affecting patients undergoing surgery and the prevention of bacterial spread between patients. In addition, successful demonstration of this approach will solidify anesthesia providers as the first professional group to bring genomic analysis to the patient bedside to improve basic preventive measures, satisfying a key initiative put forth by key stakeholders in infection control. Future applications of this work will address improved antibiotic stewardship through the generation of prospective, dynamic perioperative antibiograms and detection of emerging resistance, satisfying the third and final agenda put forth by the CDC to address the alarming issue of the persistent HAIs, associated increases in patient morbidity and mortality, and the ongoing evolution of antibiotic resistance in the postantibiotic era.

Funding: $150,000 (January 1, 2018—December 31, 2019). This grant was designated the APSF/ASA President's Research Award.

Dr. Howard is a Professor of Anesthesiology, Perioperative and Pain Medicine at Stanford University School of Medicine, Staff Anesthesiologist at the VA Palo Alto Health Care System and the Chair of the APSF's Scientific Evaluation Committee.

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

APSF Sponsors the Resident Quality Improvement Program for 3rd Straight Year

by Maria van Pelt, PhD, CRNA; Brian Cammarata, MD; Lianne Stephenson, MD; and Sandeep Markan, MD

APSF sponsored the third annual Resident Quality Improvement (RQI) Program. All U.S. and Canadian physician anesthesiology programs were invited to submit a four-minute video showcasing their best quality-improvement and patient-safety projects. All projects were evaluated in a standardized manner. APSF received a 50% increase in submissions from 2016. Additionally, project quality was consistently high. The winners were announced at the 2017 ASA Annual Meeting in Boston, MA. APSF acknowledges all residency programs who participated in the 2017 program.

The winning 2017 RQI project was submitted by Drs. S. Yalamuri and M. Plakke from Duke University Hospital. Their patient-safety video entitled "The Duke ICU Transition to OR (DITTO) Checklist," depicted a newly developed safety checklist improving transfer between the intensive care unit and operating suites. In addition to promoting safe transfers, the checklist reduced transfer time.

The APSF RQI Committee determined a tie for second place between the University of Florida (Gainesville) and Massachusetts General Hospital participants. Dr. C. Sotillo (University of Florida, Gainesville) submitted a video entitled "Reducing Pharmaceutical (Propofol) Waste Quality Improvement Project." In her submission, Dr. Sotillo analyzed and sought to improve current perioperative medication preparation/utilization practices. Dr. D. Bartels (Massachusetts General Hospital) submitted a video entitled "Improving Patient Care with Better Transitions of Care." In this project, Dr. Bartels reviewed current transition of care processes and identified/implemented improvements at her institution.

In 2018, the APSF Committee on Education and Training will develop three parallel tracks for the quality improvement program. These tracks will include physician anesthesiology residency, nurse anesthesia, and anesthesiology assistant training programs. All anesthesiology training programs will be invited to demonstrate their program's work in patient safety and quality improvement (QI) initiatives. Over the next several months, links to the 2017 winning videos and announcement details for the 2018 QI Program will be available on the APSF website.

Dr. van Pelt is the APSF Chair, Education and Training Committee and an Executive Committee and Board of Directors member.

Dr. Cammarata is Partner and Director of Quality Assurance at Old Pueblo Anesthesia in Tucson, AZ. He serves on the APSF Committee on Education and Training.

Dr. Markan is Vice Chair of Patient Safety and Quality at Ben Taub Hospital, Baylor College of Medicine, Houston, TX.

Dr. Stephensen is Vice Chair of Quality and Safety and Associate Professor of Pediatric Anesthesiology at the University of Wisconsin-Madison.

None of the authors have any disclosures to report.

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For more information about how your organization can support the APSF mission and participate in the 2018 Corporate Advisory Council, please see page 75 of this newsletter; go to: aspf.org or contact Sara Moser at: moser@apsf.org.

Special recognition and thanks to Medtronic for their support and funding of the APSF/Medtronic Patient Safety Research Grant ($150,000) and Merck for their support and funding of the APSF Patient Safety Initiative ($99,000).

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2017 Ellison C. Pierce, Jr., MD, Award for Best Abstract in Patient Safety

by Crystal M. Woodward, MD, and Maria van Pelt, PhD, CRNA

The ASA Abstract Review Committee for the Patient Safety and Practice Management Track (ASA 2017) completed a review of 143 abstracts and selected the top ten abstracts for consideration for the 2017 Ellison C Pierce Jr. (JEEP) APSF Award for Best Abstract in Patient Safety. A subcommittee of the APSF Committee on Education and Training convened and chose the 2017 winner from the top ten selected abstracts.

The 2017 JEEP Patient Safety Award winners are Crystal M. Woodward, MD, Grete H. Porteous, MD, Helen A. Bean, DO, Ryan P. Beecher, CRNA, Jennifer R. Bernstein, BA, Sarah D. Wilkerson, RN, Ian Porteous, PhD, and Robert L. Hsiung, MD, from Virginia Mason Medical Center, Seattle, WA, USA. This award was presented at the Pierce Lecture on Saturday, October 21, 2017, at the ASA Meeting 2017. A summary of their abstract entitled "A Simulation Study to Evaluate Improvements in Anesthesia Work Environment Contamination Following Implementation of a Bundle of Interventions" is discussed below.

Anesthesia professionals deliver patient care in a variety of settings in which "clean" and "contaminated" tasks are performed rapidly and often in parallel. The research team at Virginia Mason Medical Center designed a simulation study to test whether implementation of a bundle of interventions could help decrease contamination within the anesthesia work environment. The study design consisted of using UV tracers in a 2-part simulation study which allowed direct visualization of contamination within the simulated OR. Fifty simulation scenarios were completed by 25 different participants which included residents, attendings, and CRNAs. The bundle of interventions that was implemented within the simulations included tasks such as double gloving prior to intubation and hand washing prior to touching the anesthesia cart. Results showed that contamination rates decreased significantly by 27% during the scenarios in which the bundle of interventions was implemented. Further analysis revealed that the bundle also had a significant impact on decreasing contamination specifically of the anesthesia cart and the anesthesia machine. This simulation study highlighted both the extent of contamination possible within the anesthesia work environment as well as the overwhelming importance of hand hygiene among anesthesia providers. The study will also be published soon in *Anesthesia & Analgesia* and has resulted in multiple educational changes within the anesthesia department at Virginia Mason.

Dr. Woodward is a senior anesthesiology resident at Virginia Mason Center, Seattle, WA.

Dr. van Pelt is the APSF Chair, Education and Training Committee and an Executive Committee and Board of Directors member.

Neither of the authors have any conflicts of interest to declare.

Dr. Mark Warner (President of the APSF) congratulates the 2017 Ellison Pierce, Jr., MD, "Best Abstract in Patient Safety" award winners, (from left to right) Drs. Crystal Woodward and Grete Porteous from Virginia Mason Medical Center, Seattle, WA, at the 2017 ASA Annual Meeting in Boston, MA.

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.

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Use of Methadone in the Perioperative Period

by Glenn Murphy, MD, and Joseph Szokol MD, JD, MBA

Methadone, a drug that was initially developed in 1946, has a number of unique properties compared with other opioid analgesics, which give it an increasing role in the perioperative period. It has been one of the most extensively studied drugs in medicine, with over 15,000 PubMed citations. Methadone is primarily recognized and studied as a replacement treatment for heroin addiction. Despite the large number of investigations of this unique opioid, there have been only a limited number of clinical trials of methadone in surgical patients. The aim of this review is to examine the potential advantages of methadone as a perioperative analgesic agent, particularly in the context of the current opioid epidemic in the United States and other nations.

Over the past four decades, there has been a trend in the operating room towards the use of opioids with shorter half-lives and duration of effect, such as fentanyl, sufentanil, and remifentanil. Patients are then often transitioned to agents with longer half-lives (hydromorphone, morphine) for postoperative pain management. These postoperative opioids are delivered either via intermittent injection or through a patient controlled analgesia (PCA) device. The primary problem with this mechanism of delivery is that significant fluctuations in serum opioid concentrations can occur, resulting in effects which range from inadequate analgesia (pain and activation of the PCA) to overdosage and respiratory depression. These "peaks and valleys" of pain control that occur with intermittent narcotic administration may explain why a large percentage of surgical patients report moderate-to-severe pain during the first 1–3 postoperative days (POD).[1] Furthermore, poor analgesic control may be associated with increases in morbidity and mortality, lower patient satisfaction, and the development of chronic postsurgical pain.

Methadone is a unique opioid that may provide several important potential benefits for the patient in the perioperative period. It is a potent μ-receptor agonist with a rapid onset (6–8 minutes) and the longest half-life (24–36 hours) of the clinically-used opioids.[2] When used in larger doses, the clinical effect is terminated by systemic elimination. As reviewed in an editorial by Evan Kharasch, methadone dosing should be as high as possible above the minimal analgesic concentration, but below the threshold for respiratory depression; at doses of ≥ 20 mg, the duration of analgesia approximates the half-life of 24 to 36 hours.[2] Therefore, a single 20-mg dose administered to an adult at induction of anesthesia can provide significant pain relief throughout the first 1–2 POD.[2] In addition to providing long-lasting and stable analgesia throughout the most intense period of postoperative pain, methadone is a N-methyl-D-aspartate (NMDA) receptor antagonist. It has been reported to possess anti-hyperalgesic and anti-allodynic properties, to inhibit the development of tolerance, and to be effective in the treatment of neuropathic pain; these properties are likely mediated by the ability of methadone to block the NMDA receptor.[3-5] Finally, methadone has been demonstrated to decrease the reuptake of serotonin and norepinephrine in the brain, which may contribute to a mood-elevating effect of the agent and influence the affective dimensions of pain processing. However, this feature also increases the risk of serotonin syndrome in patients taking other medications that inhibit serotonin reuptake.[6]

The first clinical trials of methadone were performed in Australia in the 1980s. Gourlay et al. administered 20 mg of methadone to 23 healthy adult patients undergoing abdominal or orthopedic procedures at induction of anesthesia.[7] Nine patients (39%) required no additional postoperative analgesic agents, 6 patients (26%) requested non-narcotic pain medication, and 8 patients (35%) required an opioid agent postoperatively, but the mean duration of analgesia was 18.4 hours. In an additional trial, 16 adult patients undergoing a variety of procedures were given 20 mg of methadone at anesthesia induction.[8] Subjects were administered additional methadone in the postanesthesia care unit (PACU) until they were comfortable as long as they met all of the following criteria: 1) that the patient complained spontaneously of significant pain; 2) that there was no pronounced respiratory depresssion (unstimulated respiratory rate greater than 10 breaths per minute); and 3) there was no marked depression in the level of consciousness. One to three supplemental doses of methadone were given in the PACU (median total dose of 10 mg). The subsequent duration of analgesia was 21 hours, with reported mean pain scores of 1.5 on a scale of 1–10. A further study by the same investigators randomized 20 adult patients undergoing abdominal surgical procedures to receive either 20 mg of methadone or morphine at the induction of anesthesia.[9] Subjects were then given either 5 mg of methadone or morphine (blinded syringes) in the PACU until comfortable after meeting the same three criteria as their previously mentioned study. Both groups required 8–9 mg of either opioid in the PACU; however, the mean duration of analgesia was 21 hours in the methadone group versus 6 hours in the morphine group. No adverse events were reported in the patients administered methadone.

No further clinical trials were published examining methadone use in the perioperative period until the early 1990s. In these studies which assessed the utility of methadone in gynecologic, pediatric, and abdominal surgery patients, a reduction in pain scores and analgesic requirements was noted in patients administered methadone.[10-12] However, these investigations were limited by lack of blinding, randomization, small sample sizes, or lack of standardization of perioperative anesthetic management techniques.

In 2011, Gotttschalk et al. published a study in which 30 adult patients were randomized to receive either methadone (0.2 mg/kg at induction) or sufentanil (bolus and infusion) for complex spine surgery.[13] At 48 hours, methadone reduced postoperative opioid requirements and pain scores by approximately 50%. The same year, investigators from Washington University examined the pharmacokinetics of methadone in 31 adolescent patients undergoing complex spine surgery randomized to receive 0.1, 0.2, or 0.3 mg per kg of methadone, up to a maximum of 20 mg.[14] The investigators found that methadone pharmacokinetics were linear over the dose range studied. Although pain scores did not differ between groups, the study was not powered to examine this secondary outcome.

Murphy et al. randomized 156 patients undergoing cardiac surgery to receive either methadone (0.3 mg/kg) or fentanyl (12 μg/kg) at the start of surgery.[15] Postoperative intravenous morphine requirements in the methadone group were reduced by 40% during the first 24 hours after tracheal extubation. In addition, pain scores were decreased by 30 to 40% and patient-perceived quality of pain management was significantly improved during POD 1–3 in the methadone group. In a similar study enrolling 120 patients undergoing complex spine surgery, subjects were randomized to receive either 0.2 mg/kg of methadone at the start of surgery or 2 mg of hydromorphone at the end of surgery.[16] Patients in the methadone group required significantly less intravenous and oral opioid medication, reported lower pain scores, and had improved global satisfaction with pain management during the first three PODs, compared to subjects given intraoperative hydromorphone. No adverse events directly attributable to methadone were reported in any of previous seven investigations, though most studies were not adequately powered to detect opioid-induced ventilatory impairment.

Although methadone appears to be an effective and safe opioid for use in the perioperative period, a

See "Methadone," Next Page

Further Research on Methadone May Answer Numerous Clinical Concerns

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number of important questions remain that need to be addressed in future investigations:

1. **What is the most effective analgesic dose of methadone?**

   Only one dose-response study has been performed using methadone in surgical patients.[14] In the majority of clinical investigations, a dose of either 20 mg or 0.2 mg/kg has been administered. It is possible that larger doses may result in more effective analgesia, although the resultant risk of respiratory depression may be higher.

2. **What is the most appropriate dose of methadone for patients undergoing various surgical procedures?**

   The optimal dose of methadone likely differs depending upon the surgical procedure. In current clinical practice, methadone is most commonly used in patients undergoing complex spine surgery. The "ideal" dose of methadone for surgical procedures associated with moderate-to-severe pain has yet to be determined. In addition, the proper dose in patients who are opioid tolerant may be significantly higher.

3. **Which patients are at risk for complications related to the administration of methadone?**

   Previous clinical trials have primarily enrolled younger, healthy patients. The safety and appropriate dosing regimen in older patients (>70 years of age), those with sleep apnea, patients on drugs that may influence methadone metabolism (induce or inhibit cytochrome CYP2B6), and patients with significant underlying diseases (pulmonary, cardiac) is uncertain.

4. **Is methadone safe for use in outpatients?**

   The appropriate dosing requirements and safety of methadone in outpatient procedures has not been determined, although studies are currently underway.

5. **Does a single dose of methadone cause QT prolongation?**

   Patients receiving large doses of oral methadone for longer periods of time are at risk for QT prolongation, torsades de pointes, and cardiac death. The effect of a single dose of methadone on the risk of QT lengthening and torsades de pointes has not been examined, although no adverse cardiac events related to methadone administration have been described in clinical trials or case reports.

6. **Can intraoperative methadone reduce the risk of the development of chronic postsurgical pain?**

   Methadone has the potential to reduce chronic postsurgical pain by decreasing pain in the first 1–3 POD and via antagonism of the NMDA receptor. The effect of this agent on chronic postsurgical pain has not yet been determined. In addition, it is possible that the risk of postoperative opioid addiction may be reduced if acute and chronic pain is attenuated when methadone is administered (patients will have reduced postoperative opioid requirements). In addition, the NMDA blocking properties of this opioid result in anti-hyperalgesic and anti-allodynic effects and may inhibit the development of tolerance; this may further diminish the need for opioid treatment after surgery and lessen the narcotic dependence.

7. **Is methadone use in the operating room associated with a greater risk of postoperative respiratory depression compared to other opioids?**

   At the present time, no adverse respiratory events related to methadone use have been described in the clinical trials. However, the studies are limited by small sample sizes and a lack of close postoperative respiratory monitoring to assess the incidence of hypoxemic events and airway obstruction. Further studies are needed to assess this important outcome measure. Furthermore, due to the long half-life of methadone, if a patient exhibits opioid-induced respiratory depression, a naloxone infusion may be required, as the half-life of methadone (24 hours) is significantly longer than that of naloxone (60 minutes).

In conclusion, methadone is a long-acting opioid with promising applications in the perioperative setting. Further studies are needed to define the optimal dose of this agent and which surgical patients may derive the greatest benefit from its administration in the operating room.

Dr. Glenn Murphy is Director of Anesthesiology Research in the Department of Anesthesiology, Critical Care and Pain Medicine at NorthShore University HealthSystem and is Clinical Professor in the Department of Anesthesia/Critical Care at the University of Chicago.

Dr. Joseph Szokol is the Harris Family Foundation Chairman, Department of Anesthesiology, Critical Care and Pain Medicine, at NorthShore University HealthSystem. He is also Clinical Professor in the Department of Anesthesia/Critical Care at the University of Chicago.

Dr. Murphy discloses that he is on the advisory board of Merck and has served as a consultant for Merck.

Dr. Szokol has no conflicts of interest to disclose.

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Medication Safety Alerts for Anesthesia Professionals

by Ronald S. Litman, DO

The Institute for Safe Medication Practices (ismp.org) receives reports of medication safety issues from health care providers and regulatory agencies worldwide. Two recent reports from the latter half of 2017 will be discussed here as they are pertinent to anesthesia professional practices.

The first report is a Patient Safety Alert from the National Health Service (NHS) of Great Britain (Alert reference number: NHS/PSA/D/2017/006), which involved a patient in the PACU who accidentally received residual neuromuscular blocker that was left in the intravenous (IV) tubing following a surgical procedure. This action resulted in muscle paralysis, unconsciousness, and respiratory and cardiac arrest (Figures 1 and 2). As a result, providers should be reminded that all intravenous ports and stopcocks should be effectively flushed at the end of the procedure and before transporting the patient to another care ward.[1]

Another mechanism for the accidental administration of residual agent occurs when two or more IV lines or ports are connected to the same cannula, as flushes may not remove drugs that have back-tracked up one of the lines or accumulated in the additional space within multi-lumen connectors. Use of infusion sets and ports with one-way valves may reduce the risk of backtracking. The NHS recommends the addition of prompts to existing procedure documentation and at patient handover from clinicians in the procedural area, confirming that all cannulae and IV lines that may contain residual drugs have been fully flushed or removed.[2]

The second report is from the October 5, 2017, ISMP Acute Care Newsletter concerning the alarming rate of continued unsafe injection practices reported by the Centers for Disease Control.[3] The survey was completed by 370 physicians with a median of >14 years of clinical experience, whose specialties included **anesthesiology-pain management**, among others.[4] Physicians were asked about the frequency of injection practices by all health care personnel in their work area, along with knowledge and attitudes associated with their own injection practices. The survey suggested that there is a minority (12.4%) of physicians who are still violating basic infection control practices. Survey responses indicated that this same group of physicians (mostly oncologists) reuse a syringe for more than 1 patient, despite findings that most physicians (91.6%) believe that this is an unacceptable practice. Approximately 63% of anesthesia-pain management physician respondents reported reentering multiple-dose vials with a used syringe; while 31.7% of anesthesia-pain management physicians reported the practice of using a single-dose vial for more than 1 patient in their workplace.[4]

This survey's results suggest that health care practitioners are still violating best practices associated with safe injections and are placing patients at risk of serious infection. Given these lapses in infection control practices, academic institutions and programs, licensing bodies, and health care providers should enhance their ongoing surveillance of proper technique and devote resources to ensure that trainees and staff have the knowledge and skills associated with even the most basic concepts of infection control and injection safety (CDC guidelines—https://www.cdc.gov/injectionsafety/index.html). Provider campaigns, such as the One & Only Campaign, are available to support safe practices in any setting where injections are delivered, but should not be relied upon alone to promote safe injection practices. The One & Only Campaign (http://www.oneandonlycampaign.org) aims to raise awareness among patients and practitioners about safe injection practices. All anesthesia providers should be familiar with and advocate for these safe injection practices in the workplace.

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Dr. Ronald S. Litman, is an anesthesiologist with the Department of Anesthesiology and Critical Care Medicine at The Children's Hospital of Philadelphia. He presently serves as Medical Director of the Institute for Safe Medication Practices.

He has no conflicts of interest to disclose.

Figure 1: This figure depicts how administration of vecuronium into the medication port of a needleless stopcock can result in the presence of residual agent, which can be accidentally administered in the PACU.

Figure 2: This figure depicts how administration of vecuronium into the needleless medication port of IV tubing can result in the presence of residual agent, which can be accidentally administered in the PACU.

Letter to the Editor:

Flip-Flops and Spinal Catheters

To the Editor:

Since the Second World War, flip-flops have become an increasingly popular footwear in the United States. Nevertheless, most would agree that their wear is not appropriate in every situation and opinion might differ on what is unacceptable, acceptable, or even desired. Flips-flops at the communal pool seem appropriate, but flip-flops at a wedding may not be. What if it was a beach wedding? What about on an ascent to Machu Picchu?

What is a reasonable idea in one place might be a bad choice in different circumstances. Decisions, therefore, need to be made in the context of the surroundings.

Recently, one of our residents placed an intraspinal catheter after an inadvertent dural puncture in a laboring patient. Although this is not routinely done at our institution and the resident had no experience with this type of catheter, he defended his decision to leave the catheter *in situ* with numerous articles stating the safety and potential benefits of spinal catheters.[1,2] Our case highlights the need to explain and discuss with residents if and under what circumstances results from the current literature can be safely translated into daily practice.

Our resident failed to recognize that unfamiliarity with a spinal catheter could lead to devastating consequences for the mother as well as for the baby if the catheter was to be mistaken to be in the epidural space. For example, opioid dosages for epidural versus intrathecal administration are substantially different and could lead to unexpected respiratory depression if the typical epidural dose was given intrathecally. Consequences include hypoxemia leading to cardiac arrest, irreversible brain damage, and even death. The updated guidelines of the American Society of Anesthesiologists from 2016 regarding neuraxial opioid administration discuss appropriate considerations to prevent, detect, and manage respiratory compromise.[3] For example, in order to reduce the risk of respiratory depression, they advise using the lowest effective dose of an intrathecal opioid. An epidural dose given intrathecally would typically be far higher than needed or desired. The practice guidelines for obstetric anesthesia by the American Society of Anesthesiologists do not contain specific recommendations for the use of intraspinal catheters.[4] However, it is clear that an accidental epidural dose given intrathecally could result in serious patient harm.[5]

Our concern was that a clinician would administer a presumed epidural bolus during an attempt to increase the anesthetic level or with the aim to convert to a surgical block for cesarean section. This could lead to a high spinal and consequently severe complications. Therefore, as a department, we agreed with the attending, who upon notification of the spinal catheter, ordered the removal of the intraspinal catheter and subsequent replacement with an epidural catheter. Currently, our department has not agreed upon a clear protocol about how to label and handle intraspinal catheters. Further, education on spinal catheters had not been provided to anesthesia and other labor and delivery staff. Until this has been achieved, we feel that despite the numerous publications stating the safety of intrathecal catheters, we are just not in the "right place" as yet.

Situational awareness errors contribute to a large proportion of anesthesia-related adverse events.[6] Understanding how and if results from the current literature can be safely translated into daily practice should be part of the discussion we have to have with our residents as well as within departments.

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First Stoelting Conference Reaches Consensus on Many Perioperative Handover Recommendations

by Jeffrey B. Cooper, PhD; Meghan Lane-Fall, MD; and Aalok Agarwala, MD

The APSF convened the first Robert S. Stoelting Conference on September 6, 2017, at the Royal Palms Hotel in Phoenix, AZ, on the important topic of Perioperative Handoffs (aka handovers). With the goals of facilitating discussion about the crucial role of care transitions in safe, high-quality patient care and reaching consensus about key topics relating to handoffs, the conference was preceded by a two-stage Delphi process to help focus the conference proceedings. All attendees were invited to participate in offering their opinions on six themes related to: the common processes and behaviors of successful handovers, metrics for effective handovers, education and training for handovers, best practices for handoff process implementation, and patient engagement in perioperative handoffs.

The morning consisted of a number of presentations and Q&A sessions followed by attendees participating in a series of breakout groups with deeper discussion about each of the six themes. Each group worked through a set of draft statements created from the Delphi results by the planning committee. Following the breakout groups, the entire audience voted on the proposed consensus statements. The objective was to achieve at least 75% consensus among the participants regarding key themes related to perioperative handovers. The expectation is that such agreement will be helpful to all stakeholders in perioperative patient safety who wish to initiate new handover processes, improve existing processes, and inform the direction of research to address outstanding questions. Drs. Meghan Lane-Fall, Aalok Agarwala, and Jeffrey B. Cooper were the organizing leaders. Drs. Amanda Burden and Philip Greilich were also part of the planning committee. Over 100 people attended, representing all types of anesthesia providers, nurses, surgeons, insurance companies, educators, and researchers. Consensus was achieved on more than 50 specific statements and seven high-priority research questions. The conference, agenda, speakers, presentations, Delphi statements, photos, and additional resources can be viewed or downloaded from the conference website https://www.apsfhandoffs.info/. A full report of the findings from this important conference will appear in a future *APSF Newsletter*.

Dr. Cooper is immediate past Executive Vice President of the APSF. He is also Professor of Anaesthesia at Harvard Medical School in the Department of Anesthesia, Critical Care & Pain Medicine, Massachusetts General Hospital, Boston, MA.

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None of the authors have conflicts of interest regarding this report.

Letter to the Editor:

Carbon Dioxide Used as Insufflating Gas May Raise $ETCO_2$ During GI Endoscopy

To the Editor:

A recent change in practice amongst our gastroenterology colleagues prompts me to note this observation: gastrointestinal (GI) endoscopy is increasingly being performed with carbon dioxide (CO_2) as the insufflating gas. The reasoning is that the CO_2 is better absorbed by the body, resulting in less cramping, bloating, or other symptoms that reduce patient satisfaction, as well as a reduced risk of significant air embolism. While this has clear advantages for colonoscopy, it has produced unexpected consequences for some patients (and providers) during upper GI endoscopy.

There may be unpredictable reflux of CO_2 from the upper GI tract into the airway, producing artefactual elevations of end-tidal carbon dioxide ($ETCO_2$), an important component of ASA standard physiologic monitoring.[1] In at least one institution, this has led to the inappropriate administration of reversal agents due to an erroneous diagnosis of severe respiratory depression ($ETCO_2$ >80 mmHg). I find no reports of this artifact in either the gastroenterology or anesthesiology literature.

This artifact would, of course, not occur if the patient were intubated, as is frequently the case in longer procedures such as ERCP. However, in such prolonged cases, systemic CO_2 absorption may be significant, leading to a respiratory acidosis requiring extreme ventilatory measures. One of the original gastroenterology studies using general anesthesia set baseline ventilation at 15/min with a target $ETCO_2$ of 25 mmHg prior to insufflation. Even with this preemptive hyperventilation, arterial pCO_2 increased up to 40% after 60 minutes of insufflation.[2]

I wish to draw attention to this increasing change in GI practice so that we may be more aware of the unintended consequences. Although CO_2 insufflation during endoscopy is relatively safe, the potential for both monitoring artifact during sedation and the risk of pCO_2 elevation (especially in compromised patients) is worthy of more discussion.

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Letter to the Editor:

Concern About the Use of Very Low Flow Sevoflurane Anesthesia

To the Editor:

I read with interest the article entitled "Low Flow and CO_2 Absorbents" (*APSF Newsletter* October 2017, p.50). I was surprised to see a photograph of the flow meters of an anesthesia machine reading 0.2 liters per minute of oxygen and 0.2 liters per minute of air. I am concerned that a casual reader might conclude that these flow rates are safe to use in everyday practice. However, they barely provide enough oxygen for a normal adult requiring 3.4 mL/kg/min[1] and do not offer any margin of safety. Furthermore, in advocating flow rates of 0.3 to 1.99 liters per minute, it is important to note that even a flow of 100% oxygen at the lowest figure (0.3 liters per minute) would not provide adequate oxygen for a patient weighing over 88 kg.

I was confused by the statements of Feldman and Hendrickx in the article regarding the dangers posed by compound A. On the one hand, they state without a reference: "The clinical relevance of compound A production remains to be demonstrated and should not be a primary consideration when selecting an absorbent. Indeed NaOH containing $Ca(OH)_2$ absorbents are routinely used outside the U.S. during closed-circuit anesthesia without concern for, nor reports of, patient harm." They then go on to state: "The ideal or best suited absorbent would be the lowest cost material that does not put the patient at risk from degradation of anesthetics."

Because this article appears to advocate the use of extremely low flow anesthesia, it is important to note what the package insert[2] for sevoflurane states on this subject: "While a level of Compound A exposure at which clinical nephrotoxicity might be expected to occur has not been established, it is prudent to consider all of the factors leading to Compound A exposure in humans, especially duration of exposure, fresh gas flow rate, and concentration of sevoflurane, USP. During sevoflurane, USP anesthesia the clinician should adjust inspired concentration and fresh gas flow rate to minimize exposure to Compound A. To minimize exposure to Compound A, sevoflurane exposure should not exceed 2 MAC·hours at flow rates of 1 to < 2 L/min. Fresh gas flow rates of <1 L/min are not recommended."

In my view, deviation from the package insert should be undertaken with extreme care and with a definite important goal in mind. A small potential savings of money during a particular case does not seem to qualify.

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He has no conflicts of interest to declare.

In Response:

We appreciate the careful reading and thoughtful response by Dr. Sosis to our article entitled "Low Flow and CO_2 Absorbents" which appeared in the last issue of the *APSF Newsletter*. The comments provide an opportunity for continued debate and clarification of our recommendations.

The first concern raised related to the photograph of flowmeters reading 0.2 L/min of oxygen and 0.2 L/min of air. The original question to the newsletter related to establishing a practice of very low flow anesthesia, as low as 0.3 L/min, so we wanted to address that scenario in our response. Oxygen consumption is indeed determined by patient size and for some patients, especially pediatric patients, 300 mls/min of oxygen may be sufficient or even excessive. Managing very low flow, or even closed circuit, anesthesia requires not only setting the fresh gas flow, but monitoring the oxygen concentration in the circuit to ensure that sufficient oxygen is being delivered. A functioning oxygen monitor is required as is vigilance by the clinician, but the technique can certainly be safe. Approaches to this technique have been described.[1]

With regard to Compound A, it is true that sevoflurane is used without restrictions on minimum flow rates throughout the world without concern for, or evidence of, clinically relevant toxicity. The literature examining this topic is extensive and does not support concern for significant patient harm related to Compound A exposure.[2,3] FDA labeling recommendations may be helpful for minimizing Compound A exposure produced by CO_2 absorbents with strong bases and the decision to comply with the FDA recommendation, when using those types of absorbents becomes a matter of clinical judgement as is true with all drug labeling. The FDA recommendations, however, pre-date the development of many currently available absorbents. Concern for toxicity has stimulated the production of absorbents which are not associated with Compound A production and can be used safely at any fresh gas flow rate.[4] Based upon the literature, we believe that our recommendation to use absorbents without KOH and low concentrations of NaOH is sound, and supports the safe use of low flow or closed circuit anesthesia in the presence of sevoflurane. It is not our intent to endorse any particular absorbent product, but the chemical composition of these materials is readily available, and can help guide selection of the material that is best suited to individual practice.

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

Dr. Hendrickx has received lecture support, consulting fees, equipment loans, or travel reimbursements from the following companies: AbbVie, Acertys, Aguettant, Air Liquide, Allied Healthcare, Armstrong Medical, Baxter, Draeger, evoked, GE, Hospithera, Heinen und Lowenstein, Intersurgical, Maquet, MDMS, MEDEC, Micropore, Molecular, MSD, NWS, Orion Pharma, Pall, Piramal, Philips, Quantium Medical, Sedana.

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Pioneer in Patient Safety and Simulation Speaks at the International Forum on Perioperative Quality and Safety

by Steven Greenberg, MD, FCCP, FCCM

Dr. Jeffrey Cooper, professor of Anaesthesia at Harvard Medical School, delivered a poignant keynote lecture entitled, "Anesthesiology's Leadership in Patient Safety: Lessons from the Past and Planning for the Future," at the first International Forum on Perioperative Quality and Safety on October 20, 2017. He foreshadowed a challenge he would later ask the audience to contemplate: "The One Thing,"[a] actually one new thing, that we as professionals can do to improve anesthesia patient safety through research and action.

Dr. Cooper alluded to studies suggesting that anesthesia safety has improved throughout the years. Specifically, anesthesia related mortality was approximately 1/10,000 for healthy patients 30–40 years ago.[1] Recently, investigators suggest mortality has improved to 1/200,000 for healthy patients in developed nations.[1] While these numbers serve as benchmarks for success, they clearly do not tell the whole story or complete the action that is required to meet the APSF goal and vision that "no patient shall be harmed by anesthesia." Dr. Cooper referred to last year's EC Pierce lecture, given by Dr. Alexander Hannenberg, entitled "Safety Beyond Borders: Different But The Same," where Dr. Hannenberg suggested that surgical/anesthesia related mortality in developing nations in Africa remains alarmingly high (100–1000 fold greater than developed nations).[2] Therefore, more work is required and more leadership is needed to improve surgical/anesthesia related mortality worldwide.

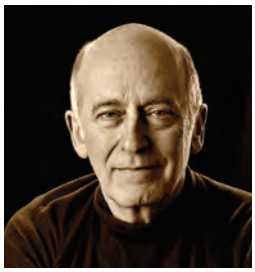
A safety pioneer in his own right, Jeff Cooper described his own experience with patient harm caused by a defect deliberately introduced into an anesthesia machine during a teaching session he was observing many years ago. He explained how his failure to speak up against an authority gradient was an example of how accidents occur. That formative event probably helped to inspire his seminal work in illuminating how human factors play a significant role in the perpetuation and magnification of medical errors resulting in patient adverse events.[3] Inspired by his own experiences coupled with observations of others, Dr. Cooper, working with the late Dr. Richard J. Kitz, to whom he dedicated his presentation, and Dr. Ellison C. (Jeep) Pierce, Jr., MD, organized the first ever meeting on anesthesia patient safety entitled the "International Symposium on Preventable Anesthesia Morbidity and Mortality," in Boston, MA, in 1984. Following this iconic meeting among 50 invited international safety leader participants, Jeep Pierce, ASA president in 1984, called for the development of an independent foundation dedicated to improving anesthesia patient safety with the mission noted above. It was Dr. Cooper who suggested that it should be called what it is today, the "Anesthesia Patient Safety Foundation, APSF." So, a new safety era began in 1985, where the APSF established the following goals:[4]

1. Sponsor research that facilitates a clearer understanding of preventable anesthetic injuries.
2. Encourage educational programs that may aid in reducing preventable anesthetic injuries.
3. Promote national and international dialogue and exchange of ideas with regard to the causes and prevention of anesthetic injuries.
4. Establish an *APSF Newsletter* to be given to all anesthesia professionals free of charge that informs them of anesthesia patient safety-related topics (which has now grown to a circulation of over 122,000 and is expected to grow internationally!).

With the continuous flow of energetic anesthesia safety leader volunteers and multidisciplinary organizational support, the APSF has been able to educate anesthesia professionals on such safety issues as: setting critical audible anesthesia machine alarms, recognizing the dangerous by-products and flammable reactions that can occur with volatile anesthetics and CO_2 absorbents, prevention of operating room fires, monitoring to prevent opioid induced ventilator impairment (OIVI), the hazards of the beach chair position, management of perioperative visual loss, and the usefulness of simulation and emergency manuals (to name just a few).

With the rise of the anesthesia safety movement and the creation and promulgation of the APSF, Dr. Cooper reflected on his original question as to whether anesthesia has become safer for patients over the last 30 years. He provided data on medical malpractice premiums that suggest that, during 1987–2015, premiums have dropped by a magnitude of 5-fold. However, Dr. Cooper cautioned the audience that new threats such as production pressure, provider fatigue, intra- and inter-disciplinary miscommunication, and provider disruptive behaviors all challenge the preservation of patient safety gains especially because, given the perceived safety, surgery is more likely to be undertaken on sicker patients and for more complex procedures. Emergency manuals, perioperative safety checklists, and structured handoffs may provide safety buffers for these emerging threats.

Dr. Cooper concluded his lecture by suggesting the "One Thing" that has been almost entirely ignored in perioperative patient safety: the relationship between surgeons and anesthesia professionals, which is a critical dyad of the perioperative team. He suggested that all anesthesia providers should seek out their surgical colleagues to engage in conversations to better understand each other's perspectives and concerns. Doing so, he believes, will not only advance patient safety but increase satisfaction and meaning of the work for those who provide perioperative care.



Dr. Jeffrey Cooper

Dr. Cooper ended with a video of Dr. Pierce's 1995 Rovenstine Lecture at the ASA Annual meeting, in which he said, "My friends and colleagues, our efforts to improve the safety of anesthesia have merely begun. Significant challenges await us, perhaps more so in the coming years than in the past four decades that I have had the pleasure and privilege to describe to you. But we must not retreat; we must not lose our collective resolve. Patient safety is truly the framework of modern anesthetic practice, and we must redouble efforts to keep it strong and growing."[5] The echoed encouragement from Dr. Pierce, inspired Dr. Cooper to urge audience members once again to find their "One Thing" that will improve the safety of our patients requiring anesthesia in the present and future.

Dr. Greenberg is presently Editor-in-Chief of the APSF Newsletter *and Vice Chairperson of Education in the Department of Anesthesiology, Critical Care and Pain Medicine at NorthShore University HealthSystem in Evanston, IL. Dr. Greenberg is also Clinical Associate Professor in the Department of Anesthesia/Critical Care at the University of Chicago.*

He has no disclosures pertaining to this report.

[a] "The One Thing," is a well-known quote provided by the character "Curly, played by Jack Palance" in the 1991 hit move, *City Slickers*.

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